

PUBLICLY AVAILABLE SPECIFICATION PRE-STANDARD

Batch control – Part 4: Batch production records

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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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PUBLICLY AVAILABLE SPECIFICATION PRE-STANDARD

Batch control – Part 4: Batch production records

INTERNATIONAL
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IEC-PAS 61512-4 has been processed by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation. This PAS is an ANSI/ISA publication 88.00.04*.

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.

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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.

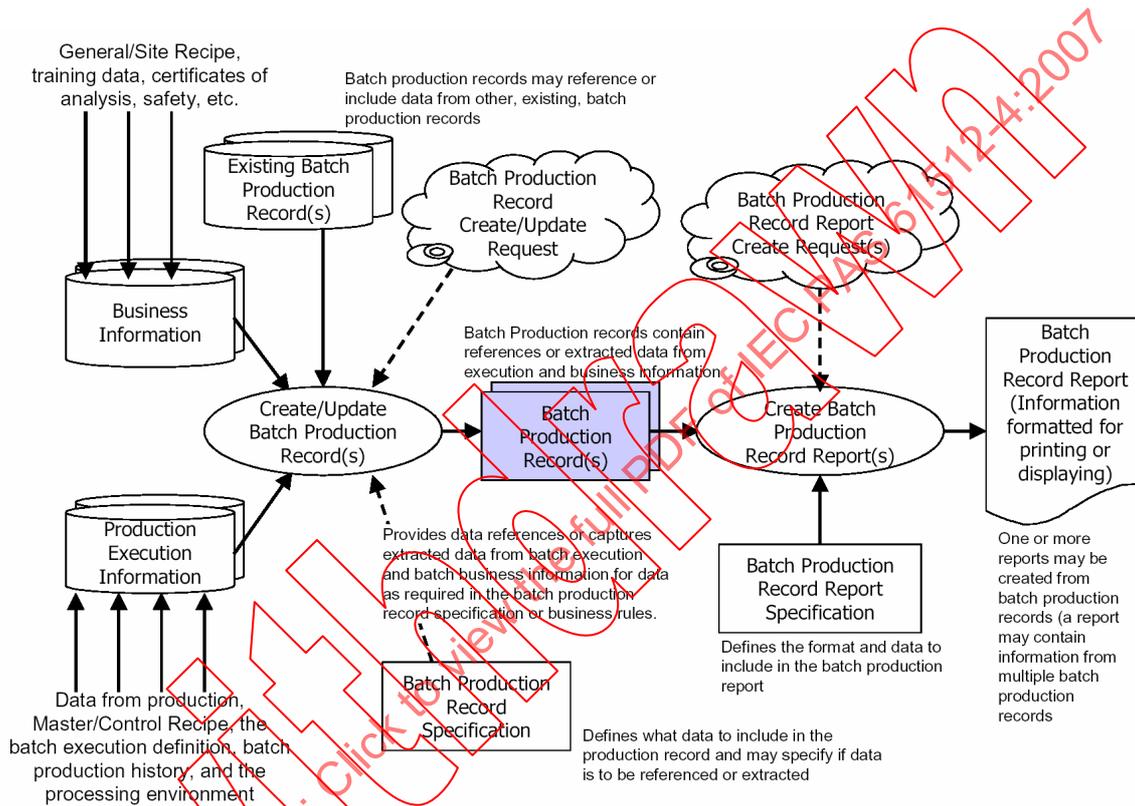


Figure 1 – Batch production record creation and use

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.

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

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

- 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 the fact 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 5: In a regulated industry, there may be one batch production record to meet predicate rule requirements and additional batch production records used to perform non-regulated production-related actions.

- production release

Batch production records can be defined for production release processes, such that all of the information, or at least most of the information, needed for release of the batch by a quality group, is available in the batch production record. In some industries, the production release sign-off information may also be included in the batch production record.

- 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.

- quality management

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

- 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.

- 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.

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

- complying with contractual requirements

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

Example 7: A manufacturer may 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 8: A manufacturer may produce one batch production record to meet contractual requirements and a second one to satisfy internal record-keeping requirements.

– 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.

– production knowledge base

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

Example 9: 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 PAS.

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

Example 2: Batch production records may be destroyed upon the end of the legally mandated record retention period or their destruction may 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 may 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 the lifecycle of a batch production record.

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 programme 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 Life-cycle 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 life-cycle states.

Example: A batch production record, which is designed to meet regulatory requirements, may have approval and signoff states; while a batch production record designed to meet *ad hoc* production analysis may have no formal life-cycle 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.

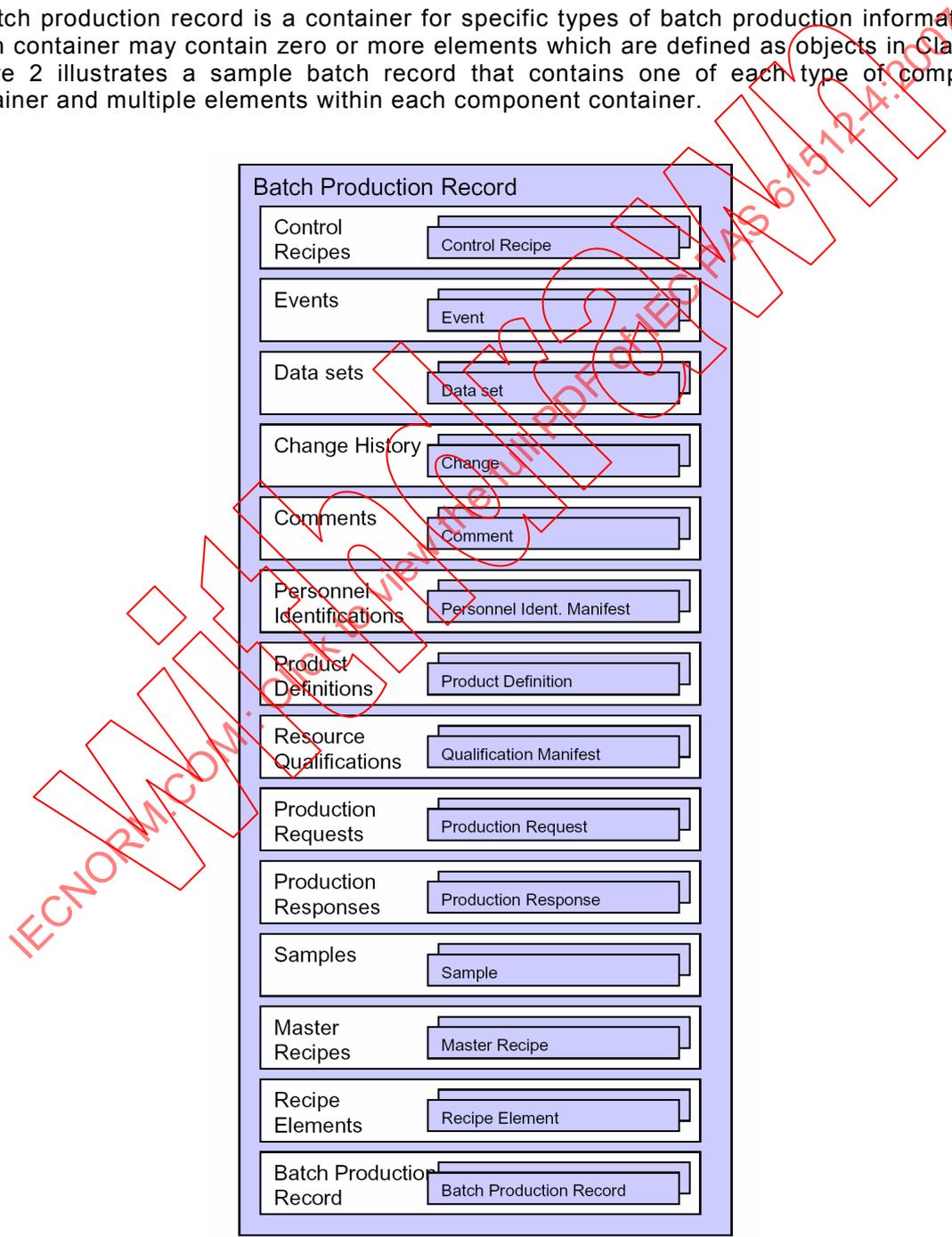


Figure 2 – Batch production record component objects

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.



Figure 3 – Example of a batch production record

Example: While a batch production record may 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 may 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.

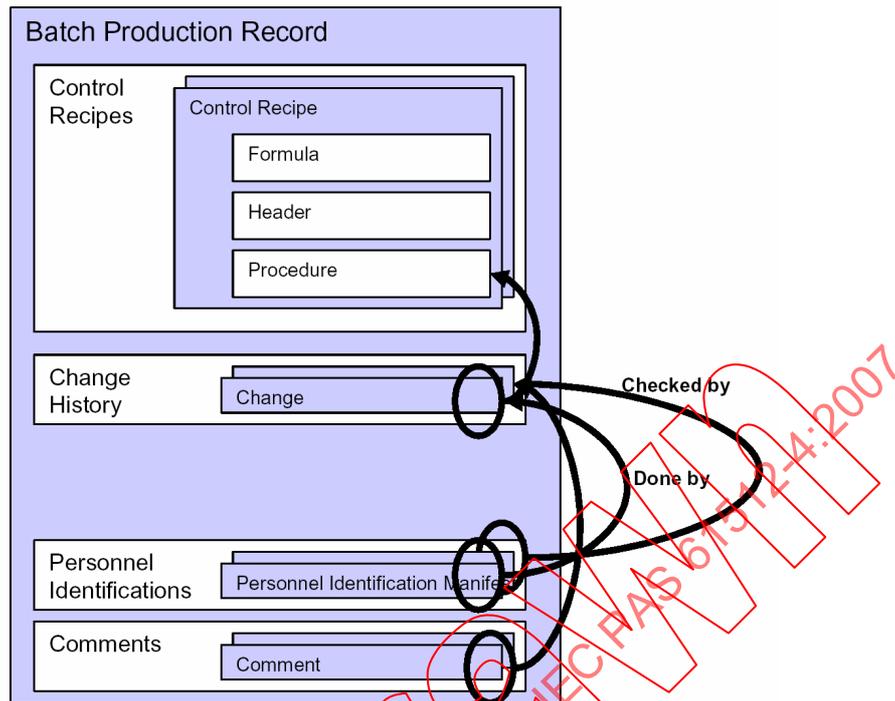


Figure 4 – Example of elements referencing another elements

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 the databases 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.

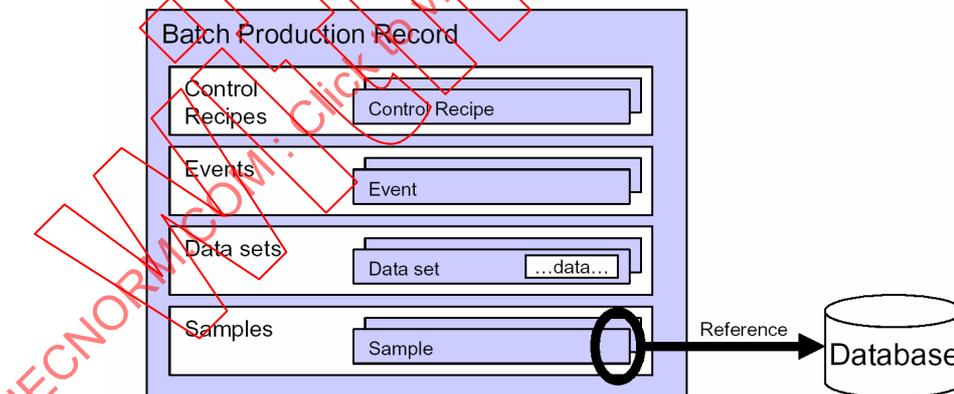


Figure 5 – Example of internal and referenced data

4.6 Production information

Production information is defined in Part 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.

