TECHNICAL SPECIFICATION

ISO/TS 23105

First edition

Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development

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ISO/PRF TS 23105 https://standards.iteh.ai/catalog/standards/sist/cdc4c5c8-0553-4319-8395-00d2819602b4/iso-prf-ts-23105

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Reference number ISO/TS 23105:2021(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/PRF TS 23105

https://standards.iteh.ai/catalog/standards/sist/cdc4c5c8-0553-4319-8395-00d2819602b4/iso-prf-ts-23105



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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's hational standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Biobanking of plant biological materials is fundamental for botanical and agro-ecosystem research, sustainable crop development and production, ensuring genetic diversity and conservation. Biobank biological material collection and accession management are strategic to optimizing plant genetic resources. A plant biobank obtains its accessions in different ways, e.g. from donors (principally researchers or breeders), by collecting the biological material from the field and by exchange with other plant biobanks. Biological collections encompass numerous biological material types, including frozen plant tissues, fluid preserved plant tissues or associated extracts or some or all of them. These collections often require specialized experts to curate and assemble the collection. Appropriate biological material processing and storage conditions are also needed to maintain high-quality collections and maximize the potential of positive outcomes. This document provides guidance on how to collect, process, store, track and distribute plant biological materials.

Standards are needed for the collection, preparation, preservation, transportation and storage of plant biological materials for academic institutions, non-profit organizations and commercial agronomic businesses. This document provides the specific requirements, guidelines and effective practices for biobanking plant biological materials based on the current and available technological and scientific knowledge.

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Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development

1 Scope

This document specifies requirements for the collection, preparation, preservation, transportation, storage, distribution and disposal of plant biological materials and associated data.

This document is applicable only to biological material that can be used for further processing of biomolecules, e.g. nucleic acids, proteins and metabolites.

This document is applicable to all organizations performing plant biobanking for research and development.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20387:2018, Biotechnology — Biobanking — General requirements for biobanking

3 Terms and definitions ISO/PRF TS 23105 https://standards.iteh.ai/catalog/standards/sist/cdc4c5c8-0553-4319-8395-

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

associated data

any information affiliated with *biological material* (3.4) including but not limited to research, phenotypic, clinical, epidemiologic, phytosanitary certificate and procedural data

Note 1 to entry: Associated data can include metadata.

[SOURCE: ISO 20387:2018, 3.3, modified — "phytosanitary certificate" and Note 1 to entry have been added.]

3.2

hiohank

legal entity or part of a legal entity that performs biobanking (3.3)

[SOURCE: ISO 20387:2018, 3.5]

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3.3

biobanking

process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, *preservation* (3.9), testing, analysing and distributing defined *biological material* (3.4) as well as related information and data

[SOURCE: ISO 20387:2018, 3.6]

3.4

biological material

<plant material biobanking> plant as a whole, or any substance derived or part obtained from the plant
entity

3.5

dried spots card

card containing chemicals that lyse cells, denature proteins and protect nucleic acids from nucleases as well as from oxidative and ultraviolet damage; can be used to process plant *biological material* (3.4) homogenates

3.6

life cycle

consecutive and interlinked processes applied to *biological material* (3.4) and *associated data* (3.1) from collection, if applicable, acquisition or reception to distribution, disposal or destruction

Note 1 to entry: This term refers to the *biobanking* (3.3) life cycle only.

[SOURCE: ISO 20387:2018, 3.29 Teh STANDARD PREVIEW

3.7

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plant genetic resource

genetic material of plant origin, containing functional units of heredity (e.g. DNA or RNA), or elements thereof (e.g. mRNA, mtDNA)ps://standards.itch.ai/catalog/standards/sist/cdc4c5c8-0553-4319-8395-

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3.8

plant biobank

plant genetic resource bank

plant gene bank

plant BRC

legal entity or part of a legal entity that performs the process of acquisitioning and storing, as well as some or all of the following activities: collection, preparation, *preservation* (3.9), testing, analysing and distributing defined *plant genetic resource* (3.7) as well as related information and data

Note 1 to entry: "Plant BRC" stands for "Plant Biological Resource Center".

3.9

preservation

act of preventing or retarding biological or physical deterioration of biological material (3.4)

[SOURCE: ISO 20387:2018, 3.34, modified — "act of preventing or retarding" has replaced "act to prevent or retard".]

3.10

processing

performing any activity on biological material (3.4) and associated data (3.1) during all stages of the life cycle (3.6)

[SOURCE: ISO 20387:2018, 3.36]

3.11

rejuvenation

growth of a vegetative propagule

3.12

vegetative structures

whole or portion of a plant not including the seeds

Note 1 to entry: In the scope of this document, vegetative structures can include propagules.

4 General requirements

The biobank shall follow ISO 20387:2018, Clauses 4 to 7.

The biobank shall establish, implement and maintain a quality management system in accordance with ISO 20387:2018, 8.2 to 8.9.

The biobank shall identify each biological material and associated data relevant to the application of this document.

The biobank shall have procedures addressing biobanking for each type of biological material (e.g. whole plant, seeds, tuber, bulbs, scion wood, leaf, root, DNA, RNA) and associated data. This includes processes such as collection, acquisition, reception, characterization/evaluation, storage, preparation, preservation, rejuvenation and distribution.

The biobank shall ensure the legitimate acquisition of biological material and its associated data, and the retention of any relevant documentation. If legitimate acquisition cannot be demonstrated, the biological material shall be discarded, according to documented procedures, and this shall be documented.

