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Batch control – **iTeh STANDARD PREVIEW**
Part 4: Batch production records
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Contrôle-commande des processus de fabrication par lots –
Partie 4: Enregistrements de production par lots
<https://standards.iteh.ai/catalog/standards/sist/414a1c06-d29c-458e-8f0c-160f3aa7e602/iec-61512-4-2009>



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IEC 61512-4

Edition 1.0 2009-10

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE **XB**
CODE PRIX

ICS 25.040.40

ISBN 978-2-88910-531-1

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BATCH CONTROL –

Part 4: Batch production records

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International Standard IEC 61512-4 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation.

This standard cancels and replaces the IEC/PAS 61512-4 published in 2007. This first edition constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
65A/537/FDIS	65A/546/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 61512 series, published under the general title *Batch control*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
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INTRODUCTION

IEC 61512-1 provides models and terminology applicable to batch control. Subclause 5.5 defines product information concepts, and subclause 6.4 defines production information management activities and functions.

Clause 4 of IEC 61512-2 provides an object model of production information, and Clause 5 defines batch history exchange tables. The batch history exchange tables given in Clause 5 are one implementation for production information.

Whereas IEC 61512-1 and IEC 61512-2 provide significant information concerning batch history and production information, they are not sufficient for use as standards for implementing specific technologies and are lacking in scope and content.

This part of IEC 61512 provides a detailed definition for batch production records. It consists of a description and object model of batch production record contents.

The intended use of this batch production record standard is to provide a reference model for developing applications for the storage and/or exchange of batch production records. Implementations based upon this standard will allow retrieval, analysis, and reporting of selected batch production record data.

This batch production record standard is compliant with the batch data model in Clause 4 of IEC 61512-2, as well as with IEC 61512-1.

Although this standard is intended primarily for batch processes, it may be of considerable value for other types of processes.

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BATCH CONTROL –

Part 4: Batch production records

1 Scope

This part of the IEC 61512 series defines a reference model for batch production records containing information about production of batches or elements of batch production. This standard is intended for batch processes.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated reference, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 61512-1:1997, *Batch Control – Part 1: Models and terminology*

IEC 61512-2:2001, *Batch Control – Part 2: Data structures and guidelines for language*

ANSI/ISA-95.00.01:2000, *Enterprise-Control System Integration – Part 1: Models and Terminology*

ANSI/ISA-95.00.02:2001, *Enterprise-Control System Integration – Part 2: Object Model Attributes*

3 Terms and definitions

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

NOTE Terms and definitions given in IEC 61512-1 also apply, except where differences are explicitly stated in this part.

3.1

batch history

all execution information collected pertaining to the production of a single batch, and may include common (non-batch specific) information

3.2

batch production record

subset of the execution and business information that is retained based upon business requirements identified by the batch production record specification

NOTE This information could include the recipe procedural element execution information, both specific equipment information, operator comments, batch-related alarms, elements related to the definition of a batch (such as control recipe, master recipe, site and/or general recipe, batch schedule information), and information important to the batch (such as training logs, maintenance records, and environmental conditions).

3.3

batch production record report

extraction of information from one or more batch production records that is formatted for printing, displaying, or sending to a collaborating system

3.4

batch production record specification

definition of the requirements of execution business information used for generation of a batch production record or the data to include in the batch production record and specification if data is to be referenced or extracted

NOTE This information could include the contents, calculations, and other rules needed to identify the pertinent information.

3.5

batch production information

execution information that is recorded during the course of batch production and the business information relating to batch production

NOTE Batch production information can be batch specific or it can be common to several batches.

4 Batch production record description

4.1 General

This clause provides an informative overview of a batch production record as defined in Clause 5 of this standard. This document defines a standard reference model for batch production records. A batch production record contains batch production information and related business information. A batch production record is created to meet a business requirement, and the contents of a batch production record are determined by the business requirement.

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EXAMPLE

A batch production record might be created to document <https://standards.itech.ai/catalog/standards/sist/414a1c06-d29c-458e-8f0c-1603aa7e602/iec-61512-4-2009>

- production of a batch;
- storage and handling of a material lot or subplot;
- production-related activities of a person or group of persons or of a piece of equipment or set of equipment.

NOTE 1 IEC 61512-1 and IEC 61512-2 define production information and batch history functions, provide lists of the types of data they encompass and provide abstract models. However, IEC 61512-1 and IEC 61512-2 do not define a formal and precise model of production information and batch history data. This part of IEC 61512 does not further define these terms and does not define production information or batch history system functions.