4.6.1 Business information

Business information is data from non-production business systems, such as: HR (human resource), CRM (customer relationship management), PLM (product life-cycle 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).

4.6.2 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.

4.6.3 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 recipes follow the appropriate structure.

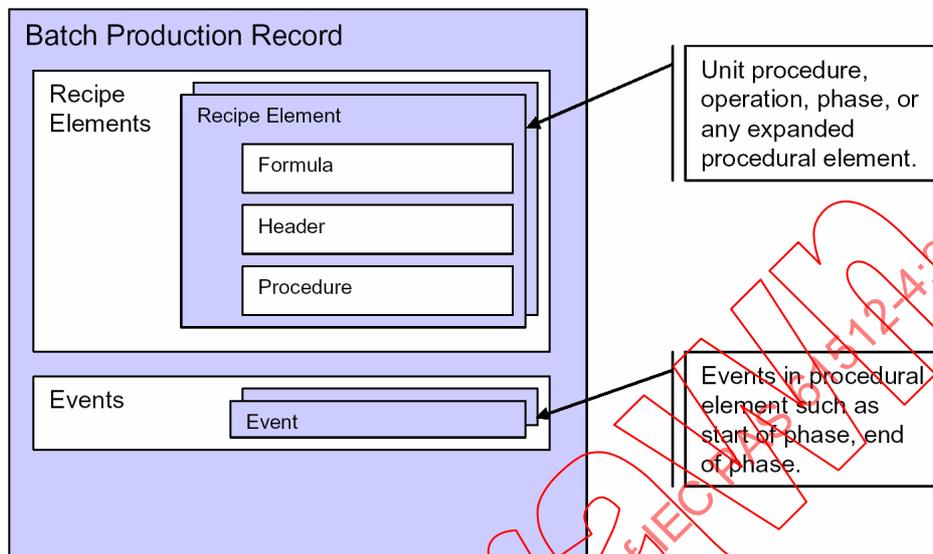


Figure 6 – Sample batch production record for a recipe element

4.6.4 Common (non-batch-specific) data

Over the life cycle 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 may be taken prior to the start of a batch. The water sampled may be used in multiple batches, but is not allocated to specific batches prior to its use. Therefore, each batch production record may 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 may 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.

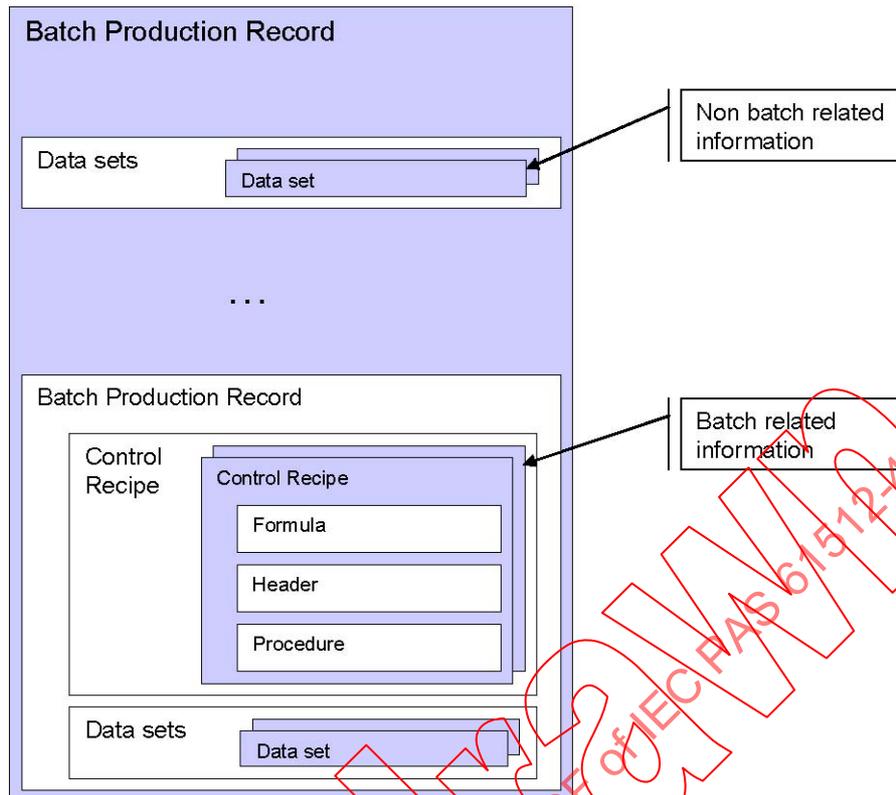


Figure 7 – Batch production record with non-batch-specific data

4.7 Batch production record elements

A batch production record may contain data about the following general categories of batch production information, defined in Table 1. This table relates the general categories of batch production information to the objects identified in Clause 5.

Table 1 – Batch production record categories

Category	Description
Actual values	<p>The actual values are the values that were returned from the equipment or personnel</p> <p>Example 1: The actual amount of material added to a vessel, such as 49,5 kg, against a target value of 50,0 kg</p> <p>Example 2: The actual yield of material produced based on a formula, such as 104,9 kg, against a target value of 1 000 kg</p> <p>Contained in the event, data set, sample, and production response objects (5.6, 5.7, 5.9 and 5.14)</p>
Batch production record identifying information	<p>Information that includes an identification of the batch production record, the date and time range covered, the element(s) of batch production covered, and the associated batch production record specification</p> <p>If the batch production record contains information from other batch production records, then it contains the identification of the other batch production records</p> <p>Defined in the batch production record object (5.4)</p>
Change history	<p>Contains a record of changes to a batch production record. This may include data such as the time the change was made, the name of the person making the change, and the reason for the change. Previous data should not be obscured</p> <p>Defined in the change object (5.10)</p>

Category	Description
Comments	<p>Comments are text from any authorized person to be included in the batch production record. For example, these may be from operators, managers, or reviewers</p> <p>Comments would typically include the date and time of the comments, as well as an identification of the person making the comment</p> <p>Defined in the comment object (5.8)</p>
Common non-batch specific information	<p>Information that may apply to one or more batches or parts of batches</p> <p>Contained in the batch production record object (5.4)</p>
Continuous trend data	<p>Data set data is time-sequenced data collected at some time frequency for some specific time</p> <p>Example 3: A vessel temperature collected every 20 s, during the execution of an operation</p> <p>The data values and information required to provide context to the data values (for example, collection time, collection frequency, quality, unit of measure) would be included in the tag identification object</p> <p>Defined in the data set object (5.7)</p>
Control recipe	<p>A copy of the control recipe(s) actually used in the element(s) of batch production. This includes an identification of the precise equipment configuration and recipe entities used</p> <p>The batch production record may contain a list of changes from the initial control recipe, such as parameter values and equipment binding</p> <p>The batch production record may include information that identifies changes to the control recipe that occurred during execution</p> <p>Defined in the control recipe object (5.16)</p>
Correlated data sets	<p>Correlated data sets include related values, which may be collected at the same time</p> <p>Example 4: A related set of volume and pH values collected during a chromatography column elution phase</p> <p>NOTE 1 This information is often used in process analytics.</p> <p>May be user extension of the event, data set, sample, and production response objects (5.6, 5.7, 5.9, and 5.14)</p>
Electronic signatures	<p>A representation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature</p> <p>Electronic signatures typically include the full name of the signatory, the date and time of the signing, and the meaning or reason for the signature</p> <p>NOTE 2 An electronic signature will have had a system check of identity before it is recorded.</p> <p>NOTE 3 The definition of the system checks are not defined in this PAS, just the means to record that the signature was checked and the signature information.</p> <p>NOTE 4 Requirements for when an electronic signature is collected, and the exact information required in an electronic signature, may be based on regulations and laws.</p> <p>Defined in the personnel identification manifest object (5.11)</p>
Equipment history	<p>Information on the equipment used in production</p> <p>Example 5: The history of cleaning, maintenance, sterilization, corrosion history, and use in other production runs</p> <p>Contained in production response and event objects (5.14 and 5.6)</p>

Category	Description
Events	<p>A representation of a discrete occurrence in time that has meaning or significance to the element of batch production</p> <p>Events may be expected (for example, the start of a batch) or unexpected (for example, an operator action or equipment alarm).</p> <p>Example 6: The start of an operation or a phase, the completion of a phase, an alarm condition detected, operator acknowledgement, or a set-point change</p> <p>Example 7: Operator intervenes to correct unexpected process upset, for example, places control module in manual mode</p> <p>Example 8: Process management events such as allocation of equipment to a batch, creation of a control recipe, etc.</p> <p>Attributes may be used to associate an event with a batch ID, person, equipment, recipe procedure or equipment procedure. These associations may be used by software applications to build an activity-based presentation of contemporaneous events (events that occurred in the same period of time) to identify an activity, for example, an instrument going into alarm, operator acknowledgement, set-point change, instrument returning to normal</p> <p>Defined in the event object (5.6)</p>
Late entries	<p>A representation of events or data regarding equipment, material, or personnel associated with a production activity that is recorded after the activity completes</p> <p>Example 9: Solvent lot number generated after performing QA analysis</p> <p>Contained in any object</p>
Material information	<p>Information on the material produced and consumed in production</p> <p>Material information supports the construction of material genealogy, the forward and backward tracing of a material's predecessors and successors</p> <p>Material information may include events that modify some aspect of the material. Each event describes a change in a material's state, quantity, quality, location, or existence. Types of material events include</p> <ul style="list-style-type: none"> • addition; • production; • consumption; • loss; • reconciliation; • movement <p>Defined in the production response and event object (5.14 and 5.6)</p>
Process values	<p>Information returned from equipment or personnel at specified points in the element of batch production</p> <p>Example 10: A pH, pressure, and temperature value at a time or point in a procedure execution</p> <p>Example 11: Minimum, maximum or average temperature during a phase</p> <p>Contained in the event, data set, control recipe (updated during execution), and production response objects (5.6, 5.7, 5.16, and 5.14)</p>
Product definition information	<p>Information about the product in production, such as the manufacturing bill, or bill of resources per element of batch production.</p> <p>Defined in the product definition object (5.13)</p>
Qualification information	<p>Information on the qualifications of personnel performing functions, qualification of the material being consumed or produced, or qualification of the equipment being used</p> <p>Example 12: Joe P. Operator has passed all required qualifications to run extractor unit</p> <p>Defined in the qualification manifest object (5.12)</p>

Category	Description
Quality information	Information about the quality of the material produced, material consumed and/or consumable materials used in production Example 13: Documentation of the workflow for batch and production release Example 14: Yields, lot release restrictions, process exceptions, etc. Contained in the master recipe, control recipe, sample, event, data set, and production response objects (5.18, 5.16, 5.9, 5.6, 5.7, and 5.14)
Target values	A recipe formula process parameter contains a target value to be used in the execution of the recipe. Example 15: A set-point for an amount of material to be added to a vessel, such as 50,0 kg Contained in product definition, control recipe and event objects (5.14, 5.16, and 5.6)
Sample and analysis data	Information that documents the analysis of process data during the production of a batch. This may include the use of pulling samples, using statistical analysis, and the results and comments of the analysis activity. It is also possible that one sample can have multiple data items associated with it Offline analysis information returned from equipment, personnel or laboratory systems. Sample and analysis data may be expected (for example, defined in recipe) or unexpected (for example, due to process excursions) Defined in the sample data and data set objects (5.9 and 5.7)
Scheduling information	Information used to schedule the element(s) of batch production Schedule information includes recipe formula values and equipment assignments that are part of the production command as well as targeted start date, targeted completion date, actual start date, and actual completion date Defined in the production request object (5.14)
Summary data	A rollup of production information, such as quality information, product disposition, and success rates, for a specified element of batch production, such as for a batch or campaign, or for a specific period of time This may include summary data that is collected before the batch is complete Contained in the event, data set, and production response objects (5.6, 5.7, and 5.14)

5 Batch production record object model

5.1 Introduction

This clause defines object models of a batch production record.

