

AMERICAN NATIONAL STANDARD

ANSI/ISA-88.00.01-2010

**Batch Control Part 1:
Models and Terminology**

Approved 6 December 2010

ANSI/ISA-88.00.01-2010
Batch Control Part 1: Models and Terminology

ISBN: 978-1-936007-75-2

Copyright © 2010 by ISA. All rights reserved. Not for resale. Printed in the United States of America. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise), without the prior written permission of the Publisher.

ISA
67Alexander Drive
P. O. Box 12277
Research Triangle Park, North Carolina 27709
USA

CONTENTS

1	Scope	17
2	Normative references	17
3	Terms, definitions and abbreviations.....	18
3.1	Terms and definitions	18
3.1.1	Introduction	18
3.2	Abbreviations	26
4	Batch processes and equipment	27
4.1	Introduction.....	27
4.2	Types of manufacturing	27
4.2.1	Introduction	27
4.2.2	Continuous process manufacturing	27
4.2.3	Discrete parts manufacturing	27
4.2.4	Batch process manufacturing	27
4.3	Process model	28
4.3.1	Introduction	28
4.3.2	Process	29
4.3.3	Process stage.....	29
4.3.4	Process operation.....	30
4.3.5	Process action.....	30
4.3.6	Collapsing and expanding the process model	30
4.4	Equipment and equipment Control	31
4.4.1	Introduction	31
4.4.2	Physical model	31
4.4.3	Equipment entity model	33
4.5	Process cell classification.....	40
4.5.1	Introduction	40
4.5.2	Classification by number of products.....	40
4.5.3	Classification by physical structure.....	41
5	Structure for batch control	44
5.1	Introduction.....	44
5.2	Basic control	44
5.2.1	Introduction	44
5.2.2	Basic control in equipment entities	44
5.3	Procedural control	45
5.3.1	Introduction	45
5.3.2	Procedural control model	46
5.3.3	Procedural control model/physical model/process model relationship	49
5.3.4	Procedural control in equipment entities	51
5.4	Coordination control	52
5.4.1	Introduction	52
5.4.2	Allocation and arbitration	52
5.4.3	Coordination control in equipment entities	53

6	Recipes and procedural elements	55
6.1	Introduction	55
6.2	Recipe types	55
6.2.1	Introduction	55
6.2.2	General recipe	56
6.2.3	Site recipe	56
6.2.4	Master recipe	57
6.2.5	Control recipe	57
6.3	Recipe contents	58
6.3.1	Introduction	58
6.3.2	Header	58
6.3.3	Formula	58
6.3.4	Equipment requirements	59
6.3.5	Procedure	59
6.3.6	Other information	59
6.4	Recipe components	59
6.5	Recipe procedures by type of recipe	60
6.5.1	Introduction	60
6.5.2	General recipe procedure	61
6.5.3	Site recipe procedure	62
6.5.4	Master recipe procedure	62
6.5.5	Control recipe procedure	64
6.6	Control recipe procedure/equipment control relationship	65
6.6.1	Introduction	65
6.6.2	Linking recipe entities and equipment entities	65
6.6.3	Linking recipe phases and equipment phases	66
6.6.4	Linking recipe procedural elements and equipment procedural elements above the phase level	67
6.6.5	Control recipe procedure/equipment control collapsibility	71
6.6.6	Linking recipe procedural elements and equipment procedural elements when using an expanded procedural control model	72
7	Batch control considerations	73
7.1	Introduction	73
7.2	Process and control engineering tasks	73
7.3	Modes and states	74
7.3.1	Introduction	74
7.3.2	Modes	75
7.3.3	States	77
7.4	Exception handling	78
7.5	Example procedural state model	80
7.5.1	Introduction	80
7.5.2	Procedural states	80
7.5.3	Procedural commands	82
7.6	Batch schedules	84
7.6.1	Introduction	84

7.6.2	Campaign.....	85
7.7	Production information	86
7.7.1	Introduction	86
7.7.2	Batch-specific information.....	86
7.7.3	Common (non-batch specific) batch information	87
7.7.4	Batch history	87
7.7.5	Batch reports.....	87
8	Activities and functions in batch control	89
8.1	Introduction.....	89
8.2	Control activity model.....	89
8.2.1	Introduction	89
8.2.2	Information handling	90
8.3	Recipe management.....	92
8.3.1	Introduction	92
8.3.2	Manage general recipes.....	92
8.3.3	Define general recipe procedural elements.....	93
8.3.4	Manage site recipes.....	94
8.3.5	Manage master recipes.....	94
8.3.6	Define master recipe procedural elements.....	94
8.4	Production planning and scheduling.....	95
8.5	Production information management.....	96
8.5.1	Introduction	96
8.5.2	Receiving and storing batch history information.....	97
8.5.3	Manipulating historical data	100
8.5.4	Producing batch reports.....	100
8.6	Process cell management.....	101
8.6.1	Introduction	101
8.6.2	Manage batches	102
8.6.3	Track and allocate process cell resources	104
8.6.4	Collect batch and process cell information.....	105
8.7	Unit supervision	106
8.7.1	Introduction	106
8.7.2	Acquire and execute procedural elements	106
8.7.3	Manage unit resources	108
8.7.4	Collect batch and unit information	108
8.8	Process control	109
8.8.1	Introduction	109
8.8.2	Execute procedural control	109
8.8.3	Execute basic control.....	110
8.8.4	Collect data	111
8.9	Personnel and environmental protection	111
9	Completeness, compliance and conformance.....	112
9.1	Completeness	112
9.2	Compliance	112

9.3 Conformance	112
Annex A (informative) Model philosophy	115
Annex B (informative) Overview of Part 1 Update	117
Annex C (informative) Frequently asked questions	139
C.1 Conformance and compliance	139
C.2 Multiple batches through units	139
C.3 Further description of basic control	140
C.4 Further description of equipment modules.....	141
C.5 Batch manufacturing roles	142
Product Responsibility Role	142
Manufacturing Responsibility Role	142
Automation Design Responsibility Role	143
C.6 Recipe building blocks.....	143
C.7 Processing a recipe.....	144
C.8 Exception handling details	144
Annex D (informative) Reference Procedural State Model.....	145
D.1 Introduction	145
D.2 Procedural States	146
D.3 Procedural Commands.....	149
D.4 Using Collapsed or Expanded Versions of the Reference Procedural State Model	152
Annex E (informative) Bibliography of safety references	155

Copyright International Society of Automation
 Provided by IHS under license with ISA
 No reproduction or networking permitted without license from IHS
 Full document details: ISA 88.00.01 2010

Figures

Figure 1 — Parts of this standard.....	15
Figure 2 — Process model (instance diagram) when not collapsed or expanded	29
Figure 3 — Physical model	32
Figure 4 — Equipment entity model	34
Figure 5 — Equipment entity model examples	40
Figure 6 — Single-path structure	41
Figure 7 — Multiple-path structure	42
Figure 8 — Network structure	43
Figure 9 — Procedural control model (instance diagram) when not collapsed or expanded...	47
Figure 10 — Typical process/procedure/equipment mapping to achieve process functionality	50
Figure 11 — Recipe types model	55
Figure 12- Master recipe component encapsulation	60
Figure 13 – General recipe procedure model.....	62
Figure 14 – Master recipe procedure model	63
Figure 15 - Information flow from general recipe to equipment entity.....	66
Figure 16 – Control recipe procedure referencing equipment procedural elements at the phase level	67
Figure 17 – Control recipe defined without phase level recipe procedural elements.....	69
Figure 18 – Control recipe defined without operation level recipe procedural elements.....	69
Figure 19 – Control recipe defined without unit procedure level recipe procedural elements	70
Figure 20 – Referencing equipment procedural elements at different levels within the same recipe procedure	71
Figure 21 — Control recipe procedure/equipment procedure collapsibility examples	72
Figure 22 — Simultaneous definition/selection of procedural elements and equipment entities	74
Figure 23 — State transition diagram for example states for procedural elements	84
Figure 24 — Control activity model	90
Figure 25 — Recipe management.....	93
Figure 26 — Process cell management	103
Figure 27 — Unit supervision.....	107
Figure 28 — Process control.....	110
Figure 29 — State transition diagram for the reference procedural state model.....	151

Tables

Table 1 — Example modes	77
Table 2 — State descriptions in the example procedural state model	81
Table 3 — State transition matrix for example states for procedural elements	83
Table 4 — State descriptions in the example full reference procedural state model	146
Table 5 — State transition matrix for the reference procedural state model	150

Batch Control Part 1: Models and terminology

FOREWORD

This foreword, as well as all footnotes and annexes, is included for information purposes and is not part of ANSI/ISA-88.00.01-2010.

This document has been prepared as part of the service of ISA, The International Society of Automation, toward a goal of uniformity in the field of automation. To be of real value, this document should not be static but should be subject to periodic review. Toward this end, the Society welcomes all comments and criticisms and asks that they be addressed to the Secretary, Standards and Practices Board; ISA; 67 Alexander Drive; P. O. Box 12277; Research Triangle Park, NC 27709; Telephone (919) 549-8411; Fax (919) 549-8288; E-mail: standards@isa.org.

The ISA Standards and Practices Department/ endeavours to introduce SI-acceptable metric units in all new and revised standards, recommended practices, and technical reports to the greatest extent possible. Standard for Use of the International System of Units (SI): The Modern Metric System, published by the American Society for Testing & Materials as IEEE/ASTM SI 10-97, and future revisions, will be the reference guide for definitions, symbols, abbreviations, and conversion factors.

It is the policy of ISA to encourage and welcome the participation of all concerned individuals and interests in the development of ISA standards, recommended practices, and technical reports. Participation in the ISA standards-making process by an individual in no way constitutes endorsement by the employer of that individual, of ISA, or of any of the standards, recommended practices, and technical reports that ISA develops.

CAUTION — ISA DOES NOT TAKE ANY POSITION WITH RESPECT TO THE EXISTENCE OR VALIDITY OF ANY PATENT RIGHTS ASSERTED IN CONNECTION WITH THIS DOCUMENT, AND ISA DISCLAIMS LIABILITY FOR THE INFRINGEMENT OF ANY PATENT RESULTING FROM THE USE OF THIS DOCUMENT. USERS ARE ADVISED THAT DETERMINATION OF THE VALIDITY OF ANY PATENT RIGHTS, AND THE RISK OF INFRINGEMENT OF SUCH RIGHTS, IS ENTIRELY THEIR OWN RESPONSIBILITY.

PURSUANT TO ISA'S PATENT POLICY, ONE OR MORE PATENT HOLDERS OR PATENT APPLICANTS MAY HAVE DISCLOSED PATENTS THAT COULD BE INFRINGED BY USE OF THIS DOCUMENT AND EXECUTED A LETTER OF ASSURANCE COMMITTING TO THE GRANTING OF A LICENSE ON A WORLDWIDE, NON-DISCRIMINATORY BASIS, WITH A FAIR AND REASONABLE ROYALTY RATE AND FAIR AND REASONABLE TERMS AND CONDITIONS. FOR MORE INFORMATION ON SUCH DISCLOSURES AND LETTERS OF ASSURANCE, CONTACT ISA OR VISIT WWW.ISA.ORG/STANDARDSPATENTS.

