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ISA-88.00.04-2006

Batch Control Part 4: Batch Production Records

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ISA-88.00.04-2006
Batch Control Part 4: Batch Production Records

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Preface

This preface, as well as all footnotes and annexes, is included for information purposes and is not part of ISA-88.00.04-2006.

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THE STANDARD IS STRUCTURED TO FOLLOW INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) GUIDELINES. THEREFORE, THE FIRST THREE CLAUSES PRESENT THE SCOPE OF THE STANDARD, NORMATIVE REFERENCES, AND DEFINITIONS, IN THAT ORDER.

CLAUSE 4 IS INFORMATIVE. IT DESCRIBES THE PURPOSE, CONTENTS, LIFECYCLE AND USE OF BATCH PRODUCTION RECORDS.

CLAUSE 5 IS NORMATIVE. IT DESCRIBES THE OBJECT MODEL ASSOCIATED WITH THE BATCH PRODUCTION RECORD.

CLAUSE 6 IS NORMATIVE. IT STATES THE COMPLETENESS, COMPLIANCE, AND CONFORMANCE REQUIREMENTS FOR THIS STANDARD.

ANNEX A IS INFORMATIVE. IT DEFINES THE DATA MODELING TECHNIQUES USED.

ANNEX B IS INFORMATIVE. IT PRESENTS A LIST OF FREQUENTLY ASKED QUESTIONS AND ANSWERS ABOUT THIS STANDARD AS IT IS CURRENTLY ENVISIONED.

THIS STANDARD IS INTENDED FOR THOSE WHO ARE:

- RESPONSIBLE FOR DEFINING PRODUCT PROCESSING REQUIREMENTS
- RESPONSIBLE FOR DEFINING PRODUCT REPORTING REQUIREMENTS
- INVOLVED IN DESIGNING AND/OR OPERATING BATCH MANUFACTURING PLANTS
- RESPONSIBLE FOR SPECIFYING CONTROLS AND THE ASSOCIATED APPLICATION PROGRAMS FOR BATCH MANUFACTURING PLANTS
- INVOLVED IN THE DESIGN AND MARKETING OF PRODUCTS IN THE AREA OF BATCH CONTROL
- USE PRODUCT INFORMATION FOR THE PURPOSES OF MANUFACTURING OR MANAGING THE MANUFACTURE OF PRODUCT

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FOREWORD

The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

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The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its recommendations.

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Introduction

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

ANSI/ISA-88.00.02-2001 (referred to as Part 2 throughout this standard) Clause 4 provides 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 the Parts 1 and 2 standards 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.

This Part 4 standard 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/ISA-88.00.02-2001 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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1 Scope

This Part 4 standard defines a reference model for batch production records containing information about production of batches or elements of batch production. This standard is intended for batch processes.

2 Normative references

The following normative documents contain provisions, which through reference in this text, constitute provisions of this part of this standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below.

- ANSI/ISA-88.01-1995, Batch Control - Part 1: Models and Terminology (referred to in this standard as “Part 1”)
- ANSI/ISA-88.00.02-2001, Batch Control - Part 2: Data Structures and Guidelines for Languages (referred to in this standard as “Part 2”)
- ANSI/ISA-88.00.03-2003, Batch Control - Part 3: General and Site Recipe Models and Representation (referred to in this standard as “Part 3”)
- 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
- IEC 60050-351:1998, International Electrotechnical Vocabulary – Part 351: Automatic Control.
- IEC 61512-1:1997, Batch control - Part 1: Models and terminology
- 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

3 Definitions

For the purposes of this Part 4 standard, the following definitions apply. Definitions and concepts expressed in the Part 1 standard apply, except where differences are explicitly stated in this Part 4 standard.

3.1 batch history:

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

3.2 batch production record:

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

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

3.3 batch production record report:

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

3.4 batch production record specification:

(a) a definition of the data to include in the batch production record and specification if data is to be referenced or extracted.

(b) an 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:

the execution information that is recorded during the course of batch production and the 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 standard. This Part 4 standard defines a standard reference model for batch production records. A batch production record contains batch production information and related business information. A batch production record is created to meet a business requirement, and the contents of a batch production record are determined by the business requirement.

Example: A batch production record 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 — The Parts 1 and 2 standards define production information and batch history functions, provide lists of the types of data they encompass and provide abstract models. However, Parts 1 and 2 do not define a formal and precise model of production information and batch history data. This Part 4 standard does not further define these terms and does not define production information or batch history system functions.

This Part 4 standard 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 standard. The other functions and data items are shown to illustrate the environment batch production records are used in. Not all sources of data, functions performed on or uses of batch production records are illustrated in this figure.

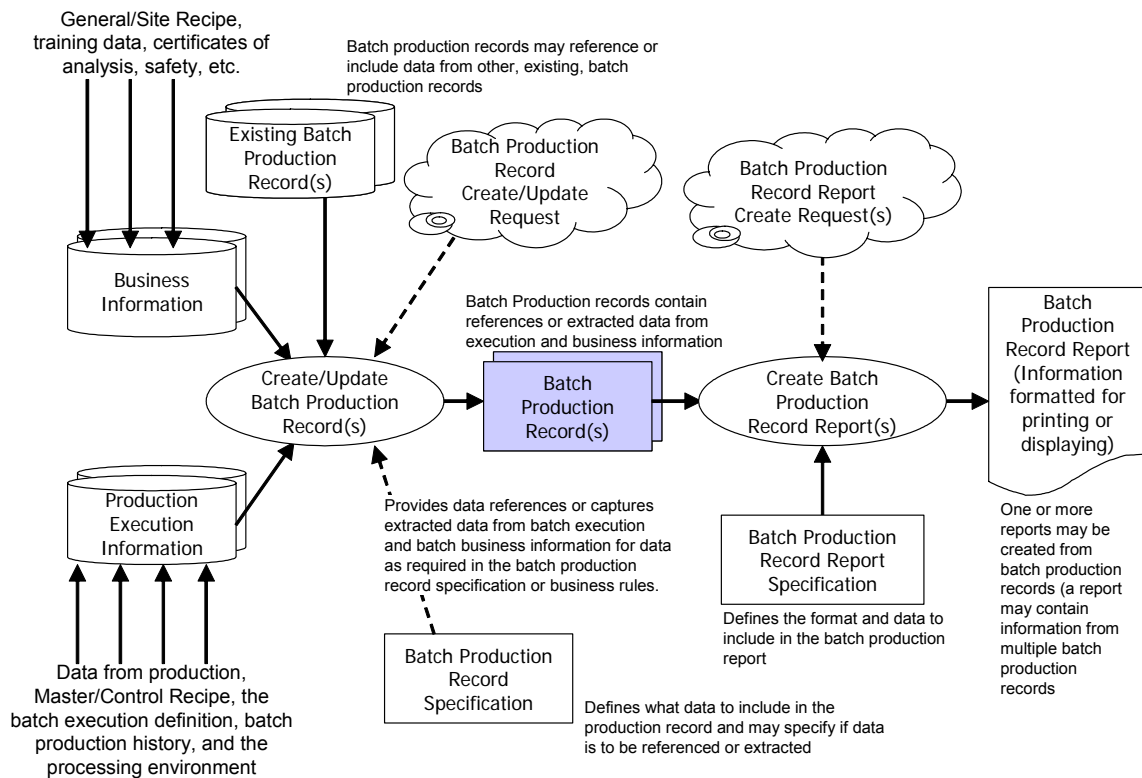


Figure 1— Batch production record creation and use

4.2 Batch production record

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

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

Example 1: The business need 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 Part 4 standard.

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 Part 4 standard.

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 the Part 1 standard 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 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 nonregulated 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 signoff 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 programs 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 Part 4 standard.

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 a batch production record's lifecycle.

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

4.4.3 Creating batch production records

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

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

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

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

4.4.4 Updating batch production records

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

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

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

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

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

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

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

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

4.4.5 Lifecycle states

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

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

Different batch production record types may have different lifecycle states.