NOTE 1 The batch production record object model provides a reference model for the creation of data schemas that may be used to store batch production records.

NOTE 2 The intended use of these models is to provide a starting point for developing specifications for software components that address batch production records. The models are not intended to address the internal system architecture of batch production record management systems.

In the cases where the objects and relationships defined in this clause are presented through an interface or data structure, then that interface or data structure shall use the object names, the attribute names and the relationships of this clause commensurate with the interface technology chosen and the capabilities offered.

5.2 Modelling information

5.2.1 Time and date manifestation

When a time stamp, date, or time is used as an attribute, the time zone reference shall be included. The date and time shall be preserved so that it can be displayed without ambiguity.

A time stamp shall indicate the time zone of reference. If the time stamp is recorded in UTC, then the time stamp shall indicate UTC as the time zone referenced.

NOTE When systems span different time zones it may be acceptable to use a single time zone for all time values. Time values should be implemented with a clear understanding of the time zone reference used. In such instances, system documentation should explain time zone references as well as zone acronyms or other naming conventions.

5.2.2 Language

A batch production record may contain data that is in multiple languages. The specific language used for data in the batch production record should be identified.

5.2.3 Common (non-batch-specific) data

Common data, information not tied to only one batch, may be included as part of any of the objects. The only difference between common and batch data is that batch data is associated with a single batch (for example, a trend of a temperature measurement used during a reaction) where common data is associated with more than one batch (for example, utility feeds used concurrently by multiple batches) or has a very loose association with a batch (for example, the ambient air temperature during a batch).

5.2.4 Units of measure

The units of measure used within a batch production record should be consistent and unambiguous.

NOTE This is the responsibility of the application that creates and populates a batch production record.

5.2.5 Referenced data

Data may be embedded in a batch production record or the batch production record may reference externally stored data. When external data is referenced it shall be referenced using the common attributes defined in the batch production record entry type. This contains the attribute named "external reference," which contains an application-appropriate reference to the external data.

NOTE If externally referenced data is moved to a new system, then the references of the batch production record to that data may need to be updated to reflect the new storage location.

5.2.6 Modelling techniques

The models that are described in this clause are based on the unified modelling language (UML) defined in ISO/IEC 19501.

The tables describe only the class attributes of the objects. The relationships between objects are described in the figures.

5.2.7 Attribute definition

All attributes are optional unless identified as required in the appropriate clause.

5.2.8 Null values

Many attributes may have a null value. Implementations of this object model shall include a method to identify when attributes have intentionally been given a null value.

5.2.9 Data quality

Implementations of this object model should include a method to identify the data quality of critical attributes.

NOTE This PAS does not define standard data quality types.

Example 1: SQL implementations may have a requirement of NOT NULL for critical attributes such as *Entry ID* and *Time stamp*, preventing invalid null entries. An SQL implementation may further restrict the *Time stamp* attribute to only valid time values.

Example 2: XML implementations using XSD definitions may place data type minOccurs="1" on critical attributes and may further restrict an *Entry ID* element to a *token* or *normalizedString* type.

5.2.10 Object identification

Many objects in the information model require unique identifications (IDs). These IDs shall be unique within the scope of the exchanged information.

NOTE The object IDs are defined only to identify objects within related information sets. The object ID attributes are not global object IDs or database index attributes. Generally, objects that are elements of aggregations, and are not referenced elsewhere in the model, do not require unique IDs.

5.2.11 Data types

The attributes defined are abstract representations, without any specific data type defined. A specific implementation may define how the information is represented.

Example: Implementations may include the following.

- a) An attribute may be represented as a string in one implementation and as a numeric value in another implementation.
- b) A date/time value may be represented in ISO standard format in one implementation and in Julian calendar format in another.
- c) A relationship may be represented by two fields (type and key) in data base tables or by a specific tag in XML.

An attribute specification containing a "list of" in the description indicates that there may be zero or more elements of the attribute.

NOTE Lists could be represented in a complete UML model as an implementation as separate objects but are only shown as single objects in order to reduce the UML model complexity.

5.2.12 Procedural element references

Several of the objects contain references to an instance of execution of a procedural element. This should be a reference to control recipe procedural element or equipment procedural element as defined in Part 2.

Example 1: Recipe procedure, recipe unit procedure, recipe operation or recipe phase.

Example 2: Equipment procedure, equipment unit procedure, equipment operation or equipment phase.

The purpose of this is to associate the data in the product record with the appropriate instance of production execution. The procedural element and an identification of the instances of execution shall be defined as part of the procedural element reference.

The format of the reference is not defined in this PAS and is implementation-specific.

Example 3: For batch B-00234, "reaction" procedure, second instance of the "charge" operation and fifth instance of the "add water" phase could be represented as:

B-00234 | Reaction | Charge [2] | Add Water [5]

Example 4: For execution of an equipment phase (without a related recipe) within process cell “fill cell” in unit “Filler-1”, fourth execution of equipment phase “clean” could be represented as:

Fill Cell | Filler-1 | Clean [4]

5.2.13 BPR internal references

Several of the objects can reference other objects in the batch production record (BPR). This is additional information captured as part of the production execution or review processes.

The following four objects may reference other objects: comments, personnel identification manifest, qualification manifest, and change history as shown in Figure 8.

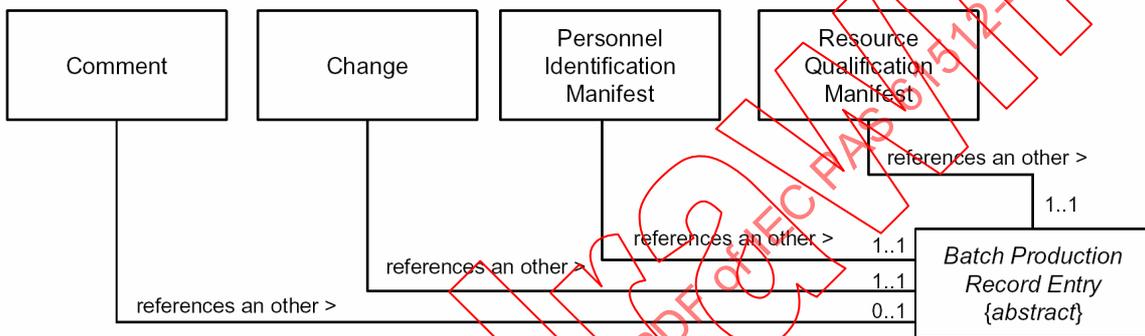


Figure 8 – Object reference model

5.2.14 Definition of examples

Examples are included with each attribute definition. Where multiple examples are used, there are multiple rows in the right-hand column. See Table 2 for how the example rows and columns are used.

Table 2 – Table example

Attribute name	Description	Examples
Name of first attribute	Description of first attribute	Example #1 for first attribute Example #2 for first attribute Example #3 for first attribute
Name of second attribute	Description of second attribute	Example #1 for second attribute Example #2 for second attribute Example #3 for second attribute
Name of third attribute	Description of third attribute	Example #1 for third attribute Example #2 for third attribute Example #3 for third attribute

When an example value is a set of values, or a member of a set of values, the set of values is defined within a set of braces { }. The examples are purely fictional. They are provided to further describe attributes in the model. No attempt was made to make the examples complete or representative of any manufacturing enterprise.

5.3 Batch production record object model overview

The top-level object model for a batch production record is shown in Figure 9.

The batch production record shall be a container object that holds all of the batch production record information; it consists of a set of container objects, each one containing a specific category of information. The purpose of container objects is to structure a batch production record so that elements of the same type (event, comment, data set, etc.) are defined together.

NOTE 1 Most container objects have no standard attributes and are only defined for structuring purposes.

NOTE 2 Batch production records could contain tens of thousand elements, and the use of container objects is expected to reduce the time needed to generate production records and to check a batch production record for syntactic correctness. Container objects are also expected to make parsing of batch production records, as well as searching for selected information, easier.

To reduce complexity, Figure 9 only shows the top-level containers. Some of the containers contain other objects shown in later sections.

All of the objects that make up a container, except for the top-level batch production record object, are optional. Any given instance of a batch production record may contain none, some or all of the container objects based upon the business purpose of the batch production record.

NOTE 3 In order to accommodate industry, business, and application requirements in the future, it may be necessary to add new objects and/or attributes to an implementation of the batch production record (see 6.4).

Over the life cycle of a batch production record, the containers and/or objects that make up the batch production record may change.

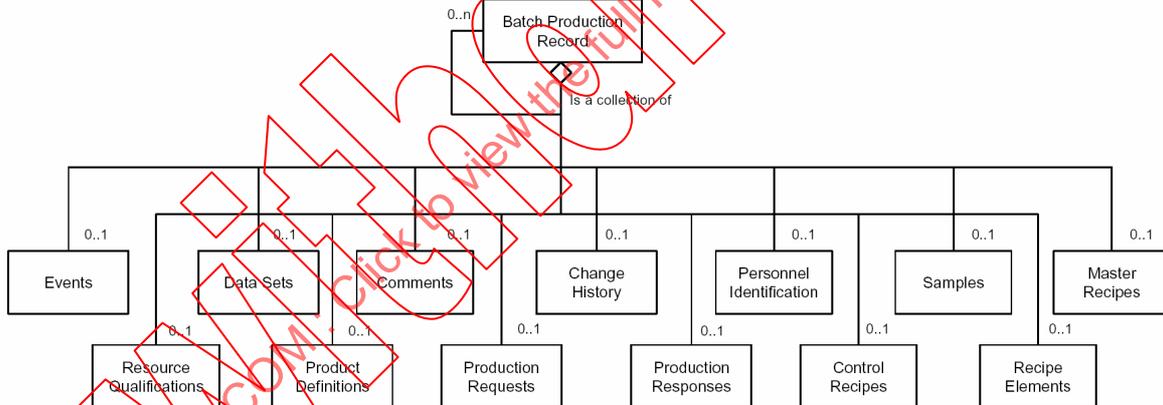


Figure 9 – Batch production record top level model

The elements within the containers are specialized types of batch production record entries as shown in Figure 10.

