ISTA
Seed Quality Assurance

ISTA Secretariat
Richtiarkade 18, 8304 Wallisellen, Switzerland
Phone: +41 44 838 60 00 | Fax: +41 44 838 60 01
Email: ista.office@ista.ch
www.seedtest.org

Guidelines for risk and opportunity assessment

Any hardcopy of this document is not controlled copy

CREATED	REVIEWED	APPROVED
April 2024	May 2024, July 2026	July 2026
ISTA Secretariat Auditors	Head of Accreditation and Technical Department	Secretary General

SCOPE

This document is guidance on how to deal with the requirements of the ISTA accreditation standard regading the asesment of risks and opportunities.

RELATED DOCUMENTS

ISTA Accreditation Standard for Seed Sampling and Testing
ISO 9000:2026 Quality Management Systems - Fundamentals and Vocabulary (definitions)
ISO 19011:2026 Guidelines for Auditing Management Systems
ISO 31000: 2018 Risk Management-Guidelines
ISO 31010:2019 Risk management - Risk assessment techniques
Acc-F-22A/B-System/Technical Audit Checklist

RESPONSIBILITIES

ISTA auditors: for applying this guideline when performing audits
Head of Accreditation and Technical Department (HoAT): for supervising the process
Secretary General: for approving the guideline
Audited members: for implementing the risk and opportunity asessment

ABBREVIATIONS

HoAT - Head of Accreditation and Technical Department
SA - System auditor
TA - Technical auditor
FMEA – Failure Mode and Effects Analysis

DEFINITIONS

Risk: effect of uncertainty (ISO 9000:2026, 3.7.2)

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

Note 5 to entry: The word “risk” is sometimes used when there is the possibility of only negative consequences.

Opportunity: Risk-based thinking (ISO 9000:2026, 4.3.8)

Risk-based thinking promotes a commitment to prioritising and managing the effects of uncertainty at all levels of the organization. It involves the consideration of the potential benefits and harms of exercising one choice of action over another when faced with a possibility of something not going as intended, including a missed opportunity.

Risk-based thinking leads to better informed decision-making when planning and performing activities.

Promoting risk-based thinking throughout the organization assists people to focus on improving how work is done. Using risk-based thinking also enables the organisation to avoid unnecessary complexity by minimizing negative consequences and taking advantage of opportunities.

1. ISTA Accreditation Standard, requirement 10.11

Introduction

The ISTA requirement 10.11 will be audited taking into account the activities of the audited members.

To adequately address risk, an analysis of this risk must be conducted. The objective is to point out possible deficiencies in audited member activities.

Influences and causes are analysed based on the risk scenario. Furthermore, risks must be classified and assessed. This assessment can lead either to the initiation of measures or to the acceptance of the risk as such. When measures are taken, their effectiveness must also be evaluated.

The risk scenario is often easy to define. In this case, similar considerations can be taken into account as in the case of "preventive measures".

The risk scenario identifies possible future scenarios through imagination, extrapolation from the present, or modeling. It can be used to anticipate how both threats and opportunities might develop and can be used for all types of risk. Scenario analysis is most often used to identify risks and explore consequences. It can be used at both strategic and operational levels, for the organization as a whole or part of it.

Risks and opportunities associated with audited member activities must be considered for:

- ensuring that the management system achieves the intended results
- enhancing opportunities to achieve the member's purpose and objectives
- preventing or reducing unintended impacts and potential failures in member activities.

General audit criteria

Ensure that the processes are adequately resourced and managed.

Planning is required for:

- actions to address these risks and opportunities
- how to integrate and implement these actions into its management system
- how to evaluate the effectiveness of these actions.

To develop a risk-management methodology, member may use different guidelines or standards (e.g. ISO 31000, FMEA, see also next paragraph).

Depending on the potential impact on the validity of the member results, actions should be taken to address risks and opportunities.

Addressing risks may include:

- identification and avoidance of threats
- taking a risk to attain an opportunity
- eliminating/mitigating the source of the risk
- modifying the plausibility or consequences of a risk
- risk sharing or risk retention/acceptance based on a documented decision.

Addressing opportunity may include opportunities and improvements that are determined, acted on and documented.

2. Methods of identifying risks and opportunities

Risk management guidelines present different possible methods for identifying risks and opportunities, for example, cause analyses like the Brainstorming method, SWOT analysis, Ishikawa-Diagram (Fish-bone diagram), Whys analysis (5-Whys, 7-Why or similar), etc.

The possible cause analysis methods range from common sense and brainstorming methods to the use of pre-established lists, or to the use of an established standard, based on the best practice approach.

Risk assessment can be performed starting with the following questions as examples:

- Which problem can occur?
- What is its impact on the work?
- What can happen if I do not address this risk?
- What is the likelihood of the same risk occurring in the future?
- Are there factors that reduce the risk or the likelihood of the risk?

Example: SWOT analysis

This is a process that identifies an organisation's strengths, weaknesses, opportunities, and threats.

The presented example is for risk analysis on staff as human resources.

