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Date: 09 February 2024

Origin: International

**Latest date for receipt of comments: 3 April 2024**

Project No. 2022/01009

Responsible committee: GEL/65 Measurement and control

Interested committees:

Title: BS EN IEC 61512-1 Batch control

Part 1: Models and terminology

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## Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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|                  |                        |
|------------------|------------------------|
| Date: xx/xx/20xx | Document: ISO/DIS xxxx |
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| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/Figure/ Table/Note | Type of comment | Commend (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |



## COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:

**IEC 61512-1 ED2**

DATE OF CIRCULATION:

**2024-02-09**

CLOSING DATE FOR VOTING:

**2024-05-03**

SUPERSEDES DOCUMENTS:

**65A/1045/CD, 65A/1066B/CC**

|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| IEC SC 65A : SYSTEM ASPECTS                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                           |
| SECRETARIAT:<br>United Kingdom                                                                                                                                                                                                                                                                                                                                                              | SECRETARY:<br>Ms Stephanie Lavy                                                                                                                           |
| OF INTEREST TO THE FOLLOWING COMMITTEES:                                                                                                                                                                                                                                                                                                                                                    | PROPOSED HORIZONTAL STANDARD:<br><input type="checkbox"/><br>Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary. |
| FUNCTIONS CONCERNED:<br><input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input type="checkbox"/> SAFETY                                                                                                                                                                                                                        |                                                                                                                                                           |
| <input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING<br><br><b>Attention IEC-CENELEC parallel voting</b><br><br>The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.<br><br>The CENELEC members are invited to vote through the CENELEC online voting system. | <input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING                                                                                        |

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TITLE:

**Batch control - Part 1: Models and terminology**

PROPOSED STABILITY DATE: 2025

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**IEC 61512-1 Ed 2.0**

**Batch Control –**

**Part 1:  
Models and Terminology**

**2<sup>nd</sup> October 2023**

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

## BATCH CONTROL –

### Part 1: Models and Terminology

#### FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61512-1 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement and control.

The text of this part of IEC 61512 is based on the following documents:

| FDIS        | Report on voting |
|-------------|------------------|
| 65A/XX/FDIS | 65A/XX/RVD       |

Full information on the voting for the approval of this part of IEC 61512 can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

217 This version of IEC 61512-1 replaces IEC 61512-1 Ed1.0:1997. The following major changes  
218 were made to this part of IEC 61512 from the previous version (Annex E for further details).

219 a) Models and text are modified to provide more detail and clarity. Key clarifications are:

- 220 1) Two types of equipment modules are defined: generic and recipe-aware. All recipe-  
221 aware equipment modules contain procedural control and can be used as phases in the  
222 recipe.
- 223 2) Execution of all procedural control contained directly in units is part of the Unit  
224 Supervision activity.
- 225 3) The relationships between types of recipes, recipe components, and equipment control  
226 are more fully described and illustrated.
- 227 4) Entity relationship diagrams have been replaced with more intuitive UML instance  
228 diagrams, except for the *equipment entity model*.
- 229 5) The transition diagram for the procedural states example has been updated with a more  
230 intuitive and complete UML state diagram.
- 231 6) References to other standards in the series and to IEC 62264 are included to provide  
232 direction for further clarification of selected topics.
- 233 7) Defined terms are italicised in the body of this document to avoid misinterpretation based  
234 on meanings outside of IEC 61512.
- 235 8) Activity names are capitalised to help prevent confusion with similar terms, such as their  
236 underlying functions.

237 b) Previous Clauses 4 through 6 (now 4 through 0) were rearranged to provide a clearer top-  
238 down organisation of the document. Key changes are:

- 239 1) Removing the lower levels of the physical (role-based equipment) model (see subclause  
240 4.4.2) to eliminate redundancy because their groupings are defined by the associated  
241 functionality in the equipment entity model and are not meaningful for batch control  
242 without those associations.
- 243 2) Describing equipment control and the equipment entity model immediately after the  
244 physical (role-based equipment) model and describing each level as completely as  
245 possible without excessive use of forward references (see subclause 4.4.3).
- 246 3) Combining the descriptions of basic, procedural, and coordination control with their  
247 usage in each type of equipment entity, providing a single consolidated discussion of  
248 each type of control (see Clause 5)
- 249 4) Additional considerations to support application of the models have been grouped in  
250 Clause 7 to clarify their supporting relationship to the core models.

251 c) Clause 9 was added to define completeness, compliance, and conformance in relation to  
252 this part of IEC 61512.

253 d) Annex B was added to provide a more expansive procedural state reference model. The  
254 model found in Clause 7 may be considered a collapsed version of this more general model.

255 e) Annex C was added to clarify a number of points concerning the models, their application,  
256 and the new Clause 9 on conformance and compliance.

257 f) Annex E was added to more fully describe the changes in this update to IEC 61512-1  
258 Ed1.0:1997.

259 The list of all the parts of the IEC 61512 series, under the general title *Batch control*, can be  
260 found on the IEC website.

261 The committee has decided that the contents of this publication will remain unchanged until the  
262 stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to  
263 the specific publication. At this date, the publication will be

- 264 • reconfirmed,
- 265 • withdrawn,
- 266 • replaced by a revised edition, or
- 267 • amended.

268

269 The National Committees are requested to note that for this publication the stability date is ....

270 THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED  
271 AT THE PUBLICATION STAGE.

272

273

## INTRODUCTION

274 The IEC 61512 batch control standard has several parts. This part of IEC 61512 describes an  
275 overarching framework of models and definitions for batch manufacturing. Other parts of the  
276 series describe in more detail particular focus areas within this framework.

277 This part of IEC 61512 is structured to follow the IEC (International Electrotechnical  
278 Commission) guidelines. Therefore, Clauses 1 through 3 discuss the Scope of this part of IEC  
279 61512, Normative References, and Definitions, in that order.

280 The models and terminology in IEC 61512 are highly interdependent, making many of the  
281 definitions in Clause 3 incomplete and circular. Note that while Clause 3 provides definitions,  
282 the entire document constitutes the models and terminology of batch control. The user should  
283 consider Clause 3 as a short glossary of terms with brief descriptions and not rely on Clause 3  
284 for a full understanding of the concepts.

285 Clauses 4 through 0 incrementally complete these definitions by starting at a very high level,  
286 progressively detailing a set of conceptual models, and describing how they collectively interact  
287 to control batch production. The models are presumed to be complete as indicated. However,  
288 they may be collapsed and expanded as described in the explanation of each model.

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

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

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

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

301 Clause 0, *Activities and functions in batch control*, is normative. The intent is to describe the  
302 control activities that are needed to address the diverse control requirements of batch  
303 manufacturing.

304 Clause 9, *Completeness, compliance, and conformance*, is normative. The intent is to define  
305 compliance and conformance relative to the normative models and terminology in this part of  
306 IEC 61512.

307 Annex A is informative. It provides guidance towards understanding the model types used in  
308 this part of IEC 61512.

309 Annex B is informative. It provides a more expansive procedural state reference model. The  
310 model found in subclause 7.5 may be considered a collapsed version of this more general  
311 model.

312 Annex C is informative. It provides answers to typical questions that may arise in applying this  
313 part of IEC 61512.

314 Annex D is informative. It provides further explanation of the software entities listed in clause  
315 4.4.2.1.

316 Annex E is informative. It provides a summary of the changes made in this update as compared  
317 with IEC 61512-1 Ed1.0:1997.

318 The bibliography is informative, giving references for further investigation concerning safety  
319 and other relevant Standards.

320 This part of IEC 61512 is intended for those who are

- 321 • involved in the design, operation, or both of batch manufacturing plants,
- 322 • responsible for specifying controls and the associated application programs for batch  
323 manufacturing plants, or
- 324 • involved in the design and marketing of products in the area of batch control.

325 This part of IEC 61512 defines standard models and terminology for specifying the control  
326 requirements for batch manufacturing plants. The models and terminology

- 327 • emphasise good practices for the design and operation of batch manufacturing plants,
- 328 • can be used to improve control of batch manufacturing plants, and
- 329 • can be applied regardless of the degree of automation.

330 This part of IEC 61512 provides standard terminology and a consistent set of concepts and  
331 models for batch manufacturing plants and batch control that are intended to

- 332 • improve communications between all parties involved,
- 333 • reduce the user's time to reach full production levels for new products,
- 334 • enable vendors to supply appropriate tools for implementing batch control,
- 335 • enable users to better identify their needs,
- 336 • make recipe development straightforward enough to be accomplished without the services  
337 of a control systems engineer,
- 338 • reduce the cost of automating batch processes, and
- 339 • reduce life-cycle engineering efforts.

340 It is not the intent of IEC 61512 to

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

344 The key concepts defined in this part of IEC 61512 are:

- 345 • description of recipes, procedures, their contents, and their structure;
- 346 • definition of levels of recipes and procedures;
- 347 • recognition of product specific recipes and procedures that are separate from process-  
348 oriented equipment and its direct control;

- 349 • identification of a hierarchy of manufacturing equipment and its dedicated control;
- 350 • recognition of equipment capabilities that are utilised during recipe and procedure driven  
351 production; and
- 352 • recognition of the need for modular and reusable control functionality.

353

# BATCH CONTROL –

## Part 1: Models and terminology

### 1 Scope

This International Standard applies to systems, specifications, and their use for implementing batch and related procedure-oriented manufacturing controls in the process industries. This part of IEC 61512 establishes a reference model framework for procedure-oriented control, defines terms to help explain the model relationships and usage, and describes general criteria for evaluating conformance.