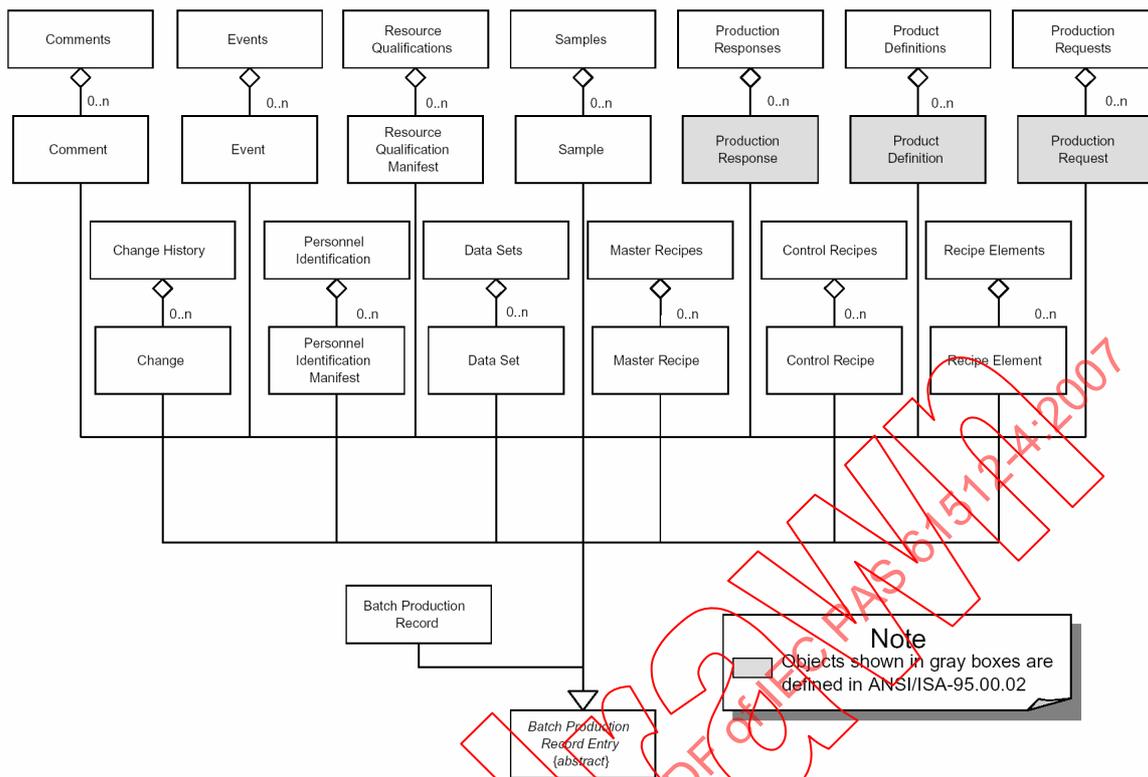


Figure 10 – Batch production record object model

5.4 Batch production record

The batch production record object shall be the root object in the data model.

A batch production record may also contain batch production records.

Table 3 defines the attributes for the batch production record object.

Table 3 – Batch production record attributes

Name	Description	Examples
ID	<p>A unique identification of the batch production record. This attribute is mandatory. The ID is required to provide a batch production record with a unique identity. The ID attribute may be modified over the life cycle of a batch production record, although it shall not be completely removed</p> <p>NOTE 1 The batch production record ID typically is based upon a single batch ID or a lot ID. When multiple elements of batch production are required to produce one lot of material, the ID may contain both the overall batch/lot ID and an element of batch production ID identifying a subset of the production.</p>	<p>492-2931</p> <p>T59482A4</p> <p>456</p>
Description	Additional information about the batch production record	<p>Lot release</p> <p>Campaign costing</p> <p>Compliance</p> <p>Material tracking data</p>

Name	Description	Examples
Equipment scope	<p>The equipment hierarchy scope of the data associated with batch production record</p> <p>This information represents the physical structure of the referenced entity to identify its context within the plant physical hierarchy</p>	<p>Process cell</p> <p>Site Area Unit</p> <p>Toledo Dog food Line 2</p>
Creation date	The date the batch production record was created	<p>2003-07-14 1454+0100</p> <p>01 March 2004 14:25 UTC</p> <p>April 23, 2002 8:30 AM ET</p>
Last changed date	The date the batch production record was last changed	<p>2003-07-14 1454+0100</p> <p>01 March 2004 14:25 UTC</p> <p>April 23, 2002 8:30 AM ET</p>
Change indication	<p>An indication enabling detection that the batch production record has not been altered</p> <p>The change indication enables detection that a batch production record has been altered, although may not identify the specific alterations</p> <p>Example 1: A string generated by an MD5 algorithm used as a hashing algorithm</p> <p>Example 2: A string representing a digital key of the entire batch production record</p> <p>Example 3: A string representing a checksum of the entire batch production record</p>	<p>E:4J9QJG;RGJAOF0</p> <p>FKG9GRKGH44FF</p> <p>KRJG49TJHVSNS</p>
Record status	<p>Current status of the batch production record. This reflects the current position in a batch production record's life cycle</p> <p>NOTE 2 Part 4 does not define standard status values.</p>	<p>In process</p> <p>Review</p> <p>Approved</p>
Batch production record specification ID	Unique identification of the batch production record specification used to create this batch production record	<p>459293A1-T423 ver 1.0</p> <p>A4Q59492-X43S</p> <p>Polymer56-PRS42</p>
Expiration date	Date and time at which the batch production record is no longer relevant	<p>2003-07-14</p> <p>1454+0100</p> <p>01 March 2004 14:25 UTC</p> <p>April 23, 2002 8:30 AM ET</p>
Version	<p>The current version of the batch production record</p> <p>NOTE 3 Change objects provide historical information concerning how this version was created.</p>	1.0 11 T
Campaign ID	The list of IDs of the campaigns associated with the batch production record	C4293 923-AKW5.7 832
Lot ID	<p>The list of IDs of the lots associated with the batch production record</p> <p>NOTE 4 This is a roll-up of detailed information about produced and consumed material lots that are included in other batch production record entries.</p>	<p>L492840</p> <p>EOVMW2</p> <p>84293</p>
Batch ID	<p>The list of IDs of the batches associated with the batch production record</p> <p>NOTE 5 This is a roll-up of detailed information about produced and consumed material lots that are included in other batch production record entries.</p>	<p>59429-35</p> <p>B-000349</p> <p>200309041435</p>
Material definition ID	<p>The list of IDs of the products associated with the batch production record</p> <p>NOTE 6 This is a roll-up of detailed information about produced and consumed material lots that are included in other batch production record entries.</p>	<p>459293A1</p> <p>A4Q59492-5942.1</p> <p>Polymer56</p>

Name	Description	Examples
Equipment ID	The list of equipment associated with batch production record NOTE 7 This is a roll up of detailed information that may be included in other batch production record entries.	Reactor1 Tank 402
Delimiter	Defines the character set to be used in delimiting elements in equipment IDs, and procedural element reference	" " "/"
Language	The language used in the batch production record should be identified. If multiple languages are used, the primary language should be identified here, and each instance where other languages are used throughout the batch production record a local reference to the language should be made	English Spanish French Korean

5.5 Batch production record entry

A batch production record entry is an abstract type used to define common attributes for many of the objects that make up a batch production record. All specialized types of batch production record entry objects (shown in Figure 10) shall have the attributes defined in Table 4.

Table 4 – Batch production record entry attributes

Name	Description	Examples
Entry ID	ID which is unique within the scope of a batch production record. This attribute is mandatory	1 239432 4A34B
Description	Additional information about the entry	The control recipe is embedded in this batch production record Data set time series data is stored in the historian database
External reference	Contains a reference to data which is stored external to the batch production record NOTE 1 If data is embedded in the batch production record this attribute is not used. NOTE 2 The format of the reference is determined by a conforming specification.	Batch control system for process cell A http://batchserver39/batch_journal/BID-39392 \\dept_share\archive2004\product_ABC
Object type	Identifies the type of object an entry is based upon.	Control recipe Data set Change history
Time stamp	The time stamp associated with the entry	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET

5.6 Event

5.6.1 Event object

An event object shall be represented by the model in Figure 11. An event is a discrete occurrence in time. Event objects document occurrences and can be stored in a batch production record. This is usually done when an event has meaning or significance to the manufacture of a product.

There are different types of event objects. Each event is identified by an event type. Within an event type there are different subtypes. Each event type and subtype may use a different subset of the event attributes.

Any event may contain zero or more user-defined attributes. Attributes not included in the event object may be defined in user-defined attribute objects. This may be required when specific systems generate event content not covered by the standard event object.

Event objects may be associated with other events. For example, a process signal may generate a high alarm, and then a high-high alarm before the high alarm is acknowledged. Then the high-high alarm may be acknowledged. All of the event objects in this scenario could be associated with each other to make the information more meaningful than a set of three unassociated event objects with some common data would be.

Figure 12 illustrates an example batch production record with multiple event objects, one associated event object, and two comment objects. The two comment objects refer to two different event objects. One event is associated with another event, and one event with a user-defined data element is associated with another event.

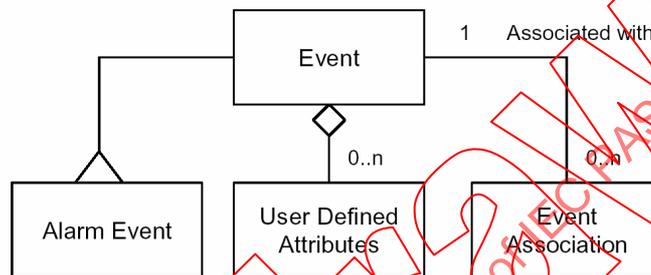


Figure 11 – Event model

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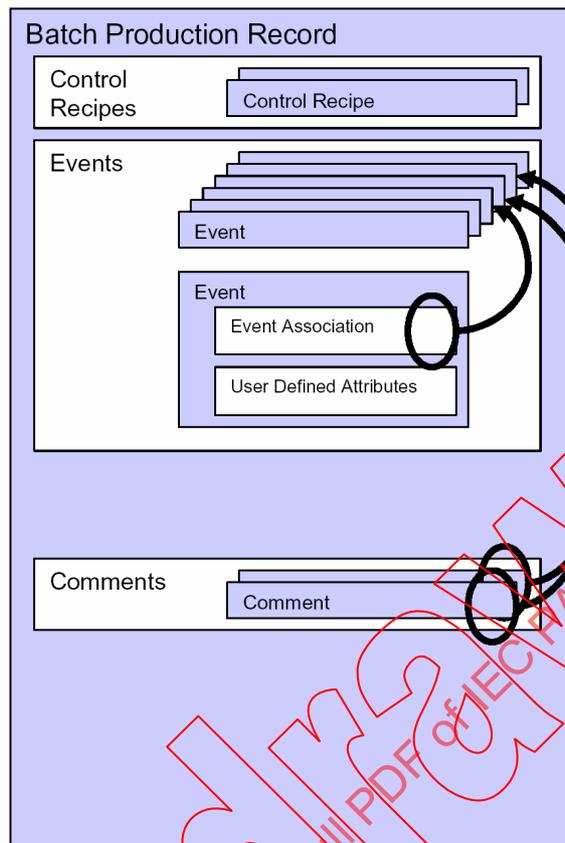


Figure 12 – Example of event element relationships

The “time stamp” attribute (inherited from batch production record entry) contains the date and time the event occurred. This attribute is required for all events.

5.6.2 Event attributes

Table 5 lists the attributes of event objects.