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

4.5 Batch production record structure

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

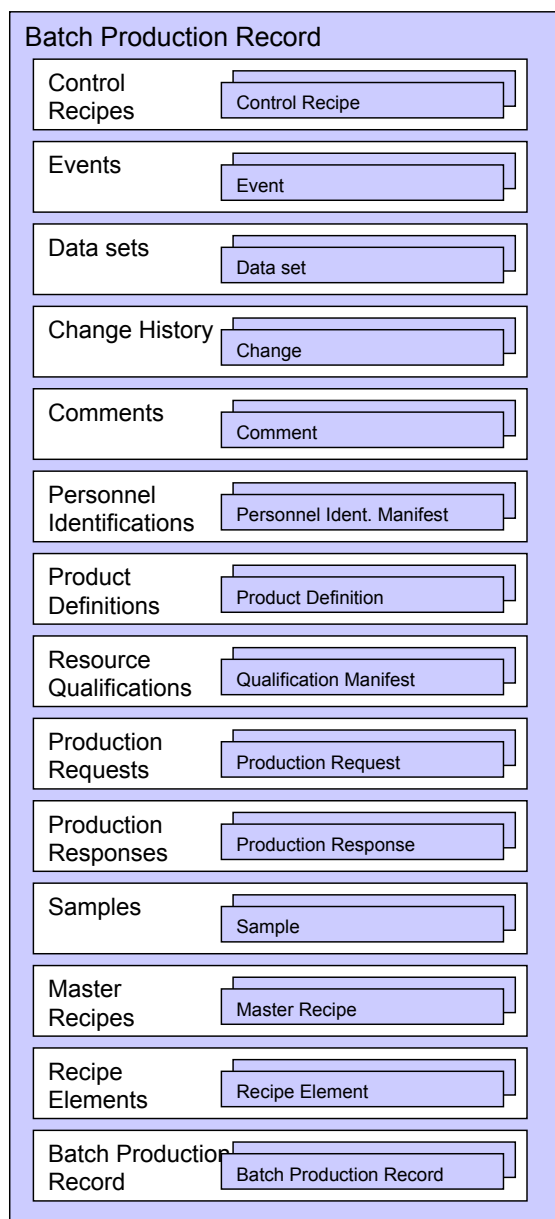


Figure 2 — Batch production record component objects

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.

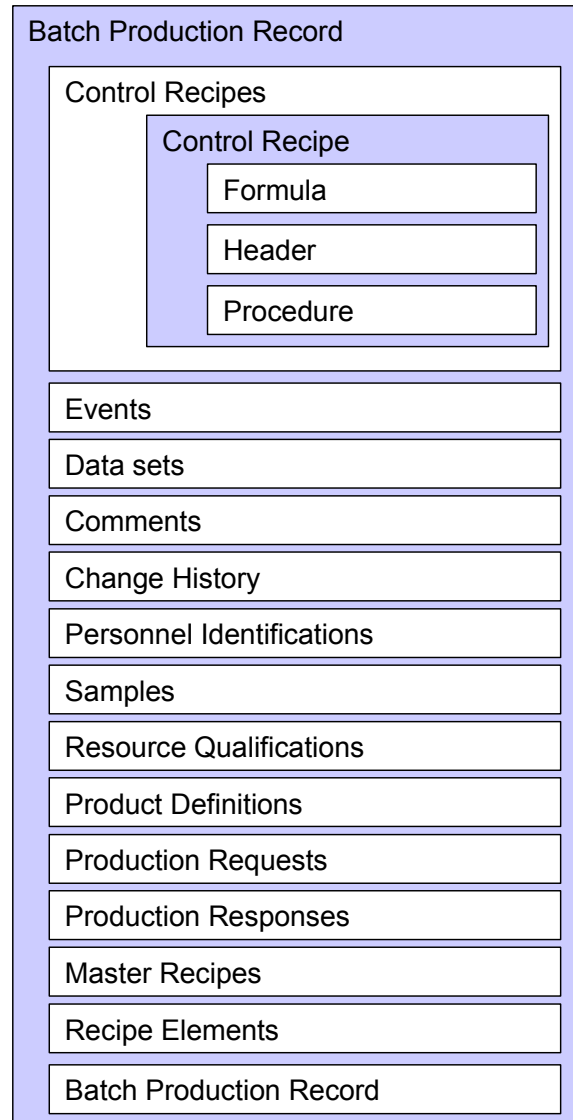


Figure 3 — Example of a batch production record

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.

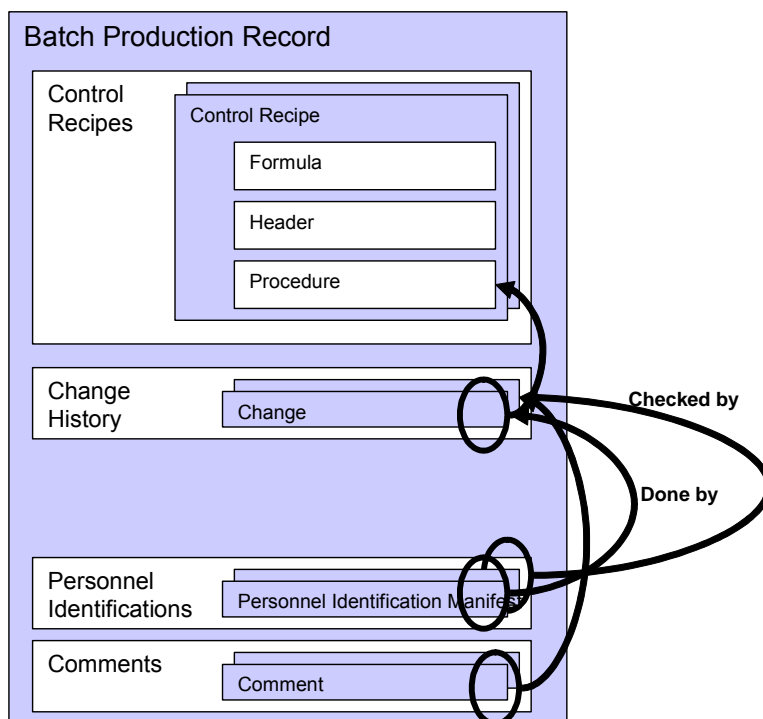


Figure 4 — Example of elements referencing another elements

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 databases as illustrated in Figure 5. It illustrates two cases of continuous trend data, where one element contains the trend data and the other element references an external database with the data.

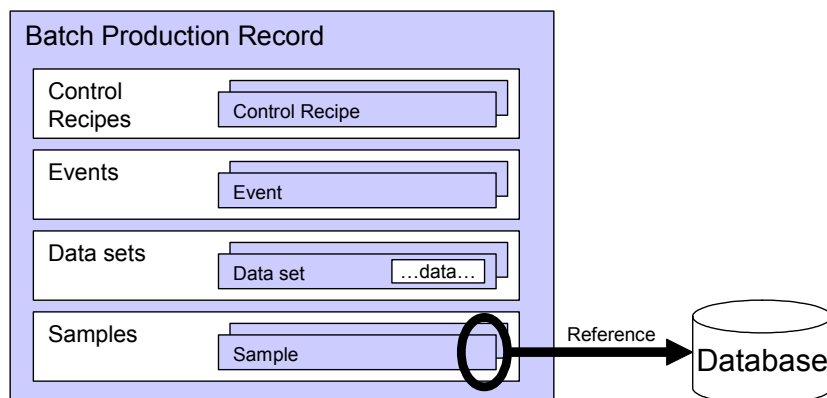


Figure 5 - Example of internal and referenced data

4.6 Production information

Production information is defined in the Part 1 standard. 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 Lifecycle Management), finance, and SCM (Supply Chain Management) systems.

Example: Business information includes but is not limited to:

- General and site recipes
- Training data
- Certificate of analysis (COA)
- Material safety data sheets (MSDS)
- Customer information
- Cost and quality information on raw materials
- Maintenance history of equipment
- Production schedule (see ANSI/ISA-95.00.01-2000)

4.6.2 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

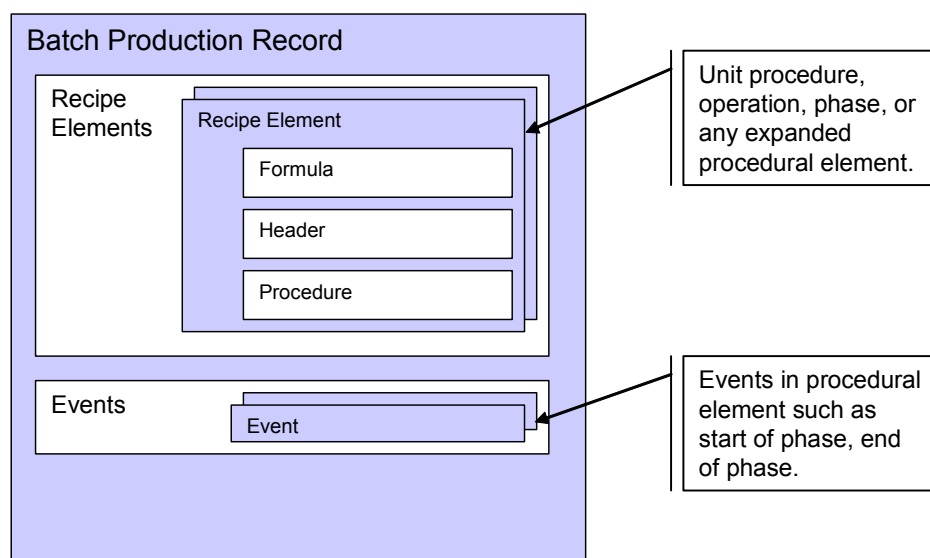


Figure 6 — Sample batch production record for a recipe element

4.6.4 Common (non-batch specific) data

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

Example 1: Non-batch specific data may include:

- Ambient temperature and humidity
- History of equipment modifications and maintenance
- Steam system pressure (trend or high/low exceptions)

Example 2: A water analysis sample 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.