### 2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15704, *Industrial automation systems – Requirements for enterprise-reference architectures and methodologies*

ISO/IEC 17000, *Conformity assessment -- Vocabulary and general principles*

ISO/IEC 19501, *Information technology — Open Distributed Processing — Unified Modelling Language (UML) Version 1.4.2*

NOTE Usage of UML instance diagrams and state diagrams is described in 111Annex A and contrasted with the corresponding Edition 1.0 figures in Annex E.

IEC 60050-351, *International Electrotechnical Vocabulary – Part 351: Control technology*

IEC 60848, *GRAFCET specification language for sequential function charts*

NOTE Structures defined in IEC 60848 may be useful in the definition of procedural control and, in particular, in the definition of a phase.

IEC 61512-2, *Batch Control - Part 2: Data Structures and Guidelines for Languages*

IEC 61512-3, *Batch Control - Part 3: General and Site Recipe Models and Representation*

IEC 61512-4, *Batch Control - Part 4: Batch Production Records*

IEC/ISO 62264-1, *Enterprise-control system integration – Part 1: Models and Terminology*

IEC 62264-3, *Enterprise-control system integration – Part 3: Activity Models of Manufacturing Operations Management*

### 387 **3 Terms, definitions and abbreviations**

#### 388 **3.1 Terms and definitions**

389 For the purposes of IEC 61512, the following terms and definitions apply.

390 The definitions supplied in this clause should be considered a summary statement for the  
391 associated term. Since this part of IEC 61512 defines models and terminology as a whole, the  
392 reader should consider all of its provisions for each term's full meaning and its relationship to  
393 the models.

##### 394 **3.1.1**

##### 395 **allocation**

396 form of *coordination control* (3.1.14) that assigns a *resource* (3.1.66) or part of a *resource* to a  
397 *batch* (3.1.5), a *procedural element* (3.1.43), or an *equipment entity* (3.1.18) as needed

##### 398 **3.1.2**

##### 399 **arbitration**

400 form of *coordination control* (3.1.14) that determines how a *resource* (3.1.66) should be  
401 *allocated* (3.1.1) when there are more requests for the *resource* than can be accommodated at  
402 one time

##### 403 **3.1.3**

##### 404 **area**

405 role-based equipment entity or component of a site (3.1.68) that is identified by physical,  
406 geographical, operational, or logical segmentation within the site.

407 Note 1 to entry: It can contain process cells, production units, production lines, and storage zones.

##### 408 **3.1.4**

##### 409 **basic control**

410 control dedicated to establishing and maintaining a specific *state* or behaviour of equipment  
411 and *process* (3.1.45)

412 Note 1 to entry: *Basic control* may include regulatory control, interlocking, physical and virtual monitoring, *exception*  
413 *handling* (3.1.25), and discrete or sequential control necessary for establishing or maintaining a specific *state* or  
414 behaviour.

##### 415 **3.1.5**

##### 416 **batch**

417 a) material that is being produced or that has been produced by a single execution of a *batch*  
418 *process* (3.1.7);

419 b) entity that represents the production of a material at any point in the *process* (3.1.45);

420 c) entity that represents the execution of a *control recipe* (3.1.13).

421 Note 1 to entry: *Batch* means both the material made by and during the *process* and also an entity that represents  
422 the production of that material. *Batch* is used as an abstract contraction of the words "the production of a *batch*."

##### 423 **3.1.6**

##### 424 **batch control**

425 control activities and functions that direct *batch processes* (3.1.7)

426 **3.1.7**

427 **batch process**

428 *process* (3.1.45) that leads to the production of finite quantities of material by subjecting  
429 quantities of input materials to an ordered set of *processing* activities over a finite period of time  
430 using one or more pieces of equipment

431 **3.1.8**

432 **batch schedule**

433 ordered list of *batches* (3.1.5) to be produced in a specific *process cell* (3.1.47)

434 Note 1 to entry: The *batch schedule* typically contains such information as what is to be produced, how much is to  
435 be produced, when or in what order the *batches* are to be produced, and what equipment is to be used.

436 **3.1.9**

437 **campaign**

438 collection of related *batches* (3.1.5) for scheduling purposes

439 **3.1.10**

440 **common resource**

441 *resource* (3.1.66) that can provide services to one or more requesters

442 Note 1 to entry: *Common resources* are identified as either *exclusive-use resources* (3.1.26) or *shared-use*  
443 *resources* (3.1.67).

444 **3.1.11**

445 **control activity model**

446 conceptual model identifying seven interdependent activities (several of which are subdivided  
447 into functions) that manage control definition, execution, and information for *batch processes*  
448 (3.1.7)

449 **3.1.12**

450 **control module**

451 lowest level functional grouping in the *equipment entity model* (3.1.19) that can carry out *basic*  
452 *control* (3.1.4)

453 Note 1 to entry: The *control module* level contains the interfaces to the role-based equipment.

454 **3.1.13**

455 **control recipe**

456 type of *recipe* (3.1.57) which, through its execution, defines the manufacture of a single *batch*  
457 (3.1.5) of a specific product

458 **3.1.14**

459 **coordination control**

460 type of control that directs, initiates, modifies, or performs a combination of these for the  
461 execution of *procedural control* (3.1.41) and the utilisation of *equipment entities* (3.1.18)

462 **3.1.15**

463 **enterprise**

464 organisation that coordinates the manufacturing at one or more *sites* (3.1.68)

465 **3.1.16**

466 **equipment**

467 collection of physical objects or resources having defined roles and capabilities in master and  
468 a control recipe for executing a process

**469 3.1.17****470 equipment control**

471 equipment-specific functionality that provides the actual control capability for an *equipment*  
472 *entity* (3.1.18), including *procedural control* (3.1.41), *basic control* (3.1.4), and *coordination*  
473 *control* (3.1.14)

**474 3.1.18****475 equipment entity**

476 collection of process equipment, control equipment, and *equipment control* (3.1.17) grouped  
477 together to perform a certain control function or set of control functions

478 Note 1 to entry: equipment entity is sometimes referred to as Cyber-Physical System (CPS) (see ISO/SAE 21434  
479 The Guide For Cyber Physical Systems: Introduction)

**480 3.1.19****481 equipment entity model**

482 hierarchical model to logically organise the role-based equipment used in a *batch process*  
483 (3.1.7) in combination with the control present at each level

**484 3.1.20****485 equipment module**

486 functional grouping in the *equipment entity model* (3.1.19) that can carry out specific minor  
487 *processing* (3.1.45) activities

488 Note 1 to entry: An equipment module is typically centred around a piece of process equipment (a weigh tank, a  
489 process heater, a scrubber, etc.).

490 Note 2 to entry: Examples of minor *processing* activities are dosing and weighing.

491 Note 3 to entry: Two types of *equipment modules* are identified: *recipe-aware equipment modules* (3.1.58) and  
492 *generic equipment modules* (3.1.30).

493 Note 4 to entry: Any reference to an *equipment module* in this part of IEC 61512 is understood to be a general  
494 reference to both the *recipe-aware equipment module* and the *generic equipment module* unless otherwise specified.

**495 3.1.21****496 equipment operation**

497 *operation* (3.1.37) that is part of *equipment control* (3.1.17)

**498 3.1.22****499 equipment phase**

500 *phase* (3.1.39) that is part of *equipment control* (3.1.17)

**501 3.1.23****502 equipment procedure**

503 *procedure* (3.1.43) that is part of *equipment control* (3.1.17)

**504 3.1.24****505 equipment unit procedure**

506 *unit procedure* (3.1.73) that is part of *equipment control* (3.1.17)

**507 3.1.25****508 exception handling**

509 those functions that deal with plant or *process* (3.1.45) contingencies and other events which  
510 occur outside the normal or desired behaviour of *batch control* (3.1.6)

511 **3.1.26**

512 **exclusive-use resource**

513 *common resource* (3.1.10) that only one user can use at any given time

514 **3.1.27**

515 **formula**

516 category of *recipe* (3.1.57) information that includes *process inputs* (3.1.51), *process*  
517 *parameters* (3.1.55), and *process outputs* (3.1.54)

518 **3.1.28**

519 **general recipe**

520 type of *recipe* (3.1.57) that expresses equipment and *site* (3.1.68) independent *processing*  
521 (3.1.45) requirements

522 **3.1.29**

523 **general recipe procedure model**

524 conceptual model for *general recipe* (3.1.28) and *site recipe* (3.1.69) *procedures* (3.1.44) that  
525 structurally conforms to the *process model* (3.1.52)

526 **3.1.30**

527 **generic equipment module**

528 *equipment module* (3.1.20) which may be initiated through execution of *equipment control*  
529 (3.1.17) but is not capable of being directly initiated through the execution of a *recipe* (3.1.57)

530 **3.1.31**

531 **header**

532 information about the purpose, source, and version of the *recipe* (3.1.57) such as *recipe* and  
533 product identification, creator, and issue date

534 **3.1.32**

535 **lot**

536 a unique amount of material having a set of common traits

537 Note 1 to entry: Some examples of common traits are material source, the *master recipe* (3.1.33) used to produce  
538 the material, and distinct physical properties.