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NOTE 1 Such documentation can relate to relevant documents such as international treaties and agreements, and a phytosanitary certificate or passport dards.iteh.al)

NOTE 2 Legitimate acquisition can refer to relevant regulation, permits or authorization.

The biobank shall ensure that biorisk management procedures (e.g. ISO 35001, WHO guidance potential plant pests and pathogens are established, documented, implemented and maintained, as appropriate.

The biobank shall take measures to prevent cross contamination.

The biobank or the legal entity of which it is a part shall ensure that human health and safety requirements are established, documented, implemented and maintained. The level of safety training required shall be determined using a comprehensive risk assessment of the biological and chemical materials, processes and equipment that is handled (see ISO 20387:2018, 6.2.1.5).

5 Biological material collection

5.1 General

Where possible, the intended purpose or final use of the biological material and associated data shall be determined, either by the biobank alone, in response to end-user criteria or by the biobank in conjunction with the end user. If determined, the intended or potential purpose shall be documented.

5.2 Collection procedure

5.2.1 The biobank shall develop and implement documented biological material collection procedures appropriate for each type of biological material according to its biological nature and intended purpose, where known. The biobank shall define biological material acceptance criteria.

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- **5.2.2** The collection procedure shall address requirements for authentication, minimum quantity, viability, stability and maintenance to satisfy the fitness for purpose, where known. The collection procedure shall also address the following aspects, including but not limited to:
- a) biological material type;
- b) fitness for purpose, where known;
- c) total number and amount comprising each biological material per collection;
- d) containers that are fit for purpose (e.g. closure integrity, composition);
- e) equipment;
- f) collection method;
- g) quality criteria for each biological material (e.g. the quantity and quality of targeted analytes such as DNA, RNA or protein);
- h) collection location(s) (e.g. by GPS), schedule, personnel and assignment;
- i) stage of maturity of the biological material.
- **5.2.3** When developing collection procedures, the following information shall be evaluated for inclusion:
- a) taxonomic information, vernacular names, morphological characters and habitat;
- b) geographical distribution and known populations (s.iteh.ai)
- c) population size and identified number of propagules to be collected;

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- e) statistical demographics for collection;
- f) physiological traits that are relevant for plant biological material sampling;
- g) information on putative plant disease or associated pests;
- h) historical collection information, the appropriate season and timing for collection, and environmental information such as climate and accessibility;
- i) permits required for collection, transportation, export and import.

The evaluation result shall be documented.

- **5.2.4** The biobank shall identify risks associated with the collection procedure for each biological material and take appropriate feasible measure(s) to mitigate the risks according to the likelihood of occurrence and the possible impacts. It is up to the biobank or the legal entity of which it is a part, or both, to determine what measures are appropriate and feasible.
- **5.2.5** The biobank shall define and document information related to the biological material (see Annex B and ISO 20387:2018, 7.2.1.1, 7.2.1.2, A.2 and B.2).

5.3 Preparation of collection containers, tools, supplies, reagents and consumables

The tools for collection, such as instruments, consumables and personal protective equipment, should be prepared and checked prior to collection. Preparing a checklist before collection can help to ensure an uninterrupted and efficient procedure.

d)

The collection procedure shall include the preparation of collection containers, tools and other supplies (e.g. ink, labels or tags) required for each biological material collection. When appropriate, this shall include, but is not limited to, the following:

- a) collection containers and seals;
- b) contamination prevention through appropriate care, cleaning or sterilization or both of collection tools such as cutting devices, instruments, containers and reagents;
- c) collection instruments;
- d) collection consumables;
- e) personal protective equipment;
- f) information recording tools;
- g) reminder systems, e.g. checklists.

NOTE When needed, containers, instruments and consumables can be sterilized prior to collection.

Specifications for collection tool requirements and recommendations by type of biological material are listed in <u>Table 1</u>.

Table 1 — Collection tool specifications by type of biological material

Biological material † type	Teh STANDARD Pspecifications W
Vegetative structures (whole or part)	Containers shall be clean and able to maintain the desired moisture content or temperature, e.g. aluminium foil can be used.
https:	If necessary, biological material, especially those containing plastids, should be protected from light (e.g. laluminium foil wrapping) dark containers). Air should be excluded as much as possible prf-ts-23105
	Debris, where present, should be removed, e.g. through use of a soft brush or clean water or both.
Seeds	Containers to maintain the desired moisture content range or which keep the biological material dry/cool shall be prepared before collection, according to the biological material properties and intended purpose.
	Seeds should be collected into containers minimizing light and air.
	As much as possible, seeds should be collected with minimized debris.
Biological material for biomolecular research	A container designed to minimize sample degradation, e.g. DNase free or RNase free or pyrogen free to preserve genetic integrity, should be used.
	Clean cryotubes with secure top lids or appropriate sealable plastic bags produced by clean manufacturing technology can be selected for transportation and storage at or below -18 °C.
	Dehydration shall be avoided in the container.
	Debris, where present, should be removed, e.g. through use of a soft brush or clean water or both. Use a collection receptacle appropriate for the biological material collection criteria, e.g. containers capable of maintaining desired moisture content or temperature range, aluminium foil to minimize exposure to light/air.
	Care should be taken during collection and processing to prevent the activity of RNases, both endogenous and those introduced by environmental contamination.