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Biotechnology — Provenance information model for biological material and data —

Part 2: Common provenance model

Biotechnologie — Modèle d'information sur la provenance des matériels et données biologiques —

Partie 2: Modèle de provenance commun

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Foreword

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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 document 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*.

A list of all parts in the ISO 23494 series can be found on the ISO website.

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

Introduction

Sharing biological material and data or reuse of existing data have become indispensable for research activities in biotechnology and biomedicine. Without meticulous documentation of the lineage of the biological material and data, recording each step in their life cycle that can affect their fitness for purpose, they are rendered unusable as the observations obtained therefrom become unreliable. In recent years the scientific community has witnessed a significant number of questionable claims, not least due to unsuited or untraceable sources of biological material or data[1].

Provenance is information about objects, and can be used to assess the quality, reliability, or trustworthiness, or, more generally, the fitness for purpose of the objects.[2] The described object is expressed in provenance as an entity, representing a snapshot of the object and documenting the actual values of its attributes at a certain point in time. The state of the object at different instants of time is represented by distinct entities. Provenance documents relations between objects, activities, persons, or organizations that account for the current state of the object.

By specifying consistent rules for the formalization and serialization of provenance of research objects, such as biological material and data, this document establishes an integrative framework for improved reproducibility and reliability of research results. By standardizing provenance information this document contributes considerably to the adoption of the FAIR principles[3] as findability, accessibility, interoperability, and reusability of provenance information are objectives central to this specification. In addition, by utilizing this document for the harmonization of provenance information the adoption of FAIR principles for physical or digital objects is facilitated.

The common provenance model (CPM)[4] described in this document specifies common entities with defined semantics that are required along the life cycle of various objects in biotechnology and biomedicine. By providing different abstraction layers, connectors, and encapsulations this document constitutes a comprehensive and versatile instrument to record and maintain provenance information. The CPM does neither prescribe the actual content, nor methods or items to be recorded in provenance information but is rather meant to provide a foundation for domain or application specific implementations. The CPM builds on a widely accepted standard for a generic data model of provenance information (PROV-DM[5]) as furnished by the World Wide Web Consortium (W3C).

Application of the CPM on a specific use case is exemplified in Annex A. Annex B shows how a provenance chain can be created using two elemental operations. A basic provenance chain algorithm is presented in Annex C. Annex D shows how versioning information in a meta provenance component can be extended with additional information. The purpose of these annexes is to provide specific examples of how the CPM can be used.

Biotechnology — Provenance information model for biological material and data —

Part 2: Common provenance model

1 Scope

This document specifies a common model for generating, maintaining, and provisioning provenance information on objects, such as biological material and data. This document also specifies requirements for provenance information serialization to achieve its interoperability. The provenance information covers any information relevant to the traceability, quality and fitness for purpose of the biological material and data generated throughout the life cycle of the biological material from collection to analysis, including data originating from analytical procedures applied to the biological material and further processing of the data.

This document is applicable to organizations, authorities and industries that are:

a) acquiring, collecting, processing, testing, analysing, storing, or distributing biological material in biotechnology and biomedicine (e.g., biobanks, laboratories, biomedical research as well as biotechnological development or production);

b) generating, collecting, analysing, processing, or storing data on and related to biological material (e.g., biobanks, laboratories, developers, manufacturers, or other institutions and commercial organizations in biotechnology or biomedicine);

c) generating, collecting, analysing, processing, or storing data or digital objects in biotechnology and biomedicine (e.g., in vitro/in vivo/in silico diagnostics developers and manufacturers, or other institutions and commercial organizations in the domain);

d) manufacturing devices or software for the afore mentioned tasks or providing facilities for these tasks.

This document is also applicable to providers of services related to provenance information management (e.g., provenance information generation, storage, provision, or validation).

Customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can use this document in confirming or recognizing the competence of the aforementioned parties.

This document does not apply to biological material and data used for medical diagnosis and therapy.

NOTE 1 This document can be applied by organizations performing laboratory or research activities as well as other activities in biotechnology and biomedicine.

NOTE 2 International, national, or regional regulations, standards, or requirements can apply to specific topics covered in this document, e.g., for organizations handling human materials procured and used for diagnostic and treatment purposes.

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.

THE PROV-JSON SERIALIZATION. A JSON Representation for the PROV Data Model: W3C Member Submission. Available also from https://www.w3.org/submissions/2013/SUBM-prov-json-20130424/

PROV-CONSTRAINTS. DE NIES, T. Constraints of the PROV Data Model. 2013. Available also from:https://www.w3.org/TR/2013/REC-prov-constraints-20130430/

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply[1)].

