

# PUBLICLY AVAILABLE SPECIFICATION PRE-STANDARD

**Batch control – Part 4: Batch production records**

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IEC PAS 61512-4:2007

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INTERNATIONAL  
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The text of this PAS is based on the following document:

This PAS was approved for publication by the P-members of the committee concerned as indicated in the following document

Draft PAS	Report on voting
65A/497A/PAS	65A502/RVN

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## INTRODUCTION

ANSI-ISA-88.01-1995 (referred to as Part 1 throughout this PAS) provides models and terminology applicable to batch control. Subclause 5.5 of Part 1 defines product information concepts and 6.4 defines production information management activities and functions.

ANSI/ISA-88.00.02-2001 (referred to as Part 2 throughout this PAS) provides, in Clause 4, an object model of production information and, in Clause 5, defines batch history exchange tables. The Clause 5 batch history exchange tables are one implementation for production information.

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

ANSI-ISA-88.00.03 (this PAS) provides a detailed definition for batch production records. This 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 ANSI/ISA88.00.02-2001 as well as with ANSI/ISA-88.01-1995.

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 PAS defines a reference model for batch production records containing information about production of batches or elements of batch production. This PAS is intended for batch processes.

#### 2 Normative references

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.

IEC 60050-351:2006, *International Electrotechnical Vocabulary – Part 351: Control technology*

IEC 61512-1 (all parts), *Batch control – Part 1: General examination*

IEC 62264-1:2003, *Enterprise-control system integration – Part 1: Models and terminology*

ISO/IEC 19501:2005, *Information technology – Open Distributed Processing – Unified Modeling Language (UML) Version 1.4.2*

ANSI/ISA-88.01:1995, *Batch control – Part 1: Models and terminology*

ANSI/ISA-88.00.02:2001, *Batch control – Part 2: Data structures and guidelines for languages*

ANSI/ISA-88.00.03:2003, *Batch control – Part 3: General and site recipe models and representation*

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*

ANSI/ISA-95.00.03:2005, *Enterprise-control system integration – Part 3: Models of manufacturing operations management*

#### 3 Terms and definitions

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

NOTE Terms, definitions and concepts expressed in Part 1 apply, except where differences are explicitly stated in this PAS.

##### 3.1

##### **batch history**

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

##### 3.2

##### **batch production record**

subset of the execution and business information that is retained on the basis of 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 record(s) that is(are) formatted for printing, displaying, or sending to a collaborating system

### 3.4

#### **batch production record specification**

- a) definition of the data to be included in the batch production record and specification if data is to be referenced or extracted.
- b) identification of the requirements of execution business information used for generation of a batch production record.

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 business information relating to batch production.

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

## 4 Batch production record description

### 4.1 Introduction

This clause provides an informative overview of a batch production record as defined in Clause 5 of this PAS. This PAS 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.

For example, a batch production record may 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 Parts 1 and 2 define production information and batch history functions, provide lists of the types of data they encompass and abstract models. However, Parts 1 and 2 do not define a formal and precise model of production information and batch history data. This PAS does not further define these terms and does not define production information or batch history system functions.

This PAS 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 "Production" implies batch production in all cases unless otherwise stated.