OTHER PATENTS OR PATENT CLAIMS MAY EXIST FOR WHICH A DISCLOSURE OR LETTER OF ASSURANCE HAS NOT BEEN RECEIVED. ISA IS NOT RESPONSIBLE FOR IDENTIFYING PATENTS OR PATENT APPLICATIONS FOR WHICH A LICENSE MAY BE REQUIRED, FOR CONDUCTING INQUIRIES INTO THE LEGAL VALIDITY OR SCOPE OF PATENTS, OR DETERMINING WHETHER ANY LICENSING TERMS OR CONDITIONS PROVIDED IN CONNECTION WITH SUBMISSION OF A LETTER OF ASSURANCE, IF ANY, OR IN ANY LICENSING AGREEMENTS ARE REASONABLE OR NON-DISCRIMINATORY.

ISA REQUESTS THAT ANYONE REVIEWING THIS DOCUMENT WHO IS AWARE OF ANY PATENTS THAT MAY IMPACT IMPLEMENTATION OF THE DOCUMENT NOTIFY THE ISA STANDARDS AND PRACTICES DEPARTMENT OF THE PATENT AND ITS OWNER.

ADDITIONALLY, THE USE OF THIS DOCUMENT MAY INVOLVE HAZARDOUS MATERIALS, OPERATIONS OR EQUIPMENT. THE DOCUMENT CANNOT ANTICIPATE ALL POSSIBLE APPLICATIONS OR ADDRESS ALL POSSIBLE SAFETY ISSUES ASSOCIATED WITH USE IN HAZARDOUS CONDITIONS. THE USER OF THIS DOCUMENT MUST EXERCISE SOUND PROFESSIONAL JUDGMENT CONCERNING ITS USE AND APPLICABILITY UNDER THE USER'S PARTICULAR CIRCUMSTANCES. THE USER MUST ALSO CONSIDER THE APPLICABILITY OF ANY GOVERNMENTAL REGULATORY LIMITATIONS AND ESTABLISHED SAFETY AND HEALTH PRACTICES BEFORE IMPLEMENTING THIS DOCUMENT.

THE USER OF THIS DOCUMENT SHOULD BE AWARE THAT THIS DOCUMENT MAY BE IMPACTED BY ELECTRONIC SECURITY ISSUES. THE COMMITTEE HAS NOT YET ADDRESSED THE POTENTIAL ISSUES IN THIS VERSION.

This Part 1 standard is structured to follow IEC (International Electrotechnical Commission) guidelines.

This document is Part 1 of a multi-part set of standards that defines batch control. Other standards in the series include, under the general title "Batch Control":

- Part 2: Data structures and guidelines for languages
- Part 3: General and site recipe models and representation
- Part 4: Batch production records
- Part 5: Implementation models and terminology for modular equipment control (in development at the time of publication; visit www.isa.org/standards)

This revised Part 1 replaces ISA-88.01-1995. The major changes made to this standard from the previous version are:

1. Models and text are modified to provide more detail and clarity. Key clarifications are:
 - a. All recipe-aware equipment modules contain procedural control
 - b. Execution of all procedural control contained directly in units is part of the unit supervision activity.
 - c. The relationships between types of recipes, recipe components, and equipment control are more fully described and illustrated.
 - d. Entity relationship diagrams have been replaced with more intuitive UML instance diagrams.
 - e. The transition diagram for the procedural states example has been updated with a more intuitive and complete UML state diagram.
 - f. References to other standards in the series and to the ANSI/ISA-95 and IEC 62264-1 are included to provide direction for further clarification of selected topics.
2. Previous Clauses 4 through 6 (now 4 through 8) were rearranged to provide a clearer top down organization of the document. Key changes are:
 - a. Simultaneous characterization of the physical and equipment entity model levels at and below the process cell to eliminate redundancy and clarify that the control in these entities is the basis for partitioning this part of the physical model (see 4.3).

- b. Combining the descriptions of basic, procedural, and coordination control with their usage in each type of equipment entity, providing a single consolidated discussion of each type of control (see Clause 5)
 - c. Additional considerations to support application of the models have been grouped in Clause 7 to clarify their supporting relationship to the core models.
- 3. Clause 9 was added to define completeness, compliance, and conformance in relation to this standard.
- 4. Annex B was added to more fully describe the changes in this document compared with the superseded 1995 version.
- 5. Annex C was added to clarify a number of points concerning the models, their application, and the new clause on conformance and compliance.
- 6. Annex D was added to provide a more expansive procedural state reference model. The model found in Clause 7 may be considered a collapsed version of this more general model.

The following served as active members of the ISA88 Part 1 Update Working Group:

Name	Affiliation
Paul Nowicki, WG Chairman/Editor	World Food Trace, Inc. / Heat and Control, Inc.
Randy Dwiggin, WG Secretary and ISA88 Chair	NNE Pharmaplan
Mark Albano	Honeywell
Shawn Baker	NNE Pharmaplan
Cindy Benedict	Siemens
Dennis Brandl	BR&L Consulting
Sean Brennan	Stone Technologies
Ed Bristol	Consultant
Dave Chappell	CMAa Consulting
Leo Charpentier	NovaTech
Lynn Craig	Consultant
Tom Crawl	Genentech
Em Delahostria	Rockwell Automation
Dave Emerson	Yokogawa
Herbert Falk	Sisco
Gus Finucci	EnteGreat
Alistair Gillanders	DynoChem Inc
Alex Habib	Consultant
Mike Hakes	Colt Engineering
Gavan Hood	Simul-Tech Pty Ltd
Baha Korkmaz	Invensys
Motoichi Kuwatani	Yokogawa
Francis Lovering	ControlDraw
Ed Lynch	Pfizer
Dawn Marruchella	Emerson Process Management
Thomas Müller-Heinzerling	Siemens
Steve Murray	Emerson Process Management
Thomas Nash	Areva
Albert Pampel	Consultant
Henry Salomons	Dow
Joseph Schipani	Invensys
Dan Seger	Rockwell Automation
Mike Smith	ABB
Marcus Tennent	Yokogawa
Jean Vieille	Control Chain Group
Frede Vinther	NNE Pharmaplan
Kate Waters	Genentech
Max Weinmann	Emerson Process Management

INTRODUCTION

This Part 1 standard is structured to follow the IEC (International Electrotechnical Commission) guidelines. Therefore, the first three clauses discuss the Scope of the standard, Normative References, and Definitions, in that order.

The models and terminology in this standard are highly interdependent, making many of the definitions in Clause 3 incomplete and circular. Clauses 4 through 8 incrementally complete these definitions by starting at a very high level, progressively detailing a set of conceptual models, and describing how they collectively interact to control batch production.

Clause 4, *Batch processes and equipment*, is normative. The intent of this clause is to provide models and terminology that describe batch processes and the equipment used to perform them.

Clause 5, *Structure for batch control*, is normative. The intent is to describe three types of control used in batch processing and their relationships to the previously defined process and equipment models.

Clause 6, *Recipes and procedural elements*, is normative. The intent is to describe the roles and contents of four types of recipes used in batch manufacturing, their use of the previously defined process and procedural control models, and their connection to equipment control.

Clause 7, *Batch control considerations*, is normative. The intent is to describe additional considerations related to iterative design, exception handling, modes and states, production plans and schedules, and production information.

Clause 8, *Activities and functions in batch control*, is normative. The intent is to describe the control activities that are needed to address the diverse control requirements of batch manufacturing.

Clause 9, *Completeness, compliance, and conformance*, is normative. The intent is to define compliance and conformance relative to the normative models and terminology in this standard.

Annex A is informative. It provides guidance towards understanding the model types used in this standard.

Annex B is informative. It provides a quick summary of the changes made in this update as compared with the original 1995 standard.

Annex C is informative. It provides answers to typical questions that may arise in applying this standard.

Annex D is informative. It provides a more expansive procedural state reference model. The model found in Clause 7 may be considered a collapsed version of this more general model.

Annex E is informative, giving references to further investigation concerning safety.

This standard (Part 1, Models and Terminology) is intended for those who are:

- involved in designing and/or operating batch manufacturing plants;

- responsible for specifying controls and the associated application programs for batch manufacturing plants; or
- involved in the design and marketing of products in the area of batch control.

This standard provides standard models and terminology for defining the control requirements for batch manufacturing plants. The models and terminology defined in this standard:

- emphasize good practices for the design and operation of batch manufacturing plants;
- can be used to improve control of batch manufacturing plants; and
- can be applied regardless of the degree of automation.

This standard provides standard terminology and a consistent set of concepts and models for batch manufacturing plants and batch control that are intended to improve communications between all parties involved, and to:

- reduce the user's time to reach full production levels for new products;
- enable vendors to supply appropriate tools for implementing batch control;
- enable users to better identify their needs;
- make recipe development straightforward enough to be accomplished without the services of a control systems engineer;
- reduce the cost of automating batch processes; and
- reduce life-cycle engineering efforts.

It is important to note that although Clause 3 of this part of the standard provides definitions, the entire document constitutes the models and terminology of batch control. The user should consider Clause 3 as a short glossary of terms with brief descriptions and not rely on Clause 3 for a full understanding of the concepts. The full context of the terms will be found in the body of this standard.

It is not the intent of this standard to

- suggest that there is only one way to implement or apply batch control;
- force users to abandon their current way of dealing with their batch processes; or
- restrict development in the area of batch control.

The key concepts defined in this standard are:

- identification of structure and format for recipes and procedures;
- definition of levels of recipes and procedures;
- recognition of product specific recipes and procedures that are separate from process oriented equipment and its direct control;
- identification of a hierarchy of manufacturing equipment and its dedicated control;
- recognition of equipment capabilities that are utilized during recipe and procedure driven production; and
- recognition of the need for modular and re-usable control functionality.

The models presented in this standard are presumed to be complete as indicated. However, they may be collapsed and expanded as described in the explanation of each model.

The series of batch control standards has several parts, as shown in Figure 1. This Part 1 standard focuses on the definitions of process cells and units, master and control recipes, recipe

coordination control, and recipe procedural control. Other parts of the series have different focus areas which cover other aspects of batch manufacturing, from the product definitions at enterprises and sites to equipment control within units, equipment modules, and control modules.

