

BS EN 61512-4:2010



BSI Standards Publication

Batch control

Part 4: Batch production records

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National foreword

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The UK participation in its preparation was entrusted by Technical Committee GEL/65, Measurement and control, to Subcommittee GEL/65/1, System considerations.

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EUROPEAN STANDARD
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EN 61512-4

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English version

**Batch control -
Part 4: Batch production records
(IEC 61512-4:2009)**

Contrôle-commande des processus
de fabrication par lots -
Partie 4: Enregistrements de production
par lots
(CEI 61512-4:2009)

Chargenorientierte Fahrweise -
Teil 4: Aufzeichnungen
zur Chargenproduktion
(IEC 61512-4:2009)

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Foreword

The text of document 65A/537/FDIS, future edition 1 of IEC 61512-4, prepared by SC 65A, System aspects, of IEC TC 65, Industrial-process measurement, control and automation, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61512-4 on 2010-09-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-06-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-09-01 |

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61512-4:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

- | | | |
|------------------|------|---|
| IEC 61512-3:2008 | NOTE | Harmonized as EN 61512-3:2008 (not modified). |
| IEC 62264-1:2003 | NOTE | Harmonized as EN 62264-1:2008 (not modified). |
-

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61512-1	1997	Batch control - Part 1: Models and terminology	EN 61512-1	1999
IEC 61512-2	2001	Batch control - Part 2: Data structures and guidelines for languages	EN 61512-2	2002
ANSI/ISA-95.00.01	2000	Enterprise-Control System Integration - Part 1: Models and Terminology	-	-
ANSI/ISA-95.00.02	2001	Enterprise-Control System Intergration - Part 2: Object Model Attributes	-	-

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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.

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.

EXAMPLE

A batch production record might be created to document:

- 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.