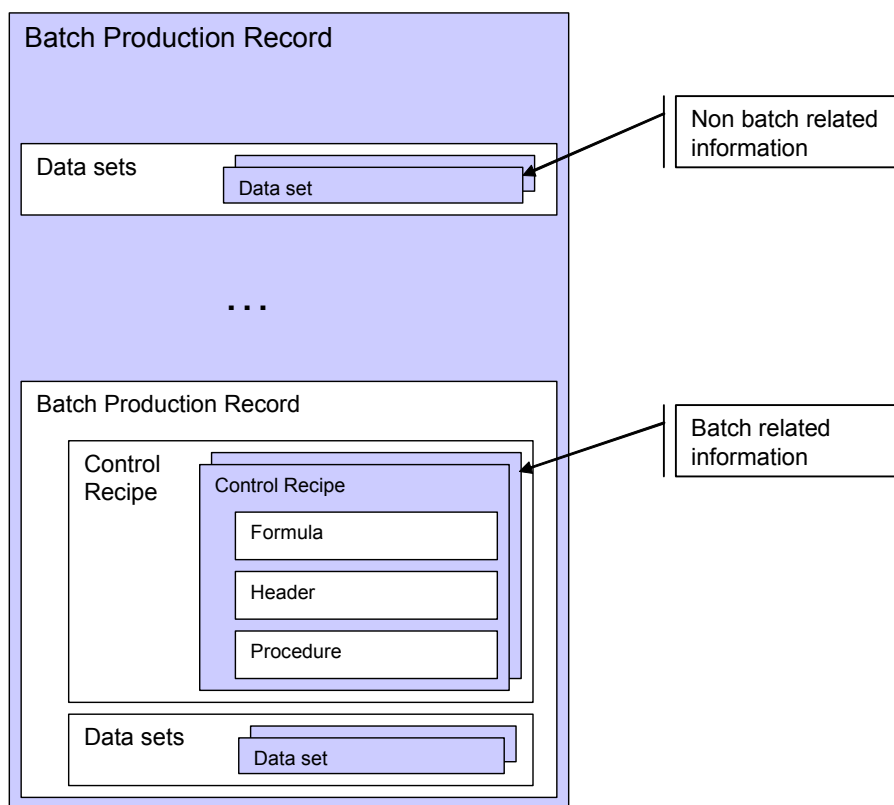


Figure 7 — Batch production record with non-batch specific data

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 1000 kg.</p> <p>Contained in the Event, Data Set, Sample, and Production Response objects. Clause 5.6, Clause 5.7, Clause 5.9, and Clause 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 - Clause 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 – Clause 5.10.</p>
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, and an identification of the person making the comment.</p> <p>Defined in the Comment object – Clause 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 – Clause 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 seconds, during the execution of an operation.</p> <p>The data values and information required to provide context to the data values (e.g., collection time, collection frequency, quality, unit of measure) would be included in the tag identification object.</p> <p>Defined in the Data set object – Clause 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 – Clause 5.16.</p>

Category	Description
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 – Clause 5.6, Clause 5.7, Clause 5.9, and Clause 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 Part 4 standard, 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 – Clause 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 – Clause 5.14 and Clause 5.6.</p>
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 (e.g., the start of a batch) or unexpected (e.g., 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 setpoint change.</p> <p>Example 7: Operator intervenes to correct unexpected process upset—e.g., 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—e.g., an instrument going into alarm, operator acknowledgement, setpoint change, instrument returning to normal.</p> <p>Defined in the Event object – Clause 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>

Category	Description
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 - Clause 5.14 and Clause 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. Clause 5.6, Clause 5.7, Clause 5.16, and Clause 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 – Clause 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 – Clause 5.12.</p>
Quality information	<p>Information about the quality of the material produced, material consumed and/or consumable materials used in production.</p> <p>Example 13: Documentation of the workflow for batch and production release.</p> <p>Example 14: Yields, lot release restrictions, process exceptions, etc.</p> <p>Contained in the Master Recipe, Control Recipe, Sample, Event, Data set, and Production Response objects – Clause 5.18, Clause 5.16, Clause 5.9, Clause 5.6, Clause 5.7, and Clause 5.14.</p>
Target values	<p>A recipe formula process parameter contains a target value to be used in the execution of the recipe.</p> <p>Example 15: A setpoint for an amount of material to be added to a vessel, such as 50.0 kg.</p> <p>Contained in Product Definition, Control Recipe and Event objects – Clause 5.14, Clause 5.16, and Clause 5.6.</p>

Category	Description
Sample and analysis data	<p>Information that documents the analysis of process data during a batch's production. 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.</p> <p>Offline analysis information returned from equipment, personnel or laboratory systems. Sample and analysis data may be expected (e.g., defined in recipe) or unexpected (e.g., due to process excursions).</p> <p>Defined in the Sample Data and Data set objects – Clause 5.9 and Clause 5.7.</p>
Scheduling information	<p>Information used to schedule the element(s) of batch production.</p> <p>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.</p> <p>Defined in the Production Request object – Clause 5.14.</p>
Summary data	<p>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.</p> <p>This may include summary data that is collected before the batch is complete.</p> <p>Contained in the Event, Data set, and Production Response objects– Clause 5.6, Clause 5.7, and Clause 5.14.</p>

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 Modeling 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 (e.g., a trend of a temperature measurement used during a reaction) where common data is associated with more than one batch (e.g., utility feeds used concurrently by multiple batches) or has a very loose association with a batch (e.g., 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 batch production record’s references to that data may need to be updated to reflect the new storage location.

5.2.6 Modeling techniques

The models that are described in this clause are based on the Unified Modeling Language (UML) defined in ISO/IEC 19501 (see Clause 2).

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 standard 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:

- 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; or
- 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 the Part 2 standard.

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 so the data in the product record can be associated 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 standard 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.

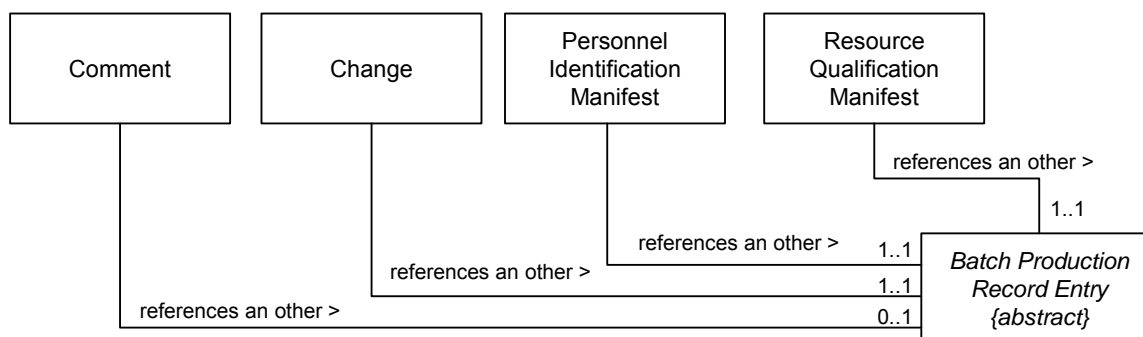


Figure 8 – Object reference model

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 reduce the time needed to check a batch production record for syntactic correctness. Container objects are also expected to make parsing of batch production records easier, and make it easier to search for selected information.

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 clause 6.4).

Over a batch production record's lifecycle, the containers and/or objects that make up the batch production record may change.