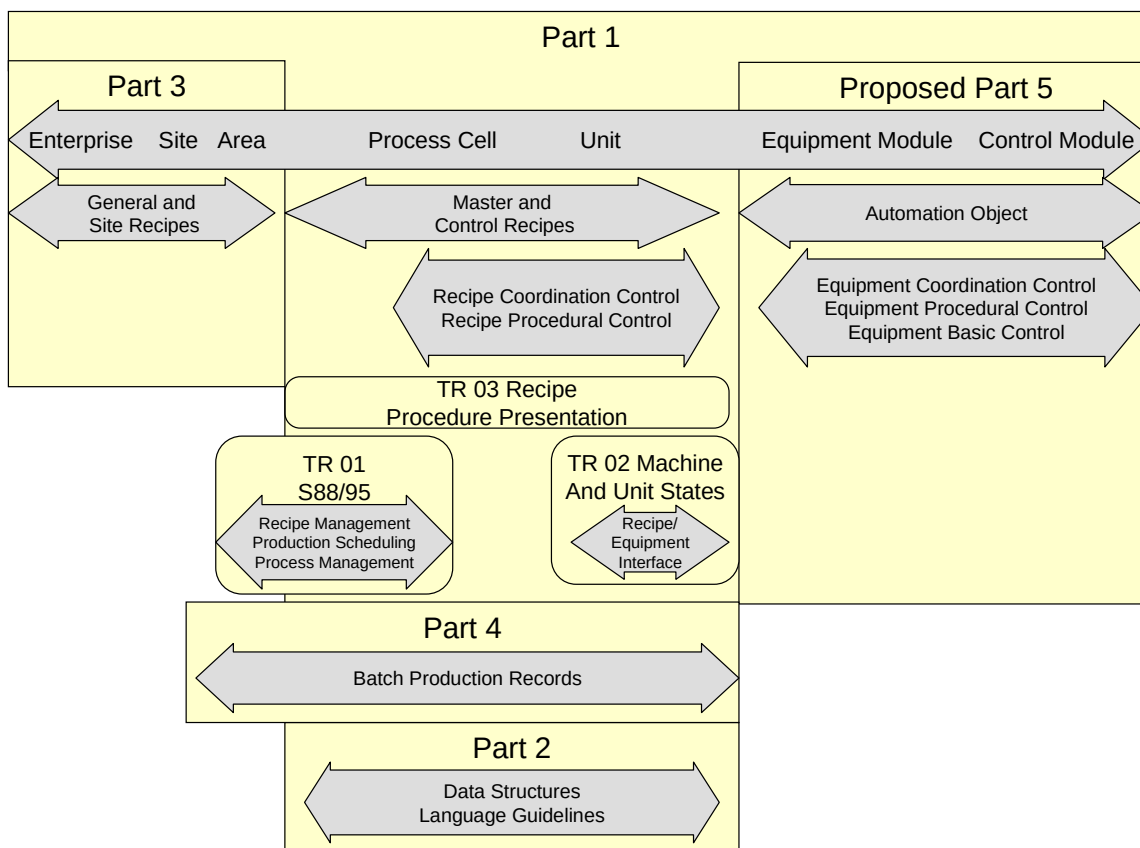


Figure 1 — Standards in the batch control series

This page intentionally left blank.

Batch Control Part 1: Models and terminology

1 Scope

This Part 1 standard on Batch Control defines reference models for batch and related procedure-oriented manufacturing as used in the process industries, and terminology that helps explain the relationships between these models and terms. Conformance criteria to this standard are defined in Clause 9.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions 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 standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. ISA, ANSI, IEC and ISO maintain registers of currently valid normative documents.

- IEC 60848: 2002, GRAFCET specification language for sequential function charts
- IEC 60050-351: 2006, International Electrotechnical Vocabulary – Part 351: Control technology.
- ANSI/ISA-95.00.01-2010 (IEC 62264-1 Mod), Enterprise-Control System Integration – Part 1: Models and Terminology
- ANSI/ISA-95.00.02-2010 (IEC 62264-2 Mod), Enterprise-Control System Integration – Part 2: Object Model Attributes
- IEC/ISO 62264-1, Enterprise-Control System Integration - Part 1: Models and Terminology
- IEC/ISO 62264-2, Enterprise-Control System Integration - Part 2: Object Model Attributes
- ANSI/ISA-18.2-2009, Management of Alarm Systems for the Process Industries

3 Terms, definitions and abbreviations

3.1 Terms and definitions

3.1.1 Introduction

For the purposes of this document, the following terms and definitions apply. The definitions supplied in this clause should be considered a summary statement for the associated term. Since this part of the standard defines models and terminology as a whole, the reader should consider all clauses for the full concept intended for any terms or definition called out in this clause.

3.1.2

allocation

a form of coordination control that assigns a resource or part of a resource to a batch, a procedural element, or an equipment entity as needed

3.1.3

arbitration

a form of coordination control that determines how a resource should be allocated when there are more requests for the resource than can be accommodated at one time

3.1.4

area

a component of a manufacturing site that is identified by physical, geographical, operational, or logical segmentation within the site

NOTE An area may contain process cells, units, equipment modules, and control modules.

3.1.5

basic control

the control dedicated to establishing and maintaining a specific state or behavior of equipment and process

NOTE Basic control may include regulatory control, interlocking, monitoring, exception handling, and discrete or sequential control necessary for establishing or maintaining a specific state or behavior.

3.1.6

batch

- 1) the material that is being produced or that has been produced by a single execution of a batch process;
- 2) an entity that represents the production of a material at any point in the process;
- 3) an entity that represents the execution of a control recipe.

NOTE Batch means both the material made by and during the process and also an entity that represents the production of that material. Batch is used as an abstract contraction of the words "the production of a batch."

3.1.7

batch control

control activities and functions that direct batch processes

3.1.8

batch process

a process that leads to the production of finite quantities of material by subjecting quantities of input materials to an ordered set of processing activities over a finite period of time using one or more pieces of equipment

3.1.9

batch schedule

a list of batches to be produced in a specific process cell

NOTE The batch schedule typically contains such information as what is to be produced, how much is to be produced, when or in what order the batches are to be produced, and what equipment is to be used.

3.1.10

campaign

a collection of related batches for scheduling purposes

3.1.11

common resource

a resource that can provide services to one or more requesters

NOTE Common resources are identified as either exclusive-use resources or shared-use resources.

3.1.12

control activity model

a conceptual model identifying seven interdependent activities (several of which are subdivided into functions) that manage control definition, operation, and information for batch processes

3.1.13

control module

the lowest level grouping of equipment in the physical model that can carry out basic control

NOTE 1 This term applies to both the physical equipment and the equipment entity.

NOTE 2 The control module level may not be omitted from the physical model.

NOTE 3 The control module level contains the interfaces to the physical equipment.

3.1.14

control recipe

a type of recipe which, through its execution, defines the manufacture of a single batch of a specific product

NOTE The control recipe may not be omitted from the recipe types model.

3.1.15

coordination control

a type of control that directs, initiates, and/or modifies the execution of procedural control and the utilization of equipment entities

3.1.16

enterprise

an organization that coordinates the operation of one or more sites

3.1.17**equipment control**

the equipment-specific functionality that provides the actual control capability for an equipment entity, including procedural, basic, and coordination control

3.1.18**equipment entity**

a collection of physical processing and control equipment and equipment control grouped together to perform a certain control function or set of control functions

3.1.19**equipment entity model**

a hierarchical model to logically organize the physical assets used in a batch process in combination with the control present at each level

3.1.20**equipment module**

a functional group of equipment that can carry out a finite number of specific minor processing activities

NOTE 1 An equipment module is typically centered around a piece of process equipment (a weigh tank, a process heater, a scrubber, etc.). This term applies to both the physical equipment and the equipment entity.

NOTE 2 Examples of minor process activities are dosing and weighing.

NOTE 3 Two types of equipment modules are identified: recipe-aware equipment modules and generic equipment modules.

NOTE 4 Any reference to an equipment module in this standard is understood to be a general reference to both the recipe-aware equipment module and the generic equipment module unless otherwise specified.

3.1.21**equipment operation**

an operation that is part of equipment control

3.1.22**equipment phase**

a phase that is part of equipment control

3.1.23**equipment procedure**

the top level procedural element in the procedural control model that is part of equipment control

3.1.24**equipment unit procedure**

a unit procedure that is part of equipment control

3.1.25**exception handling**

those functions that deal with plant or process contingencies and other events which occur outside the normal or desired behavior of batch control

3.1.26**exclusive-use resource**

a common resource that only one user can use at any given time

3.1.27

formula

a category of recipe information that includes process inputs, process parameters, and process outputs

3.1.28

general recipe

a type of recipe that expresses equipment and site independent processing requirements

3.1.29

general recipe procedure model

a conceptual model for general and site recipe procedures that structurally conforms to the process model

3.1.30

generic equipment module

an equipment module which may be initiated through execution of equipment control but is not capable of being directly initiated through the execution of a recipe

3.1.31

header

information about the purpose, source and version of the recipe such as recipe and product identification, creator, and issue date

3.1.32

lot

a unique amount of material having a set of common traits

NOTE Some examples of common traits are material source, the master recipe used to produce the material, and distinct physical properties.

NOTE 2 As defined in ANSI/ISA-95 and IEC 62264-1 as *material lot*: uniquely identifiable amount of a material.

3.1.33

master recipe

a type of recipe that accounts for equipment capabilities and may include process cell-specific information

NOTE 1 The master recipe may not be omitted from the recipe types model.

3.1.34

master recipe procedure model

a conceptual model for master and control recipe procedures that structurally conforms to the procedural control model

3.1.35

mode

the manner in which the transition of sequential functions are carried out within a procedural element or the accessibility for manipulating the states of equipment entities manually or by other types of control

3.1.36

operating schemes

mutually exclusive process actions executed by the same equipment or control module

NOTE 1 Examples for operating schemes are Inner-Temperature / Jacket-Temperature / Delta Temperature Control for a heating/cooling equipment module or Venting / Nitrogen Purge / Evacuation / High Pressure Control for a pressure system equipment module.

NOTE 2 Operating schemes may be implemented in an equipment module entity by alternative branches within one single equipment phase or by multiple mutually exclusive equipment phases of which only one can be active at any given time.

3.1.37

operation

a procedural element defining an independent processing task to accomplish all or part of a process operation, typically specifying the initiation, organization, and control of phases

3.1.38

path

the order of equipment within a process cell that is used in the production of a specific batch

3.1.39

personnel and environmental protection

the control activity that

- 1) prevents events from occurring that would cause the process to react in a manner that would jeopardize personnel safety and/or harm the environment; and/or
- 2) takes additional measures, such as starting standby equipment, to prevent an abnormal condition from proceeding to a more undesirable state that would jeopardize personnel safety and/or harm the environment; and/or
- 3) issues notification of an abnormal condition.

NOTE Personnel and environmental protection are outside of the scope of this part of the standard and is included for completeness in understanding and not to define the required content.

3.1.40

phase

the lowest level procedural element in the procedural control model that is intended to accomplish all or part of a process action

3.1.41

physical model

a hierarchical model to logically organize the physical assets of a manufacturing enterprise

3.1.42

procedural control

the type of control that executes a procedure

3.1.43

procedural control model

a hierarchical model which depicts the orchestration of procedural elements to carry out process-oriented tasks

3.1.44

procedural element

a building block for procedural control that is defined by the procedural control model

NOTE This general definition is applied to all levels of the procedural hierarchy in the definitions for procedure, unit procedure, operation, and phase.

**3.1.45
procedure**

- 1) a specification of a sequence of steps, actions or activities with a defined beginning and end that is intended to accomplish a specific objective or task
- 2) the highest level procedural element within the procedural control model, which defines the required set of processing activities for a single batch, typically through the initiation, organization, and control of unit procedures

NOTE Such a procedure may define a process that does not result in the production of product, such as a clean-in-place procedure.