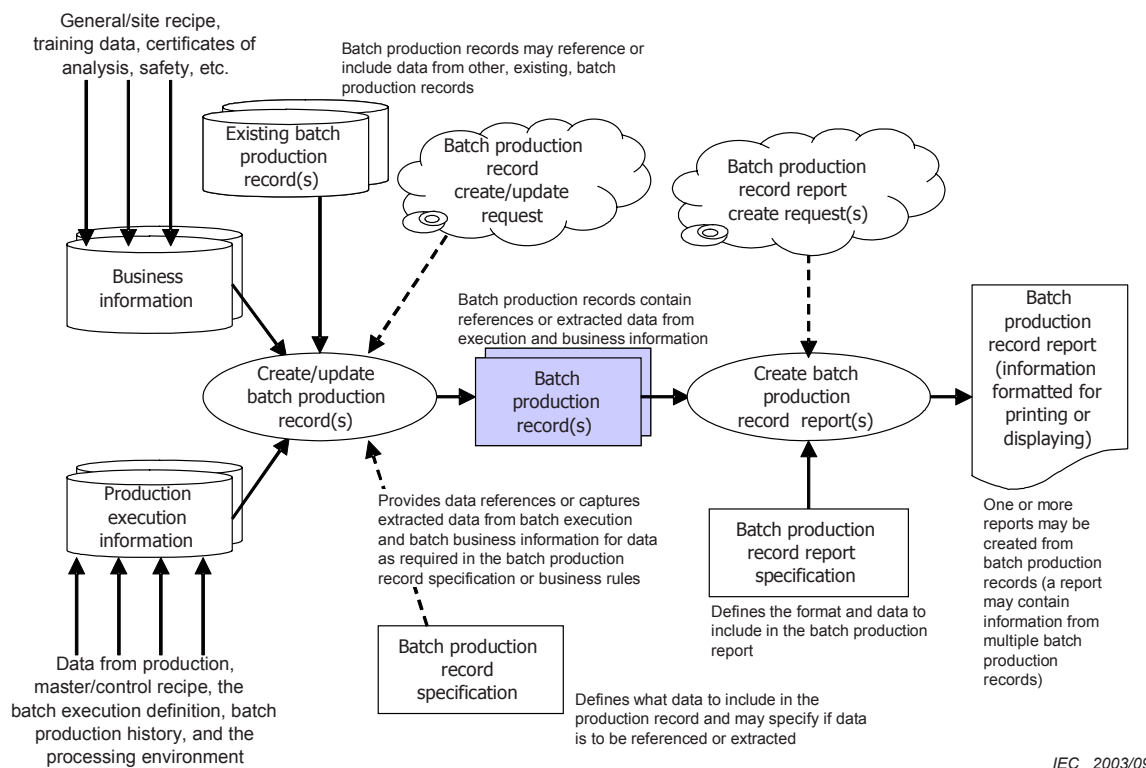


Figure 1 – Batch production record creation and use

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

batch production record. In some industries the production release signoff information may also be included in the batch production record.

4.3.5 Deviation management

Batch production records may be used in deviation management to document information about a batch. Usually the batch production record will include alarm and event information associated with the deviations. In some industries, the batch production record may also contain the resolution information of the deviation.

4.3.6 Quality management

Batch production records may be retained to meet one or more requirements, such as internal quality programs or to guard against future product liability claims.

4.3.7 Material tracking and tracing

Batch production records may be used to document which input materials contributed to the production of a lot. This may include which lots are produced from specific lots of material, and which lots were consumed in the production of a material lot.

4.3.8 Equipment tracking and tracing

Batch production records may be used to document which equipment contributed to the production of a batch. This may include the status of the equipment, such as its cleaning status or maintenance status, and may include location information about equipment. This may include which material lots are produced from specific equipment.

4.3.9 Personnel tracking

Batch production records may be used to document which personnel contributed to the production of a batch. This may include the qualification status of the personnel.

EXAMPLE Hazardous environment exposure tracking, hours spent in the operation, compliance to work rules, location of work.

4.3.10 Complying with contractual requirements

Batch production records may be used to document the information required to meet contractual requirements.

EXAMPLE 1 A manufacturer might need to document product quality information in a COA (Certificate of Analysis), or equipment information such as sterility periods, or cleaning verification of equipment.

EXAMPLE 2 A manufacturer could produce one batch production record to meet contractual requirements and a second one to satisfy internal record-keeping requirements.

4.3.11 Costing

Batch production records may contain the information about the resources (material, equipment, and personnel) used in the production of the batch. This information may be required to allocate costs associated with specific activities or costs associated with specific products.

4.3.12 Production knowledge base

A batch production record may be used to create batch production record reports that answer questions about production. Production questions may be:

- Who was involved?
- What actions were taken?

- When was it produced?
- Where was it produced?
- Why was it produced?
- How was it produced?
- What was the status of equipment used?
- What was consumed?
- What was produced?
- What were the deviations?

4.4 Batch production record data management

4.4.1 Data retention

The retention period of a batch production record and the referenced data is determined by business needs.

Definitions of standards for data archiving and retrieving are outside the scope of this part of IEC 61512.

Most batch production records and the data they reference have a finite life, at the end of which they may be deleted from storage based on established business processes.

EXAMPLE 1 There could be a regulatory requirement to maintain information for a period of three years after the production of a batch. After that period, there could be a business process that specifies that the batch production records and referenced data are automatically deleted.

EXAMPLE 2 Batch production records might be destroyed upon the end of the legally mandated record retention period or their destruction could require a review and/or approval process.

EXAMPLE 3 In some industries and companies, there is a requirement to retain batch production data for long periods (such as 10 to 20 years) and for different business or legal purposes.

NOTE If the retained data is moved to new versions of a storage system or a new storage system, then the batch production record's references to that data might need to be updated to reflect the new storage location.

4.4.2 Data integrity

If data is copied into a batch production record, care should be taken to ensure its integrity. The integrity of the data in the batch production record is intended to be ensured throughout a batch production record's lifecycle.

NOTE The precise requirements for data integrity are determined by business rules, which are often created to meet regulatory, contractual, quality and other requirements.

4.4.3 Creating batch production records

A batch production record is populated by copying, moving, or referencing entries from production execution and business information and placing them in a batch production record according to the batch production record specification.