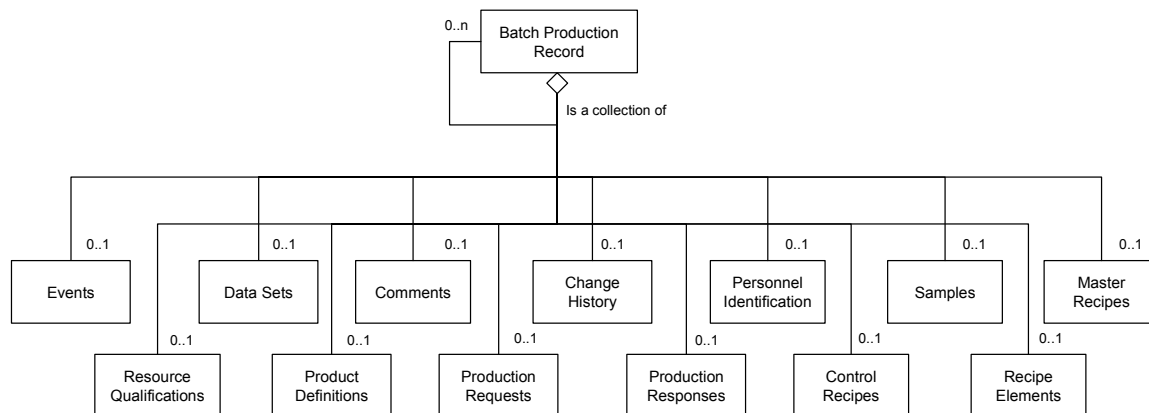


Figure 9 - Batch production record top level model

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

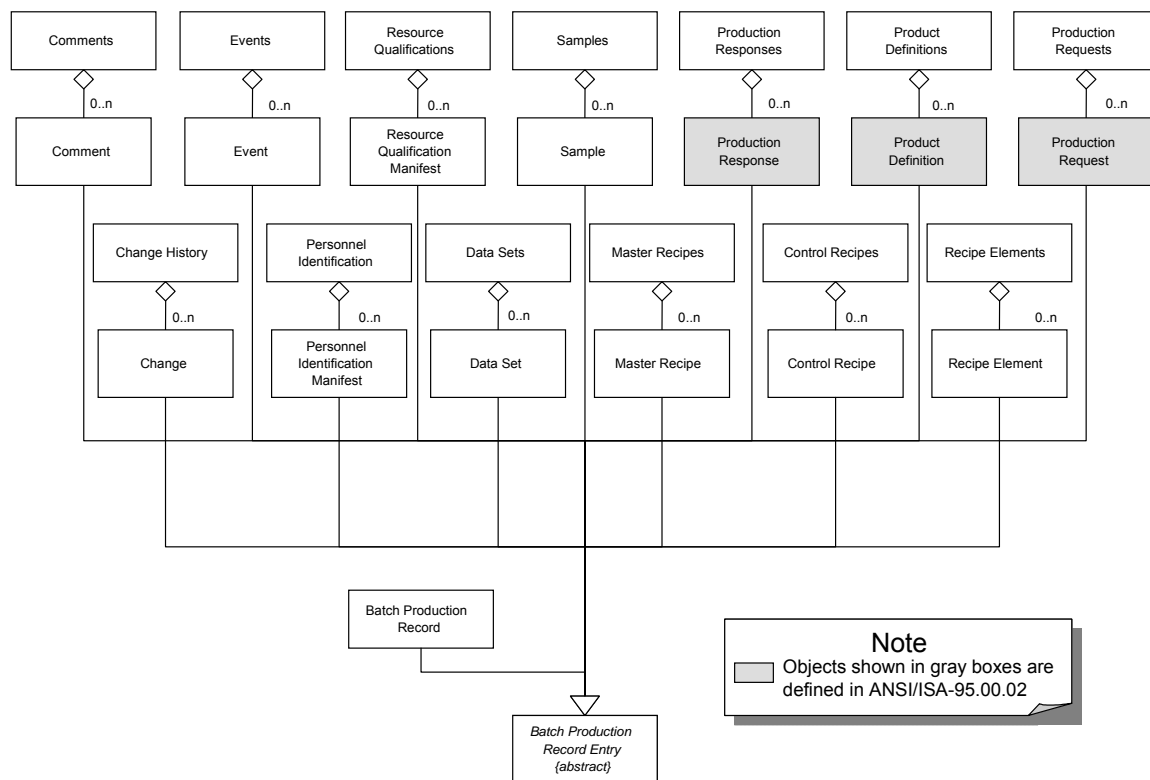


Figure 10 - Batch production record object model

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 lifecycle 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>	492-2931 T59482A4 456
Description	Additional information about the batch production record.	Lot Release Campaign costing Compliance Material tracking data
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>	Process Cell Site area unit Toledo Dog food line 2
Creation Date	The date the batch production record was created.	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Last Changed Date	The date the batch production record was last changed.	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
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>	E;4J9QJG;RGJAOF0 FKG9GRKGH44FF KRJG49TJHVSNS
Record Status	<p>Current status of the batch production record. This reflects the current position in a batch production record's lifecycle.</p> <p>Note 2: This Part 4 standard does not define standard status values.</p>	In Process Review Approved
Batch production record Specification ID	Unique identification of the batch production record specification used to create this batch production record.	459293A1-T423 ver 1.0 A4Q59492-X43S Polymer56-PRS42

Name	Description	Examples
Expiration Date	Date and time at which the batch production record is no longer relevant.	2003-07-14 1454+0100 01 March 2004 14:25 UTC April 23, 2002 8:30 AM ET
Version	The current version of the batch production record. Note 3: Change objects provide historical information concerning how this version was created.	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	The list of IDs of the lots associated with the batch production record. 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.	L492840 EOVMW2 84293
Batch ID	The list of IDs of the batches associated with the batch production record. 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.	59429-35 B-000349 200309041435
Material Definition ID	The list of IDs of the products associated with the batch production record. 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.	459293A1 A4Q59492-5942.1 Polymer56
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.	" " "/t"
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 sub-types. 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.

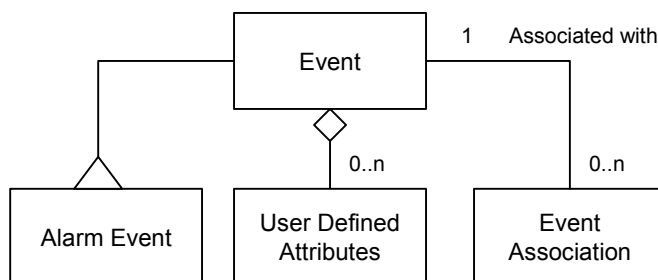


Figure 11 - Event model

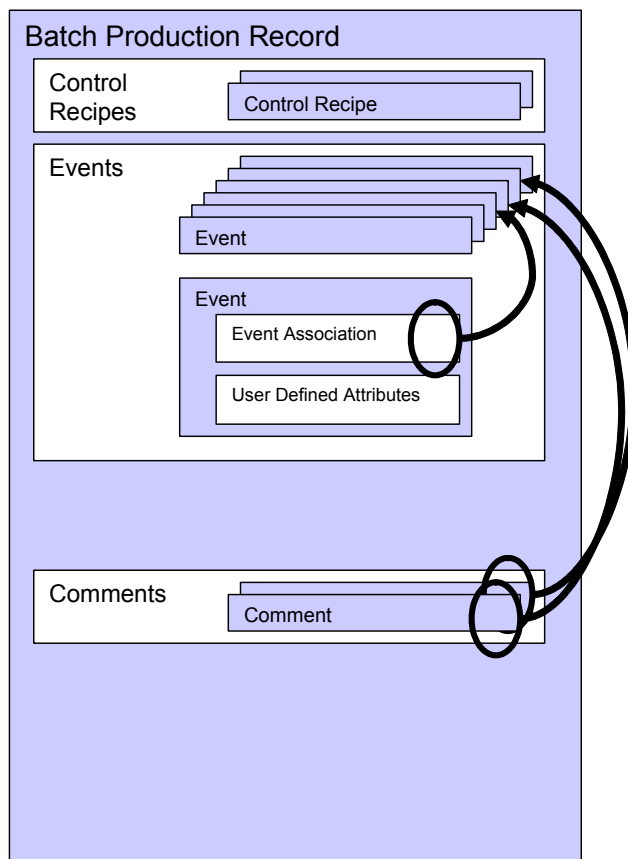


Figure 12 - Example of event element relationships

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.	R101 Company E 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 Gal. 5,230,439 ea Red Open Failed Normal 0.3928356834
Previous Value	The value prior to the change documented by the event. Note 2: For example, when a setpoint 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 a vessel's status changes from Dirty to Clean.	50.0 Deg 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

Name	Description	Examples
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 standard.	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 lifecycle. Note 1: Standard alarm events are not defined as part of this standard.	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 standard.	High Deviation Rate of Change
Priority	Indication of the importance of an event. Note 3: Standard priorities are not defined as part of this standard. 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 Sub-Type	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 the Part 1 standard. Example 5: Step 4 started, step 54 stopped.
Equipment	State Command	Record of a command to change equipment state as defined in the Part 1 standard. 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 standard.
Equipment	Mode Change	Record of an equipment mode change as defined in Part 1 of this standard.
Equipment	Mode Command	Record of a command to change equipment mode as defined in Part 1 of this standard.
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.

Event Type	Event Sub-Type	Description
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.
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: Program failed to start, program crashed, program 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, user rights violation.
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 second 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.

Event Type	Event Sub-Type	Description
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.
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	A change in the status of a material (e.g., quarantine, hold, release). Previous value contains the old status, Value contains new status.
Material	Property Value Change	A change in the property of a material (e.g., 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 addition 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 Deg. 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 vs. 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.