**3.1.46
process**

- 1) a sequence of chemical, physical, or biological activities for the conversion, transport, or storage of material or energy
- 2) a sequence of chemical, physical, or biological activities that change the condition of equipment. An example would be a clean-in-place process

**3.1.47
process action**

a minor processing task that may be combined with other minor processing activities to make up a process operation

NOTE Process actions are the lowest level of processing task within the process model.

**3.1.48
process cell**

a logical grouping of equipment that includes the equipment required for production of one or more batches.

NOTE This term applies to both the physical equipment and the equipment entity.

**3.1.49
process cell management**

the control activity that includes the functions needed to manage batch production within a process cell

**3.1.50
process control**

the control activity that includes the functions needed to provide sequential, regulatory, and discrete control and to gather and display data

**3.1.51
process input**

an identification and quantity of materials, energy, or other resources required for a recipe

**3.1.52
process model**

a hierarchical model which illustrates the subdivision of a batch process

**3.1.53
process operation**

a major processing task that usually results in a chemical or physical change in the material being processed and that is defined without consideration of the actual target equipment configuration

3.1.54**process output**

an identification and quantity of materials, energy, or other resources resulting or expected to result from one execution of a control recipe

3.1.55**process parameter**

information that is needed to manufacture a material but does not fall into the classification of process input or process output

NOTE Examples of process parameter information are temperature, pressure, and time.

3.1.56**process stage**

a part of a process that usually operates independently from other process stages and that usually results in a planned sequence of chemical or physical changes in the material being processed

3.1.57**recipe**

the necessary set of information that uniquely defines the production requirements for a specific product or operational task

NOTE There are four types of recipes defined in this standard: general, site, master, and control.

3.1.58**recipe-aware equipment module**

an equipment module containing one or more equipment phases that is capable of being initiated directly through the execution of a recipe

3.1.59**recipe management**

the control activity that includes the functions needed to create, store, and maintain general, site, and master recipes

3.1.60**recipe operation**

the part of a recipe which either defines the sequencing and ordering of recipe phases, or references an equipment operation

3.1.61**recipe phase**

the part of a recipe which defines the references to an equipment phase

3.1.62**recipe procedure**

- 1) a general reference to any one of the four levels of the Procedural Element Model applied in the recipe
- 2) the part of a recipe which either defines the sequencing and ordering of recipe unit procedures, or references an equipment procedure

NOTE A recipe procedure is intended to provide product specific flexibility beyond parameter and formula changes, without making equipment modifications.

3.1.63

recipe types model

a conceptual model identifying the relationships between the types of recipes that are defined in an enterprise

3.1.64

recipe unit procedure

the part of a recipe which either defines the sequencing and ordering of recipe operations, or references an equipment unit procedure

3.1.65

resource

See ANSI/ISA-95 and IEC 62264-1.

NOTE This standard focuses on equipment resources. Other resource types defined in ANSI/ISA-95 and IEC 62264-1 are for the most part not considered

3.1.66

shared-use resource

a common resource that can be used by more than one user at a time

3.1.67

site

a component of a manufacturing enterprise that is identified by physical, geographical, operational, or logical segmentation within the enterprise

NOTE A site may contain areas, process cells, units, equipment modules, and control modules.

3.1.68

site recipe

a type of recipe that is site specific

NOTE Site recipes may be derived from general recipes recognizing local constraints, such as language and available raw materials.

NOTE Site recipes may include routing information necessary for coordinating manufacturing across process cells and production scheduling activities.

3.1.69

state

the condition of an equipment entity or of a procedural element at a given time

NOTE The number of possible states and their names vary for equipment and for procedural elements.

3.1.70

train

a collection of one or more units and associated lower level equipment groupings that has the ability to be used to make a batch of material

3.1.71

unit

a collection of associated equipment modules and/or control modules that can carry out one or more major processing activities

NOTE Examples of major processing activities are react, crystallize, and make a solution.

3.1.72**unit procedure**

a strategy for carrying out a major processing task within a unit to accomplish all or part of a process stage typically through the initiation, organization, and control of operations.

3.1.73**unit recipe**

the part of a control recipe that uniquely defines the contiguous production requirements for a unit

NOTE The unit recipe contains the unit procedural element and its related formula, header, equipment requirements, and other information.

3.1.74**unit supervision**

the control activity that includes functions needed to supervise the unit and the unit's resources

3.2 Abbreviations

For the purposes of this standard, the following abbreviations apply.

ID Identification (A unique identifier for batches, lots, operators, technicians, and raw materials.)

4 Batch processes and equipment

4.1 Introduction

The models and terminology defined in this clause provide a foundation for understanding the application of batch control based on this standard. Specifically, this clause provides

- an overview of continuous, discrete, and batch manufacturing
- hierarchical models of equipment groupings (physical model) and functional equipment entities (equipment entity model) for use in batch manufacturing
- criteria for classifying batch manufacturing facilities

4.2 Types of manufacturing

4.2.1 Introduction

A process is a sequence of chemical, physical or biological activities for the preparation, conversion, transport or storage of material or energy. Industrial manufacturing processes can generally be classified as either process manufacturing or discrete parts manufacturing. Process manufacturing can generally be further classified as continuous, batch, or some combination of the two. How a process is classified depends on whether the output from the process appears in a continuous flow (continuous), in finite quantities of parts (discrete parts manufacturing), or in finite quantities of material (batches).

4.2.2 Continuous process manufacturing

In continuous process manufacturing, materials are passed in a continuous flow through processing equipment. Once established in a steady operating state, the nature of the process is not dependent on the length of time of operation. Start-ups, transitions, and shutdowns are usually treated as separate activities and do not necessarily contribute to achieving the desired processing.

The concepts of batch processing in this standard may be applied to continuous processing for such control as start-ups, grade changes, and shutdowns. Minor modifications to the models in this standard could be applied to address these unique processing needs.

EXAMPLE When a grade change occurs, a new product or recipe may need to be started without stopping material flows through the equipment.

4.2.3 Discrete parts manufacturing

In discrete parts manufacturing, a specified quantity of parts moves as a unit (group of parts) between workstations and each part maintains its unique identity. Products are classified into production lots that are based on common raw materials, production requirements, and production histories.

The concepts of batch processing in this standard may be applied to discrete parts manufacturing for such control as start-ups, change-overs, and shutdowns. Minor modifications to the models in this standard could be applied to address these unique processing needs.

4.2.4 Batch process manufacturing

The batch process manufacturing addressed in this standard leads to the production of finite quantities of material (batches) by subjecting quantities of input materials to a defined order of

processing actions using one or more pieces of equipment. Both a single execution of a batch process and the product or intermediate material it produces are referred to as a batch. Batch processes are discontinuous processes, which are neither discrete nor continuous but have characteristics of both.

The models in this standard facilitate batch process manufacturing by

- providing a consistent structure for design and operation of batch processing facilities
- separating recipes that define product-specific processing sequences from equipment control that implements fixed equipment-specific processing capabilities
- segmenting both recipes and equipment control based on modular hierarchies of relatively simple and reusable entity structures
- describing a set of required activities and functions (activity model) for
 - initiating recipes based on a batch schedule
 - interpreting the active recipes' defined processing tasks and executing them through equipment control
 - managing recipe and production data

4.3 Process model

4.3.1 Introduction

The process model is a multi-level hierarchical model for subdivision of a batch process and is the basis for defining equipment independent recipe procedures. Each individual element in the model is a procedure, whose directly subordinate elements (if any) comprise its steps. The ultimate goal of the hierarchy is to efficiently organize the processing activities that are specified (either directly or by referencing an external requirement) at its lowest level.

The process model levels are illustrated in Figure 2 and described below based on use of the full model. Clause 4.3.6 describes how the process model may be collapsed or expanded.

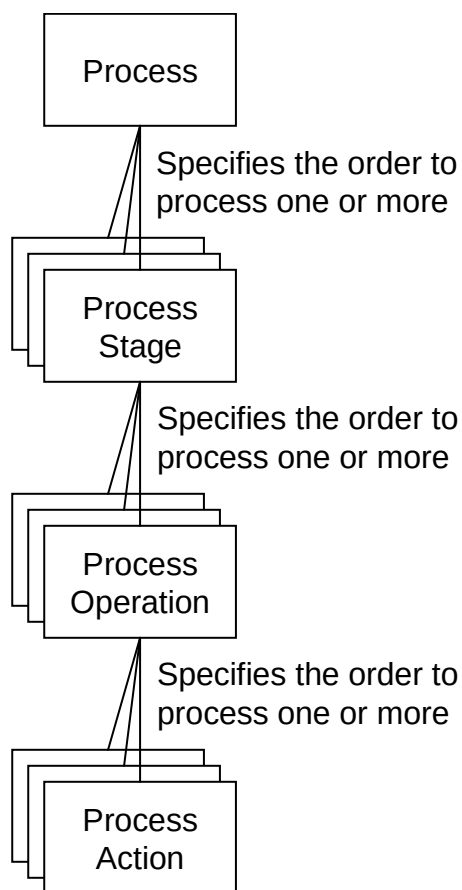


Figure 2 — Process model (instance diagram) when not collapsed or expanded

4.3.2 Process

The order of processing for an entire batch is called the process. When the full model is used, the process shall specify the order to process one or more process stages, which may be in series, in parallel, or a combination of both.

EXAMPLE The production of polyvinyl chloride by polymerization of vinyl chloride monomer is used in this clause as an example batch process.

4.3.3 Process stage

A process stage is a major part of a process that usually operates independently from other process stages. It usually results in a planned sequence of chemical or physical changes in the material being processed. When the full model is used, each process stage shall specify the order to process one or more process operations, which may be in series, in parallel, or a combination of both.

EXAMPLE Typical process stages in the polyvinyl chloride process might be the following:

- Polymerize: Polymerize vinyl chloride monomer into polyvinyl chloride.
- Recover: Recover residual vinyl chloride monomer.
- Dry: Dry polyvinyl chloride.

4.3.4 Process operation

Process operations represent major processing activities. A process operation usually results in a chemical, biological or physical change in the material being processed. The processing associated with the term “unit operation” used in chemical engineering often relates to a process operation in the process model. When the full model is used, each process operation shall specify the order to process one or more process actions, which may be in series, in parallel, or a combination of both.

EXAMPLE Typical process operations for the polymerization of vinyl chloride monomer into polyvinyl chloride process stage might be the following:

- Prepare reactor: Evacuate the reactor to remove oxygen.
- Charge: Add demineralized water and surfactants.
- React: Add vinyl chloride monomer and catalyst, heat to 55 - 60°C, and hold at this temperature until the reactor pressure decreases.

4.3.5 Process action

Process actions represent minor processing activities. The scope of a process action is usually small enough that the specification of its activities (with appropriate variants, such as target values) is highly reusable from one process to another. When the full model is used, the process actions shall specify the required processing activities, either directly or by referencing an external requirement.

EXAMPLE Typical process actions for the react process operation might be the following:

- Add: Add the required amount of catalyst to the reactor.
- Add: Add the required amount of vinyl chloride monomer to the reactor.
- Heat: Heat the reactor contents to 55 - 60°C.
- Hold: Hold the reactor contents at 55 - 60°C until the reactor pressure decreases.

