

ICS 25.040

CCS N 10



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 19892.4-2022

Batch control - Part 4: Batch production records

Issued on: October 12, 2022

Implemented on: May 1, 2023

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

Preface	
Introduction	
1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Batch Production Record Instructions	2
4.1 Overview	2
4.2 Overview	3
4.2.1 Batch Production Record	3
4.2.2 Business Information	4
4.2.3 Production Execution Information	4
4.2.4 Batch Production Record Specification	4
4.2.5 Batch Production Record Report	4
4.3 Purpose of batch production records	4
4.3.1 Overview	4

foreword

This document is in accordance with GB/T 1.1-2020 "Guidelines for Standardization Work Part 1. Structure and Drafting Rules for Standardization Documents" and

GB/T 1.2-2020 "Guidelines for Standardization Work Part 2. Rules for Drafting Standardization Documents Based on ISO /IEC Standardization Documents"

regulations drafted.

This document is part 4 of GB/T 19892 "Batch Control". GB/T 19892 has issued the following parts.

- Part 1. Models and terminology;
- Part 2. Data structure and language guidelines;
- Part 3. General and field prescription models and representations;
- Part 4. Batch production records.

This document is equivalent to IEC 61512-4:2008 "Batch Control Part 4. Batch Production Records".

Introduction

GB/T 19892 is a standard for batch process and guidance for batch control, consisting of four parts.

--- Part 1. Models and terminology. The purpose is to establish the model and terminology to be followed for batch control.

--- Part 2. Data Structures and Language Guidelines. The purpose is to illustrate the language's data structures and guidelines.

--- Part 3. General and field prescription models and representations. The purpose is to define additional information for generic and field prescriptions.

--- Part 4. Batch production records. The purpose is to provide a reference model for developing applications for storing and/or exchanging batch production records.

This document is further implemented to allow retrieval, analysis and reporting of selected batch record data, and to provide

Defined in detail, it consists of an object model that describes and batches the contents of records. Batch production record standards comply with GB/T 19892.2-2007

The batch data model in Chapter 4 and GB/T 19892.1.

Although this document is primarily directed to batch processes, it can also be referenced for other types of processes.

Batch control part 4. batch production records

1 Scope

This document defines a reference model for batch records containing information about batches or batch elements.

This document is suitable for batch processing.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references

For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

this document.

GB/T 19892.1-2005 Batch Control Part 1. Models and Terminology (IEC 61512-1.1997, IDT)

GB/T 19892.2-2007 Batch Control Part 2.Data Structure and Language Guidelines (IEC 61512-2.2001, IDT)

ANSI/ISA-95.00.01-2000 Enterprise Control System Integration Part 1.Models and Terminology (Enterprise-controlsystem

ANSI/ISA-95.00.02-2001 Enterprise control system integration Part 1.Object model attributes (Enterprise-controlsys-

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

batch history batchhistory

Collect all execution information related to individual batches, which may include common (non-batch-specific) information.

3.2

A subset of executive and business information retained based on business requirements, identified in accordance with a batch production record specification.

NOTE. This information can include prescription program element execution information, device-specific information, operator notes, batch-related alarms, batch-definition-related elements such as

Control recipes, master recipes, field and/or generic recipes, batch scheduling information) and critical batch information (such as training logs, maintenance records, and environmental conditions).

3.3

Formatted information extracted from one or more batch records for printing, displaying, or sending to a collaborative system.

3.4

Data used for the generation of batch production records or contained in batch production records and specifications (if the data are used for reference or extraction)

Completed execution business information requirements definition.

NOTE. This information may include content, calculations, and other rules that require identifying relevant information.