539 Note 2 to entry: Defined in IEC 62264-1 as *material lot*: uniquely identifiable amount of a material.

540 **3.1.33**

541 **master recipe**

542 type of *recipe* (3.1.57) that accounts for equipment capabilities and may include *process cell*  
543 (3.1.47) specific information

544 **3.1.34**

545 **master recipe procedure model**

546 conceptual model for *master recipe* (3.1.33) and *control recipe* (3.1.13) *procedures* (3.1.44) that  
547 structurally conforms to the *procedural control model* (3.1.42)

548 **3.1.35**

549 **mode**

550 characterisation of the way and extent an operator may intervene in *procedural element* (3.1.43)  
551 *state* (3.1.70) transitions and *equipment control* (3.1.17)

**552 3.1.36****553 operating schemes**

554 mutually exclusive *Process Control* (3.1.49) requirements implemented by the same *equipment*  
555 *module* (3.1.20) or *control module* (3.1.12)

556 EXAMPLE Examples of *operating schemes* are Inner-Temperature / Jacket-Temperature / Delta Temperature  
557 Control for a heating/cooling *equipment module* or Venting / Nitrogen Purge / Evacuation / High Pressure Control for  
558 a pressure/venting *equipment module*.

559 Note 1 to entry: *Operating schemes* may be implemented in an *equipment module* entity by alternative branches  
560 within one single *equipment phase* (3.1.22) or by multiple mutually exclusive *equipment phases* of which only one  
561 can be active at any given time.

**562 3.1.37****563 operation**

564 *procedural element* (3.1.43) defining an independent *processing* (3.1.45) task within a *unit*  
565 (3.1.72), typically through the initiation, organisation, and control of *phases* (3.1.39)

566 Note 1 to entry: An *operation* may be designed to accomplish all or part of a *process operation* (3.1.53), but mappings  
567 to other levels of the *process model* (3.1.52) are also possible.

**568 3.1.38****569 path**

570 order of equipment within a *process cell* (3.1.47) that is used in the production of a specific  
571 *batch* (3.1.5)

**572 3.1.39****573 phase**

574 lowest level *procedural element* (3.1.43) in the *procedural control model* (3.1.42), which defines  
575 a minor *processing* (3.1.45) task within a *unit* (3.1.72) or *equipment module* (3.1.20)

576 Note 1 to entry: A *phase* may be designed to accomplish all or part of a *process action* (3.1.46), but mappings to  
577 other levels of the *process model* (3.1.52) are also possible.

**578 3.1.40****579 role-based equipment model**

580 hierarchical model to logically organise the role-based equipment of a manufacturing *enterprise*  
581 (3.1.15)

**582 3.1.41****583 procedural control**

584 type of control that executes a *procedure* (3.1.44)

**585 3.1.42****586 procedural control model**

587 hierarchical model that depicts the orchestration of *procedural elements* (3.1.43) to carry out  
588 *process* (3.1.45) oriented tasks

**589 3.1.43****590 procedural element**

591 building block that defines a procedure

592 Note 1 to entry: This general definition applies to all levels of the *procedural control model* (3.1.42) and to both  
593 *recipes* (3.1.57) and *equipment control* (3.1.17).

594 Note 2 to entry: A *procedural element* may be defined as part of a *recipe* (3.1.57) or as part of *equipment control*  
595 (3.1.17) and referred to respectively as a “*recipe procedural element*” or an “*equipment procedural element*.”

596 Note 3 to entry: A *recipe procedural element* either defines the sequencing and ordering of lower level *recipe*  
597 *procedural elements* (3.1.43) or references an *equipment procedural element* at the same level. The former does not  
598 apply at the phase level; at higher levels it is intended to provide product specific flexibility beyond *formula* (3.1.27)  
599 changes, without making modifications to *equipment control* (3.1.17).

#### 600 **3.1.44**

##### 601 **procedure**

602 a) specification of a sequence of steps, actions or activities with a defined beginning and end  
603 that is intended to accomplish a specific objective or task

604 b) highest level *procedural element* (3.1.43) within the *procedural control model* (3.1.42),  
605 which defines the required set of *processing* (3.1.45) activities for a single *batch* (3.1.5),  
606 typically through the initiation, organisation, and control of *unit procedures* (3.1.73)

607 Note 1 to entry: A *procedure* may be designed to accomplish all or part of a *process* (3.1.45), even one that does not  
608 result in the production of product, such as a clean-in-place *procedure*.

#### 609 **3.1.45**

##### 610 **process**

611 a) sequence of chemical, physical, or biological activities for the conversion, transport, or  
612 storage of material or energy

613 b) sequence of chemical, physical, or biological activities that change the condition of  
614 equipment.

615 EXAMPLE An example corresponding to definition b would be a clean-in-place *process*

#### 616 **3.1.46**

##### 617 **process action**

618 minor *processing* (3.1.45) task that may be combined with other minor *processing* activities to  
619 make up a *process operation* (3.1.53)

620 Note 1 to entry: *Process actions* are the lowest level of *processing* task within the *process model* (3.1.52).

#### 621 **3.1.47**

##### 622 **process cell**

623 a) functional grouping in the *equipment entity model* (3.1.19) that can carry out production of  
624 one or more *batches* (3.1.5)

625 b) lowest level role-based equipment grouping in the role-based equipment *model* (3.1.40),  
626 consisting of all equipment in a *process cell* (3.1.47) *equipment entity* (3.1.18)

#### 627 **3.1.48**

##### 628 **process cell management**

629 control activity that includes the functions needed to manage *batch* (3.1.5) production within a  
630 *process cell* (3.1.47)

#### 631 **3.1.49**

##### 632 **process control**

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

#### 635 **3.1.50**

##### 636 **process element**

637 building block that defines a *process*

638 Note 1 to entry: This general definition applies to all levels of the *process model* (3.1.52) and to *general recipes*  
639 (3.1.28) and *site recipes* (3.1.69)

640 **3.1.51**641 **process input**

642 identification and quantity of materials, energy, or other *resources* (3.1.66) required for one  
643 execution of a *control recipe* (3.1.13)

644 **3.1.52**645 **process model**

646 hierarchical model that illustrates the subdivision of a *batch process* (3.1.7)

647 **3.1.53**648 **process operation**

649 major *processing* (3.1.45) task that usually results in a chemical or physical change in the  
650 material being processed and that is defined without consideration of the actual target  
651 equipment configuration

652 **3.1.54**653 **process output**

654 identification and quantity of materials, energy, or other *resources* (3.1.66) resulting or expected  
655 to result from one execution of a *control recipe* (3.1.13)

656 **3.1.55**657 **process parameter**

658 information that is needed to manufacture a material but does not fall into the classification of  
659 *process input* (3.1.51) or *process output* (3.1.54)

660 EXAMPLE            Examples of *process parameter* information are temperature, pressure, and time.

661 **3.1.56**662 **process stage**

663 part of a *process* (3.1.45) that usually operates independently from other *process stages* and  
664 that usually results in a planned sequence of chemical or physical changes in the material being  
665 processed

666 **3.1.57**667 **recipe**

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

670 Note 1 to entry: There are four types of *recipes* defined in this part of IEC 61512: *general recipe* (3.1.28), *site recipe*  
671 (3.1.69), *master recipe* (3.1.33), and *control recipe* (3.1.13).

672 **3.1.58**673 **recipe-aware equipment module**

674 *equipment module* (3.1.20) containing one or more *equipment phases* (3.1.22) that is capable  
675 of being initiated directly through the execution of a *recipe* (3.1.57)

676 **3.1.59**677 **recipe component**

678 building block for a *recipe* (3.1.57), combining a *recipe procedural element* (3.1.43) with its  
679 associated *header* (3.1.31), *formula* (3.1.27), equipment requirements, and other information.

680 Note 1 to entry: This general definition applies for *recipe procedural elements* at all levels of the *master recipe*  
681 *procedure model* (3.1.34).

682 Note 2 to entry: A *recipe component* may or may not be part of a library.

683 **3.1.60**

684 **recipe management**

685 control activity that includes the functions needed to create, store, and maintain *general recipes*  
686 (3.1.28), *site recipes* (3.1.69), and *master recipes* (3.1.33)

687 **3.1.61**

688 **recipe operation**

689 part of a *recipe* (3.1.57) which either defines the sequencing and ordering of *recipe phases*  
690 (3.1.62), or references an *equipment operation* (3.1.21)

691 **3.1.62**

692 **recipe phase**

693 part of a *recipe* (3.1.57) which defines the references to an *equipment phase* (3.1.22)

694 **3.1.63**

695 **recipe procedure**

696 a) general reference to any level of the *procedural control model* (3.1.42) applied in the *recipe*  
697 (3.1.57)

698 b) part of a *recipe* which either defines the sequencing and ordering of *recipe unit procedures*  
699 (3.1.65), or references an *equipment procedure* (3.1.23)

700 Note 1 to entry: A *recipe procedure* is intended to provide product specific flexibility beyond *formula* (3.1.27) changes,  
701 without making equipment modifications.

702 **3.1.64**

703 **recipe types model**

704 conceptual model identifying the relationships between the types of *recipes* (3.1.57) that are  
705 defined in an *enterprise* (3.1.15)

706 **3.1.65**

707 **recipe unit procedure**

708 part of a *recipe* (3.1.57) which either defines the sequencing and ordering of *recipe operations*  
709 (3.1.61), or references an *equipment unit procedure* (3.1.24)

710 **3.1.66**

711 **resource**

712 *enterprise* (3.1.15) entity that provides some or all of the capabilities required by the execution  
713 of an *enterprise* activity and/or business process

714 EXAMPLE: Personnel, equipment, material.

715 Note 1 to entry: IEC 61512 focuses on equipment *resources*. Other *resource* types defined in IEC 62264-1 are for  
716 the most part not considered, except as *process inputs* (3.1.51) and *process outputs* (3.1.54).

717 [SOURCE: ISO 15704, modified – Note 1 to entry has been added.]