4.3.6 Collapsing and expanding the process model

The process model presented is complete as indicated and the levels defined shall not be rearranged, but may be collapsed or expanded to suit different processing requirements. Collapsing in this context means omitting one or more defined levels of the process model. Expanding in this context means inserting an additional level into the model.

It shall be permissible to collapse the process model in an implementation if the following requirements are satisfied

- The process level shall not be omitted.
- If a level is not used and one or more lower levels still remain
 - the next higher implemented level shall take over its procedural functions, including specification of ordering logic for the next lower level.
 - the procedural functions of the lower level(s) shall not be impacted.
- The lowest implemented level of the process model should specify the required process functionality, either directly or by referencing an external requirement.

Expanding the model shall be restricted to allowing one or more additional levels in the model

- Between process and process stage
- Between process stage and process operation
- Between process operation and process action

Any additional levels must be structurally consistent with the process model and shall not use names defined in this standard.

4.4 Equipment and equipment control

4.4.1 Introduction

The concept of equipment capabilities and usage of these capabilities to accomplish desired processing tasks is a major point of this standard. Equipment control is the equipment-specific control functionality that supports such capabilities and that may be utilized by recipes to carry out their specified processing tasks and by operators to perform direct manipulation of control settings.

An equipment entity comprises a grouping of physical equipment and associated equipment control that has been engineered to perform a certain process or control function or set of such functions. Physical equipment in this context includes processing equipment, instrumentation, and control equipment.

The notion of equipment control being part of an equipment entity is to be understood as an abstract concept. The association may be physical or logical. It is not a statement of the physical implementation of equipment control. However, it should be possible to associate equipment control with a particular equipment entity. The control part of any equipment entity can be satisfied by human actions, automation or a combination of both.

This interaction of equipment control and physical equipment is purposely described without any reference to language or implementation. The intent is to describe a framework within which equipment control and physical equipment may be defined and discussed.

4.4.2 Physical model

4.4.2.1 Introduction

The physical equipment groupings defined for equipment entities, as well as their relationship to a manufacturing enterprise, may be described in terms of a physical model that hierarchically organizes the enterprise into sites, areas, process cells, units, equipment modules, and control modules. Figure 3 illustrates how lower level groupings are combined to form higher levels in this hierarchy in batch process manufacturing.

The enterprise, site, and area levels are more precisely defined in the IEC/ISO 62264 and ANSI/ISA-95 standards. These levels in Figure 3 are shown with dashed lines to indicate that they are often beyond the scope of batch control and criteria for configuring their boundaries are not defined in this standard.

Each equipment grouping comprising a process cell, unit, equipment module, or control module corresponds to a single equipment entity and its boundaries are engineered to satisfy the functional requirements for that entity. The defining characteristics for these levels in the physical model, therefore, correspond exactly to the levels of the equipment entity model and are described more fully in the following discussion of equipment entities in Clause 4.4.3.

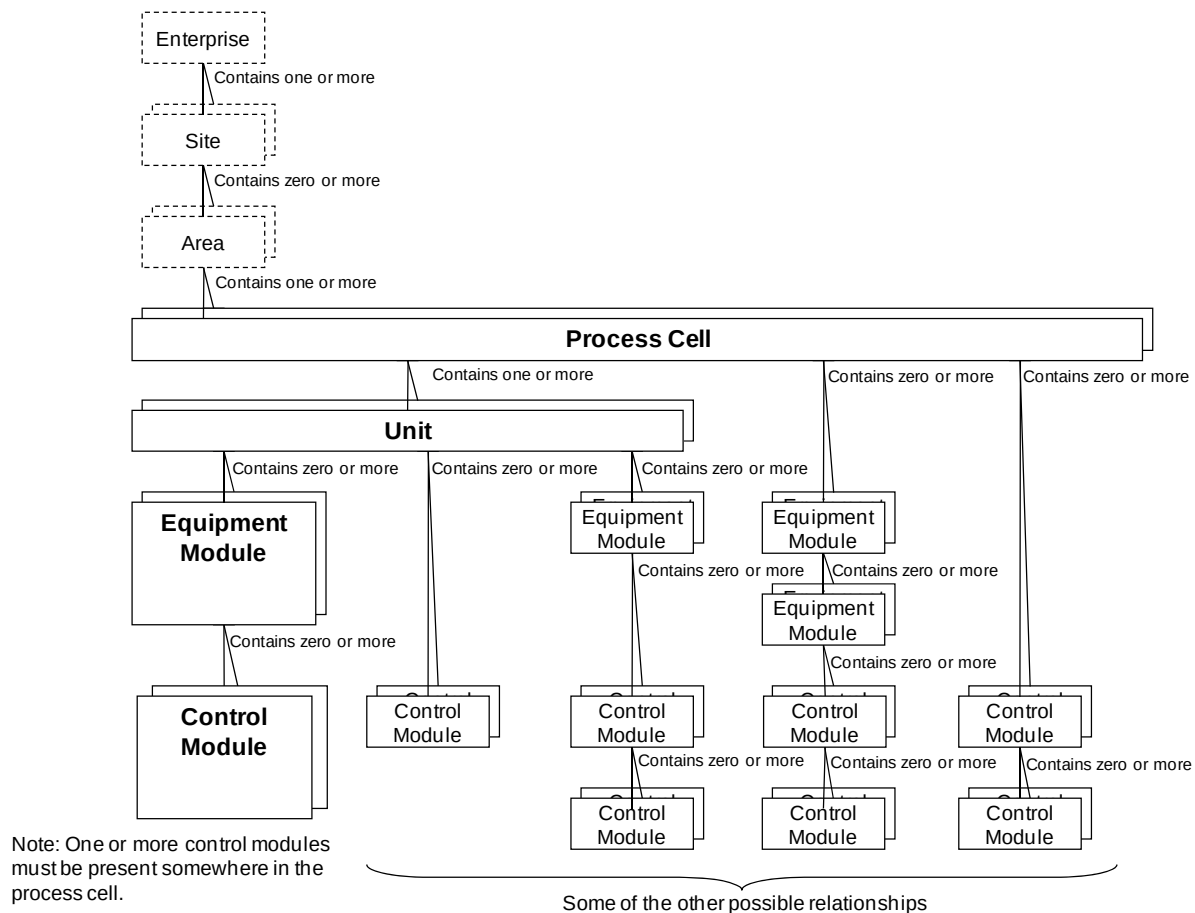


Figure 3 — Physical model

4.4.2.2 Enterprise

An enterprise is a collection of one or more sites and their subordinate areas, process cells, units, equipment modules, and control modules.

Personnel responsible for this level generally determine what products will be manufactured, at which sites they will be manufactured, and in general how they will be manufactured.

There are many factors other than batch control that affect the boundaries of an enterprise. Therefore, the criteria for configuring the boundaries of an enterprise are not covered in this standard.

4.4.2.3 Site

A site is a physical, geographical, operational, or logical subdivision of the enterprise. It may contain areas and their subordinate process cells, units, equipment modules, and control modules.

The boundaries of a site are usually based on organizational or business criteria as opposed to technical criteria. There are many factors other than batch control that affect these boundaries. Therefore, the criteria for configuring the boundaries of a site are not covered in this standard.

4.4.2.4 Area

An area is a physical, geographical, operational or logical subdivision of a site. In batch manufacturing, it shall contain one or more process cells and their subordinate units, equipment modules, and control modules.

The boundaries of an area are usually based on organizational or business criteria as opposed to technical criteria. There are many factors other than batch control that affect these boundaries. Therefore, the criteria for configuring the boundaries of an area are not covered in this standard.

4.4.2.5 Collapsing and expanding the physical model

The physical model presented is complete as indicated and the levels defined shall not be rearranged, but may be collapsed or expanded. Collapsing in this context means omitting one or more defined levels of the physical model. Expanding in this context means inserting an additional level into the model.

When using a collapsed or expanded physical model, the levels defined in this standard shall not be rearranged, the site level shall not be omitted. Below the process cell level, the rules described in Clause 4.4.3.7 for collapsing and expanding the equipment entity model also apply to the physical model.

4.4.3 Equipment entity model

4.4.3.1 Introduction

This clause discusses equipment entities that are formed from the combination of equipment control and physical equipment. The equipment entity model (see Figure 4) hierarchically organizes equipment entities based on the lower four equipment groupings of the physical model shown in Figure 3: the process cell and its included units, equipment modules, and control modules.

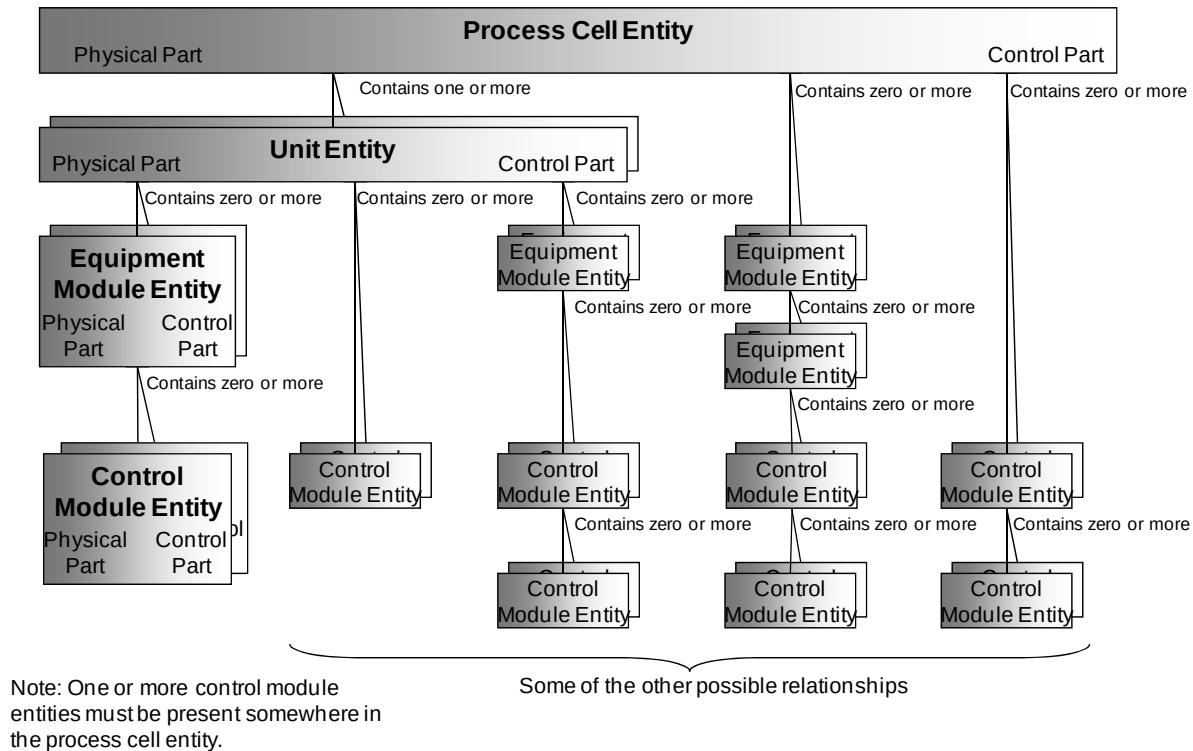


Figure 4 — Equipment entity model

These groupings are created to simplify equipment operation by clearly defining the overall functions of each entity and treating it as a single larger piece of controlled equipment. Once created, the equipment groupings in the equipment entity model cannot be split up except by re-engineering the equipment entities.