A batch production record may be created at any time before, during, or after execution. The time a batch production record is created, or the event that causes it to be created, is ultimately determined by a business rule. There is no requirement for a batch or other element of batch production to be started, a batch ID to be assigned, or a batch to be completed in order to create a batch production record.

A batch production record may also be built when no formal batch production record specification exists. When this occurs, a person or computer program serves as the batch production record specification. In these cases, there may be no permanent batch production

record specification unless a manual or computer record is made to document the specification.

NOTE There is often some kind of standard operating procedure (SOP), business rule or specification for manually or programmatically creating batch production records.

4.4.4 Updating batch production records

After the initial creation and population of a batch production record, additional data may need to be added, changed or deleted from a batch production record. This may involve the addition of postproduction or product history data to the batch production record.

EXAMPLE 1 A one-time addition of data that was previously collected and stored in other systems.

EXAMPLE 2 Addition of data obtained after release of the material produced in the batch.

EXAMPLE 3 Modification of data in the batch production record after recalibrating an instrument.

EXAMPLE 4 Deletion of data in the batch production record that is no longer relevant.

The addition, modification, and deletion of data in a batch production record may have to comply with applicable corporate and legal requirements and government regulations. In this case, any change to a batch production record is intended to be done according to change control procedures and audit trail recording procedures based on business requirements and government regulations.

Depending upon business rules, records in the batch production record may be manually or programmatically added to a batch production record even if they are not in the batch production record specification.

EXAMPLE 5 In the pharmaceutical industry, if batch data is used to determine whether a product can be released, then that data is required to be available for later inspection, even if the data is not in the batch production record specification.

4.4.5 Lifecycle states

A batch production record may be assigned states that identify its status. The states are intended to be used in conjunction with business rules and authorizations to identify the permitted operations that may be carried out on the batch production record.

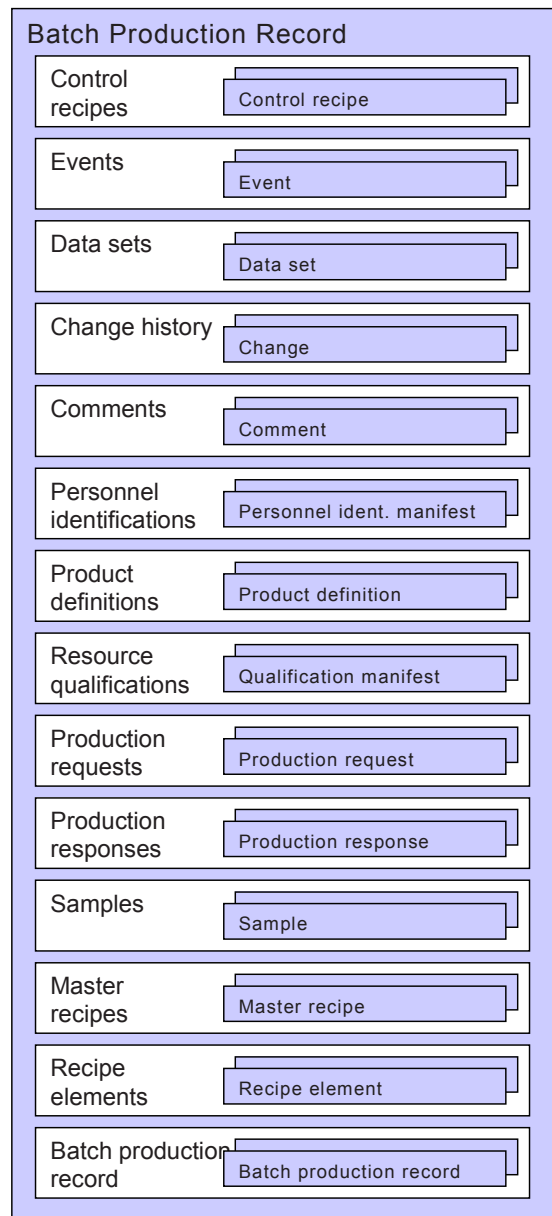
The possible states and state transitions of a batch production record are specified by business rules.