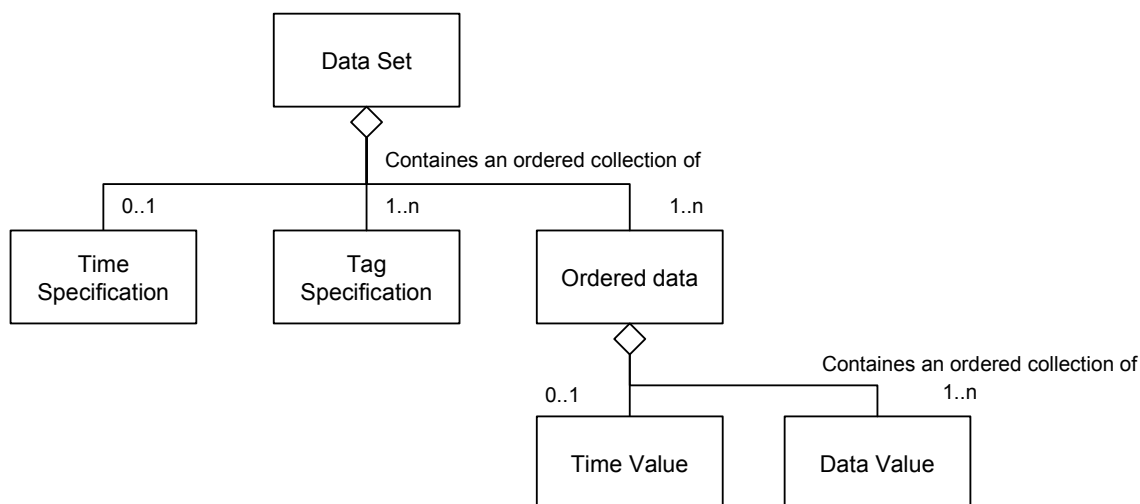


Figure 13 – Data set model

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

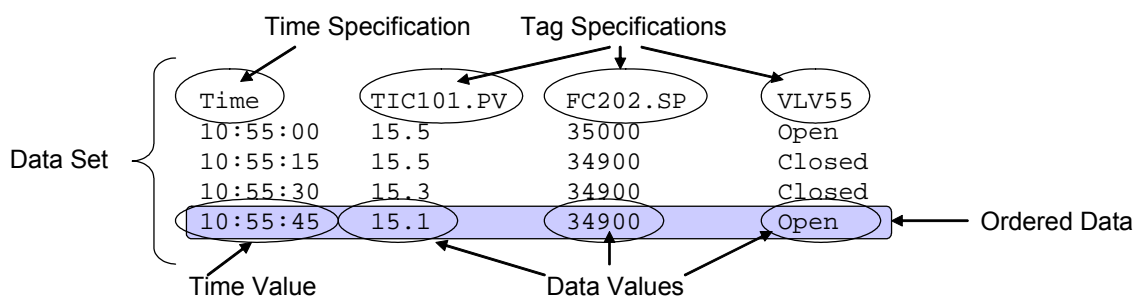


Figure 15 - Elements of a time series data set

Example 2: The flow rate into a vessel may only be trended when it is being used by certain phases. So 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

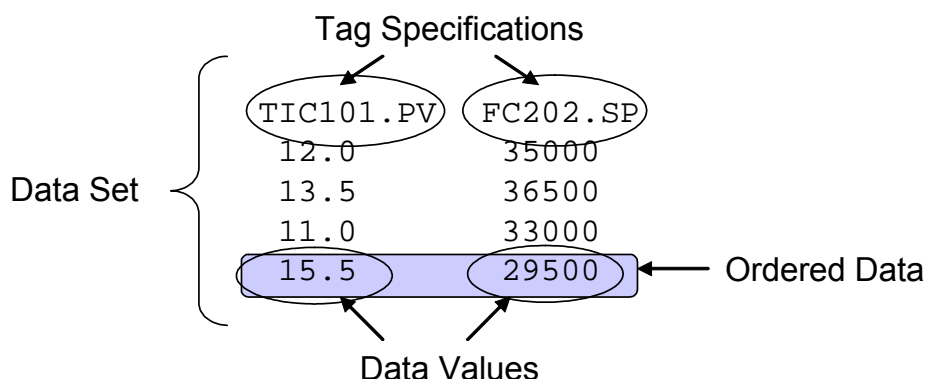


Figure 17 - Elements of a correlated data set

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 standard.	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 Note 3: 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 standard. Note 5: Standard units of measure should not change across trend segments.	pH deg C deg F kgs Liters
Data type	Type of data. Note 6: Standard data types are not defined as part of this standard.	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 standard.	Boxcar backslope Change delta None

Name	Description	Examples
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 standard.	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 standard.	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.

Note2: 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 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 that the comment is associated with. Note: 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 standard.	SampleTestResult%3445/pH ControlRecipe%42 Formula TargetWater 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 minutes during the React phase and are then mixed together to determine overall quality of a material being produced.

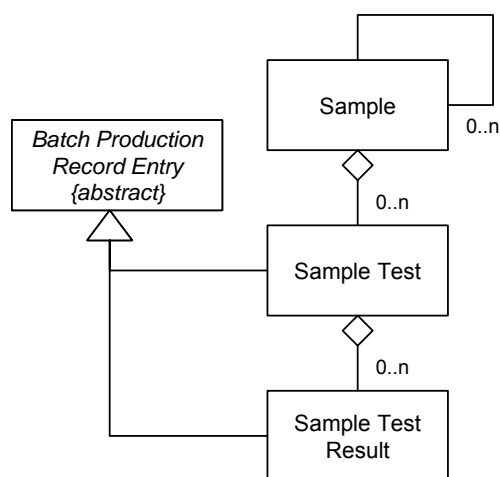


Figure 18 –Sample model

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 the sample material was taken from.	SD2348 LOT2 B12384 SAMPLE2
Sample Size	Amount of sample taken.	100 3x10 ≥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 standard.	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 that the sample expires. Note 3: The quality of the sample may degrade over time. Example: A sample of milk must be tested within 24 hours 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. Must 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 10001
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 a 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 standard.	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 standard.	Average Min Max
Expiration time stamp	The 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; or
- 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 that the change is associated with. 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 standard.	SampleTestResult%3445/pH ControlRecipe%42 Formula TargetWater 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 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 electronic signature is optional.

The “Time stamp” attribute (inherited from 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 that the personnel identification is associated with. Note 3: 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 standard.	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	An 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 FKG9GRKGH44FF 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 – batch production record model. 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 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 that the qualification manifest is associated with. 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 Part 4 standard.	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 (e.g., 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 as 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 standard, 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 standard 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/ISA-95.00.01-2000 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 standard 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 the Part 1 standard and derived from the abstract reference models in the Part 2 standard.

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 lifecycle. 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.