The general functionality associated with each level of the equipment entity model is described below. The types of control needed for batch manufacturing and their usage within each level are discussed in Clause 5.

In the equipment module and control module levels, an equipment entity may be directly contained either in a larger grouping at the same level (for which the unrestricted level of nesting is not depicted) or in a higher level grouping. Inclusion of process control equipment (sensors and actuators) shall be exclusively at the control module level.

When the terms process cell, unit, equipment module, and control module are used, they most often refer to the equipment entity, not just the physical equipment. Whether equipment control in an equipment entity is implemented manually or by way of automation, it is only through the exercise of equipment control that the equipment can produce a batch.

All control related clauses of the standard assume that each process cell entity has been subdivided into well defined units, equipment modules, and control modules. Effective subdivision of the process cell into well defined equipment entities is a complex task, highly dependent on the individual requirements of the specific environment in which the batch process

exists. Inconsistent or inappropriate equipment subdivisions can compromise the effectiveness of the modular approach to recipes suggested by this standard.

Subdivision of the process cell requires a clear understanding of the purpose of the process cell's equipment. Such understanding allows the identification of equipment entities that should work together to serve an identifiable processing purpose.

The control capability possible in the different equipment entities are important characteristics and a main basis for classification of equipment entities. In the following paragraphs equipment control for the individual equipment entities is discussed.

This clause discusses some general principles involved in segmenting a process cell into equipment entities that can carry out specified processing tasks or equipment-specific actions. A more exhaustive explanation of process segmentation principles is beyond the scope of this standard.

It is important to note that the physical process cell design can greatly influence the implementation of batch control. Minor differences in the physical system can dramatically affect the organization of equipment entities and procedural elements.

The subdivision of a process cell should follow the principles listed below:

- The function any equipment entity serves in product processing is clear and unambiguous.
- The function performed by the equipment entity is consistent in terms of processing task, and should be usable for that task no matter what product is being manufactured at a given time.
- Equipment entities within a process cell are clearly defined, including processing capabilities, relationships with other equipment entities and allowable equipment interconnections.
- Subordinate equipment entities are able to execute their task(s) independently and asynchronously, allowing a higher level equipment entity to orchestrate the activities of its subordinates.
- Interactions between equipment entities are minimized. While planned interaction is periodically necessary, each equipment entity should perform its functions while influencing the functioning of other equipment entities as little as possible.
- Equipment entities have clear boundaries.
- A consistent basis for the definition of equipment entities. An operator subsequently interacting with similar equipment entities should be able to do so naturally and without confusion.
- Necessary interaction between equipment entities is, insofar as possible, coordinated by equipment entities at the same level or at the next higher level.

NOTE Portable equipment entities may not have a permanent relationship to one specific process cell, but are allowed to be moved between process cells to improve the flexibility of the facility. In general, moving equipment entities from one process cell to another should only occur when the equipment is not acquired or allocated to a batch.

4.4.3.2 Process cell entity

In the physical model, a process cell is an engineered equipment grouping within an area. In both the physical and equipment entity models, each process cell shall contain one or more units and their subordinate equipment modules and control modules. It may also directly contain physical processing equipment, equipment modules, and control modules that are not part of any unit.

The boundaries of a process cell entity shall be engineered to include the full set of physical processing equipment, units, equipment modules, control modules, and additional equipment control (as described in Clause 5) that will be used to produce batches of one or more products.

The process cell as described in this standard corresponds to a type of Work Center defined in IEC/ISO 62264 and ANSI/ISA-95. A Work Center may be specialized for different manufacturing types and functions. More than one type of Work Center, such as a Storage Zone or a Production Line is often required in an area or site. Unless specifically identified otherwise, the Work Center referred to in this standard as a "Process Cell" is a batch process cell and does not refer to the other types of work centers identified in IEC/ISO 62264 and ANSI/ISA-95.

The existence of the process cell allows for production scheduling on a process cell basis. It also allows for process cell-wide control strategies to be designed, such as for emergency response to process conditions or to comply with administrative requirements such as documentation for good manufacturing practices.

All batch processing tasks are orchestrated at the process cell level based on recipes containing procedure, parameter, and other information and a batch schedule containing operational requirements for each batch. The process cell management activity described in Clause 8.6 performs this orchestration by interpreting the schedule and top level procedural elements of the recipes it specifies.

A frequently recognized subdivision of a process cell is the train. A train is composed of all units and other equipment that (a) make up a recognizable subset of a process cell and (b) is sufficient to produce all batches for one or more of the process cell's recipes. Any given batch may use only part of the equipment in a train or process cell. Furthermore, more than one batch (including batches for more than one product) may be active in a train or process cell simultaneously. Although a process cell may contain multiple (possibly overlapping) trains, no train may contain equipment outside the boundaries of the process cell.

NOTE A train is not considered an additional level in the physical hierarchy.

The process cell will also need to prepare and monitor equipment or resources not currently involved in batch processing, such as which units are available, what units and piping are going through a clean-in-place (CIP) routine, and what the current inventories of raw materials are. This could be initiated by internal logic in the process cell itself or through the batch schedule and recipes.

The complexity of control within the process cell will depend on the equipment available within the process cell, the interconnectivity among this equipment, the degree of freedom of movements of batches through this equipment, and the arbitration of the use of this equipment so that the equipment can be used most effectively.

Equipment modules and control modules may exist as separate entities under direct control of the process cell.

4.4.3.3 Unit entity

A unit entity is an engineered subdivision of a process cell. It may contain physical processing equipment, equipment modules, and control modules.

Each unit shall be engineered to combine all necessary physical processing equipment, equipment modules, control modules, and additional equipment control (as described in Clause 5) required to perform one or more major processing tasks, such as react, crystallize, and make

a solution. It is usually centered on a relatively independent major piece of processing equipment, such as a mixing tank or reactor. The complete set of required equipment may be entirely contained within the unit boundaries or may include common use equipment modules or control modules within the same process cell that can be acquired temporarily by the unit to carry out specific tasks.

The unit as described in this standard corresponds to a type of Work Unit defined in IEC/ISO 62264 and ANSI/ISA-95. A Work Unit may be specialized for different manufacturing types and functions. More than one type of Work Unit, such as a Storage Unit or a (Continuous Process) Unit may even be required in a batch oriented Process Cell. Unless specifically identified otherwise, the Work Unit referred to in this standard as a "unit" is a batch processing unit and does not refer to the other types of work units identified in IEC/ISO 62264 and ANSI/ISA-95.

In a batch manufacturing process, a unit may contain or operate on up to one complete batch of material at some point in the processing sequence of that batch. This generally results in a physical separation between batches that is in many cases also a business requirement. However, in other types of work units the separation is not as clear and a logical boundary between batches is used. This is often found in hybrid batch/continuous or batch/discrete (e.g., packaging) processes, in which both types of process equipment are used within a process cell. In such processes, it is not unusual for two or more batches to be within a unit at the same time.

NOTE In continuous and discrete processes, that apply this model, a unit may operate on different products entering and exiting at the same time. This requires appropriate control in the unit to monitor, track, and control the logical separation between the different products.

Units coordinate the functions of the lower level entities, such as equipment modules and control modules. The primary purpose of equipment control in a unit is to control the processing of the batch that is currently associated with the unit.

The definition of a unit's boundaries and control functions requires knowledge of the major processing tasks it will perform, as well as the innate processing capabilities of the equipment itself. The following guidelines apply:

- One or more major processing tasks, such as reaction or crystallization, may take place in a unit.
- Units should be defined such that they operate independently of each other.
- Units operate on only one batch at a time.

4.4.3.4 Equipment module entity

An equipment module entity is an engineered subdivision of a process cell, a unit, or another equipment module. When contained directly in a process cell, it is usually a common use resource (see Clause 4.4.3.6) that may be acquired temporarily to carry out a specific task. It may contain physical processing equipment, other equipment modules, and control modules.

NOTE When an equipment module contains another equipment module, it may be referred to as a compound equipment module. A compound equipment module is not considered an additional level in the physical hierarchy.

Each equipment module shall be engineered to combine the necessary physical processing equipment, other equipment modules, control modules, and additional equipment control (as described in Clause 5) required to perform one or multiple minor processing tasks or process actions. Equipment modules may be engineered around processing equipment such as a heating/cooling system, an agitator, a pressure and venting system of a unit or auxiliary equipment such as a dosing system. Multiple mutually exclusive process actions which can be performed on the same equipment module are called operating schemes.

NOTE Examples for operating schemes of a heating/cooling system may be Inner-Temperature Control, Jacket-Temperature Control and Delta Temperature Control. Operating schemes for a venting system may be Evacuation, Nitrogen-gassing, and High Pressure Control.

The complete set of required equipment may be entirely contained within the equipment module boundaries or may include common use equipment modules or control modules within the same process cell that can be acquired temporarily by the equipment module to carry out specific tasks.

4.4.3.5 Control module entity

A control module entity is an engineered subdivision of a process cell, a unit, an equipment module, or another control module. When contained directly in a process cell, it is usually a common use resource (see Clause 4.4.3.6) that may be acquired temporarily to carry out a specific task. It may contain control equipment (sensors and actuators) and other control modules.

NOTE When a control module contains another control module, it may be referred to as a compound control module. A compound control module is not considered an additional level in the physical hierarchy.

Each control module shall be engineered to combine the necessary sensors, actuators, other control modules, and additional equipment control (as described in Clause 5) that are required to perform some basic control function. The complete set of required equipment may be entirely contained within the control module boundaries or may include common use control modules within the same process cell that can be acquired temporarily by the control module to execute specific functions.

EXAMPLE Some examples of control modules are

- an individual sensor or actuator
- a regulating loop consisting of a transmitter, a controller, and a control valve that is operated via a set point signal
- state-oriented equipment that consists of an on/off automatic block valve with position feedback switches, that is operated via the set point of the equipment
- a header that contains several on/off automatic block valves that coordinates the valves to direct flow to one or several destinations based upon the set point directed to the header control module

A control module can direct commands to actuators if they have been configured as part of the control module. A control module can also direct commands to other control modules if they are contained or in some way referenced by that control module. Control of the process is affected through the equipment specific manipulation of control modules and actuators.

EXAMPLE Some examples of equipment control in control modules include

- opening or closing a valve, with confirmation failure alarms;
- regulating the position of a control valve based on a sensor reading and PID control algorithm;
- setting and maintaining the state of several valves in a material header. This could be a single control module configured to contain all of the valves directly or a compound control module configured to contain several control modules, each of which is configured to directly contain a single valve.