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General terms

3.1.1
biological material
organic entity or any substance derived or part obtained from:

a) an organic entity, such as microorganism(s) or multicellular organism(s) (e.g. human, animal, fungus, brown seaweed, plant); or

b) an environmental sample (e.g.. soil, sediment, water, air), that contains an organic entity of interest

[SOURCE: ISO/DIS 20387:2025, 3.6]

3.1.2
described activity
activity performed on a *described object* (3.1.3)

Note 1 to entry: Examples for activities performed on physical objects can be biobanking activities as specified in ISO 20387, Examples for activities performed on digital objects can be data analytics as specified in ISO/IEC 20546.

[SOURCE: ISO 23494-1:2026, 3.3]

3.1.3
described object
physical or digital object to be traced

[SOURCE: ISO 23494-1:2026, 3.4]

3.1.4
provenance information
information that documents the history of a *described object* (3.1.3) and related *described activities* (3.1.2), and that contains information about origin or source of the described object, any changes that have occurred since it was created, and who has had custody of it since it was created

[SOURCE: ISO 23494-1:2026, 3.15]

3.1.5
finalized provenance component
provenance component (3.1.9) which is prepared to be conserved or archived and which is considered as being immutable

[SOURCE: ISO 23494-1:2026, 3.6]

1) With permission from W3C, this document contains copied or modified definitions from the W3C PROV Data Model, a Recommendation from 30 April 2013, available online at https://www.w3.org/TR/prov-dm/.

3.1.6
common provenance model
CPM
data model for *provenance information* (3.1.4) representation

[SOURCE: ISO 23494-1:2026, 3.2]

3.1.7
PROV-DM
conceptual data model forming a basis for the World Wide Web Consortium (W3C) provenance (PROV) family of specifications

[SOURCE: W3C PROV-DM:2013[5]]

3.1.8
finalization event
event at which *provenance information* (3.1.4) is transformed into a *finalized provenance component* (3.1.5)

[SOURCE: ISO 23494-1:2026, 3.5]

3.1.9
provenance component
provenance information (3.1.4) represented according to the *common provenance model* (3.1.6) with a unique identifier assigned to it

[SOURCE: ISO 23494-1:2026, 3.12]

3.1.10
meta-component
provenance component (3.1.9) that contains *provenance information* (3.1.4) about *finalized provenance components* (3.1.5)

[SOURCE: ISO 23494-1:2026, 3.9]

3.1.11
provenance controller
party (3.1.20) that determines the purposes for which and the means by which *provenance information* (3.1.4) and *finalized provenance components* (3.1.5) are collected, stored, and provided, and that collects *finalized provenance components* documenting relevant *described activities* (3.1.2)

[SOURCE: ISO 23494-1:2026, 3.13]

3.1.12
sender
provenance controller (3.1.11) that is providing a *described object* (3.1.3) to a provenance controller

3.1.13
receiver
provenance controller (3.1.11) that is receiving a *described object* (3.1.3) from a provenance controller

3.1.14
provenance structure
object in a *provenance component* (3.1.9), such as a *PROV entity* (3.3.14), *PROV activity* (3.3.1), *PROV agent* (3.3.2) or a relation

Note 1 to entry: In PROV-DM the term is used without an exact definition. PROV-DM distinguishes core structures which form the essence of provenance information, and extended structures, that enhance and refine core structures with more expressive capabilities.

3.1.15
qualified name
set consisting of the [prefix], [namespace name], and [local name] properties of an element information item or attribute information item

[SOURCE: ISO/IEC 24824-1:2007, 3.4.11]

3.1.16
specialization
property of an object with regard to another object, meaning that the former object presents all the aspects of the latter, along with some additional aspects

3.1.17
external identifier
identifier for a physical or digital object

Note 1 to entry: An external identifier can be a label on a container for *biological material* (3.1.1), an identifier of a data set, or a registration number

Note 2 to entry: an external identifier need not be persistent nor unique

3.1.18
namespace
term, identified by an IRI RFC 3987[6]

[SOURCE: W3C PROV-DM:2013 [5]]

3.1.19
persistent identifier
unique identifier that ensures permanent access for a digital object by providing access to it independently of its physical location or current ownership

[SOURCE: ISO 24619:2011, 3.2.4 [11]]

3.1.20
party
natural person or legal person, whether or not incorporated, or a group of either

[SOURCE: ISO 27729:2024, 3.1]

3.2 Terms related to CPM Provenance Structures

3.2.1
connector
provenance structure (3.1.14), that serves as an interconnection between *finalized provenance components* (3.1.5) and represents a *described object* (3.1.3), which can be or has been exchanged between a *sender* (3.1.12) and a *receiver* (3.1.13)

3.2.2
backward connector
connector (3.2.1) that represents a received *described object* (3.1.3)

Note 1 to entry: The backward connector is present in the receiver's finalized provenance component, documenting information necessary to locate and access respective sender's finalized provenance component.