Different batch production record types may have different lifecycle states.

EXAMPLE A batch production record, which is designed to meet regulatory requirements, could have approval and signoff states; while a batch production record designed to meet ad-hoc production analysis might have no formal lifecycle state.

4.5 Batch production record structure

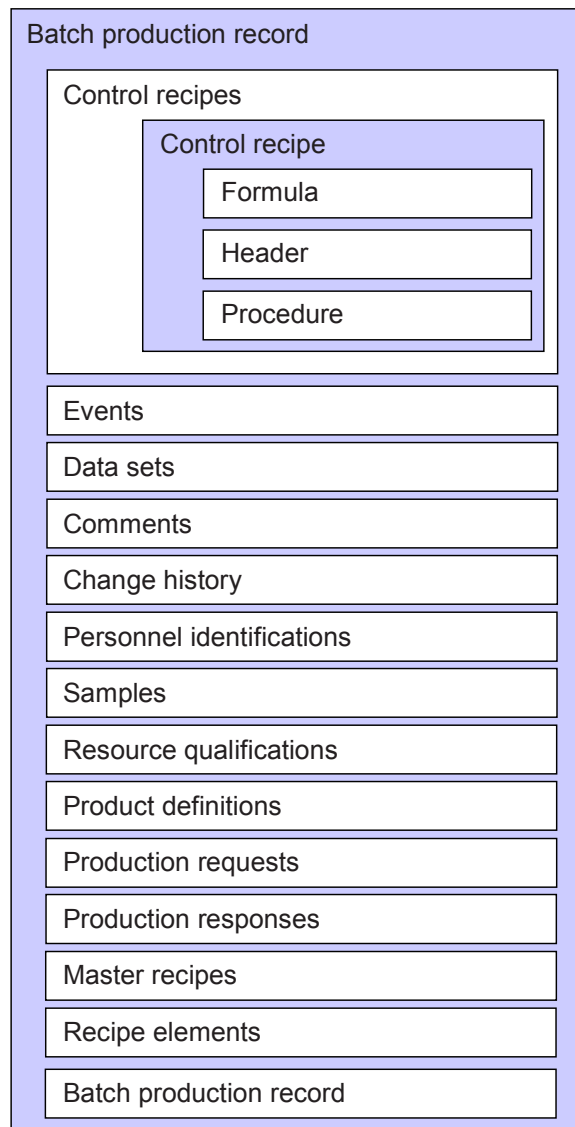
A batch production record is a container for specific types of batch production information. A batch container may contain zero or more elements which are defined as objects in Clause 5. Figure 2 illustrates a sample batch record that contains one of each type of component container and multiple elements within each component container.



IEC 2004/09

Figure 2 – Batch production record component objects

Some types of information are also containers and contain specific types of information, such as control recipe information containing the formula, header, and procedure information. Batch production records may also contain other batch production records. Figure 3 illustrates multiple containers using a subset of the batch production record component elements.



IEC 2005/09

Figure 3 – Example of a batch production record

EXAMPLE While a batch production record can contain any information, a typical use would be to contain a copy of the control recipe for a batch, a list of events that documented the events that occurred during the execution of the batch, continuous trend data collected during the execution of the batch, and a production response to define the personnel and equipment used, the material consumed, and the material produced as a result of execution of a batch.

Elements of a batch production record can reference other elements within the batch production record, as illustrated in Figure 4. It shows an example with one change history that references a changed control recipe formula, two personnel identification manifests, and one comment that references a change history element. One personnel identification manifest identifies the person and “Done by” action on the change history. The second identifies the person and “Checked by” action on the change history. The comment contains a comment associated with the change.