Table 5 – Event attributes

Name	Description	Examples
Event type	Defines the type of the event See Table 7 for the list of standard event types	Equipment Procedural execution
Event subtype	Defines the subtype of the event See Table 7 for the list of standard event subtypes	Process data State change
Equipment ID	Identification of the equipment associated with the event NOTE 1 This is a reference to an equipment entity in the batch control system equipment model.	R101CompanyE Site 456 Area 51 Cell 6 R101 TIC203 TIC439
Value	Value associated with the event See the event type and event subtype for the meaning of the value	5,0 gallons 5,230,439 ea Red Open Failed Normal 0,3928356834

Name	Description	Examples
Previous value	The value prior to the change documented by the event NOTE 2 For example, when a set-point is changed from 50,0 to 69,4. In this case the previous value is 50,0 and the value is 69,4. NOTE 3 This may be used to document changes in equipment status as when the status of a vessel changes from dirty to clean.	50,0 °C Clean High alarm
Message text	Text describing the event	Unit recipe started Ingredient A charge complete – 50,3 kg Batch complete
Person ID	Identification of the person associated with the event	48392 \\AMER\JackNicholson01 Chiaki Shimada
Computer ID	Unique identification of the computer where the event originated. For example, this may be a general-purpose computer, a controller, or a field instrument	Process cell 1 historian Line 4 control system
Procedural element reference	Reference to a procedural element This maps to an element of the procedural hierarchy, such as a phase in a control recipe, or an operation in a control recipe	B-00234 Reaction Charge[2] Add water[5] <NULL>
Category	The use category of the event NOTE 4 Standard use categories of events are not defined as part of this PAS.	Informational 5 Critical Escalation

5.6.3 Alarm event

Table 6 lists the attributes of alarm event objects.

Table 6 – Alarm event attributes

Name	Description	Examples
Alarm event	Record of different events during an alarm life cycle NOTE 1 Standard alarm events are not defined as part of this PAS.	Alarm Detection Acknowledgement Clear escalation level 3
Alarm limit	Value a measurement exceeded that caused the alarm	459 193 3,38
Alarm type	The type of alarm from a process perspective NOTE 2 Standard alarm events are not defined as part of this PAS.	High Deviation Rate of change
Priority	Indication of the importance of an event NOTE 3 Standard priorities are not defined as part of this PAS. Each conforming specification should provide a key for determining what the priority value means, for example, is 1 the highest or lowest priority.	1 Low 10

5.6.4 Standard event type

Table 7 lists the standard event types and event subtypes. Additional event types and event subtypes may be used as required if events do not fall into an existing category.

Table 7 – Standard event types

Event type	Event subtype	Description
Control recipe	Modification	Change in value for a parameter in a control recipe Value attribute contains the new data value. The previous value contains the old data value Example 1: Temperature set-point changed to 500, scaling factor applied to control recipe
Control recipe	Equipment	Change in equipment assigned to or bound to a unit procedure Value attribute contains the new unit name. The previous value contains the old data unit name Example 2: Reactor 34 bound/assigned to unit procedure 2 in batch 5942
Equipment	Allocation	Allocation of a unit or shared resource to a batch and/or unit recipe Value attribute contains the equipment ID Example 3: Unit or equipment module acquired
Equipment	Deallocation	Deallocation of a unit or shared resource by a batch and/or unit recipe Value attribute contains the equipment ID Example 4: Unit or equipment module released
Equipment	State change	Record of an equipment state change as defined in Part 1 Example 5: Step 4 started, step 54 stopped
Equipment	State command	Record of a command to change equipment state as defined in Part 1 Example 6: Pause procedural elements
Equipment	Status change	Record of an equipment status change NOTE 1 Equipment statuses are not defined as part of this PAS.
Equipment	Mode change	Record of an equipment mode change as defined in Part 1.
Equipment	Mode command	Record of a command to change equipment mode as defined in Part 1
Equipment	Process data	Record of a process value received from equipment that has no procedural execution reference
Equipment	Message	Informative information generated by logic controlling a piece of equipment Example 7: Field button used to start manual skid washing sequence
Equipment	Prompt	A request from equipment logic to the operator to provide information for the completion of the logic Value attribute contains text sent to the operator
Equipment	Prompt response	Operator response to an equipment prompt Value attribute contains text or data entry made in response to a prompt
Equipment	Modification	Change in value for a parameter in equipment Value attribute contains the new data value. The previous value contains the old data value Example 8: Temperature set-point changed to 500

Event type	Event subtype	Description
Alarm	Process	Alarm on a process value or quality measurement Example 9: Measured value high, manually entered value out of range, calculated value low, temperature traps did not reach target, assay out of limits, or bad quality status on a measurement
General	Message	Informative information generated by an application or control logic
Message	System	Message regarding a system component Example 10: Computer virtual memory low, free disk space low, controller failed, I/O card failure, communications subsystem failure
Message	Application	Message regarding an application Example 11: Programme failed to start, programme crashed, programme shutdown, batch server removed batch 3493 from batch list, event file name for a batch
Message	Security	Message regarding security Example 12: Invalid login password, invalid account name, valid login, violation of user rights
Procedural execution	Prompt	A request from a phase to the operator to provide information for the completion of the phase logic Value attribute contains text sent to the operator Example 13: Execute SOP 324, perform line clearance per SOP 394
Procedural execution	Prompt response	Operator response to a prompt Value attribute contains text or data entry made in response to a prompt
Procedural execution	Process data	Record of a process value. Example 14: Actual amount of material C-39393 charged is 49,3 kg, 49 gpm
Procedural execution	Message	Informative text Example 15: Start data collection on tag XYZ-123, change data collection frequency to 0,1 s on tag DTY-384, data value collected by phase logic reported to batch server, MSDS referenced
Procedural execution	State change	A procedural element state change Value attribute contains the new state, previous value attribute contains the old state Example 16: Active step change NOTE 2 This subtype may be used to record activity in subdivisions of a procedural element such as step start/stop.
Procedural execution	State command	A request to a procedure element to change its state Value attribute contains the command
Procedural execution	Mode change	A procedural element mode change Value attribute contains the new mode, previous value attribute contains the old mode
Procedural execution	Mode command	A request to a procedural element to change mode Value attribute contains the command
Procedural execution	Target start time	Target start time for a procedural element Value attribute contains a time and date
Procedural execution	Target end time	Target end time for a procedural element Value attribute contains a time and date

Event type	Event subtype	Description
Operator	Message	Information generated by personnel Example 17: It started to rain and the P2 drain is clogged
Material	Movement	Material enters or exits the process cell. Material storage location has changed
Material	Consume	Material was used in production
Material	Produce	Material was created in production
Material	Reconciliation	Material amount changed, usually as a result of inventory counts. Negotiated response to inventory amount
Material	Status change	Change in the status of a material (for example, quarantine, hold, release). Previous value contains the old status, value contains new status
Material	Property value change	Change in the property of a material (for example, pH changed since last measurement). Previous value contains the old value, value contains new value

5.6.5 User-defined attribute

Table 8 lists the attributes of user-defined attribute objects.

The user-defined attribute element is used to include additional information about an event, when the event information cannot be represented in the event object.

Table 8 – User-defined attribute attributes

Name	Description	Examples
ID	Identification of the attribute	Operator station timestamp Equipment binding digital key
Description	Additional information about the user-defined attribute	Hash value for the event <NULL>
Value	The value of the ID	2003-07-14 1454+0100 Reactor 3 D49E9DEE3439932939578
Unit of measure	The unit of measure for the value	kg L °C
Data type	Identification of the data type contained in the value NOTE Each implementation of this model should document the allowed data types.	Float date string

5.6.6 Event association

Event objects may be associated to other event objects, such as through a time-based or equipment-based relationship. Event association objects contain the associations.

Table 9 lists the attributes of event association objects.

Table 9 – Event association attributes

Name	Description	Examples
Associated entry ID	Identification of the associated event object	1 239432 4A34B
Association	Description of the association	Charge phase Pump failure E-stop

5.7 Data set

5.7.1 Data set object

A data set object shall be represented by the model in Figure 14. A data set defines arrays of related data values that can be used to represent time series or correlated data values. Correlated data sets are a representation of related data values.

NOTE 1 Time series data sets are data arrays where the time value represents time, and other elements represent the values for specific tag at the specified time.

NOTE 2 Correlated data sets are data arrays which do not have time as one of the elements, such as any array of pressures versus temperatures where time is irrelevant.

Data set objects provide the ability to store time series data points that are not contiguous, to account for variable collection rates, and to store time-insensitive correlated data sets.

Data set objects contain ordered collections of zero or more time specifications, one or more tag identification definitions, and one or more tag data definitions. Tag data definitions contain an optional time value and an ordered set of one or more data values.

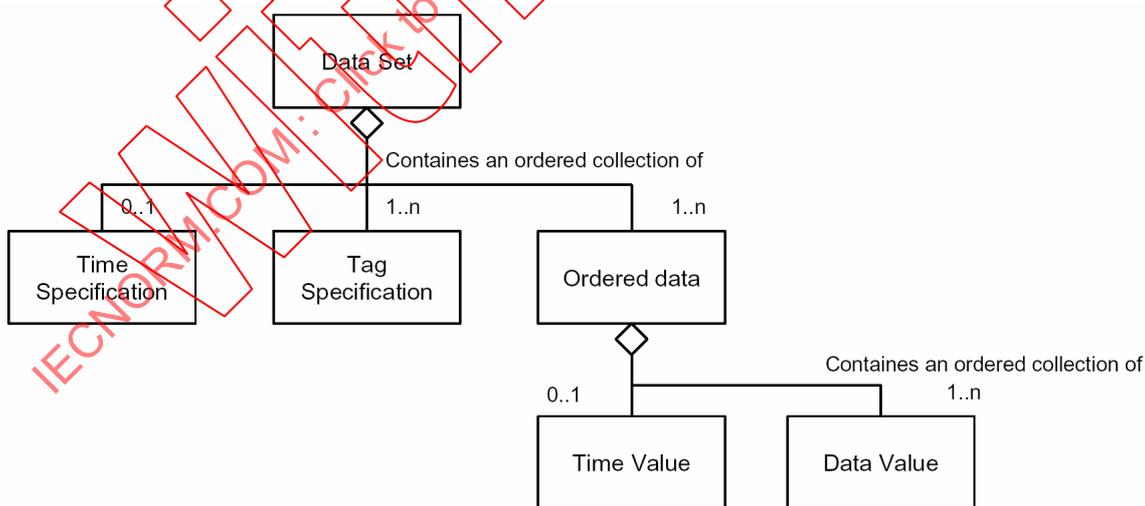


Figure 13 – Data set model

Example 1: Data set objects are a means to represent the time series data that might be collected or displayed in a table similar to that of Figure 14. The elements that would be used to describe the data in Figure 14 are illustrated in Figure 15.

