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ISA-88.00.04-2006

Batch Control Part 4: Batch Production Records

Approved 25 April 2006

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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
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- 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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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).