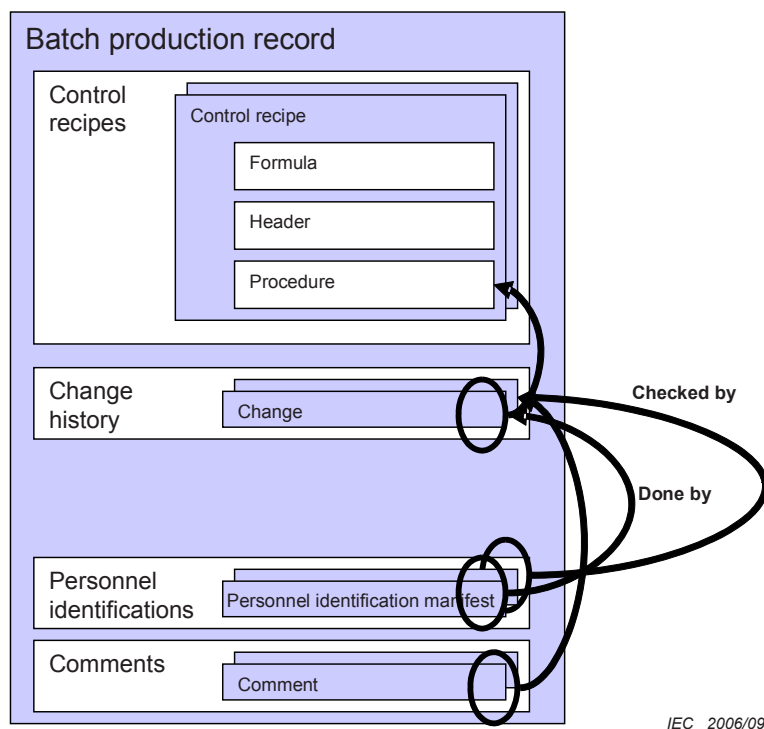


Figure 4 – Example of elements referencing other elements

Elements of batch production records may contain the relevant information or they may reference, or point to, the information in other data stores, such as databases as illustrated in Figure 5. It illustrates two cases of continuous trend data, where one element contains the trend data and the other element references an external database with the data.

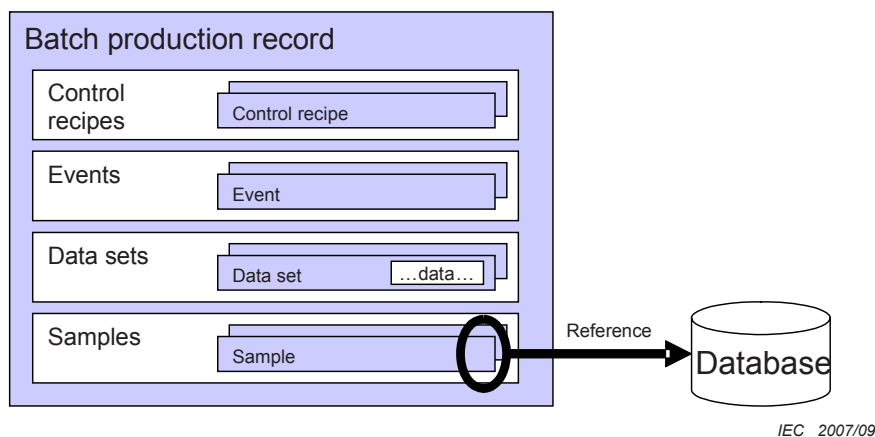


Figure 5 – Example of internal and referenced data

4.6 Production information

4.6.1 General

Production information is defined in IEC 61512-1. Production information is information that is collected during the course of production. It may include information collected prior to the start of production and information that is collected after the production of the batch. Production information may be batch specific or it may be common to several batches. Production information may also include other types of information such as: training records, discrepancy system information, and information from suppliers.

Production information is made up of business information and production execution information. The determination if an information source is business information or production execution information is determined by business rules.

4.6.2 Business information

Business information is data from non-production business systems, such as: HR (Human Resource), CRM (Customer Relationship Management), PLM (Product Lifecycle Management), finance, and SCM (Supply Chain Management) systems.

EXAMPLE Business information includes but is not limited to:

- general and site recipes;
- training data;
- certificate of analysis (COA);
- material safety data sheets (MSDS);
- customer information;
- cost and quality information on raw materials;
- maintenance history of equipment;
- production schedule (see ANSI/ISA-95.00.01-2000).