Time	TIC101.PV	FC202.SP	VLV55
10:55:00	15.5	35000	Open
10:55:15	15.5	34900	Closed
10:55:30	15.3	34900	Closed
10:55:45	15.1	34900	Open

Figure 14 – Sample time series data set

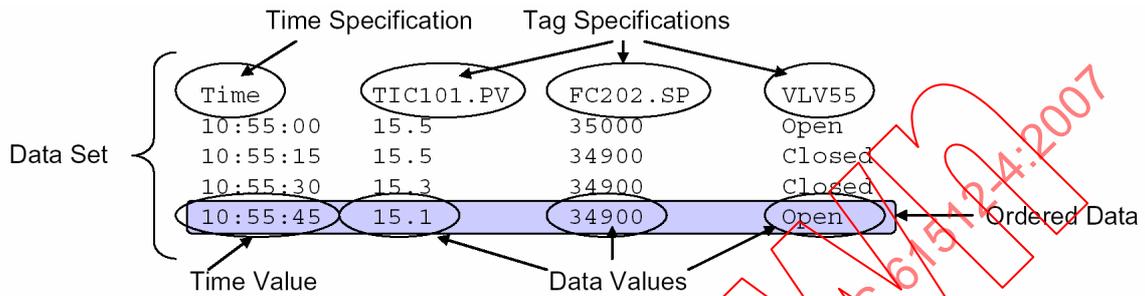


Figure 15 – Elements of a time series data set

Example 2: The flow rate into a vessel may only be trended when it is being used by certain phases. Thus, during a unit procedure there may be three occurrences of use at different times. This could be stored as three data set objects, each one sampled at a high rate. Alternatively, in between uses, instead of not including any trend data for the data point, the batch production record may include trends at a much slower rate. This could then result in up to seven data set objects, three with a high sample rate and four with a low sample rate.

Example 3: Data set objects are a means to represent correlated data that might be collected or displayed in a table similar to Figure 16. The elements that would be used to describe the correlated data in Figure 16 are illustrated in Figure 17.

TIC202.PV	FC202.PV
12.0	35000
13.5	36500
11.0	33000
15.5	29500

Figure 16 – Sample correlated data set

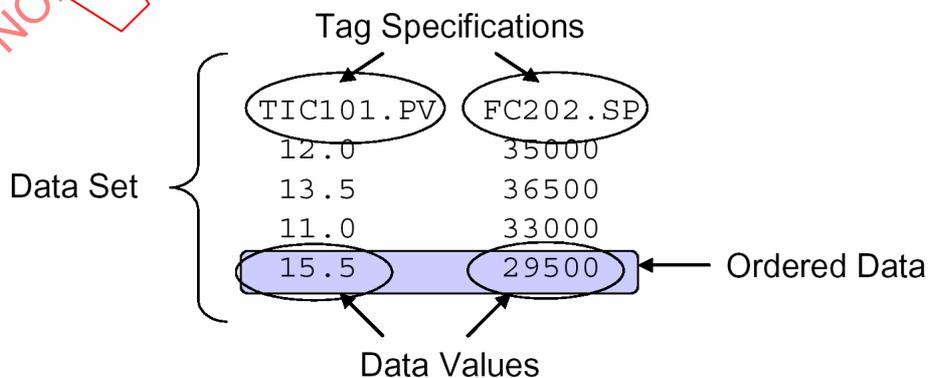


Figure 17 – Elements of a correlated data set

5.7.2 Data set attributes

A data set defines a related set of tags and data values. It represents a span of time for a time series data or a set of related data values for correlated data sets.

Table 10 lists the attributes for data set objects.

Table 10 – Data set attributes

Name	Description	Examples
Start time	Date and time of the start of data in the data set	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
End time	Date and time of the end of data in the data set	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Trend system reference	Used to specify the location where the data set data is stored in an external system NOTE Standard formats for referencing trend systems are not defined as part of this PAS.	Toledo Dogfood Historian Toledo Dogfood Line2 Historian Toledo Fishfood Line 4 Archiver

If the data is physically stored in an external system, then the trend system reference attribute contains the information necessary to identify the external data.

5.7.3 Time specification

A time specification object defines the attributes of the time values in the data values set. Table 11 lists the attributes for time specification objects.

Table 11 – Time specification attributes

Name	Description	Examples
Relative	Indicates if the time specification is relative or absolute	ABSOLUTE RELATIVE
Offset	If the time is relative, then the offset defines the absolute time that may be added to the relative times to determine the absolute times	10:55:15 2005-05-23 16:59:00 2005-09-18

5.7.4 Tag specification

A tag specification object uniquely identifies a data source. It contains the information to identify a single data source (called a tag) and any data required to interpret the data values, such as data compression information required to use the data.

Multiple tag specification objects may refer to the same data source.

The same data source may be used in multiple data sets.

Table 12 lists the attributes for tag specification objects.

Table 12 – Tag identification attributes

Name	Description	Examples
Data source ID	Identification of the source of data for the object NOTE 1 This is usually the identification of the data point for a data collection system, such as a tag name for a SCADA system.	TIC002 AG542.PV XYZ224.BLND
Alias	Information of an alternate ID used to alias the data source ID NOTE 2 This is often an operational identification of the data source, indicating the role the data source performs in operational functions.	Reactor temp Reactor pH Total XYZ224 inventory
Description	Additional information about the data source or the tag identification object.	Reactor Temperature at midpoint in the vessel pH taken from vessel top Inventory amount difference between production and consumption
Equipment ID	Reference to equipment. Must be specific enough such that each data source ID is unique This information represents the physical structure above the referenced entity to identify its context within the plant physical hierarchy NOTE3 This may be a unit, a process cell, an area or even a site if that defines the scope of the data source.	Site Area Unit Toledo Dogfood Line 2 Process
Procedural element reference	Reference to the procedural element, such as procedure, unit procedure, operation, recipe phase, equipment phase, or equipment step associated with the data source ID for the time period of the trend segment	B-00234 Reaction <NULL>
Unit of measure	Unit of measure NOTE 4 Standard units of measure are not defined as part of this PAS. NOTE 5 Standard units of measure should not change across trend segments.	pH °C °F kg litres
Data type	Type of data NOTE 6 Standard data types are not defined as part of this PAS.	Discrete Float Text
Deadband	Deadband value used for collecting and storing data values	0,2 % 1 0
Significant digits	Significant digits used for collecting and storing data values	F4.2 I2 F7.4
Data compression ID	Identification of the data compression algorithm used when the data was collected and stored. NOTE 7 Data compression algorithms are not defined as part of this PAS.	Boxcar backslope Change delta None
Sampling type	Type of sample and associated data and time the data was collected and stored. NOTE 8 Standard sampling types are not defined as part of this PAS.	Actual/Raw Interpolated Best fit

5.7.5 Ordered data

Ordered data is a container object for data values. There are no attributes for ordered data objects.

Ordered data contains an ordered collection of data values. The data values correspond to data values for the trend tags, and shall be in the same order as the tag specification definitions.

5.7.6 Data value

A data value object defines the value of a tag. Table 13 lists the attributes of data value objects.

The data values within a tag data container correspond to data values for the tag identifications specified in the tag identification object and shall be in the same order as the trend tag definitions.

Table 13 – Data value attributes

Name	Description	Examples
Value	Value of the data	130,9 Red <Null>
Quality	Indication of the lack of or presence of problems associated with collecting the data value. NOTE 1 Standard quality indications are not defined as part of this PAS.	Good Uncertain Bad

Each data value object contains a data value and the information required to provide context to the data value in the context of the data set. The contextual information is dependent upon the data compression algorithm used by the data set.

NOTE 2 The change object may be used to record changes to data values.

Example: Manual changes may occur when data is incorrectly recorded, such as when an instrument has failed and the correct manually measured value must be recorded.

5.7.7 Time value

A time value object defines the time that data values are associated with. Table 14 lists the attributes of time value objects.

Table 14 – Time value attributes

Name	Description	Examples
Time stamp	Time stamp of either the absolute or relative time associated with the data values within the same tag data container	2003-07-14 1454+0100

5.8 Comment

A comment object contains comments added to a batch production record that are related to other specific elements of the batch production record. A comment object shall be represented by the attributes defined in Table 15.

NOTE 1 This enables comment annotations to be added to a batch production record after the original record is generated.

NOTE 2 If comments are changed over time then batch production record change objects may be used to track changes to the comments.

NOTE 3 If electronic signatures are required for comments, they can be recorded using the personnel identification manifest referencing the comment.

The “time stamp” attribute (inherited from the batch production record entry) contains the date and time the comment was applied in the batch production record.

Table 15 lists the attributes of comment objects.

Table 15 – Comment attributes

Name	Description	Examples
BPR data reference	Reference to a data element in the batch production record (BPR) The reference includes the BPR element and the attribute in the element with which the comment is associated NOTE The format for a BPR data reference is not defined in this PAS; the format will be based on the technology used for an implementation of this PAS.	SampleTestResult%3445/pH ControlRecipe%42 Formula Target water Value Comment@A645 Comment
Person ID	ID of the person who authored the comment	R. Atkinson Henri Laurent J. van Dyke
Comment	Text entered as the comment	Coffee spilled on keyboard of operator station 4

5.9 Sample

5.9.1 Sample object

A sample object shall be represented by the model in Figure 18. A batch production record may contain information that documents a material to be sampled, testing of the sample and results of the test. The material may be associated with a batch, a lot of raw material, intermediate material, or finished product, or another sample that is not associated with a batch ID.

A sample may consist of multiple samples as required to meet the material testing requirements. Example: Samples may be required to be taken every 30 min during the react phase and are then mixed together to determine overall quality of a material being produced.

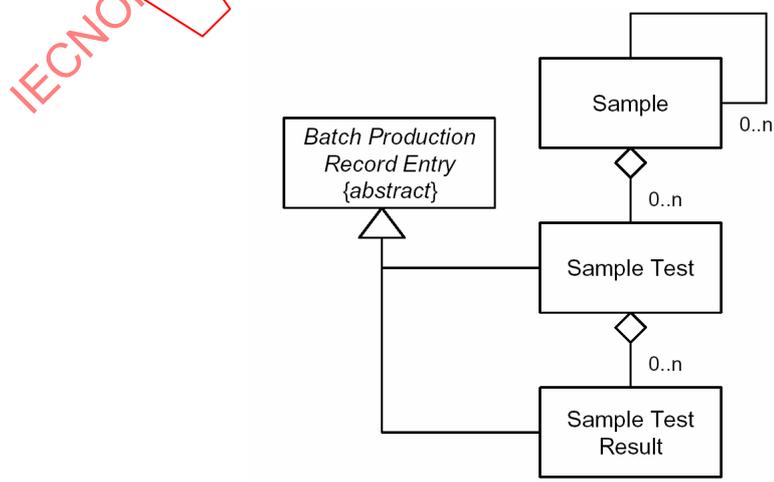


Figure 18 – Sample model

5.9.2 Sample attributes

A sample object contains information about a sample of material tested. The attributes of sample objects are listed in Table 16.

The ID of the sample is the entry ID from the batch production record entry type.

The time stamp the sample was taken is the time stamp from the batch production record entry type.

Table 16 – Sample attributes

Name	Description	Example
Sample source ID	Identification of the lot, batch or sample from which the sample material was taken	SD2348 LOT2 B12384 SAMPLE2
Sample size	Amount of sample taken	100 3 × 10 ≥2
Unit of measure	Unit of measure for sample size	Each mL kg
Sample type	Type of sample NOTE 1 Standard sample types are not defined as part of this PAS.	Physical sample Lab analysis Online sample Semi-continuous data
Sample pull reason	Reason the sample was pulled NOTE 2 Standard sample pulling reasons are not defined as part of this standard.	Routine Process excursion Shift Procedural trigger
Sample expiration	Time/date on which the sample expires NOTE 3 The quality of the sample may degrade over time. For example, a sample of milk should be tested within 24 h of taking the sample.	2003-07-14 1454+0100 01 July 2004 14:25 UTC April 23, 2002 8:30 AM ET
Equipment ID	Reference to equipment hierarchy scope of the data used to manufacture product associated with batch production record. Shall be specific enough such that each data source ID is unique This information represents the physical structure of the referenced entity to identify its context within the plant physical hierarchy	Site Area Unit Toledo Dogfood Line 2 Sample port 10 001
Procedural element reference	Reference to the procedural element, such as procedure, unit procedure, operation, recipe phase or equipment phase, associated with the sample pull	B-00234 Reaction Wash[2]
SOP reference	Reference to standard operating procedure (SOP) used to pull sample	SOP15234

5.9.3 Sample test

A sample test object contains information about a specific test that was performed on the sample and records information about the test. Sample test object attributes are listed in Table 17.