This part of IEC 61512 defines an object model, object attributes, and relationships between object instances that can be used to implement data structures used for the exchange of a subset of a production information and batch history data. The object model is called a batch production record. This standard is intended to be used as a reference model for the creation of technology-specific specifications for the data that make up batch production records.

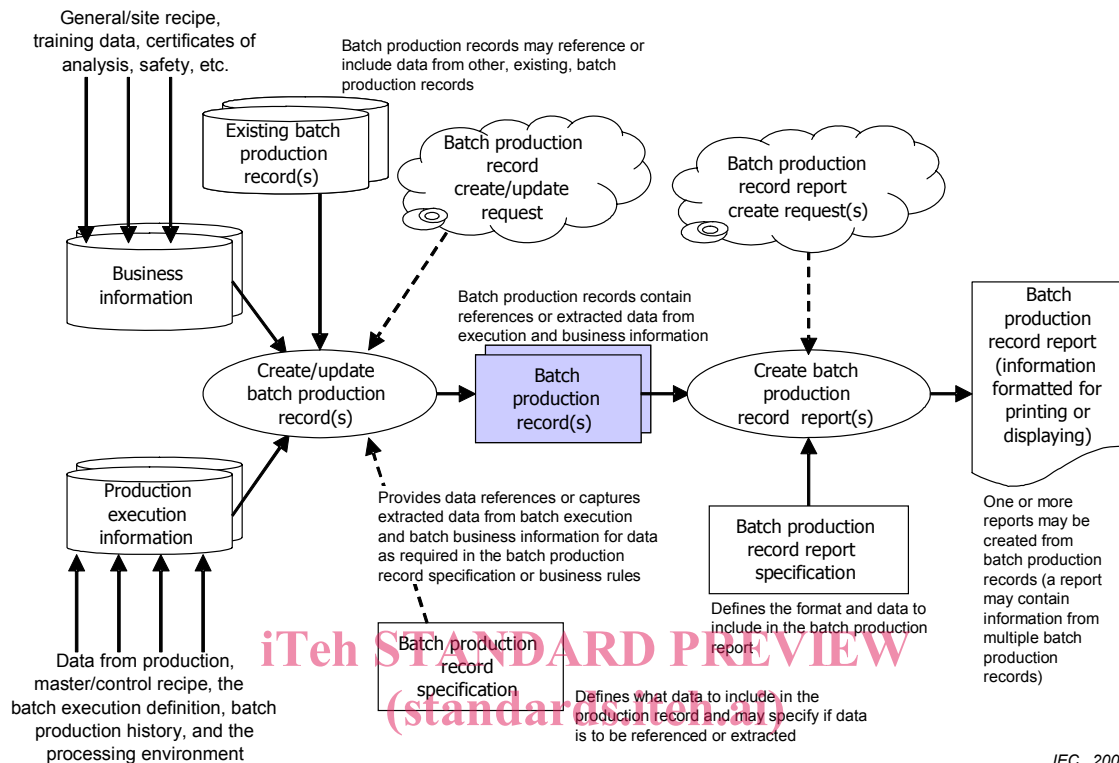
Batch production may require the involvement of multiple control systems, related computer systems, and manual actions. Therefore, it is possible that the information making up batch production information may be distributed among multiple computer systems and also contain components in paper form.

NOTE 2 “Production” implies batch production in all cases unless otherwise stated.

Standardization of batch production records is intended to enable development of solutions that support specific interfaces and repositories that can be used and supported by multiple operating companies and vendors. The existence of a batch production record standard may also enable improved communication within a single company, between different companies, and between companies and government or regulatory agencies.

Figure 1 illustrates data flows associated with creating, maintaining, and using a batch production record. Of these functions and data items, only the batch production record is

defined in this standard. The other functions and data items are shown to illustrate the environment batch production records are used in. Not all sources of data, functions performed on or uses of batch production records are illustrated in this figure.



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Figure 1 – Batch production record creation and use

4.2 Overview

4.2.1 Batch production record

A batch production record is a subset of the production execution and business information that is retained based upon pre-defined business requirements identified by the batch production record specification. The structure of the batch production record is based on the logical object model defined in Clause 5.

A batch production record consists of data about the manufacture of the product plus all supporting data required to meet the business requirements of the record. The data may come from multiple sources and may be either extracted (captured into the record) or referenced in the source system.

EXAMPLE 1 The business need could be a record of production quality.

EXAMPLE 2 The business need could be a record of equipment maintenance such as cleaning or sterilization.

Each batch production record is created to satisfy the specific business requirements as defined by a unique batch production record specification.

EXAMPLE 3 The system could create a batch production record for the operational execution of an element of batch production.

EXAMPLE 4 The system could create a batch production record for the personnel efficiency of an element of batch production.