718 **3.1.67**

719 **shared-use resource**

720 *common resource* (3.1.10) that can be used by more than one user at a time

721 **3.1.68**

722 **site**

723 role-based equipment entity or component of a manufacturing *enterprise* (3.1.15) that is  
724 identified by physical, geographical, operational, or logical segmentation within the *enterprise*

725 Note 1 to entry: A *site* may contain *areas* (3.1.3), *process cells* (3.1.47), and role-based equipment.

726 **3.1.69**727 **site recipe**

728 type of *recipe* (3.1.57) that is *site* (3.1.68) specific

729 Note 1 to entry: *Site recipes* may be derived from *general recipes* (3.1.28) recognising local constraints, such as  
730 language, units of measurement, and available raw materials.

731 Note 2 to entry: *Site recipes* may include routing information necessary for coordinating manufacturing across  
732 *process cells* (3.1.47) and for production scheduling activities.

733 **3.1.70**734 **state**

735 condition of an *equipment entity* (3.1.18) or of a *procedural element* (3.1.43) at a given time

736 Note 1 to entry: The number of possible *states* and their names vary for *equipment entities* and for *procedural*  
737 *elements*.

738 **3.1.71**739 **train**

740 subset of a *process cell* (3.1.47) that is capable of making a *batch* (3.1.5) of material

741 **3.1.72**742 **unit**

743 functional grouping in the *equipment entity model* (3.1.19) that can carry out one or more major  
744 *processing* (3.1.45) activities

745 EXAMPLE Examples of units are reactor, fermenter, buffer.

746 **3.1.73**747 **unit procedure**

748 *procedural element* (3.1.43) defining a major *processing* (3.1.45) task within a *unit* (3.1.72),  
749 typically through the initiation, organisation, and control of *operations* (3.1.37).

750 Note 1 to entry: A *unit procedure* may be designed to accomplish all or part of a *process stage* (3.1.56), but mappings  
751 to other levels of the *process model* (3.1.52) are also possible.

752 **3.1.74**753 **unit recipe**

754 part of a *control recipe* (3.1.13) that uniquely defines the contiguous production requirements  
755 for a *unit* (3.1.72)

756 Note 1 to entry: The *unit recipe* is a *recipe component* (3.1.59) containing the *unit procedure* (3.1.73) and its related  
757 *formula* (3.1.27), *header* (3.1.31), equipment requirements, and other information.

758 **3.1.75**759 **Unit Supervision**

760 control activity that includes functions needed to supervise the *unit* (3.1.72) and the *unit's*  
761 *resources* (3.1.66)

762 **3.2 Abbreviations**

763 For the purposes of IEC 61512, the following abbreviations apply.

764 **3.2.1**765 **ID**

766 Identification

767 unique identifier for *batches* (3.1.5), *lots* (3.1.32), personnel, equipment, and raw materials

## 768 **4 Batch processes and equipment**

### 769 **4.1 General**

770 The models and terminology defined in this clause provide a foundation for understanding the  
771 application of *batch control* based on IEC 61512. Specifically, this clause provides the following:

- 772 • an overview of continuous, discrete, and *batch* manufacturing;
- 773 • hierarchical models of *batch processes (process model)*, role-based equipment groupings  
774 (role-based equipment *model*), and functional *equipment entities (equipment entity model)*  
775 for use in *batch* manufacturing;
- 776 • criteria for classifying *batch* manufacturing facilities.

### 777 **4.2 Types of manufacturing**

#### 778 **4.2.1 General**

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

#### 787 **4.2.2 Continuous process manufacturing**

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

793 The concepts of *batch processing* in IEC 61512 may be applied to continuous *processing* for  
794 such control as start-ups, grade changes, and shutdowns. Minor modifications to the models in  
795 this part of IEC 61512 could be applied to address these unique *processing* needs.

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

#### 798 **4.2.3 Discrete parts manufacturing**

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

803 The concepts of *batch processing* in IEC 61512 may be applied to discrete parts manufacturing  
804 for such control as start-ups, changeovers, and shutdowns. Minor modifications to the models  
805 in this part of IEC 61512 could be applied to address these unique *processing* needs.

#### 806 **4.2.4 Batch process manufacturing**

807 The *batch process* manufacturing addressed in IEC 61512 leads to the production of finite  
808 quantities of material (*batches*) by subjecting quantities of input materials to a defined order of

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

813 The models in this part of IEC 61512 facilitate *batch process* manufacturing by describing the  
814 following:

- 815 • a consistent structure for design and operation of *batch processing* facilities;
- 816 • logical separation of *recipes* that define product-specific *processing* sequences from  
817 *equipment control* that implements fixed equipment-specific *processing* capabilities;
- 818 • hierarchical segmentation of both *recipes* and *equipment control* based on relatively simple  
819 and reusable modular structures (*recipe* and *equipment entities*);
- 820 • a set of required activities and functions (activity model) for
  - 821 – initiating *recipes* based on a *batch schedule*,
  - 822 – interpreting the active *recipes*' defined *processing* tasks and executing them through  
823 *equipment control*, and
  - 824 – managing *recipe* and production data.

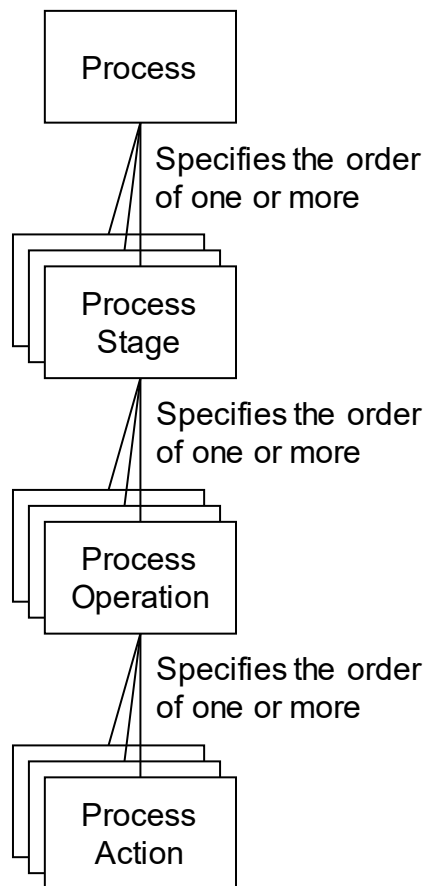
## 825 4.3 Process model

### 826 4.3.1 General

827 The *process model* is a multi-level hierarchical model for subdivision of a *batch process* and is  
828 the basis for defining equipment independent *recipe procedures*. Each individual element in the  
829 model is a *process element*, whose directly subordinate elements (if any) comprise its steps.  
830 The ultimate goal of the hierarchy is to efficiently organise the *processing* activities that are  
831 specified (either directly or by referencing an external requirement) at its lowest level. See IEC  
832 61512-3 for further information on equipment independent recipes that use the *process model*  
833 for the General Recipe procedure.

834 The *process model* levels are illustrated in Figure 1 and described below based on use of the  
835 full model. Subclause 4.3.6 describes how the *process model* may be collapsed or expanded.

836



837

838 **Figure 1 — Process model (instance diagram) when not collapsed or expanded**

### 839 4.3.2 Process

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

843 **EXAMPLE** The production of polyvinyl chloride by polymerisation of vinyl chloride monomer is an example of  
844 a *batch process*.

### 845 4.3.3 Process stage

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

851 **EXAMPLE** Typical *process stages* in the polyvinyl chloride *process* might be the following.

- 852 • Polymerise: Polymerise vinyl chloride monomer into polyvinyl chloride.
- 853 • Recover: Recover residual vinyl chloride monomer.
- 854 • Dry: Dry polyvinyl chloride.

#### 855 4.3.4 Process operation

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

862 EXAMPLE Typical *process operations* for the polymerisation of vinyl chloride monomer into polyvinyl chloride  
863 *process stage* might be the following.

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

#### 868 4.3.5 Process action

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

874 EXAMPLE Typical *process actions* for the react *process operation* might be the following.

- 875 • Add: Add the required amount of catalyst to the processed material.
- 876 • Add: Add the required amount of vinyl chloride monomer to the processed material
- 877 • Heat: Heat the processed material to 55-60°C
- 878 • Hold: Hold the processed material at 55-60°C until the reaction pressure starts to decrease.

#### 879 4.3.6 Collapsing and expanding the process model

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

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

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

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

- 894 • between *process* and *process stage*,

- 895 • between *process stage* and *process operation*,
- 896 • between *process operation* and *process action*, or
- 897 • in a combination of the above locations.

898 Any additional levels shall structurally consistent with the *process model* and shall not use  
899 names defined in this part of IEC 61512.

## 900 **4.4 Equipment and equipment control**

### 901 **4.4.1 General**

902 The concept of equipment capabilities and usage of these capabilities to accomplish desired  
903 *processing* tasks is a major point of IEC 61512. *Equipment control* is the equipment-specific  
904 control functionality that supports such capabilities and that may be utilised by *recipes* to carry  
905 out their specified *processing* tasks and by operators to perform direct manipulation of control  
906 settings.

907 An *equipment entity* comprises a grouping of role-based equipment and associated *equipment*  
908 *control* that has been engineered to carry out a certain *process* or control function or set of such  
909 functions. Role-based equipment in this context includes process equipment, instrumentation,  
910 and control equipment.

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

916 This interaction of *equipment control* and role-based equipment is purposely described without  
917 any reference to language or implementation. The intent is to describe a framework within which  
918 *equipment control* and role-based equipment may be defined and discussed.