3.2.3
forward connector
connector (3.2.1) that represents a *described object* (3.1.3) that can be sent from a *sender* (3.1.12) to a *receiver* (3.1.13)

3.2.4
specialized forward connector
connector (3.2.1) that represents a *described object* (3.1.3) that has been sent from a *sender* (3.1.12) to a *receiver* (3.1.13)

Note 1 to entry: A specialized forward connector is present in the sender's finalized provenance component documenting information necessary to locate and access respective receiver's finalized provenance component.

3.2.5
identifier entity
provenance structure (3.1.14) that represents an *external identifier* (3.1.17)

3.2.6
main activity
provenance structure (3.1.14) that represents the *described activity* (3.1.2) documented in a particular *finalized provenance component* (3.1.5)

3.2.7
receiver agent
provenance structure (3.1.14) that represents a *receiver* (3.1.13) in a sender's *finalized provenance component* (3.1.5) in the context of passing a *described object* (3.1.3) between two *provenance controllers* (3.1.11)

3.2.8
sender agent
provenance structure (3.1.14) that represents a *sender* (3.1.12) in a receiver's *finalized provenance component* (3.1.5) in the context of passing a *described object* (3.1.3) between two *provenance controllers* (3.1.11)

3.2.9
current agent
provenance structure (3.1.14) that represents a *provenance controller* (3.1.11)

3.3 Terms related to PROV-DM provenance structures

3.3.1
PROV activity
provenance structure (3.1.14) that represents something that occurs over a period of time and acts upon or with *PROV entities* (3.3.14) and it can include consuming, processing, transforming, modifying, relocating, using, or generating PROV entities

Note 1 to entry: The definition is derived from Reference [5]. The original definition in PROV-DM where the definition explicitly refers to a provenance structure was modified. The term is prefixed by "PROV" for disambiguation. Introducing this syntax makes it possible to express things like "a real-world entity is represented by a PROV entity" in provenance information. The original PROV definitions are saying that, for instance, "PROV entities" are "real-world entities".

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.2
PROV agent
provenance structure (3.1.14) that represents something or someone that bears some form of responsibility for a *PROV activity* (3.3.1) taking place, for the existence of a *PROV entity* (3.3.14), or for another agent's PROV activity

Note 1 to entry: The definition is derived from.[5] The original definition in PROV-DM where the definition explicitly refers to a provenance structure was modified. The term is prefixed by "PROV" for disambiguation.

Note 2 to entry: PROV-DM defines the following additional types of PROV agents: *PROV person* (3.3.21), PROV *organization* (3.3.20), and *PROV Software Agent* (3.3.24)

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.3
PROV alternate
provenance structure (3.1.14) that represents a relation between two *PROV entities* (3.3.14) – alternates – which present the same or different aspects of the same thing, and the alternate PROV entities can overlap in time

Note 1 to entry: The definition is derived from Reference [5]. The original definition in PROV-DM where the definition explicitly refers to a provenance structure was modified. The term is prefixed by "PROV" for disambiguation. The reference to temporal overlap was reworded in accordance with the ISO house style, without altering its original meaning.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.4
PROV association
provenance structure (3.1.14) that represents assignment of responsibility to a *PROV agent* (3.3.2) for a *PROV activity* (3.3.1), indicating that the PROV agent had a role in the PROV activity

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.5
PROV attribution
provenance structure (3.1.14) that represents ascribing of a *PROV entity* (3.3.14) to a *PROV agent* (3.3.2)

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.6
PROV bundle
named set of provenance descriptions, and is itself a *PROV entity* (3.3.14), so allowing provenance of provenance to be expressed

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.7
PROV communication
provenance structure (3.1.14) that represents exchange of some unspecified *PROV entity* (3.3.14) by two *PROV activities* (3.3.1), one *PROV activity* using some PROV entity generated by the other

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.8
PROV collection
type of a *PROV entity* (3.3.14) that provides a structure to some constituents that must themselves be PROV entities