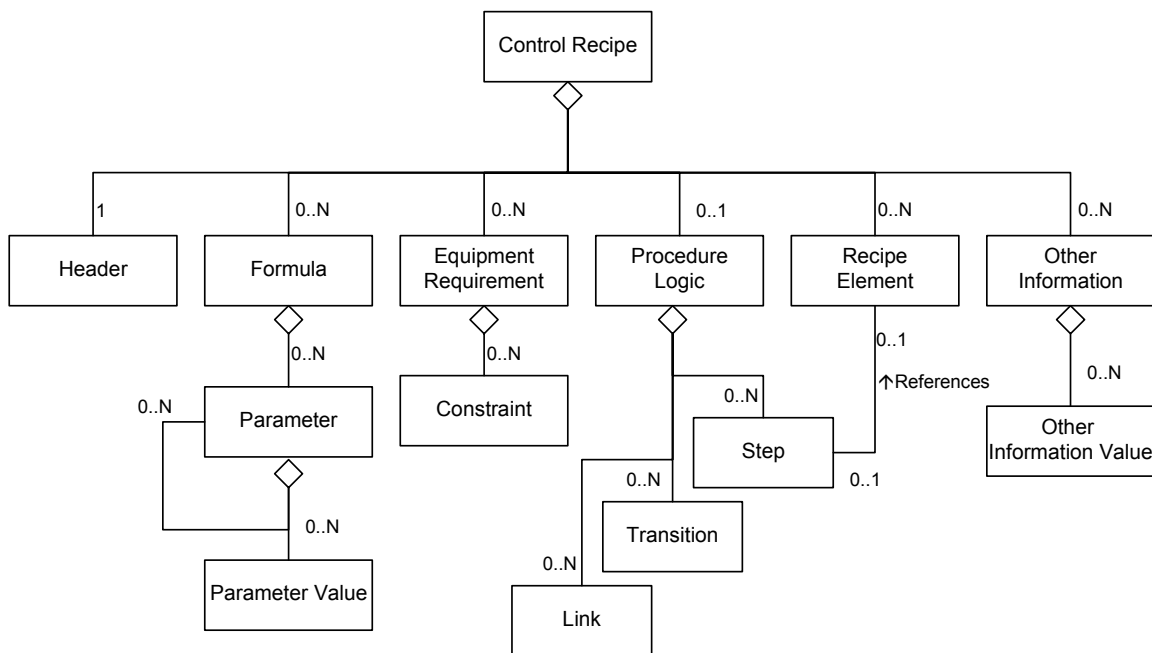


Figure 19 –Control recipe model

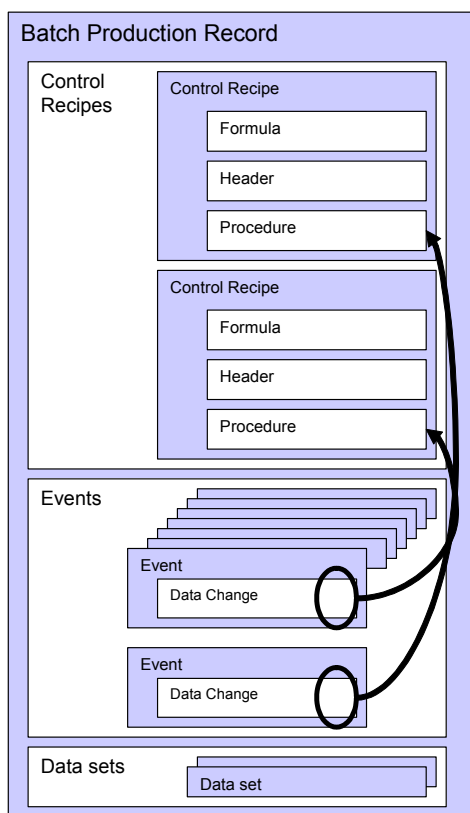


Figure 20 - Sample batch production record with two control recipe copies

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	The commonly used name for a product	Acetone Amber Beer Plastic
Batch Size	A 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 kgs 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	A 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 standard.	
Approval History	A 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 standard.	
Status	Identification of a recipe's status	Released for Production Under Development Expired

Name	Description	Example
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 must 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	The 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	The constraint's value	4 293.45 Red
Unit of Measure	Unit of measure of the value	kg Gallons Meters
Datatype	Datatype 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 the Part 1 standard.

A recipe's formula information 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 Setpoint Settle Time #1
Description	Additional information about the parameter	Amount of ingredient A to add
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 a parameter’s value is to be scaled when the control recipe is scaled. ‘True’ means to scale the parameter value, ‘False’ means to not scale it	True False
Scale Reference	The scaling factor to use when the parameter value is scaled. If Scaled=True and Scale Reference is not specified, then the parameter is scaled using the control recipe’s scaling factor.	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	The 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 use 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 the Part 2 standard. 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 a link starts at	L438 S2 T003
To ID	Identification of the link, step, or transition a link ends at	N2404 H2 T004
Link Type	Specifies if the link is a procedural control flow or a material transfer association. Valid values are "Control Link", "TransferLink," "SynchronizationLink," "ParallelDivergent," "ParallelConvergent," "SerialDivergent," "SerialConvergent."	Control Link ParallelConvergent TransferLink
Depiction	Defines how the link will be presented. Valid values are "None," "Line," "ID," "LineAndID," "LineAndArrow," "LineArrowAndID."	LineAndID ID LineArrowAndID

Name	Description	Example
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

5.16.11 Step

A step object in a procedural logic object describes a single instance of use of a recipe element (unit operation, operation, or phase). Steps may also correspond to nonprocedural elements used in procedure diagrams, such as the Begin and End symbols, and the Allocation and Deallocation symbols.

Step objects may be associated with a control recipe procedure logic object as defined in the recipe object model presented in Figure 19.

Table 29 lists the attributes of step objects.

Table 29 – Step attributes

Name	Description	Example
ID	Identification of a step.	3 23 S008
Recipe Element ID	Identification of a recipe element, usually a unit procedure, operation or phase.	Reaction Distillation Heat
Recipe Element Version	Identification of version of the recipe element.	1.0 4.01.13A D
Description	Additional information about the step.	Distillation Operation

5.16.12 Transition

A transition object in a procedure logic object describes a single instance of a transition in the logic.

Table 30 lists the attributes of transition objects.

Table 30 – Transition attributes

Name	Description	Example
ID	Identification of a transition.	4 84 T00029
Condition	An expression to be evaluated as part of the transition.	TI101 > 100.0
Condition Annotation	Text associated with transition for visualization purposes.	Temp exceeds target
Description	Additional information about the transition.	Check temperature reached target

5.16.13 Other information

The other information object may be associated with a control recipe as defined in the control recipe object model presented in Figure 19.

Table 31 lists the attributes of other information objects.

Table 31 – Other information attributes

Name	Description	Example
ID	Identification of other information.	3 43 A5433
Description	Additional information about the information	Color.jpg Operator Comment System ID

5.16.14 Other information value

Table 32 lists the attributes of other information value objects.

Table 32 – Other information value attributes

Name	Description	Example
Value String	The 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

5.17 Recipe element

A recipe element object shall be represented by the model in Figure 21. A control recipe may contain one or more recipe element objects. A recipe element is a representation of a procedural element in a control recipe (e.g., unit procedure, operation, or phase). A recipe element contains the same objects as the control recipe, and may contain lower-level recipe elements. See the clause describing the Control Recipe for definitions of the contained objects.

The recipe procedure structure is recursive, and the ANSI/ISA-88 standards allows for collapsing or expansion of the recursive procedural hierarchy. The element recipe object is used to describe the recursive definition of the recipe structure. A recipe's procedural definition is defined in the recipe element and procedure logic objects.

A recipe element object contains a header, formula (described in parameters), equipment requirements, other information, and recipe procedure (described in recipe elements and procedure logic). The procedure logic object defines the steps and transitions in the procedural logic. The elements that the steps reference (unit procedures, operations, or phases) are described in the enclosed recipe element. Alternately, the recipe element object may identify a recipe element described in a recipe building block.

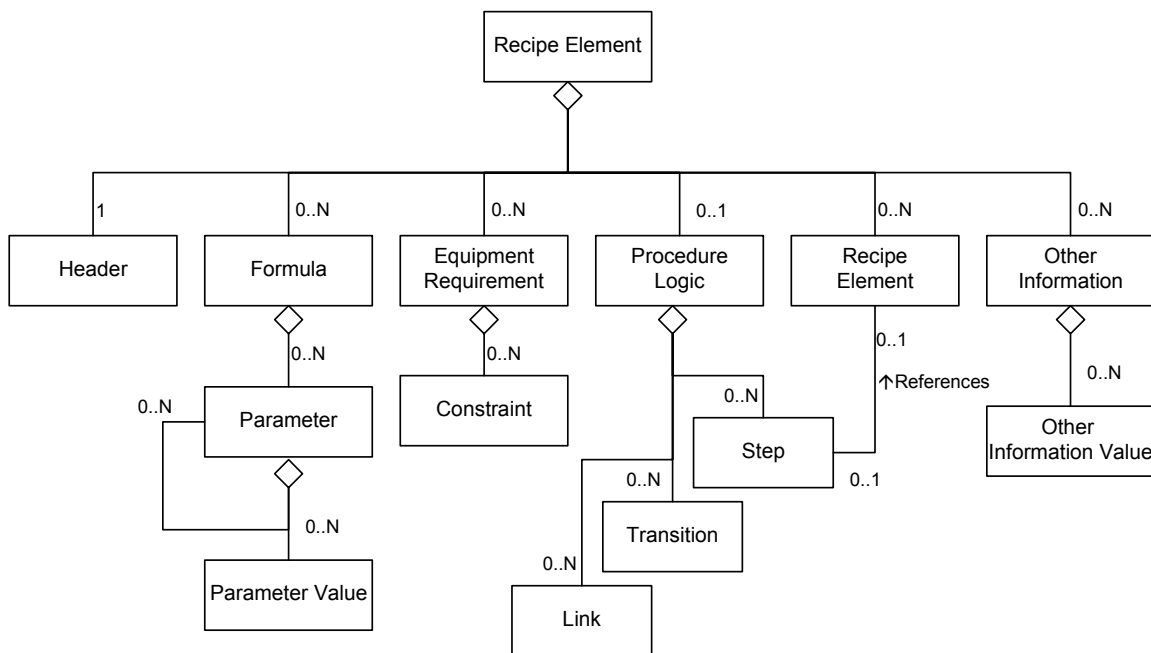


Figure 21 - Recipe element model

Table 33 lists the attributes of recipe element objects.