### 919 **4.4.2 Role Based Equipment model**

#### 920 **4.4.2.1 General**

921 The equipment groupings defined for a manufacturing *enterprise* may be described in terms of  
922 a *model* that hierarchically organises the *enterprise* into sites, *areas*, *process cells*, and role-  
923 based equipment. Figure 2 illustrates how lower level groupings are combined to form higher  
924 levels in this hierarchy in *batch process* manufacturing.

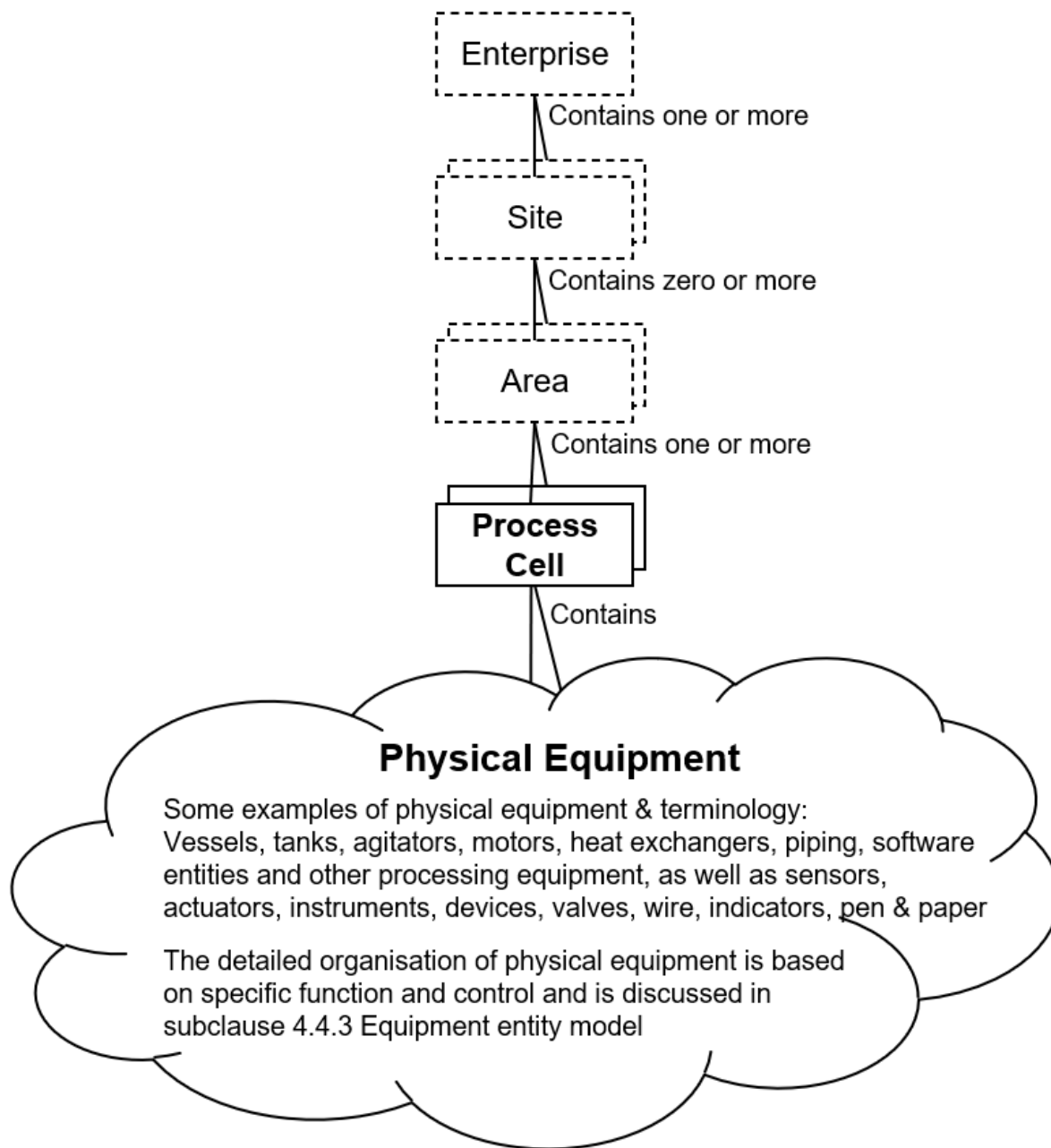
925 The *enterprise*, *site*, and *area* levels are more precisely defined in the IEC/ISO 62264 standard.

926 NOTE IEC/ISO 62264 defines two models, one for the role based equipment and the second for the physical assets,  
927 the model in this standard is equivalent to the IEC/ISO 62264 role-based equipment model.

928 These levels in Figure 2 are shown with dashed lines to indicate that they are often beyond the  
929 scope of *batch control* and criteria for configuring their boundaries are not defined in IEC 61512.



930



931

932

**Figure 2 — Example of Role Based Equipment model**

933 NOTE Software entities have a physical scope and interfaces and include but not limited to

- 934 • enhanced PID configurations (e.g., cascade, ratio, feedforward),
- 935 • advanced process control (e.g., MPC, fuzzy logic),
- 936 • virtual (soft) sensors based on a single measurement,
- 937 • virtual (soft) sensors based on multiple measurements,
- 938 • permanent software interlocks (i.e., independent of batch steps), and

939 • data validity checking, data reduction, etc. algorithms.

940 See 126Annex D for further explanations of software entities.

#### 941 **4.4.2.2 Enterprise**

942 An *enterprise* as a role-based equipment entity is a collection of one or more *sites* and their  
943 subordinate *areas*, *process cells*, and role-based equipment.

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

946 There are many factors other than *batch control* that affect the boundaries of an *enterprise*.  
947 Therefore, the criteria for configuring the boundaries of an *enterprise* are not covered in IEC  
948 61512.

#### 949 **4.4.2.3 Site**

950 A *site* as a role-based equipment entity is a physical, geographical, operational, or logical  
951 subdivision of the *enterprise*. It may contain *areas* and their subordinate *process cells*, and role-  
952 based equipment.

953 The boundaries of a *site* are usually based on organisational, or business criteria as opposed  
954 to technical criteria. There are many factors other than *batch control* that affect these  
955 boundaries. Therefore, the criteria for configuring the boundaries of a *site* are not covered in  
956 IEC 61512.

#### 957 **4.4.2.4 Area**

958 An *area* as a role-based equipment entity is a physical, geographical, operational, or logical as  
959 role-based equipment entity or subdivision of a *site*. In *batch* manufacturing, it shall contain one  
960 or more *process cells* and their role-based equipment.

961 The boundaries of an *area* are usually based on organisational, or business criteria as opposed  
962 to technical criteria. There are many factors other than *batch control* that affect these  
963 boundaries. Therefore, the criteria for configuring the boundaries of an *area* are not covered in  
964 IEC 61512.

#### 965 **4.4.2.5 Process cell (role-based equipment entity)**

966 Each *process cell* in the role-based equipment entity *model* corresponds to a single *process*  
967 *cell equipment entity* and its boundaries are engineered to satisfy the functional requirements  
968 for that entity. The defining characteristics for this level in the *role-based equipment entity*  
969 *model*, therefore, correspond exactly to the top level of the *equipment entity model* and are  
970 described more fully in the discussion of *equipment entities* in subclause 4.4.3. When the term  
971 *process cell* is used in this part of IEC 61512, it refers to the *equipment entity*, except where  
972 clearly a reference to the *role-based equipment entity model*.

#### 973 **4.4.2.6 Role-based equipment**

974 The detailed organisation of physical equipment and its specific function and control that  
975 performs a specific role in the process cell where the role is defined in a master and control  
976 recipe. This is discussed in subclause 4.4.3 *Equipment entity model*.

977 Example: Some examples of physical equipment & terminology are Vessels, tanks, agitators, motors, heat  
 978 exchangers, piping, software entities and other processing equipment, as well as sensors, actuators, instruments,  
 979 devices, valves, wire, indicators, pen & paper

980

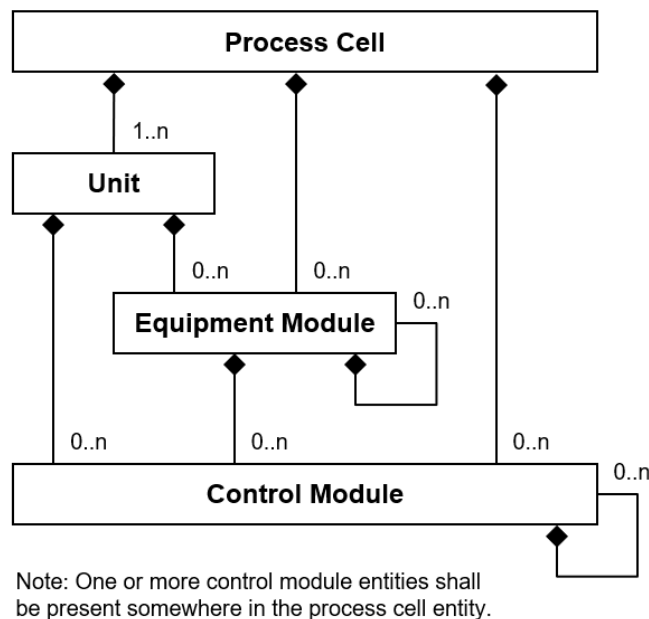
#### 981 4.4.2.7 Collapsing and expanding the role-based equipment model

982 The *role-based equipment model* presented is complete as indicated and the levels defined  
 983 shall not be rearranged or replaced, but the model may be collapsed or expanded. Expanding  
 984 in this context means inserting one or more additional levels into the model. Collapsing in this  
 985 context means omitting one or more defined levels of the *role-based equipment model*. When  
 986 using a collapsed *role-based equipment model*, the *site* and *process cell* levels shall not be  
 987 omitted.