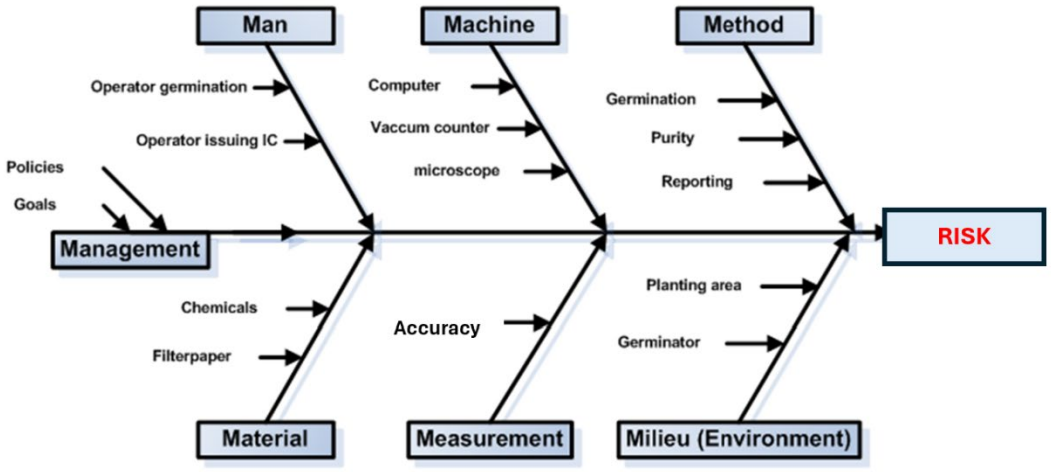
The four fields (S, W, O, T) are completed with relevant information classified according to the mitigation importance:

Strengths (S) **(positive internal factors)**	**Opportunities (O)** **(positive factors)**
• Competent staff • Management strategy in terms of the human resources is in place • Procedures to meet the ISTA accreditation requirements are established • Procedure for staff competence evaluation is in place • Staff competence exceeds the evaluation criteria • Encouragement of professional development is implemented	• Revised policy regarding better communication may minimise errors in different working areas. • Timely allocation of financial resources for staff training will lead to realisation of the development objectives. • Timely identifying/solving the issues will lead to the improvement of staff performance.
Weaknesses (W) **(internal negative factors)**	**Threats (T)** **(negative factors)**
• Poor internal communication • Frequent staff turnover • Succession plan not in place • Missing tools for staff training (e.g.too small seed collection for purity and other seed identification tests; only one shared binocular microscope available between 10 staff)	• Possible misunderstanding and doubling the performed tasks • Deputising system not in place • Continuity of the work may be jeopardised • Seed misidentification in purity and other seed determination tests

Example: Ishikawa-Diagram (Fishbone diagram)

The aim of the diagram is to analyses the possible reasons for a problem. The possible sources of the problem can be material, machine, method, humans, environment, etc. (presented by the vertical arrows on the graph). The potential causes of the problem are identified using creativity techniques, such as brainstorming (cross-functional teamwork is an advantage):

- check if all possible causes have been taken into account
- estimate potential causes according to their importance and influence on the problem
- identify the causes with the highest probability.



3. Risk classification and assessment

The audited member decides which method for risk management to use.

For risk classification and assessment, one should evaluate the impact, the probability of occurrence, and the likelihood that a risk will be discovered quickly. When detectability is also considered, the three levels are quoted in reverse (low detectability high score, high detectability, low score).

For the risk evaluation, it is required to develop a scale of values, regardless of their presentation which can be quantitative or qualitative, tabular, or graphical.

A risk assessment can be carried out, for example, through 'three-tier quotation system' stages:

Impact

- Low (1) - easy to correct, low impact
- Moderate (2) - errors occurring again but already solved
- High (3) - serious errors with possibly irreparable consequences.

Probability (likelihood) of occurrence

- Very rare (1)
- Rare (2)
- Frequent (3)

The graphical presentation can be following:

Impact	3			
	2			
	1			
		1	2	3
Probability of occurrence				

Legend:

Risk eliminated
The lowest risk (1/1 - green) can be classified as an acceptable risk, no additional risk control measures are required but require monitoring.
In the case of a low-risk (yellow), it is necessary to decide whether it is still acceptable or whether action needs to be taken.
In the case of medium (orange), the actions are established but the risk is not eliminated. Risk is accepted and kept under control (always monitored).
The highest risk (3/3 - red) usually requires immediate action. Work cannot be performed until the risk level is reduced to an acceptable level. Mitigation/eradication actions must be implemented to reduce the risk. Immediate management intervention is required to ensure the risk is reduced to an acceptable level before reinitiating work.

Examples of risk classification

Risk category	Risk Score	Range	Risk assessment (criteria)	Needed actions (control measures)
1	**Negligible**	1 - 4	Acceptable impact	No action is to be taken but the employee to be informed
2	**Moderate**	5 - 10	Acceptable risk with increased attention	Need to plan actions, seek improvement, instruct staff to manage risk
3	**Significant**	11 - 50	Risk cannot be accepted without action	Technical, organisational, measures to be taken
4	**Adverse**	51 - 100	High potential for substantial non-conformities	Immediate corrective action is required or a corrective action plan with the shortest possible due date is required
5	**Unacceptable**	101 - 125	Permanent threat, non-reparable losses	Must stop sampling/testing immediately

4. When and how is the risk and opportunity assessment carried out?

The audited member is asked to establish a policy and written procedures to address risks and opportunities. As a general principle, this will help achieve the objectives of the management system. This is also needed for addressing specific situations, such as customer requirements. It can be done on a routine basis, or occasionally, in the case of deviations or changes in the procedures and policies, as it is described by the member.