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

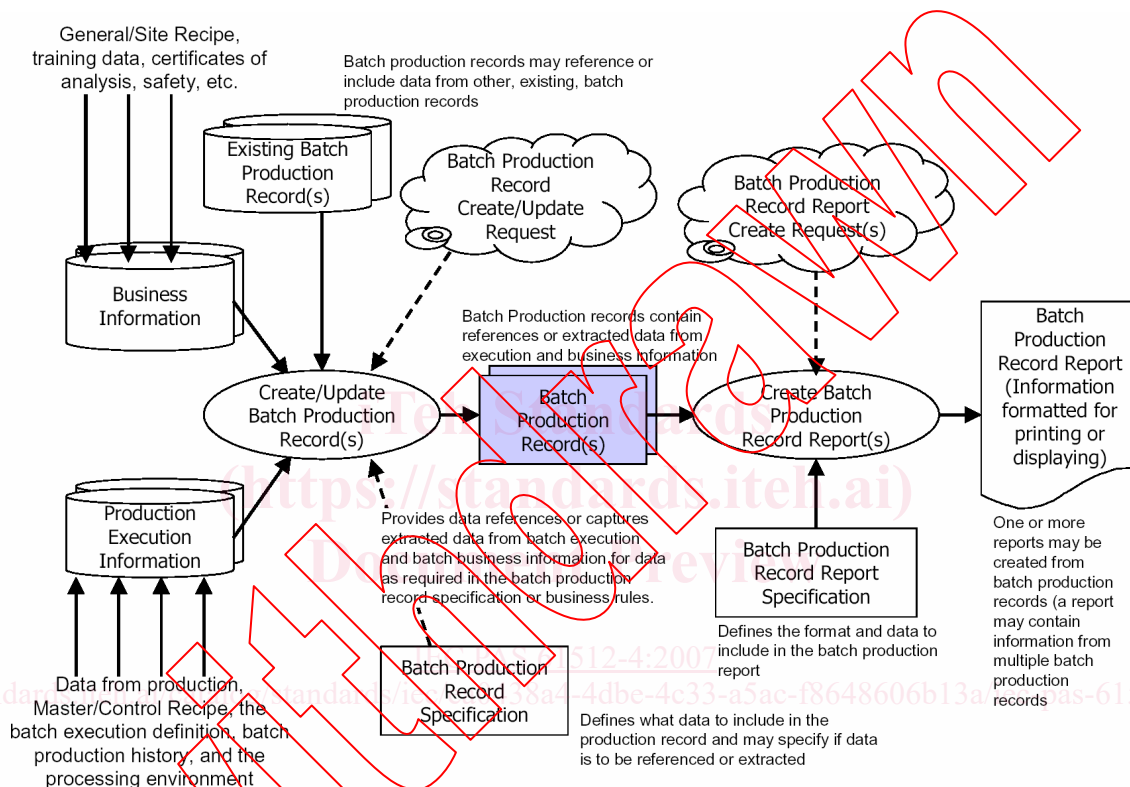


Figure 1 – Batch production record creation and use

#### 4.2 Batch production record

A batch production record is a subset of the production execution and business information that is retained on the basis of 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 may be a record of production quality.

Example 2: The business need may 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 may create a batch production record for the operational execution of an element of batch production.

Example 4: The system may create a batch production record for the personnel efficiency of an element of batch production.

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

A batch production record may reference other batch production records.

Example 5: A batch production record may reference the records for intermediate materials.

Example 6: A batch production record may include the records received with purchased ingredients.

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

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

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

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

Example 8: A control system may create a batch production record for the execution of an element of batch production and an MES/ERP system may 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.

#### **4.2.1 Business information**

Business information is data from non-production business systems.

Example: Business information may include material, training, or safety data.

#### **4.2.2 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 may include equipment status, material consumption, the definition of production rules, or production history.

Example 2: Production execution information may include environmental monitoring, utilities status or other information on the processing environment.

#### **4.2.3 Batch production record specification**

A batch production record specification is the information that may be used to define a batch production record. The content and format for batch production record specifications are not defined in this PAS.

There may 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 may be used to generate multiple batch production records, one for each batch of product XYZ produced.

Example 2: A single batch production record specification may be used to generate a single batch production record for all batches of product XYZ.

Example 3: A batch production record specification may be used to generate a batch production record for all production done during a shift.

Example 4: A batch production record specification may 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.

#### 4.2.4 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 PAS.

Example: A batch production record report may 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 Part 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

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

- 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 may be performed for the improvement of production processes, scheduling, or equipment utilization.

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