#### 988 4.4.3 Equipment entity model

##### 989 4.4.3.1 General

990 This subclause (4.4.3) discusses *equipment entities* that are formed from the combination of  
 991 *equipment control* and physical equipment. The *equipment entity model* (see Figure 3)  
 992 hierarchically structures *equipment entities* into four levels that organise the contents of each  
 993 *process cell* and determines the final mapping of role-based equipment entity for the *role-based*  
 994 *equipment model* shown in Figure 2. The four levels of the *equipment entity model* are the  
 995 *process cell*, *unit*, *equipment module*, and *control module*, as shown in Figure 3.



996

997 **Figure 3 — Equipment entity model**

998

999 Each equipment grouping comprising a *process cell*, *unit*, *equipment module*, or *control module*  
 1000 corresponds to a single *equipment entity* and its boundaries are engineered to satisfy the  
 1001 functional requirements for that entity.

1002 EXAMPLE Examples of functional requirements for equipment entities are operation modes, operating  
 1003 schemes, equipment states, parameters and properties, recording, diagnostics, alarming and visualization.

1004 Note : In the context of Plattform Industrie 4.0 an equipment entity would be called I4.0 Component with its Asset  
1005 Administration Shell (AAS) or Digital Twin, or in the context of Modular Type Package (MTP) it would be a Function  
1006 Equipment Assembly or a Process Equipment Assembly (PEA).

1007 These groupings are created to simplify equipment operation by clearly defining the overall  
1008 functions of each entity and treating it as a single larger piece of controlled equipment. Once  
1009 created, the equipment groupings in the *equipment entity model* cannot be split up except by  
1010 re-engineering the *equipment entities*.

1011 The general functionality associated with each level of the *equipment entity model* is described  
1012 below. The types of control needed for *batch* manufacturing and their usage within each level  
1013 are discussed in Clause 5.

1014 In the *equipment module* and *control module* levels, an *equipment entity* may be directly  
1015 contained either in a larger grouping at the same level or in a higher level grouping. Inclusion  
1016 of control equipment shall be exclusively at the *control module* level.

1017 EXAMPLE Some examples of control equipment are motor starters, variable speed motor controllers,  
1018 controller algorithms, software safety interlocks, pneumatic and electric actuators, temperature sensors, weight  
1019 indicating instruments, flow measurement instruments, switches (e.g., mechanical, proximity sensing), connecting  
1020 medium (e.g., wire, fibre optic, radio waves), indicators (e.g., panel lights, controller inputs displayed on graphics).

1021 Whether *equipment control* in an *equipment entity* is implemented manually or by way of  
1022 automation, it is only through the exercise of *equipment control* that the equipment can produce  
1023 a *batch*.

1024 All control related provisions of IEC 61512 assume that each *process cell* entity has been  
1025 subdivided into well-defined *units*, *equipment modules*, and *control modules*. Effective  
1026 subdivision of the *process cell* into well-defined *equipment entities* is a complex task, highly  
1027 dependent on the individual requirements of the specific environment in which the *batch process*  
1028 exists. Inconsistent or inappropriate equipment subdivisions can compromise the effectiveness  
1029 of the modular approach to *recipes* suggested by this part of IEC 61512.

1030 Subdivision of the *process cell* requires a clear understanding of the purpose of the *process*  
1031 *cell's* equipment. Such understanding allows the identification of *equipment entities* that should  
1032 work together to serve an identifiable *processing* purpose.

1033 The control capabilities possible in the different *equipment entities* are important characteristics  
1034 and a main basis for classification of *equipment entities*. In the following paragraphs *equipment*  
1035 *control* for the individual *equipment entities* is discussed.

1036 This subclause (4.4.3) discusses some general principles involved in segmenting a *process cell*  
1037 into *equipment entities* that can carry out specified *processing* tasks or equipment-specific  
1038 actions. A more exhaustive explanation of segmentation principles is beyond the scope of this  
1039 part of IEC 61512.

1040 It is important to note that the physical *process cell* design can greatly influence the  
1041 implementation of *batch control*. Minor differences in the physical system can dramatically affect  
1042 the organisation of *role-based equipment entities* and *procedural elements*.

1043 The subdivision of a *process cell* should follow the principles listed below.

- 1044 • *Equipment entities* within a *process cell* are clearly defined, including their boundaries,  
1045 *processing* capabilities, relationships with other *equipment entities* and allowable equipment  
1046 interconnections.
- 1047 • The function any *equipment entity* serves in product *processing* is clear and unambiguous.

- 1048 • The function performed by the *equipment entity* is consistent in terms of *processing* task  
1049 and should be usable for that task no matter what product is being manufactured at a given  
1050 time.
- 1051 • Interactions between *equipment entities* are minimised. While planned interaction is  
1052 periodically necessary, each *equipment entity* should perform its functions while influencing  
1053 the functioning of other *equipment entities* as little as possible.
- 1054 • Necessary interaction between *equipment entities* is, insofar as possible, coordinated by  
1055 *equipment entities* at the same level or at the next higher level.
- 1056 • Subordinate *equipment entities* are able to execute their task(s) independently and  
1057 asynchronously, allowing a higher level *equipment entity* to orchestrate the activities of its  
1058 subordinates.
- 1059 • A consistent basis for the definition of *equipment entities*, enabling a user interacting with  
1060 similar *equipment entities* to do so naturally and without confusion.
- 1061 • An entity passes appropriate information up to higher levels in the hierarchy, passes  
1062 commands down to lower levels and monitors the state of lower levels.

1063 NOTE Portable *equipment entities* may not have a permanent relationship to one specific *process cell* but are allowed  
1064 to be moved between *process cells* to improve the flexibility of the facility. In general, moving *equipment entities*  
1065 from one *process cell* to another should only occur when the equipment is not acquired or *allocated* to a *batch*.

#### 1066 4.4.3.2 Process cell (equipment entity)

1067 In the *role-based equipment model*, a *process cell* is an equipment grouping within an *area* and  
1068 its defined role boundaries match those of the corresponding *equipment entity*. In the *equipment*  
1069 *entity model*, each *process cell* shall contain one or more *units* and their subordinate *equipment*  
1070 *modules* and *control modules*. It may also directly contain role-based *processing* equipment,  
1071 *equipment modules*, and *control modules* that are not part of any *unit*.

1072 Each *process cell* entity shall be engineered to combine all required role-based processing  
1073 equipment, *units*, *equipment modules*, *control modules*, and additional *equipment control* (as  
1074 described in Clause 5) that will be used to produce *batches* of one or more products.

1075 The *process cell* as described in IEC 61512 corresponds to a type of work centre defined in  
1076 IEC/ISO 62264. A work centre may be specialised for different manufacturing types and  
1077 functions. More than one type of work centre, such as a storage zone or a production line, is  
1078 often required in an *area* or *site*. The *process cell* defined in IEC 61512 does not refer to the  
1079 other types of work centre identified in IEC/ISO 62264.

1080 The existence of the *process cell* allows for production scheduling on a *process cell* basis. It  
1081 also allows for *process cell*-wide control strategies to be designed, such as for emergency  
1082 response to *process* conditions or to comply with administrative requirements such as  
1083 documentation for good manufacturing practices (GMP).

1084 All *batch processing* tasks are orchestrated at the *process cell* level based on *recipes* containing  
1085 *procedure*, parameter, and other information and a *batch schedule* containing operational  
1086 requirements for each *batch*. The *Process Cell Management* activity described in subclause 8.6  
1087 performs this orchestration by interpreting the schedule and top level *procedural elements* of  
1088 the *recipes* it specifies.

1089 A frequently recognised subdivision of a *process cell* is the *train*. A *train* is composed of all *units*  
1090 and other *equipment entities* that (a) make up a recognisable subset of a *process cell* and (b)  
1091 is sufficient to produce all *batches* for one or more of the *process cell's recipes*. Any given *batch*  
1092 may use only part of the equipment in a *train* or *process cell*. Furthermore, more than one *batch*  
1093 (including *batches* for more than one product) may be active in a *train* or *process cell*.

1094 simultaneously. Although a *process cell* may contain multiple (possibly overlapping) *trains*, no  
1095 *train* may contain equipment outside the boundaries of the *process cell*.

1096 NOTE A *train* is not considered an additional level in the *equipment entity model*.

1097 The *process cell* will also need to prepare and monitor equipment or *resources* not currently  
1098 involved in *batch processing*, such as which *units* are available, what *units* and piping are going  
1099 through a clean-in-place (CIP) routine, and what the current inventories of raw materials are.  
1100 This could be initiated by internal logic in the *process cell* itself or through the *batch schedule*  
1101 and *recipes*.

1102 The complexity of control within the *process cell* will depend on the equipment available within  
1103 the *process cell*, the interconnectivity among this equipment, the degree of freedom of  
1104 movements of *batches* through this equipment, and the *arbitration* of the use of this equipment  
1105 so that the equipment can be used most effectively.

1106 *Equipment modules* and *control modules* may exist as separate entities under direct control of  
1107 the *process cell*.

#### 1108 4.4.3.3 Unit

1109 A *unit* entity is an engineered subdivision of a *process cell*. It may contain role-based  
1110 *processing* equipment, *equipment modules*, and *control modules*.