Table 33 – Recipe element attributes

Name	Description	Example
ID	Identification of a recipe element.	Reaction Unit Procedure Distillation Operation Heat Phase
Version	Identification of the version of the recipe element.	1.0 4.01.13A D
Version Time Stamp	The date and time the recipe element 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 recipe element.	Heat the reactor
Recipe Element Type	Identification of the type of recipe element. Valid values are "Procedure," "Unit Recipe," "Unit Procedure," "Operation," "Phase," "Allocation," "Deallocation," "Begin," "End."	Phase Unit Recipe Operation
Actual Equipment ID	Identification of the actual equipment used by the recipe element.	R-101 T-830 D-1

5.18 Master recipe

A master recipe object shall be represented by the model in Figure 22. A master recipe is a template recipe that is used to create control recipes. A master recipe defines the formula and procedure for a product (batch) and is targeted to a process cell (or process cell class).

A master recipe object contains the same elements as the control recipe. See the clause describing the Control Recipe for definitions of the contained objects.

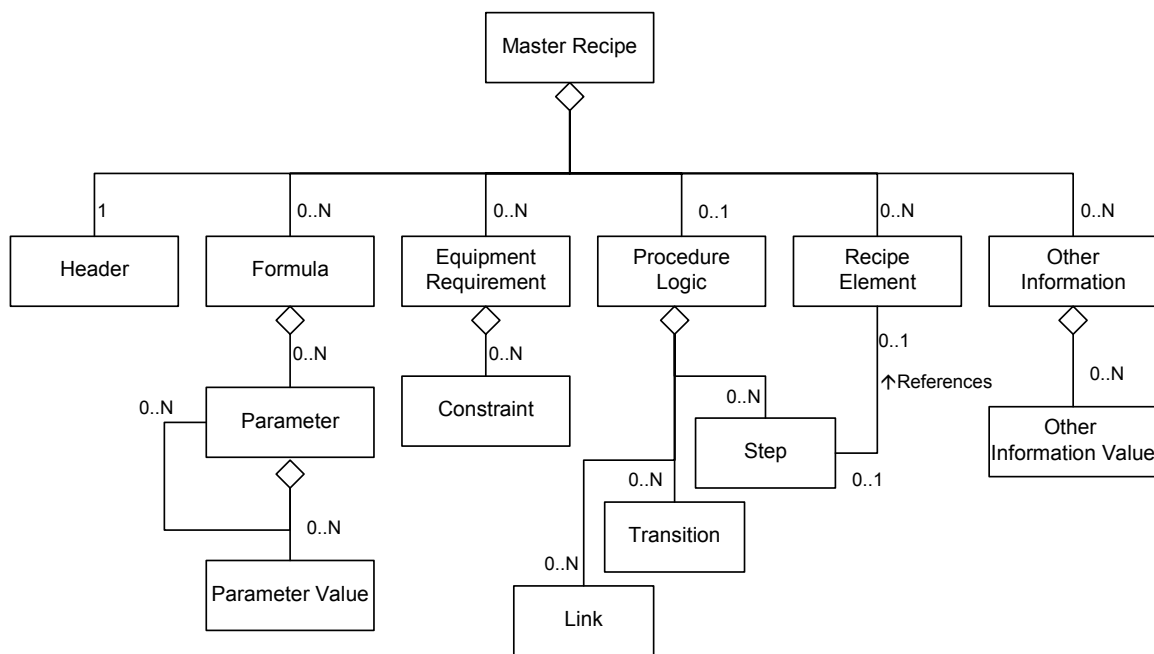


Figure 22 – Master recipe model

Table 34 lists the attributes of master recipe objects.

Table 34 – Master recipe attributes

Name	Description	Example
ID	Identification of a master recipe.	MR-1 Polymer X12.004 4593021
Version	Identification of the version of the master recipe.	1.0 4.01.13A A
Version Time Stamp	The date and time the master 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 master recipe	Recipe for Tasty Treats using corn feed in pellets in reactor 134

6 Completeness, compliance and conformance

6.1 Completeness

The number of object models, objects and attributes supported, as defined in Clause 5, shall determine the degree of completeness of a specification or application.

6.2 Compliance

Any assessment of the degree of compliance of a specification shall be qualified by the following:

1. The use of object names.
2. The use of the attributes for each supported object.
3. A statement of the degree to which they then conform partially or totally to definitions and attribute names.

In the event of partial compliance, areas of noncompliance shall be explicitly identified.

6.3 Conformance

Any assessment of the degree of conformance of an application shall be qualified by the following:

1. Documentation of the object models and objects, as listed in Clause 5.6 through Clause 5.18, conformed to.
2. Documentation of the attributes conformed to.
3. A statement of the mapping of the application's attributes and object names to the objects and attributes listed in this standard.

In the event of partial conformance, areas of nonconformance shall be explicitly identified.

Any additional batch production record objects and attributes supported by an application should be explicitly identified as extensions to the standard format.

6.4 Extending the object model

The objects in a batch production record represent a wide range of data types and formats intended to cover common requirements in the industry. 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.

When objects or attributes are added to an implementation of the object model, the following rules shall be followed to be in compliance with this standard:

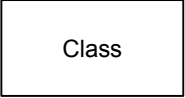

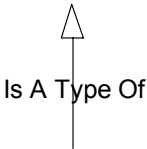
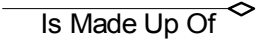
1. Existing objects and attributes shall not be redefined.
2. New objects and attributes may be created provided their names clearly identify them as different from objects and attributes defined in Clause 5 of this standard.

Annex A (informative) — Data modeling technique

A.1 UML notation

Table A.1 defines the UML notation (see definition A.2.7 below) that is used throughout this standard.

Table A.1 — UML notation

Symbol	Definition
	Defines a class of objects, each with the same types of attributes. Each object is uniquely identifiable or enumerable. No operations or methods are listed for the classes.
	An association between elements of a class and elements of another or the same class. Each association is identified. Can have the expected number or range of members of the subclass, where 'n' indicates an indeterminate number (e.g., 0,n means that zero or more members of the subclass may exist).
	Generalization (arrow points to the super class) shows that an element of the class is a specialized type of the super class.
	Aggregation (i.e., made up of) shows that an element of the class is made up of elements of other classes.

A.2 Definitions

A.2.1 class:

a description of a set of objects that share the same attributes, behaviors, relationships, and semantics.

A.2.2 encapsulation:

a technique that separates the external aspects of an object from the internal, implementation details of the object (also called information hiding).

A.2.3 instance:

a term that is used to refer to an object that belongs to a particular class but that is not itself a class or a subclass. For example, "reactor401" is an instance of the class "reactor."

A.2.4 model:

a formal abstract representation of a system. A model is usually presented as a collection of diagrams and a data dictionary.

A.2.5 object:

an entity that is composed of state and behavior. State is the value of all attributes at a given time. An attribute is a piece of information that qualifies the object. The behavior of an object is the functionality that is contained in the object that is necessary to manipulate the attributes.

A.2.6 subclass:

a class that is a special case of a more general class (e.g., glass-lined reactor is a subclass of reactor class).

A.2.7 unified modeling language (UML):

a language that is used for specifying, visualizing, constructing, and documenting the artifacts of software systems, as well as for business modeling and other non-software systems.

Annex B (informative) — Questions and Answers

B.1 Introduction

This section uses a question and answer format to record ISA-SP88 committee discussions and correspondences that occurred during the creation and review of this standard.

B.2 Levels of batch production record specifications

Question: Are there general, site, master and control batch production record specifications?

Answer: Batch production record specifications are independent of recipes.

However, batch production record specifications can be considered analogous to recipes. A batch production record specification is similar to a master recipe in that the single specification is used many times, once per batch. Each batch production record may include a copy of the batch production record specification, which would be analogous to a control recipe. There could be the equivalent of a general and site batch production record specifications, which are developed in parallel with general and site recipes to document the type of information that should be collected when a corresponding recipe is used to produce a batch.

B.3 Batch production record specification content

Question: What does the batch production record specification include?

Answer: The contents of a batch production record specification may include:

1. The rules for naming the associated batch production records.
2. A specification that determines which elements of batch production it applies to, such as a batch or a definition of a product class or product family.
3. The business requirement for the batch production records.
4. The rules defining which elements of production execution information are copied to, or referenced in, the batch production record and rules that map the information into elements of the batch production record.

B.4 Batch production record specification format

Question: What are some of the formats for batch production record specifications?

Answer: The format of the batch production record specification may be in any format or level of complexity. For example, they may be simple text explanations or complicated conditional expressions used to determine if a batch production record is required for a batch, specify the inclusion of data upon certain conditions, or the lack of other conditions.

B.5 Batch production record specification format

Question: Why do objects have both Person ID and Computer ID?