The audited member is responsible for deciding what risks and opportunities are to be addressed.

ISTA auditors assess whether appropriate actions to address risks and opportunities has been established. The member should deal with risks that may lead to failure, loss, damage, or other impacts, and treat them appropriately.

Opportunities could lead to expanding the scope of member activities, gaining new customers, using new technologies, and other possibilities to fulfill customer needs.

The risks documented by related records must be reviewed regularly (at least annually) to ensure they are accurate and that certain aspects of them have not changed. Changes in member practice, new equipment purchased, staff changes, and implementation of the advance technology, are examples of reasons why regular reviews are necessary.

The updated action plan is analysed during the management review and the effectiveness of the implemented risk control actions is assessed.

5. How to record the opportunities?

The audited member should identify opportunities for improvement of its management system and take the necessary actions. Sources of improvement can also be identified by assessing the risks.

In the context of risk management, continuous improvement means continuously and effectively taking advantage of opportunities to improve the member's resilience to risks and threats. Member team with other organisational departments may need to work together to implement the improvements and address the risks, for example:

- monitoring and reviewing the performance
- reviewing the record and systems to ensure they remain relevant and fit for purpose
- aim to encourage a culture where people share ideas and
- understanding the impact of any changes and ensuring they are managed appropriately.

When the member records the opportunities for improvement, the following steps need to be considered:

- describe the opportunity,
- actions needed to improve the activity,
- responsible staff for the established actions,
- timing of implementing the actions,
- establish frequencies for the monitoring of the actions,
- other deadlines/responsible staff for the unsolved actions,
- making decisions where any major changes/investments are needed,
- evaluation of the effectiveness of the established actions.

ANNEX

Annex 1: Examples of Registers of Risk Analyses

Annex 2: Example of registering the opportunities

DISTRIBUTION LIST

ISTA website

REVISION HISTORY

Version #	Changes
2.0	Document renamed (formerly “Guidelines for ~~the ISTA auditors regarding the~~ risk and opportunity assessment”) Scope, Responsibilities, Abreviations, References and Definitions updated ISTA Accreditation Standard title updated Term “laboratory” changed to “accredited member” or “member”, as appropriate

ISTA Secretariat
Richtiarkade 18, 8304 Wallisellen, Switzerland
Phone: +41 44 838 60 00 | Fax: +41 44 838 60 01
Email: ista.office@ista.ch
www.seedtest.org

Annex 1: Examples of Registers of Risk Analyses

Ref No.	Risk description	Registered date	Potential consequence	Existent risk (before controls) 1=low, 3=high				Need to Act		Actions	Control mechanisms	Residual risk (RR) (remaining risk after controls have been applied)				Risk owner
				Likeli-hood (L) 1-3	Impact (I) 1-3	Detection (D) 1-3	Inherent risk (LxI)	Yes	No			Likelihood (L) 1-3	Impact (I) 1-3	Detection (D) 1-3	Residual risk (RR)	
1.	Undescribed procedure of how to issue OIC	04.04.2005	Incorrect completion of ISTA orange certificates	3	3	1	9	Yes	-	1.Documentation of procedures, 2.Distribution of the procedure to responsible staff 3. Training of responsible staff. 4. Control randomly of some issued OIC's	Training Monitoring Internal audit	1	2	1	2	Administration
2.	Unchecked divider in sampling warehouses	23.03.2016	Obtaining a non-heterogeneous sample, unrepresentative of the seed lot	2	3	1	6	Yes	-	Establishing of a plan of checking in dividers - Check the divider.	Internal audit Training of samplers Monitoring	1	2	1	2	Samplers
3.	Poor results of germination in PT's rounds participation	13.12.2000	Reporting of wrong results in ISTA Certificates	1	3	1	3	Yes	-	1.Ask a new testing sample from ISTA Secretariat, 2. Performing of retest 3.Comparing the results, 3. Identification of corrective actions, 4.Training of analists, 5. Monitoring analysts in the near future regarding germination	Retest Root cause analysis Training of analyst Internal audit	1	2	1	2	Analysts
4.	Failure of critical equipment	11.01.2022	Wrong test results	3	3	1	9	Yes	-	-Level and frequency of maintenance calibration and control - Define frequency of control, - Ddefine tolerance limits/alert levels.	Training and trend analysis Alarm system and triggers	1	To be defined by the lab what is the level of acceptance	3	3	Financial and reputation Even losing accreditation

Annex 2: Example of registering the opportunities

Opportunity for improvement	Actions	Responsible staff	Deadline for implementing actions	Monitoring of the established actions	Other deadlines/responsible staff for the unsolved actions	Making decisions if any major change/investment	Effectiveness of the established actions