1111 Each *unit* shall be engineered to combine all role-base *processing* equipment, *equipment*  
1112 *modules*, *control modules*, and additional *equipment control* (as described in Clause 5) that are  
1113 required to perform one or more major *processing* tasks, such as react, crystallise, and make a  
1114 solution. The *unit* is usually centred on a relatively independent major piece of *processing*  
1115 equipment, such as a mixing tank or reactor. The complete set of required equipment may be  
1116 entirely contained within the *unit* boundaries or may include *equipment modules* or *control*  
1117 *modules* that are *common resources* (see 4.4.3.6) within the same *process cell* and can be  
1118 acquired temporarily by the *unit* to carry out specific tasks.

1119 The *unit* as described in IEC 61512 corresponds to a type of work unit defined in IEC/ISO 62264.  
1120 A work unit may be specialised for different manufacturing types and functions. More than one  
1121 type of work unit, such as a storage unit or a (continuous process) unit may even be required  
1122 in a *batch* oriented *Process Cell*. Unless specifically identified otherwise, the work unit defined  
1123 in IEC 61512 as a *unit* and does not refer to the other types of work units identified in IEC/ISO  
1124 62264.

1125 In a *batch* manufacturing *process*, a *unit* may contain or operate on up to one complete *batch*  
1126 of material at some point in the *processing* sequence of that *batch*. This generally results in a  
1127 physical separation between *batches* that is in many cases also a business requirement.

1128 NOTE 1 When applying the standard to continuous or discrete work units in hybrid batch/continuous or  
1129 batch/discrete (e.g., packaging) process, it may be necessary to disregard the requirement for only one *batch* in a  
1130 *unit* at a time. This is because two or more *batches* may be within a *unit* at the same time while the *unit* processes  
1131 the tail end of one *batch* and the front end of another *batch*.

1132 NOTE 2 In continuous and discrete *processes*, that apply this model, a *unit* may operate on different products  
1133 entering and exiting at the same time. This requires appropriate control in the *unit* to monitor, track, and control the  
1134 logical separation between the different products.

1135 *Units* coordinate the functions of the lower level *equipment entities*, such as *equipment modules*  
1136 and *control modules*. The primary purpose of *equipment control* in a *unit* is to control the  
1137 *processing* of the *batch* that is currently associated with the *unit*.

1138 The definition of a *unit's* boundaries and control functions requires knowledge of the major  
1139 *processing* tasks it will perform, as well as the innate *processing* capabilities of the equipment  
1140 itself. The following guidelines apply.

- 1141 • One or more major *processing* tasks, such as reaction or crystallisation, may take place in  
1142 a *unit*.
- 1143 • *Units* should be defined such that they operate independently of one another.
- 1144 • *Units* operate on only one *batch* at a time.

#### 1145 4.4.3.4 Equipment module

1146 An *equipment module* entity is an engineered subdivision of a *process cell*, a *unit*, or another  
1147 *equipment module*. When contained directly in a *process cell*, it is usually a *common resource*  
1148 (see subclause 4.4.3.6) that may be acquired temporarily to carry out a specific task. It may  
1149 contain role-based processing equipment, other *equipment modules*, and *control modules*.

1150 NOTE When an *equipment module* contains another *equipment module*, it may be referred to as a compound  
1151 *equipment module*. A compound *equipment module* is not considered an additional level in the *equipment entity*  
1152 *model*.

1153 Each *equipment module* shall be engineered to combine the necessary role-based processing  
1154 equipment, other *equipment modules*, *control modules*, and additional *equipment control* (as  
1155 described in Clause 5) required to perform one or multiple minor *processing* tasks. *Equipment*  
1156 *modules* may be engineered around processing equipment such as a heating/cooling system,  
1157 an agitator, a pressure and venting system of a *unit* or auxiliary equipment such as a dosing  
1158 system. Multiple mutually exclusive *processing* tasks which can be performed by the same  
1159 *equipment module* are called *operating schemes*.

1160 EXAMPLE 1 *Operating schemes* of a heating/cooling system may be Inner-Temperature Control, Jacket-  
1161 Temperature Control and Delta Temperature Control.

1162 EXAMPLE 2 *Operating schemes* for a venting system may be Evacuation, Nitrogen-gassing, and High Pressure  
1163 Control.

1164 The complete set of required equipment may be entirely contained within the *equipment module*  
1165 boundaries or may include *equipment modules* or *control modules* that are *common resources*  
1166 (see 4.4.3.6) within the same *process cell* and can be acquired temporarily by the *equipment*  
1167 *module* to carry out specific tasks.

#### 1168 4.4.3.5 Control module

1169 A *control module* entity is an engineered subdivision of a *process cell*, a *unit*, an *equipment*  
1170 *module*, or another *control module*. When contained directly in a *process cell*, it is usually a  
1171 *common resource* (see subclause 4.4.3.6) that may be acquired temporarily to carry out a  
1172 specific task. It may contain control equipment (sensors and actuators) and other *control*  
1173 *modules*.

1174 NOTE When a *control module* contains another *control module*, it may be referred to as a compound *control*  
1175 *module*. A compound *control module* is not considered an additional level in the *equipment entity model*.

1176 Each *control module* shall be engineered to combine the necessary sensors, actuators, other  
1177 *control modules*, and additional *equipment control* (as described in Clause 5) that are required  
1178 to perform some *basic control* function. Multiple mutually exclusive functions which can be  
1179 performed by the same *control module* are called *operating schemes*.

1180 The complete set of required equipment may be entirely contained within the *control module*  
1181 boundaries or may include *control modules* that are *common resources* within the same *process*  
1182 *cell* and can be acquired temporarily by the *control module* to carry out specific functions.

1183 EXAMPLE 1 The following are examples of *control modules*:

- 1184 • an individual sensor or actuator and the associated logic;
- 1185 • a position sensing device and the associated logic;
- 1186 • a regulating loop consisting of a transmitter, a controller, and a control valve that is operated via a set point  
1187 signal;
- 1188 • *state*-oriented equipment that consists of an on/off automatic block valve with position feedback switches  
1189 and is operated via the set point of the equipment;
- 1190 • a header that contains several on/off automatic block valves that coordinates the valves to direct flow to  
1191 one or several destinations based upon the set point directed to the header *control module*.

1192 A *control module* can direct commands to actuators if they have been configured as part of the  
1193 *control module*. A *control module* can also direct commands to other *control modules* if they are  
1194 contained or in some way referenced by that *control module*. Control of the *process* by all  
1195 *equipment entities* is ultimately affected through the equipment specific manipulation of  
1196 actuators by *control modules*.

1197 EXAMPLE 2 The following are examples of *equipment control* in *control modules*:

- 1198 • opening or closing a valve, with confirmation failure alarms;
- 1199 • filtering or de-bouncing the signal from a position sensing device;
- 1200 • regulating the position of a control valve based on a sensor reading and PID control algorithm;
- 1201 • setting and maintaining the *state* of several valves in a material header. This could be a single *control*  
1202 *module* configured to contain all of the valves directly or a compound *control module* configured to contain  
1203 several *control modules*, each of which is configured to directly contain a single valve.

#### 1204 4.4.3.6 Common resources

1205 If more than one requestor (which may be an *equipment entity*, a *batch*, or an operator) can  
1206 acquire or request the services of a single *equipment entity*, then that *equipment entity* is  
1207 designated as a *common resource*. *Common resources* are often present within complex *batch*  
1208 *processes* and are often implemented as either *equipment modules* or *control modules*. A  
1209 *common resource* may be either an *exclusive-use resource* or a *shared-use resource*.

1210 NOTE IEC 61512 focuses on *equipment entity resources*. Other *resource* types defined in IEC 62264-1 are for the  
1211 most part not considered.

1212 If designated as an *exclusive-use resource*, only one requestor may use the *resource* at a time.

1213 EXAMPLE A shared weigh tank in a *batch* plant might be an example of an *exclusive-use resource*. It can be  
1214 used by only one reactor at a time. The *batch schedule* or some other basis for assignment of its services must take  
1215 this *exclusive-use resource* into consideration. If a reactor is waiting for the use of the weigh tank while another is  
1216 using it, the waiting reactor is idle and is not making product, which has a negative effect on equipment utilisation.

1217 If designated as a *shared-use resource*, several requestors may use the *resource* at the same  
1218 time.

1219 EXAMPLE Some *shared-use resources* in a *batch* plant might be a process heater serving multiple *units* at  
1220 the same time or a raw material distribution system which is capable of delivering material to more than one *unit* at  
1221 a time.

1222 If the capabilities of a *shared-use resource* are limited, then it is possible that the requests for  
1223 service might exceed the capacity of the *resource*. In that case, some of the same concerns  
1224 about *allocation* which apply to *exclusive-use resources* also apply to the *shared-use resource*.  
1225 Care must also be taken so that one requestor does not improperly shut off or deactivate a  
1226 *resource* while other requestors are using it.