Table 17 – Sample test attributes

Name	Description	Example
Test code	Identification of the test procedure used Example: A pointer into an LIMS historical record of all data secured in the course of this test	TestCode2334 Chemometric Technique 123 Condition model 234
Test name	Name associated with the test performed	Bio burden Spectral data

5.9.4 Sample test result

Test results on samples are recorded in sample test result objects. Sample test result object attributes are listed in Table 18.

Table 18 – Sample test result attributes

Name	Description	Example
Results	The actual value or list of values returned from the performance of the sample test	Pass 6.8 Red
Unit of measure	The unit of measure of the sample test results	pH kgs
Test disposition	Indication that the sample test results are acceptable	Pass Fail
Equipment ID	Equipment used to perform the sample test Example 1: the identity of the equipment where the PAT test was performed Example 2: the identity of the equipment where the LAB test was performed	GC0201
Expected results	The expected results of the test NOTE 1. Standard test results are not defined as part of this PAS.	Pass Fail 6.2 – 7.4 pH
Statistical sampling analysis results	The type of statistical sampling analysis used to determine the result NOTE 2 Standard sampling analysis methods are not defined as part of this PAS.	Average Min Max
Expiration time stamp	Date and time sample test results expire	2000-10-25 13:30 <Null>

5.10 Change

The change object is used to record changes to any object of a batch production record. This may provide information used to maintain an audit trail of changes to a batch production record. A change object shall be represented by the attributes defined in Table 19.

Example: Changes to a batch production record include

- addition of new continuous trend segments or a control recipe snapshot;
- extending objects with new attributes;
- modification of a formula value;
- deletion of redundant control recipe snapshot;

- initial creation of the batch production record;
- change in state of the batch production record.

NOTE 1 The inclusion of the change history in a batch production record may be based upon the requirement to meet government regulations or to meet the requirements of change management business rules.

Table 19 defines the attributes for change objects.

Table 19 – Change attributes

Name	Description	Examples
BPR data reference	Reference to a data element that has been changed in the batch production record (BPR) The reference includes the BPR element and the attribute in the element with which the change is associated NOTE 2 The format for a BPR data reference is not defined in this standard; the format will be based on the technology used for an implementation of this PAS.	SampleTestResult%3445/pH ControlRecipe%42 Formula Target water Value Comment@A645 Comment
Pre-change data	The previous data for the changed item	No data 2003-10-24 13:14-0600 Batch sent to warehouse 93
Reason	Cause or need for the change	Temperature probe failure, offline data entered. Corrected typo

The “time stamp” attribute (inherited from the batch production record entry) contains the date and time the change was made to the batch production record.

NOTE 3 A change object would typically be supported with one or more personnel identifications for the person performing the change (“Done by”) and the person checking the change (“Checked by”), as shown in Figure 4.

NOTE 4 A change object would typically be supported with one or more comments on the change, as shown in Figure 4.

5.11 Personnel identification manifest

The personnel identification manifest is used to provide evidence of who performed an action associated with a specific attribute for an object instance. This can be used to document an electronic signature. A personnel identification manifest object shall be represented by the attributes defined in Table 20.

NOTE 1 Any attribute that is the identification of a person may require a personnel identification manifest.

NOTE 2 Use of an electronic signature is optional.

The “time stamp” attribute (inherited from the batch production record entry) contains the date and time the personnel identification was applied in the batch production record.

Table 20 defines the attributes for personnel identification manifest objects.

Table 20 – Personnel identification manifest attributes

Name	Description	Examples
BPR data reference	Reference to a data element in the batch production record (BPR). The reference includes the BPR element and the attribute in the element with which the personnel identification is associated NOTE 3 The format for a BPR data reference is not defined in this PAS; the format will be based on the technology used for an implementation of this PAS.	SampleTestResult%3445/pH ControlRecipe%42 Formula TargetWater Value Comment@A645 Comment
Name	Unambiguous and unique name of the person performing the signing	48392 Jack Nicholson Chiaki Shimada
Reason	Reason for signature	Done by Reviewed by Approved by
Change indication	Indication enabling detection that the personnel identification manifest has not been altered The change indication enables detection that the record has been altered, although it may not identify the specific alterations Example 1: A string generated by an MD5 algorithm used as a hashing algorithm Example 2: A string representing a digital key of the entire batch production record Example 3: A string representing a checksum of the entire batch production record.	E;4J9QJG;RGJAOF0 FKG9GRKGGH44FF KRJG49TJHVSNS

5.12 Resource qualification manifest

A resource qualification manifest is used to document the qualification of a resource (personnel, equipment or material) associated with production. A resource qualification object shall be represented by the attributes defined in Table 21.

NOTE 1 A qualification is a quality ability or attribute that makes a resource suitable for a particular task.

Example: Documented evidence indicates an operator has been trained and training has not expired on procedure "fill explosive proof vessel."

Personnel qualification objects are associated with the relevant batch production record entry as depicted in Figure 2. These entries can also be associated with elements defined in ISA 95.00.01-2000, such as personnel model elements.

The "time stamp" attribute (inherited from the batch production record entry) contains the date and time the resource qualification was applied in the batch production record.

Table 21 lists the attributes of qualification manifest objects.

Table 21 –Qualification manifest attributes

Name	Description	Examples
BPR data reference	Reference to a data element in the batch production record (BPR). The reference includes the BPR element and the attribute in the element with which the qualification manifest is associated NOTE 2 The format for a BPR data reference is not defined in this PAS; the format will be based on the technology used for an implementation of this PAS.	SampleTestResult%3445/pH ControlRecipe%42 Formula TargetWater Value Comment@A645 Comment
Resource ID	Identification of the personnel, equipment, material or procedures	Fred Oakly Buffer Tank 34 M-4938923 SOP 49392.323
Effective time stamp	Date and time the qualification became effective	2003-07-14 1454+0100 01 MAR 2004 14:25 UTC April 23, 2002 8:30 AM ET
Expiration time stamp	Date and time the qualification expired	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Qualification status	The criteria that were recorded	Equipment sterile Ingredient 43A released for use Operator trained on SOP 1055.234

5.13 Product definition

Product definition objects shall contain information about expected resources (for example, manufacturing bill, materials, personnel, and equipment) required to manufacture a product on a per-segment basis. Product definition objects contain product segments and the manufacturing bill. However, the segment definitions used within a batch production record may differ from those used in the ANSI/ISA-95 level 4/3 data exchanges.

Product definition information shall use the structure of product definition defined in ANSI/ISA 95.00.01-2000 and ANSI/ISA-95.00.02-2001 with batch production record entry extensions.

NOTE 1 The process and product segments defined in ANSI/ISA-95 are business views of production; the segments used here may represent physical or operational views of production.

NOTE 2 In the use of these structures for this PAS, segments should be appropriately defined as needed for batch production information.

5.14 Production response

Production response objects shall contain information about actual production (materials consumed, material produced, equipment used, personnel used, etc.) on a per-segment basis. However, the segment definitions used within a batch production record may differ from those used in the ANSI/ISA-95 level 4/3 data exchanges.

Production response information shall use the structure of production responses as defined in ANSI/ISA 95.00.01-2000 and ANSI/ISA-95.00.02-2001 with batch production record entry extensions.

NOTE 1 Production responses are made up of segment responses. A segment response contains information on an element of batch production and is made up of zero or more sets of information on production data, personnel actual, equipment actual, materials consumed actual, materials produced actual, and consumables actual.

NOTE 2 The segments used in this PAS will normally relate to elements of batch production such as campaigns, unit procedures, and operations.

Example: Segments may be defined for the entry of material into the process cell, exit of the material from the process cell, and reconciliation of material between actual and recorded values (usually the result of inventory counts).

5.15 Production request

Production request objects shall contain information about planned production (planned materials consumption, target material produced, planned equipment, planned personnel, etc.) on a per-segment basis. However, the segment definitions used within a batch production record may differ from those used in the ANSI/ISA-95 level 4/3 data exchanges.

Production request information shall use the structure of production request as defined in ANSI/ISA95.00.01-2000 and ANSI/ISA-95.00.02-2001 with batch production record entry extensions.

NOTE 1 Production requests are made up of segment requests. A segment request contains definitions of a request for production that includes zero or more sets of information on production parameters, personnel to be used, equipment to be used, materials expected to be consumed, materials expected to be produced, and consumables expected to be used in production.

NOTE 2 The segments used in this PAS will normally relate elements of batch production such as campaigns, unit procedures, and operations.

5.16 Control recipe

5.16.1 Control recipe object

A control recipe object shall be represented by the model in Figure 19. The model contains a representation of a control recipe as defined in Part 1 and derived from the abstract reference models in Part 2.

The control recipe model is a copy of the master recipe model with some slight differences. A control recipe does not need to indicate all steps and transitions contained in the master recipe. Unexecuted (or unreachable) steps and transitions do not need to be included in the definition of the control recipe. For example, the master recipe modification log and approval history do not apply to the control recipe while the control recipe has additional attributes such as actual start and end time not found in the master recipe.

Control recipe contents can change throughout its life cycle. Multiple snapshots, or copies, of a control recipe can be stored in one batch production record. Figure 20 illustrates a batch production record with the control recipe information at the start of the batch, the events and continuous trend data recorded in the batch production record about the execution of the batch, and the control recipe information at the end of the batch.