Answer: It is sometimes important to record both the person making a change and the computer, terminal or device she or he used to make the change.

B.6 Recording reasons why data is in a batch production record

Question: Should each object in the batch production record object model have an attribute that provides the reason it is in the batch production record?

Answer: No. If it is important to record why data is in the batch production record, then the batch production record specification should provide documentation for this.

Reasons why data is in a batch production record include:

- Specified by a recipe
- Ad hoc (human or programmatic decision during a batch)
- Specified outside of a recipe (e.g., business rule)
- Continuously collected data (e.g., a trend of a temperature value)

B.7 How many audit trails are in a batch production record?

Question: Shouldn't each object in the batch production record object model have its own audit trail?

Answer: Since the object model is a logical model, one audit trail object has been used that is intended to record audit trail entries for all the objects in the batch production record. In a physical implementation of this model, technology limitations or business requirements may result in multiple audit trails, with each covering different objects.

B.8 Recording discrete events

Question: Where are application-specific discrete events stored?

Answer: Application-specific discrete events, such as the amount of material actually added to a vessel, are either recorded as events or as part of a control recipe. Each implementation and application of a batch production record has discretion concerning the actual storage location of values recorded as discrete events. Wherever the values are stored there should be sufficient context to explain what the numbers mean and where they came from.

B.9 Production schedules and schedule changes

Question: How are production schedules and schedule changes stored in the batch production record?

Answer: Production and batch schedule entries pertaining to a batch may be stored as events; there is no separate schedule object.

B.10 Material data safety sheets

Question: Are material data safety sheets (MSDS) part of a batch production record?

Answer: No. Material data safety sheets are not typically part of a batch production record. MSDSs are typically common information that would be used in many different batches and are not usually batch

specific, so it is better to record and track MSDS history in a separate system and have a batch production record reference that system as appropriate.

B.11 Label scans

Question: When the label of a material container is scanned does the label need to be stored in the batch production record?

Answer: Labels are usually a source of data and therefore may be referenced as the source of data for a material transaction, but the label or a copy of it does not usually need to be stored in a batch production record.

B.12 Production Information

Production information may include data from the production of a batch of material, the specifications used to produce the batch, and information about the environment the batch was produced in. Production information may include data that is recorded on paper, not as part of a computer system, or stored on various computer systems.

NOTES:

An example of this is the configuration data of a batch control system. The configuration data includes the equipment phase logic that performed the actual control and user interface screens used by the operator to monitor and control the phase. However, this data should be archived outside of a batch production record since it is common to many batches and would not be practical to include as part of each batch production record. An appropriate place to store batch control system configuration data would be in a configuration database that permits reconstruction of the batch control system's configuration for any given point in time. It would then be appropriate for a batch production record to contain a pointer to the batch control system's configuration database including the identifying information needed to retrieve the pertinent configuration data.

Since batch production records may be retained for long time periods, information about changes in a production environment between the time the batch was produced and the time the batch production record was accessed should be maintained. In order to meet good manufacturing practices, system information that is needed to interpret data in a batch production record should be available for historical purposes.

For example, if, during a batch, tag TI610 was identified with the alias "Reactor Bottom Temperature" yet three years later on the same reactor the alias "Reactor Bottom Temperature" identified the tag TI611, then it is critical to include either sufficient data to determine the actual tag used or references to external history systems that can provide this information.

B.13 Equipment history

Question: Where is equipment history data stored?

Answer: Equipment history data is documented as a series of events, which are stored using the event object.

Equipment history events may include information such as status changes, done by/checked by entries with ties to electronic signatures, time stamps, description of the event, and an expiration date for the action.

A common example of equipment history is equipment use logs common in the pharmaceutical and biotech industries. Equipment use logs must be maintained to provide documentation that equipment

such as vessels and units were properly prepared (e.g., sterilized, cleaned, checked) for use by a batch and how they were used by a batch.

It is common for equipment use logs to cover time periods preceding a batch in order to include sufficient information to demonstrate the equipment was properly prepared and the preparation was not expired. This information can be included in a batch record as a series of events that occurred on the equipment.

If the events occurred prior to the start of the batch, the events may still be included in the batch production record. The production recipe specification can contain time-based and/or event-based rules to be used in selecting the events to be included in a batch production record.

Example: Include all events for Vessel 8 that occurred prior to the end of the unit recipe that used it, and are after the start of the latest successful cleaning operation, and are no more than 5 days before the start of the batch.

Example: The rules would list the events related to Vessel 8 from up to 5 days before the batch started through the end of the unit recipe that used the Vessel 8. The time period of the events may be shortened by a rule that only requires events be included since the latest successful cleaning since in this case that would provide sufficient documentation the vessel was properly prepared. The 5-day limitation is included since in this example any vessel not used for 5 days after it is cleaned is deemed dirty and must be cleaned again. Therefore, there is no need to include older events in the batch production record.

B.14 Regulated industries?

Question: Many of the objects and attributes in the object model seem intended for the pharmaceutical and other U.S. FDA regulated industries. Can the batch production record object model be used in nonregulated industries?

Answer: The batch production record object model was designed for use by all batch processing industries. In order for the batch production record object model to accommodate as many industries as possible, it contains the union of the requirements of each industry. Since the U.S. FDA regulated industries are required to maintain extensive production documentation, the batch production record object model contains objects and attributes commonly used in U.S. FDA regulated industries but not commonly used in industries not regulated by the U.S. FDA.

While the batch production record object model contains objects and attributes used primarily for the U.S. FDA regulated industries, when the object model is used in applications that are not regulated these objects and attributes may be omitted from batch production records.

B.15 ISA-88 Batch Production Record versus ISA-95 Standards

Question: How does the batch production record relate to the ISA-95 standards?

Answer: The batch production record is primarily intended for use within the level 3 activities defined in ANSI/ISA-95.00.03-2005 specifically for batch manufacturing. It could be used as a data model for data produced or consumed by activities in the ISA-95 models. The data models in this standard include models from the ISA-95 standards for those cases where data structures exist.

B.16 ISA-88 versus ISA-95 terminology

Question: Why is the terminology in this ISA-88 Part 4 standard slightly different from the earlier ISA-88 standards?

Answer: This Part 4 standard uses terminology from the ISA-95 standards to utilize the latest standards terminology. A partial mapping of the terminology is listed here:

ISA-88 Term	ISA-95 Term
Product ID	Material Definition ID
Actual Product Produced	Material Produced Actual

B.17 ISA-88 Batch Production Record versus ISA-95 Production Performance

Question: What is the difference between a batch production record and the ISA-95 production performance model?

Answer: Batch production records are designed to contain greater granularity, detail, and more types of data than is typically sent to business systems using the ISA-95 production performance model. The additional information in batch production records is capable of meeting a wider set of business requirements than the production performance model. Production performance messages are intended to inform business systems of work completed based upon the production schedule as a reference and will not typically include data such as control recipes, master recipes, and continuous trend data. The ISA-95 production performance data structure is included as part of the batch production record for cases where the information sent to the business system needs to be retained.

B.18 What format should a data reference use?

Question: Should external references provide a specific or general reference to the externally stored data?

Answer: Data references may be in any format, including very specific references enabling a computer to look up the data or very generic references that will require a person to perform a look up. The format and amount of detail in the reference is determined by business rules. There are advantages and disadvantages to each method, for example:

A very specific reference, such as a URL or SQL query to a specific database on a specific computer, will enable a computer program to look up the data and display it when a person is looking at a batch production record on the computer. This provides very tight coupling. Using this method can reduce the amount of time required to collect referenced data. However, use of this method requires that all the data references are maintained. For example, if a referenced database is moved or archived, a value referenced in a batch production record using a URL or SQL query may no longer be valid. This would cause the computer program attempting to obtain the data to return an error condition. Use of tight coupling can be helpful, but will place increased demands upon system coordination and synchronization.

A very general reference, such as the program the data resides in or a filename, will not enable a computer program to show the data to a person viewing a batch production record. To access the data will require a human to research where the data is stored (this may be different than when the data was

collected since it may have been archived), and extract sufficient data from the batch production record (e.g., batch ID, equipment reference) to look up the data in another computer or in a paper record system. This type of reference may make it more difficult, or time consuming, to find the data, but it should be more robust since the references can survive changes in the referenced system (a person can look up the configuration changes in the referenced system to determine where the data is currently stored).

Either type of reference will meet this standard's requirements.

B.19 Personnel Actions

Question: How do I track personnel actions?

Answer: The personnel identification manifest object may be used to track who pulled the sample, who performed the test, who entered the sample test results, who reviewed, and the like.

Developing and promulgating sound consensus standards, recommended practices, and technical reports is one of ISA's primary goals. To achieve this goal the Standards and Practices Department relies on the technical expertise and efforts of volunteer committee members, chairmen and reviewers.

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