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a type of a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.9
PROV delegation
provenance structure (3.1.14) that represents assignment of authority and responsibility to a PROV agent (by itself or by another *PROV agent* (3.3.2)) to carry out a specific *PROV activity* (3.3.1) as a delegate or representative, while the PROV agent it acts on behalf of retains some responsibility for the outcome of the delegated work

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.10
PROV derivation
provenance structure (3.1.14) that represents transformation of a *PROV entity* (3.3.14) into another, an update of a PROV entity resulting in a new one, or the construction of a new PROV entity based on a pre-existing PROV entity

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.11
PROV document
document that consists of an unnamed *PROV instance* (3.3.17) together with zero or more *PROV bundles* (3.3.6)

Note 1 to entry: Technically detailed definition: let a PROV document contain *n* named PROV bundles *b1...bn*, as a tuple *(I0,[b1=I1,...,bn=In])* where *I0* is the top level instance, for each *i*, *Ii* is the instance associated with the PROV bundle *b* .

[SOURCE: W3C PROV-CONSTRAINTS:2013 [7]]

3.3.12
PROV empty collection
PROV collection (3.3.8) without members

Note 1 to entry: The definition is derived from Reference [5]. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.13
PROV end
provenance structure (3.1.14) that represents a moment, when a *PROV activity* (3.3.1) is deemed to have been ended by a *PROV entity* (3.3.14), known as trigger

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.14
PROV entity
provenance structure (3.1.14) that represents physical, digital, conceptual, or other kind of thing with some fixed aspects which can be real or imaginary

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation. The definition was reworded in accordance with the ISO house style, without altering its original meaning.

Note 2 to entry: PROV-DM defines the additional types of *PROV entities* (3.3.14), e.g., *PROV collection* (3.3.8), *PROV empty collection* (3.3.12), *PROV plan* (3.3.22), or *PROV bundle* (3.3.6)

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.15
PROV generation
provenance structure (3.1.14) that represents completion of production of a new *PROV entity* (3.3.14) by a *PROV activity* (3.3.1)

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.16
PROV influence
provenance structure (3.1.14) that represents capacity of a *PROV entity* (3.3.14), *PROV activity* (3.3.1), or *PROV agent* (3.3.2) to have an effect on the character, development, or behaviour of another by means of *PROV usage* (3.3.29), *PROV start* (3.3.26), *PROV end* (3.3.13), *PROV generation* (3.3.15), *PROV invalidation* (3.3.18), *PROV communication* (3.3.7), *PROV derivation* (3.3.10), *PROV attribution* (3.3.5), *PROV association* (3.3.4), or *PROV delegation* (3.3.9)

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

Note 2 to entry: Some relations between provenance structures are not considered as PROV influence, e.g., PROV membership, PROV alternate, or PROV specialization

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.17
PROV instance

set of *PROV statements* (3.3.27)

[SOURCE: W3C PROV-CONSTRAINTS:2013[7]]

3.3.18
PROV invalidation
provenance structure (3.1.14) that represents start of the destruction, cessation, or expiry of an existing *PROV entity* (3.3.14) by a *PROV activity* (3.3.1)

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.19
PROV membership
provenance structure (3.1.14) defined for stating the members of a *PROV Collection* (3.3.8)

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.20
PROV organization
type of a *PROV agent* (3.3.2) that represents a social or legal institution, such as a company, society, etc.

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a type of a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.21
PROV person
type of a *PROV agent* (3.3.2) that represents a person

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a type of a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.22
PROV plan
type of a *PROV entity* (3.3.14) that represents a set of actions or steps intended by one or more agents to achieve some goals.

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a type of a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.23
PROV revision
PROV derivation (3.3.10), for which the resulting *PROV entity* (3.3.14) is a revised version of some original

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.24
PROV software agent
type of a *PROV agent* (3.3.2) that represents a running software

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a type of a provenance structure. The term is prefixed by "PROV" for disambiguation.

[SOURCE: W3C PROV-DM:2013 [5]]

3.3.25
PROV specialization
provenance structure (3.1.14) that represents a relation between two *PROV entities* (3.3.14), which happens in a case when a PROV entity shares all aspects of the latter, and additionally presents more specific aspects of the same thing as the latter

Note 1 to entry: The definition is derived from Reference [5]. Compared to the original definition in PROV-DM, the definition in this document was modified by explicitly referring to a provenance structure. The term is prefixed by "PROV" for disambiguation. The original definition has been adapted accordingly.

[SOURCE: W3C PROV-DM:2013 [5]]