4.4.3.6 Common resources

If more than one requestor (which may be an equipment entity, a batch, or an operator) can acquire or request the services of a single equipment entity, then that equipment entity is designated as a common resource. Common resources are often present within complex batch

processes. Common resources are often implemented as either equipment modules or control modules. A common resource may be either exclusive-use or shared-use.

NOTE This standard focuses on equipment entity resources. Other resource types defined in ANSI/ISA-95 and IEC 62264-1 are for the most part not considered.

If the resource is designated as exclusive-use, only one requestor may use the resource at a time.

EXAMPLE A shared weigh tank in a batch plant might be an example of an exclusive-use resource. It can be used by only one reactor at a time. The schedule or some other basis for assignment of its services must take this exclusive-use resource into consideration. If a reactor is waiting for the use of the weigh tank while another is using it, the waiting reactor is idle and is not making product, which has a negative effect on equipment utilization.

If the common resource is designated as shared-use, several requestors may use the resource at the same time.

EXAMPLE Some shared-use resources in a batch plant might be a process heater serving multiple units at the same time or a raw material distribution system which is capable of delivering material to more than one unit at a time.

If the capabilities of a shared-use resource are limited, then it is possible that the requests for service might exceed the capacity of the resource. In that case some of the same concerns about allocation which apply to exclusive-use resources also apply to shared-use resources. Care must also be taken so that one requestor does not improperly shut off or deactivate a resource while other requestors are using it.

4.4.3.7 Collapsing and expanding the equipment entity model

The equipment entity model presented is complete as indicated and the levels defined shall not be rearranged, but may be collapsed or expanded to suit different processing requirements. Collapsing in this context means omitting one or more defined levels of the equipment entity model. Expanding in this context means inserting an additional level into the model.

In an implementation, subdivisions of each process cell or unit may directly contain any non-overlapping lower level equipment groupings, however, process cells may not be omitted and each must contain at least one unit entity and in some way a control module entity (either directly or indirectly). Since the physical assets of batch processing facilities vary greatly, the application of the equipment entity model shall be flexible and allow for any combination of lower level subdivisions of each process cell, unit, and equipment module.

Expanding the model below the process cell level shall be restricted to allowing one or more additional levels in the model between the process cell and unit, however, they shall be structurally consistent with the physical model and shall not use names defined in this standard.

EXAMPLE Figure 5 illustrates some expected equipment entity architectures that could be found in typical batch environments. The example shows that in some cases the equipment module level may be collapsed (i.e. Unit 2 contains Control Module 5 directly).

Copyright International Society of Automation
Provided by IHS under license with ISA
No reproduction or networking permitted without license from IHS
Full document details: ISA 88.00.01 2010

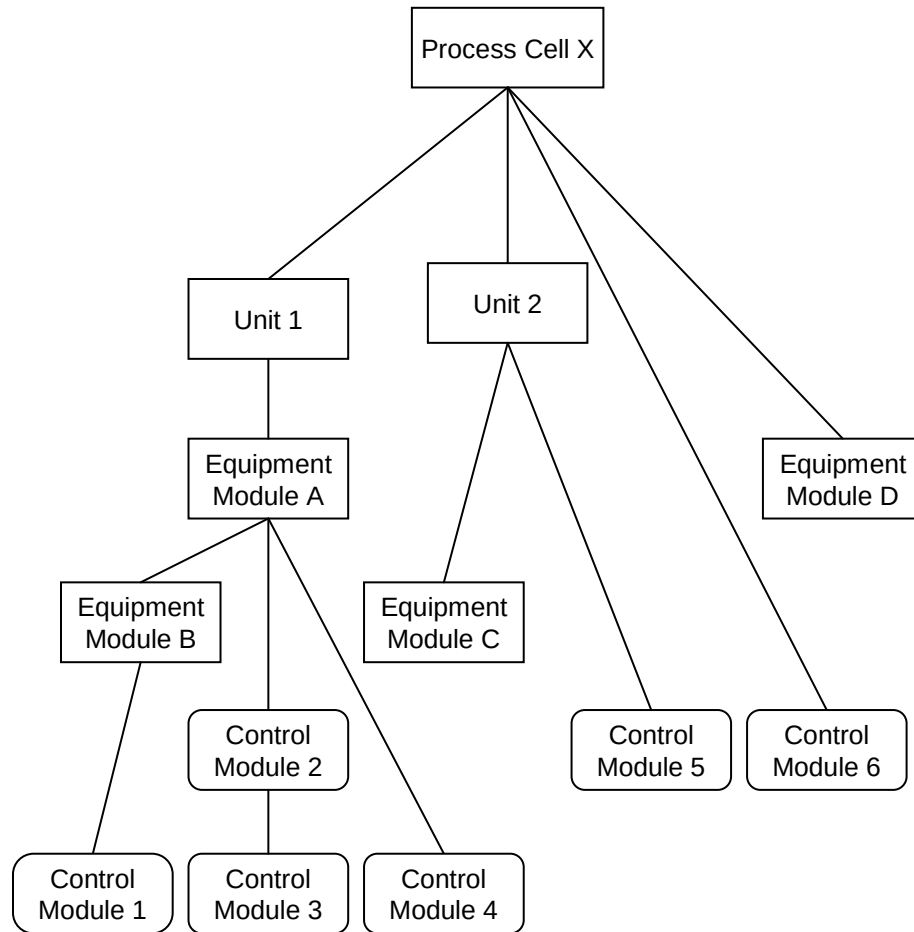


Figure 5 — Equipment entity model examples

4.5 Process cell classification

4.5.1 Introduction

This clause discusses the classification of process cells by the number of different products manufactured in the process cell and by the physical structure of the equipment used in the manufacturing.

4.5.2 Classification by number of products

A process cell is classified as single-product or multi-product based on the number of products planned for production in that process cell.

A single product process cell produces the same product in each batch. Variations in procedures and parameters are possible. For example, variations may occur in order to compensate for differences in equipment, to compensate for substitute raw materials, to compensate for changes in environmental conditions, or to optimize the process.

A multi-product process cell produces different products utilizing different methods of production or control. There are three possibilities:

- All products are produced with the same procedure using different formula values (varying materials and/or process parameters). Sometimes products produced in this way are referred to as grades of a product.
- The products are produced using different procedures.
- The products produced are grouped into families, each sharing a unique procedure among its products, but providing different formula values for each product.

4.5.3 Classification by physical structure

The order of equipment actually used or expected to be used by a specific batch is called the path. A process cell is classified as single path, multiple path, or network based on its physical structure. Regardless of which structure is used, several batches may be in progress at the same time (in different units), multiple input materials may be used, multiple finished materials may be generated, and units may share input material sources and product storage.

A single-path structure is a group of units through which a batch passes sequentially (see Figure 6). A single-path structure could be a single unit, such as a reactor, or several units in sequence.

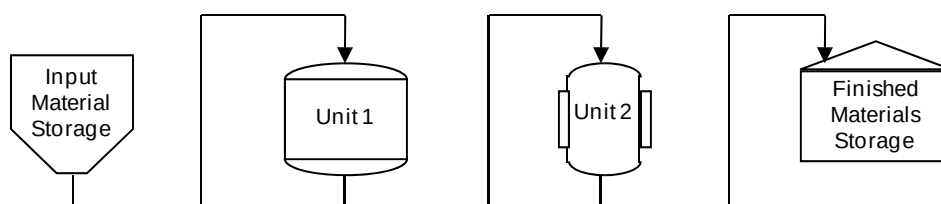


Figure 6 — Single-path structure

A multiple-path structure is shown in Figure 7. It consists of multiple single-path structures in parallel with no product transfer between them. Although units within a multi-path structure may be physically similar, it is possible to have paths and units that are of radically different physical design.

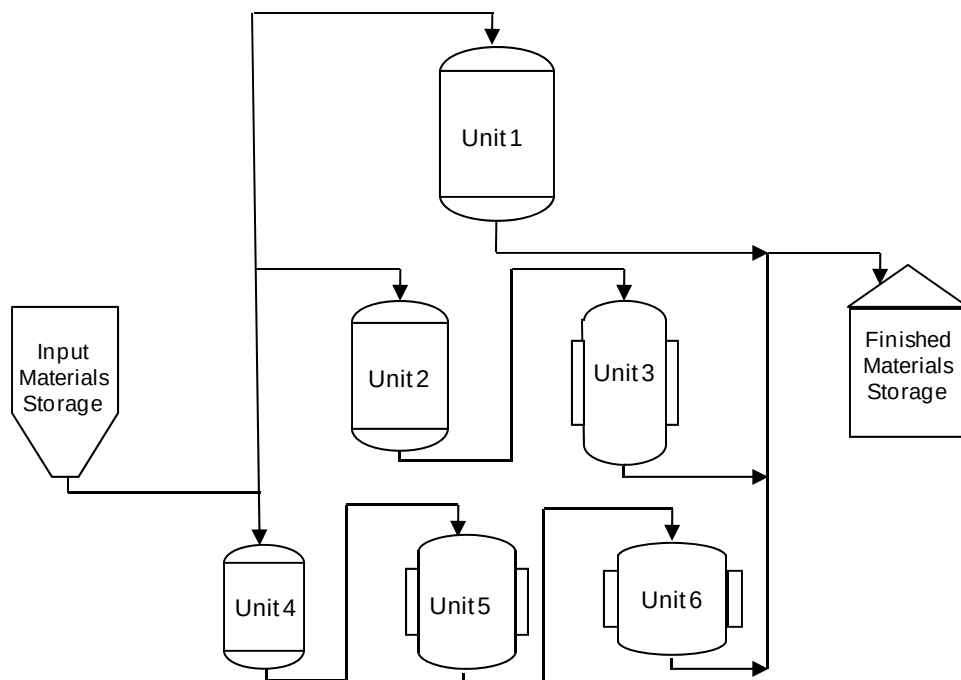


Figure 7 — Multiple-path structure

A network structure is shown in Figure 8. The paths may be either fixed or variable. When the paths are fixed, the same units are used in the same sequence. When the path is variable, the sequence may be determined at the beginning of the batch or it may be determined as the batch is being produced. The path could also be totally flexible. For example, a batch would not have to start at either Unit 1 or Unit 3; it could start with any unit and take multiple paths through the process cell. The units themselves may be portable within the process cell. In this case, verification of the process connections may be an important part of the procedures.