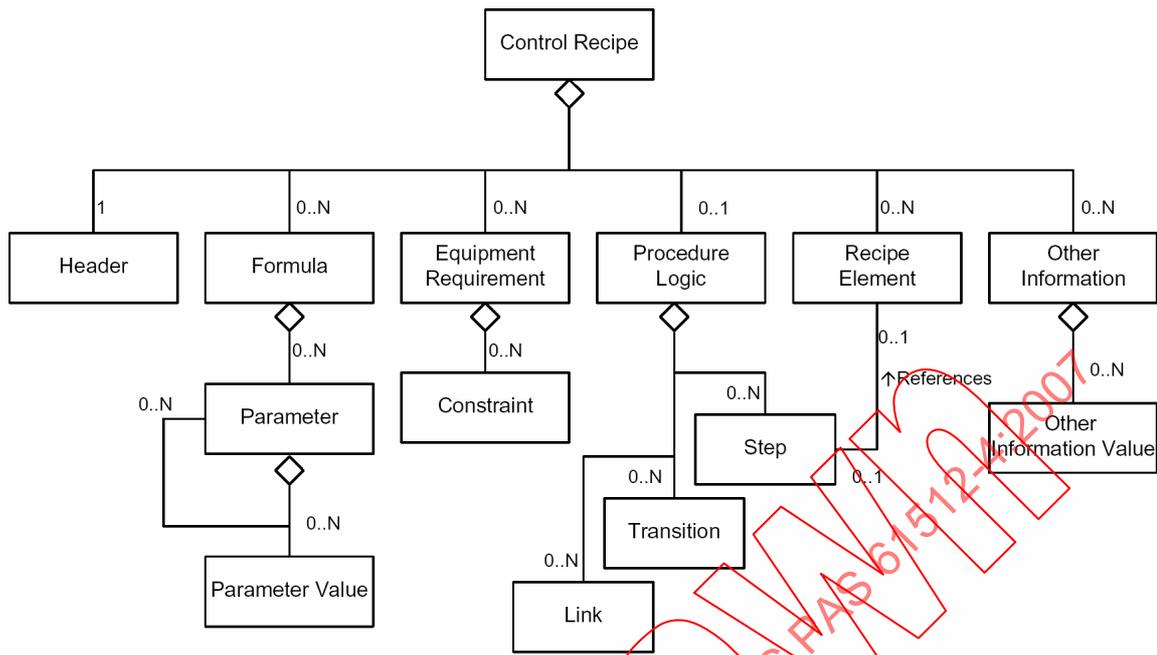


Figure 19 – Control recipe model

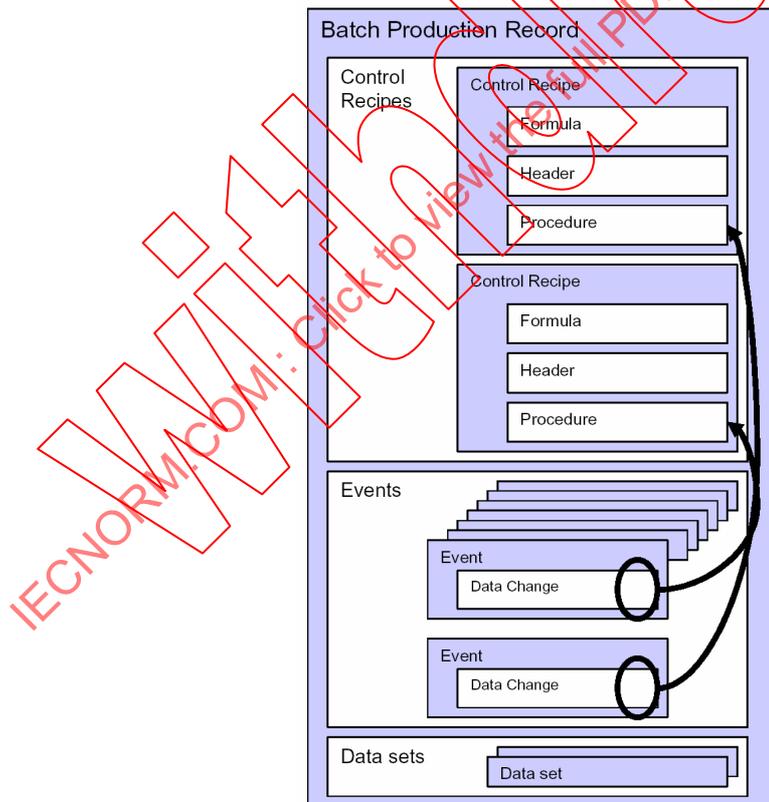


Figure 20 – Sample batch production record with two control recipe copies

The procedural execution event type in the event object model may be used to store a record of each recipe and equipment procedural element's execution. However, the control recipe allows storing of the representation of the actual control recipe.

An example of the difference between storing a snapshot of a control recipe, recording process management events and data changes to a control recipe is seen in the case of an operation that can be repeated any number of times based upon a transition condition in the procedure.

The procedural logic and the transition condition would be preserved as part of the control recipe. The actual number of times the operation was repeated and the cause of each repetition (the result of the transition condition) would be preserved as process management events. If the transition condition expression or data values, or the value of a formula item was modified during the batch, these changes should be recorded as events, thereby providing an audit trail of control recipe changes.

Procedural elements that are not part of a control recipe execution would be recorded as equipment state change or procedural execution state change events.

5.16.2 Control recipe attributes

Table 22 lists the attributes for control recipe objects.

Table 22 – Control recipe attributes

Name	Description	Example
ID	Identification of a control recipe	MR-1 Polymer X12 4593021
Version	Identification of the version of a control recipe	1.0 4.01.13A D
Version time stamp	The date and time the control recipe version was assigned a version identification	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Description	Additional information about the control recipe	Recipe for tasty treats using corn feed in pellets

5.16.3 Control recipe header

A recipe header contains information about the purpose, source and version of the recipe, such as recipe and product identification, creator, status, approvals, and issue date.

Recipe header information is described in header objects. The header has information that may only be pertinent to control recipes, such as the actual produced product, as well as information provided by master recipes and recipe building blocks.

Table 23 lists the attributes for control recipe header objects.

Table 23 – Control recipe header attributes

Name	Description	Example
Effective date	The date the recipe may be used for production	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Expiration date	The date the recipe may no longer be used for production	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Product ID	Identification of or code for a product	459293A1 A4Q59492-5942.1 Polymer56
Product name	Commonly used name for a product	Acetone Amber beer Plastic
Batch size	Reference value for the size of the batch generated by the execution of the recipe This has an application-specific meaning Example: May be the nominal size if default parameter values are used, amount of material used, maximum volume of a unit, key ingredient quantities	200 kg 10,000 ea 20 mL
Actual product produced	The list of products produced as a result of the recipe execution	Acetone 1.024 Real good amber beer Mearlastomer
Modification log	List of the modifications made to the recipe prior to being stored in a batch production record Each modification shall contain the time stamp of the modification, the description of the modification, and the author of the modification NOTE 1 Standard modification log format is not defined as part of this PAS.	
Approval history	List of the approvals made to the recipe prior to being stored in a batch production record. Each approval shall contain the date of the approval, a description of the approval, the version after approval, a description of each individual approval containing the individual approving entity, individual approval date, and description of the individual approval NOTE 2 Standard approval history format is not defined as part of this PAS.	
Status	Identification of a recipe's status	Released for production under development Expired
Master recipe ID	Link to master recipe; version, date, etc.	1237-1232 LKE83214.-12 10-Aug-05_RMR
Master recipe version	Version identifier for the associated item	1.0 4.01.13A D

5.16.4 Equipment requirement

Table 24 lists the attributes for equipment requirement objects.

Table 24 – Equipment requirement attributes

Name	Description	Example
ID	Identification of the equipment requirement	Material of construction Heating capacity Capacity
Description	Additional information about the equipment requirement	The reactor shall have this material of description
Equipment class	Identifies the associated equipment class or set of equipment classes of the requirement for a specific segment requirement	Widget polishing machine
Equipment	Identifies the associated equipment set of equipment of the requirement for a specific segment requirement Typically either equipment class or equipment is specified, but not both	WPM-19 Fill Line 3
Quantity	Specifies the amount of equipment resources required, if applicable. Applies to each member of the equipment and equipment class sets	1 19000 200
Unit of measure	Unit of measure of the associated quantity, if applicable	Units

5.16.5 Constraint

Constraint objects may be associated with an equipment requirement object as defined in the constraint model presented in Figure 19.

Table 25 lists the attributes of constraints.

Table 25 – Constraint attributes

Name	Description	Example
ID	Identification of the specific constraint	Operating volume
Description	Additional information about the constraint	Volume greater than 500 L
Value	Value of the constraint	4 293.45 Red
Unit of measure	Unit of measure of the value	kg Gallons Metres
Data type	Data type of the value	Float Date String

5.16.6 Formula

A recipe's formula is a category of information that includes process inputs, process parameters, and process outputs as defined in Part 1.

The formula information of a recipe is described in a list of formula elements. The formula object does not have attributes. Formula objects are containers for parameter objects.

5.16.7 Parameter

Parameter objects may be associated with a control recipe formula object as defined in the recipe formula model presented in Figure 19. Parameter objects are recursive; a parameter object may contain other parameter objects as presented in the recipe formula model.

Table 26 lists the attributes for parameter objects.

Table 26 – Parameter attributes

Name	Description	Example
ID	Identification of a parameter	Add_Ingredient_A Heat set-point Settle time #1
Description	Additional information about the parameter	Amount of ingredient A to be added
Parameter type	Identification of the parameter as a "process input," "process parameter" or "process output"	Process input Process parameter Process output
Parameter subtype	Classification of a parameter according to user-defined classes. Used to enhance filtering and sorting operations	User input KPI Release criteria
Scaled	Flag indicating if the value of a parameter is to be scaled when the control recipe is scaled. 'True' means the parameter value should be scaled; 'false' means it should not be scaled	True False
Scale reference	Scaling factor to be used when the parameter value is scaled. If scaled=true and the scale reference is not specified, then the parameter is scaled using the scaling factor of the control recipe	2 1,59 ,93

5.16.8 Parameter value

Table 27 lists the attributes for parameter value objects.

Table 27 – Parameter value attributes

Name	Description	Example
Value string	Value of the parameter	127 Red A*(B+C+D)
Data interpretation	Identification of how to interpret the value string. Choices are "constant," "reference," "equation," "external"	Constant Reference Equation
Data type	Identification of the data type contained in the value string. Each implementation of this model will define the allowed data types. If one supported data type is an enumeration, then the data type shall be called "enumeration"	Float Date String
Unit of measure	Unit of measure associated with the value string	kg Tons kL

Name	Description	Example
Enumeration set ID	When the data type is "enumeration," this contains an integer identifying the enumeration set ID to be used to understand the meaning of the value string	1 6 28

5.16.9 Procedure logic

Procedure logic objects contain a definition of the procedural logic in a recipe procedure, as defined in Part 2. Procedure logic is made up of steps, transitions, and links between steps and transitions, steps and steps, and transitions and transitions.

The procedure logic object does not have attributes. Procedure logic objects are containers for link, step, and transition objects associated with the same procedure logic.

5.16.10 Link

A link object in a procedure logic object describes an execution sequence link between the steps and transitions. The FromID and ToID attributes may be StepIDs or TransitionIDs, allowing step to transition, transition to step, step to step, and transition to transition links. The ordering of the links, as required for proper procedure execution, is defined in the evaluation order object. Link objects may be associated with a control recipe procedure logic object as defined in the recipe object model presented in Figure 19.

Table 28 lists the attributes of link objects.

Table 28 – Link attributes

Name	Description	Example
ID	Identification of a link	1 44 L56
From ID	Identification of a link, step, or transition at which a link starts	L438 S2 T003
To ID	Identification of the link, step, or transition at which a link ends	N2404 H2 T004
Link type	Specifies if the link is a procedural control flow or a material transfer association. Valid values are "control link," "transfer link," "synchronization link," "parallel divergent," "parallel convergent," "serial divergent," "serial convergent"	Control link ParallelConvergent TransferLink
Depiction	Defines how the link will be presented. Valid values are "none," "line," "ID," "LineAndID," "LineAndArrow," "LineArrowAndID."	LineAndID ID LineArrowAndID
Evaluation order	An integer that defines the specified order of evaluation of the link (if required) to meet the left-to-right evaluation of procedural logic transition checks that are specified in Clause 6 of ANSI/ISA-88.00.02-2001 All links from the same step to multiple transitions are assumed to be evaluated in the order that is specified by the order field. Lower numbers are evaluated first	1 5 21
Description	Additional information about the link	Connects the initial step and transition T001