An element of batch production might be a batch, lot, campaign or other batch activity such as pre-weigh.

A batch production record can reference other batch production records.

EXAMPLE 5 A batch production record can reference the records for intermediate materials.

EXAMPLE 6 A batch production record can include the records received with purchased ingredients.

EXAMPLE 7 A batch production record can be the union of all batch production records for all processing segments that create a final product.

Individual batch production records can be combined into a larger batch production record.

Multiple batch production records can be created for a single element of production.

Multiple batch production records can contain the same and/or mutually exclusive data.

EXAMPLE 8 A control system can create a batch production record for the execution of an element of batch production and an MES (Manufacturing Execution System)/ERP (Enterprise Resource Planning) system can create another batch production record for the same element of batch production that includes some of the same data included in the control system record and additional data known only to the MES/ERP system.

A key factor that differentiates batch production records from traditional time-based plant history records is that batch production records are stored and retrieved on an element of batch production basis, such as on batch basis or on a control recipe's unit procedure, operation or phase basis.

4.2.2 Business information

Business information is data from non-production business systems.

EXAMPLE Business information might include material, training or safety data.

4.2.3 Production execution information

Production execution information is data about production resources (equipment, materials, and personnel), recipe execution, and information from the processing environment.

EXAMPLE 1 Production execution information might include equipment status, material consumption, the definition of production rules, or production history.

EXAMPLE 2 Production execution information might include environmental monitoring, utilities status or other information on the processing environment.

4.2.4 Batch production record specification

A batch production record specification is the information that is intended to be used to define a batch production record. The content and format for batch production record specifications are not defined in this part of IEC 61512..

There can be any number of batch production record specifications per element of batch production.

Each batch production record is based upon a single batch production record specification. The same batch production record specification may be used to produce batch production records for multiple batches, multiple executions of similar elements of batch production, different material lots/sublots, equipment or personnel use.

EXAMPLE 1 A single batch production record specification can be used to generate multiple batch production records, one for each batch of product XYZ produced.

EXAMPLE 2 A single batch production record specification might be used to generate a single batch production record for all batches of product XYZ.

EXAMPLE 3 A batch production record specification might be used to generate a batch production record for all production done during a shift.

EXAMPLE 4 A batch production record specification might be used to generate a batch production record for a lot of intermediate material in order to track its storage and handling between its production and consumption in different batches.

4.2.5 Batch production record reports

A batch production record report is an extraction of production information that is formatted for printing, displaying, or sending to a collaborating system. The definition of the format and data content for batch production record reports is outside the scope of this part of IEC 61512.

EXAMPLE A batch production record report might be a computer-displayed shift report, a printed batch end report, or an XML message containing production performance information sent from a batch control system to a business system.

Batch reports are defined in IEC 61512-1 as an extraction of data related to one or more batches. A batch production record report is a specific type of batch report that is based on the information from one or more batch production records for one or more elements of batch production.

4.3 Batch production record purpose

4.3.1 General

Each batch production record meets one or more business requirements. Batch production records may be useful to support business functions such as:

4.3.2 Process and/or production analysis, optimization and reporting

This function includes analysis of bad batches or runs to determine the root cause, and the analysis of exceptional quality batches (golden batch) to determine optimal running conditions or achieving pre-defined business objectives.

EXAMPLE 1 Process analysis provides feedback about specific manufacturing processes for a single element of batch production or across multiple elements of batch production. This information is used to optimize or modify specific production processes.

EXAMPLE 2 The analysis might be performed for the improvement of production processes, scheduling, or equipment utilization.

EXAMPLE 3 The collection of key parameters could enable observation and/or detection of trends within or across batches. For example, this might be done to detect future quality problems, observe if a plant is performing consistently, or observe yield management.

EXAMPLE 4 A batch production record might be generated for tracking of material consumption, production, losses, and corrections for mass balances or inventory updates. This could apply to consumables, intermediates, raw materials, and finished products.

NOTE This can include calculated or aggregate values such as averages, minimums, maximums, etc.

4.3.3 Regulatory compliance

Batch production records may contain the information used to generate formal documents to meet the needs of regulatory compliance (such as U.S. FDA, OSHA, USDA, EPA, TUV, etc.). A batch production record may be used to document that processes are under control, the quality of the product, the conditions under which it was produced, or the work process of producing and/or releasing the product.

EXAMPLE In a regulated industry, there might be one batch production record to meet regulatory requirements and additional batch production records used to perform nonregulated production-related actions.

4.3.4 Production release

Batch production records can be defined for production release processes, such that all of the necessary information needed for release of the batch by a quality group, is available in the