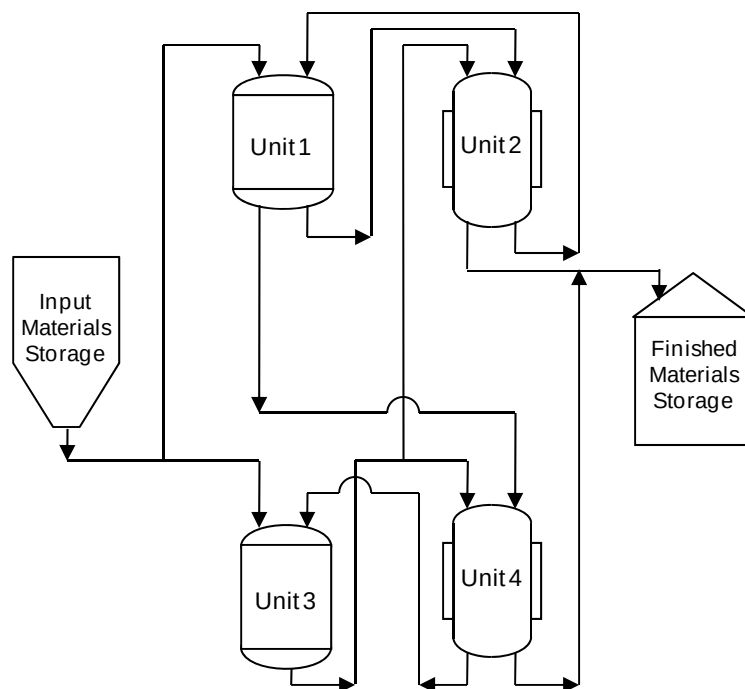


Figure 8 — Network structure

These are three possible structures for a process cell, actual implementations can vary widely. In addition, the structure of the process cell may include or exclude material storage.

5 Structure for batch control

5.1 Introduction

This clause describes

- three types of control (basic control, procedural control, and coordination control) typically needed to provide process functionality and control capabilities for batch manufacturing
- the relationship of equipment entities to each type of control
- the forms of coordination control referred to as allocation and arbitration
- the relationship of both the process model and the equipment entity model to the procedural control model.

The controls described may be implemented entirely through automation, through human intervention, or through a combination of both.

5.2 Basic control

5.2.1 Introduction

Basic control comprises a subset of equipment control that is dedicated to establishing and maintaining a specific state or behavior of equipment and process. Basic control

- includes regulatory control, interlocking, monitoring, exception handling, and discrete or sequential control necessary for establishing or maintaining a specific state or behavior;
- may respond to process conditions that in turn influences the control outputs or triggers corrective actions;
- may be activated, deactivated, or modified by operator commands or by procedural or coordination control;
- exposes equipment and process condition information.

NOTE 1 Regulatory control is dedicated to maintaining a process variable or variables at or near some desired value. Complex control strategies such as multivariable control, model-based control, and artificial intelligence techniques also fit into this category of regulatory control.

NOTE 2 State-oriented control refers to setting the state of a piece of equipment as opposed to the state of a process variable or variables. State-oriented equipment has a finite number of states. It defines a product independent processing sequence.

NOTE 3 Basic control strategies may include exception handling logic that is activated when an equipment malfunction or abnormal process deviation occurs.

The actions of basic control in a batch environment are in principle no different from the control of continuous processes. However, in the batch environment, there may be higher requirements on the ability for basic control to receive commands and to modify its behavior based on these commands.

5.2.2 Basic control in equipment entities

5.2.2.1 Introduction

This clause describes the role of basic control in each level of the equipment entity model.

5.2.2.2 Basic control in process cells

Basic control in a process cell is generally performed by equipment modules and control modules that are either directly within the process cell or within units the process cell contains. Equipment modules and control modules directly within the process cell may support basic control that spans or is referenced by several units.

EXAMPLE 1 A main supply valve on a common header line whose position needs to be monitored by multiple units in the process cell.

EXAMPLE 2 A process cell may contain basic control for an interlock that shuts one unit down and propagates the shutdown to upstream units that are feeding this particular unit.

5.2.2.3 Basic control in units

Basic control in a unit is generally performed by equipment modules and control modules that are within the unit or in some way referenced by the unit.

EXAMPLE A rupture disk indicator on a reactor is used to generate an interlock condition on the unit.

5.2.2.4 Basic control in equipment modules

Basic control in an equipment module is generally performed by control modules that it contains or references. Equipment modules may also directly execute basic control. However, direct interaction with physical equipment, such as actuators or sensors, is accomplished through referenced or included control modules.

EXAMPLE 1 Basic control through contained control modules: An equipment module opens a supply valve that is driven by a control module which is subordinate to the equipment module by issuing commands to the valve control module.

EXAMPLE 2 Direct basic control: An equipment module may calculate a temperature compensated set-point for use by other equipment entities through the use of basic control.

EXAMPLE 3 Interaction with equipment through control modules: An equipment module opens a common supply valve that is outside of its defined scope by issuing commands to the referenced control module that operates it. (In this case, the referenced control module is a common resource that must be allocated to the equipment module before issuing such commands.)

5.2.2.5 Basic control in control modules

Control modules may execute basic control.

EXAMPLE The common supply valve of the preceding example is instead automatically opened by the control module if the temperature is within limits and the downstream valve is open. (Allocation is not required in this case because the valve is contained in the control module.)

5.3 Procedural control

5.3.1 Introduction

Procedural control executes procedures, which are characteristic of batch processes. A procedure is a specification of a sequence of steps, actions, or activities with a defined beginning and end that is intended to accomplish a specific process-oriented objective or task.

A procedure consists of any combination of steps in series and/or in parallel. Transition conditions may be inserted between any steps to modify which steps will execute and in what order, usually based on equipment, process, and operator responses. Steps are initiated only after the immediate predecessor(s) in series with them have completed and any intervening transition conditions are true.

There is a difference between the implicit sequences in basic control and the explicit sequences in procedural control. In basic control, the sequence is primarily equipment oriented, is implicit in the design of the basic control element, usually does not vary from one execution of the basic control element to another, and is an inseparable part of setting and maintaining a state or condition in the process.

EXAMPLE A basic control sequence may control the order in which valves open and shut to change a double block and bleed valve assembly from open to closed; another may control the sequence of actions necessary to properly change the speed of a two-speed motor.

Explicit sequences in procedural control are overtly stated. They are not implicit in the design of a control element, may vary from one execution of the procedure to the next, and are intended to achieve a process-oriented result. In procedural control, the sequence causes the execution of a series of planned state or condition changes or a planned and ordered series of process oriented tasks to take place.

EXAMPLE Procedural control includes the sequence of actions necessary to carry out a process oriented task, such as charging a reactor with a specific amount and type of raw material and reporting the result; another higher level procedure may direct the order in which to charge different raw materials and how much of each to charge.

5.3.2 Procedural control model

5.3.2.1 Introduction

The procedural control model is a multi-level hierarchical model to accomplish the task of a complete process (or part of a process) based on the resources of a specific process cell. It is also the basis for defining equipment dependent recipe procedures. Each individual element in the model is a procedure, whose directly subordinate elements (if any) comprise its steps. The ultimate goal of the hierarchy is to efficiently organize the process-oriented tasks that are to be executed (either automatically or manually) at its lowest level.

The procedural control model levels are illustrated in Figure 9 and described below based on use of the full model. Clause 5.3.2.6 describes how the procedural control model may be collapsed or expanded.

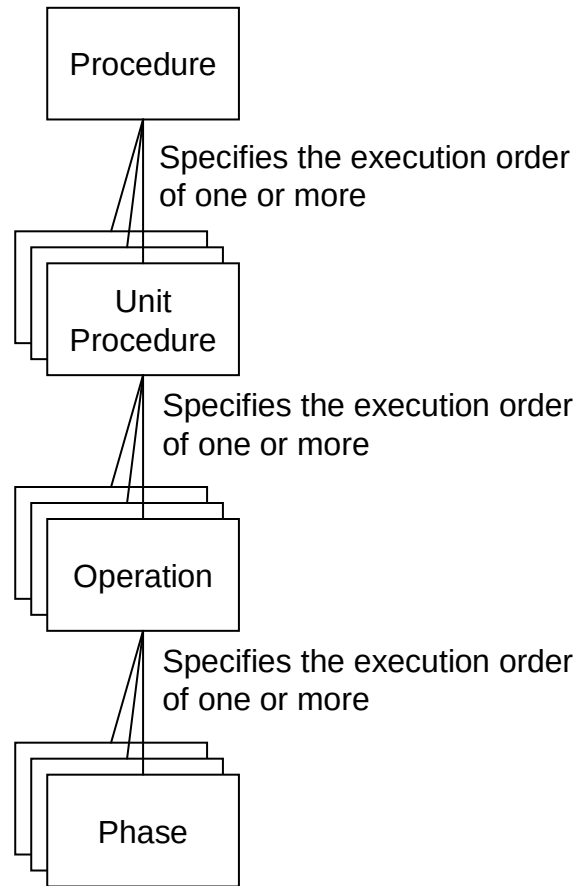


Figure 9 — Procedural control model (instance diagram) when not collapsed or expanded

5.3.2.2 Procedure

The procedure that defines the order of processing for an entire batch represents an alternative, more specific, application of the term procedure. This usage equates to the top level in the procedural control model. When the full model is used, the procedure shall specify the execution order of one or more unit procedures, which may be in series, in parallel, or a combination of both.

NOTE In this context, a procedure is often referred to as a batch procedure.

EXAMPLE An example of a procedure is "Make polyvinyl chloride."

5.3.2.3 Unit procedure

A unit procedure specifies a contiguous production sequence that takes place within a single unit. No more than one unit procedure shall be active in a unit at any time, however, multiple unit procedures specified by one or multiple procedures may run concurrently in different units. When the full model is used, each unit procedure shall specify the execution order of one or more operations, which may be in series, in parallel, or a combination of both.

EXAMPLE Examples of unit procedures include the following:

- Polymerize vinyl chloride monomer.
- Recover residual vinyl chloride monomer.

- Dry polyvinyl chloride.

5.3.2.4 Operation

An operation specifies a major processing sequence, usually to take material being processed from one state to another involving a chemical or physical change. The procedure associated with the term “unit operation” used in chemical engineering often relates to an operation element in the procedural control model. When the full model is used, each operation shall specify the execution order of one or more phases, which may be in series, in parallel, or a combination of both.

An operation is carried to completion in a single unit. Typically only one operation will be active in a unit at given time, but in some cases it may be necessary for multiple operations to be active within the same unit at the same time. Operation boundaries should normally be located at points in the procedure where normal processing can safely be suspended.

EXAMPLE Examples of operations include the following:

- Preparation: Pull a vacuum on the reactor and coat the walls with antifoulant.
- Charge: Add demineralized water and surfactants.
- React: Add vinyl chloride monomer and catalyst, heat, and wait for the reactor pressure to drop.

5.3.2.5 Phase

A phase is the lowest level procedural element in the procedural control model which is either a representation in a recipe or an implementation in equipment control that is intended to accomplish all or part of a process action

A phase is the lowest level of procedural control that can accomplish a process-oriented task, however, the set of steps that define its actions are usually equipment specific. The scope of a phase is usually small enough that the specification of its actions (with appropriate variants, such as target values) is highly reusable from one procedure or set of equipment to another. When the full procedural control model is used, phases shall execute the required processing task(s), either automatically or through operator actions. A phase is carried to completion in a single unit or equipment module.

EXAMPLE Examples of phases include the following:

- Add vinyl chloride monomer.
- Add catalyst.
- Ramp and Soak.

The execution of a phase may result in one or more (typically several) of the following actions

- commands to basic control, such as
 - changing controller modes, initializing their outputs, and adjusting their set-points
 - setting, clearing, and changing alarm and other limits
 - modifying algorithm selections and tuning constants
- the collection of
 - process measurement values, such as tank level or liquid density
 - operator entered data