4.6.3 Production execution information

Production execution information is data from production resources such as equipment, material, energy, and personnel; the definition of production rules; production history; and information on the processing environment.

EXAMPLE Execution information includes:

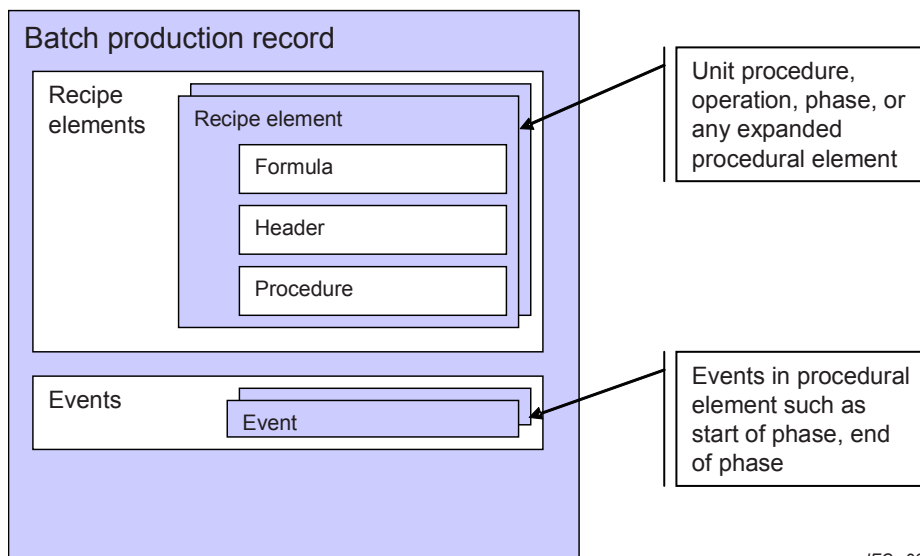
- master/control recipes;
- recipe parameters;
- schedule information;
- historical trending data;
- material quantity and property information;
- equipment status;
- equipment and control software configuration;
- standard operating procedures (SOPs);
- environmental conditions;
- alarms and abnormal events;
- information on the physical processing equipment and its configuration(s);
- work instructions used by operators.

4.6.4 Procedural element data

A batch production record may contain data about any recipe or equipment procedural element smaller than a complete batch, such as a unit procedure, operation, or phase. In this case, the batch production record may contain a recipe element object that contains data on the associated procedural element.

The procedural element may also contain data on any expanded procedural element hierarchy, when the standard procedural hierarchy has been extended in the control recipe. Figure 6 shows a sample batch production record that contains a recipe element and events related to the recipe element execution.

NOTE The recipe element data may be used to describe equipment procedural information if the equipment procedural elements follow the standard procedural hierarchy.



IEC 2008/09

Figure 6 – Sample batch production record for a recipe element

4.6.5 Common (non-batch specific) data

Over the lifecycle of a batch, there may be non-batch specific data that is stored in a batch production record. Non-batch specific data may be represented in a batch production record.

EXAMPLE 1 Non-batch specific data may include:

- ambient temperature and humidity;
- history of equipment modifications and maintenance;
- steam system pressure (trend or high/low exceptions).

EXAMPLE 2 A water analysis sample might be taken prior to the start of a batch. The water sampled might be used in multiple batches, but is not allocated to specific batches prior to its use. Therefore, each batch production record could need to include the water analysis results for the sample taken prior to its use from the water source used.

EXAMPLE 3 Storage and handling data for a lot of intermediate material produced in a single batch that will be used as a raw material in multiple batches.

EXAMPLE 4 Non-batch specific data can be represented in a batch production record, which does not include batch identification information, such as a continuous trend.

Figure 7 illustrates a batch production record containing two batch production records. The top level batch production record contains common data, such as data sets of environmental trends, and the inner batch production record contains the “batch-related-data-set” data within a batch production record.