#### 1227 4.4.3.7 Collapsing and expanding the equipment entity model

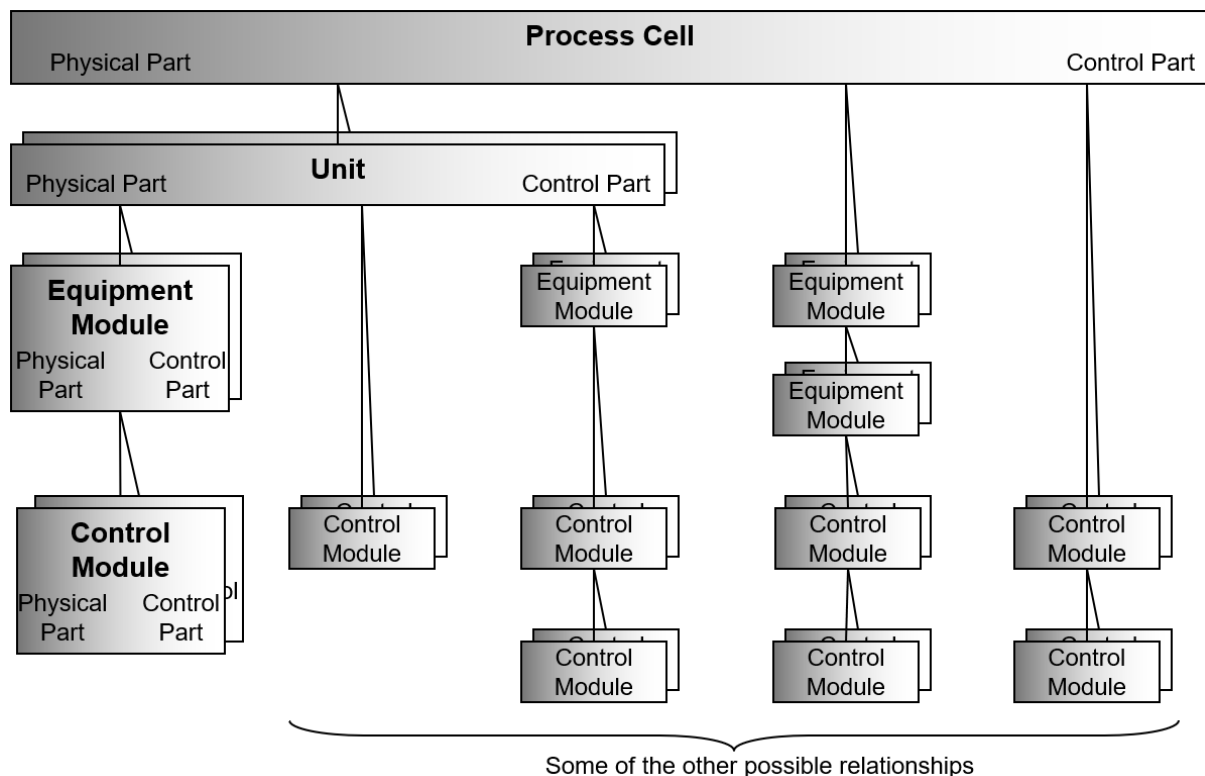
1228 The *equipment entity model* presented is complete as indicated and the levels defined shall not  
 1229 be rearranged or replaced but may be collapsed or expanded to suit different *processing*  
 1230 requirements. Collapsing in this context means omitting one or more defined levels of the  
 1231 *equipment entity model*. Expanding in this context means inserting an additional level into the  
 1232 model.

1233 In an implementation, subdivisions of each *process cell* or *unit* may directly contain any non-  
 1234 overlapping lower level equipment groupings, however, *process cells* may not be omitted and  
 1235 each must contain at least one *unit* entity and in some way a *control module* entity (either  
 1236 directly or indirectly). Since the physical assets of *batch processing* facilities vary greatly, the  
 1237 application of the role-based *equipment entity model* shall be flexible and allow for any  
 1238 combination of lower level subdivisions of each *process cell*, *unit*, and *equipment module*.

1239 Expanding the model below, the *process cell* level shall be restricted to allowing one or more  
 1240 additional levels in the model between the *process cell* and *unit*, however, they shall not use  
 1241 names defined in this part of IEC 61512.

1242 EXAMPLE 1 Figure 4 illustrates *equipment entity* architectures that could be found in typical *batch*  
 1243 environments. The *equipment entities* in this example are shown by type, not by instance name, and the shading  
 1244 highlights that each is in general comprised of both a physical part and a control part.

1245 Note A control module or an equipment module as a software entity can have a scope associated with a particular  
 1246 equipment entity.



1248 **Figure 4 — Equipment entity model example 1**

1249 EXAMPLE 2 Figure 5 illustrates some expected *equipment entity* architectures that could be found in typical  
 1250 *batch* environments. The example shows that in some cases the *equipment module* level may be collapsed (i.e. Unit  
 1251 2 contains Control Module 5 directly).

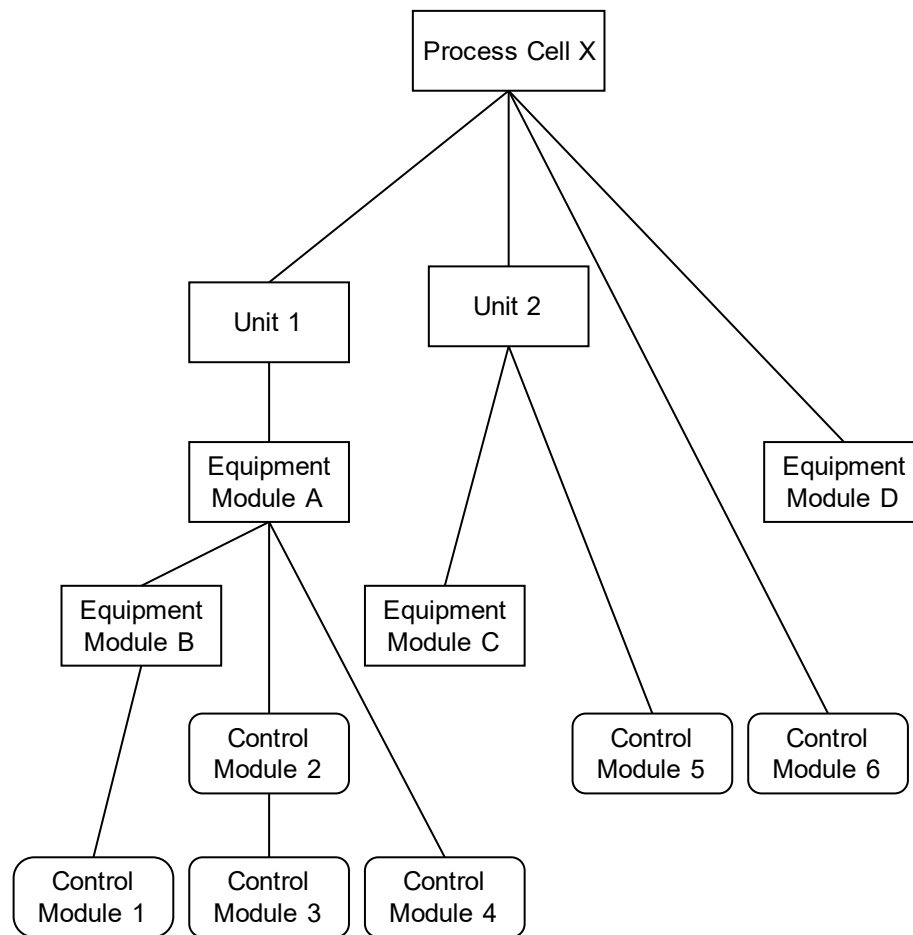


**Figure 5 — Equipment entity model example 2**

## 4.5 Process cell classification

### 4.5.1 General

This subclause (4.5) discusses the classification of *process cells* by the number of different products manufactured in the *process cell* and by the physical structure and role-based equipment entity hierarchy 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 recipe *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 optimise the *process*.

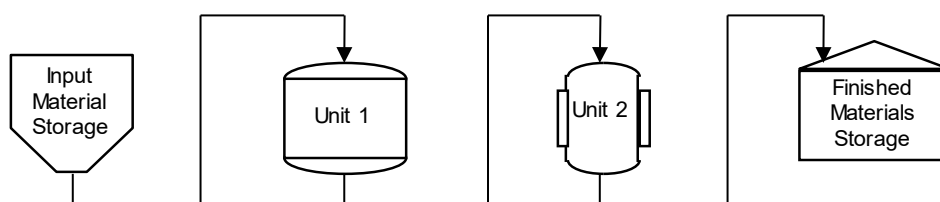
A multi-product *process cell* produces different products utilising different methods of production or control. There are three possibilities.

- 1268 • All products are produced with the same recipe *procedure* using different recipe *formula*  
 1269 values (varying materials, *process parameters*, or both). Sometimes products produced in  
 1270 this way are referred to as grades of a product.
- 1271 • The products are produced using different recipe *procedures*.
- 1272 • The products produced are grouped into families, each sharing a unique recipe *procedure*  
 1273 among its products, but providing different recipe *formula* values for each product.

### 1274 4.5.3 Classification by role-based equipment structure

1275 The order of equipment actually used or expected to be used by a specific *batch* is called the  
 1276 *path*. A *process cell* is classified as single *path*, multiple *path*, or network based on its role-  
 1277 based equipment structure. Regardless of which structure is used, several *batches* may be in  
 1278 progress at the same time (in different *units*), multiple input materials may be used, multiple  
 1279 finished materials may be generated, and *units* may share input material sources and product  
 1280 storage.

1281 A single-*path* structure is a group of *units* through which a *batch* passes sequentially (see Figure  
 1282 6). A single-*path* structure could be a single *unit*, such as a reactor, or several *units* in sequence.



1284 **Figure 6 — Single-path structure**

1285 NOTE Input Material Storage and Finished Materials Storage may be multiple locations.

1286 A multiple-*path* structure is shown in Figure 7. It consists of multiple single-*path* structures in  
 1287 parallel with no product transfer between them. Although *units* within a multi-*path* structure may  
 1288 be physically and/or role-based similar, it is possible to have *paths* and *units* that are of radically  
 1289 different physical design.

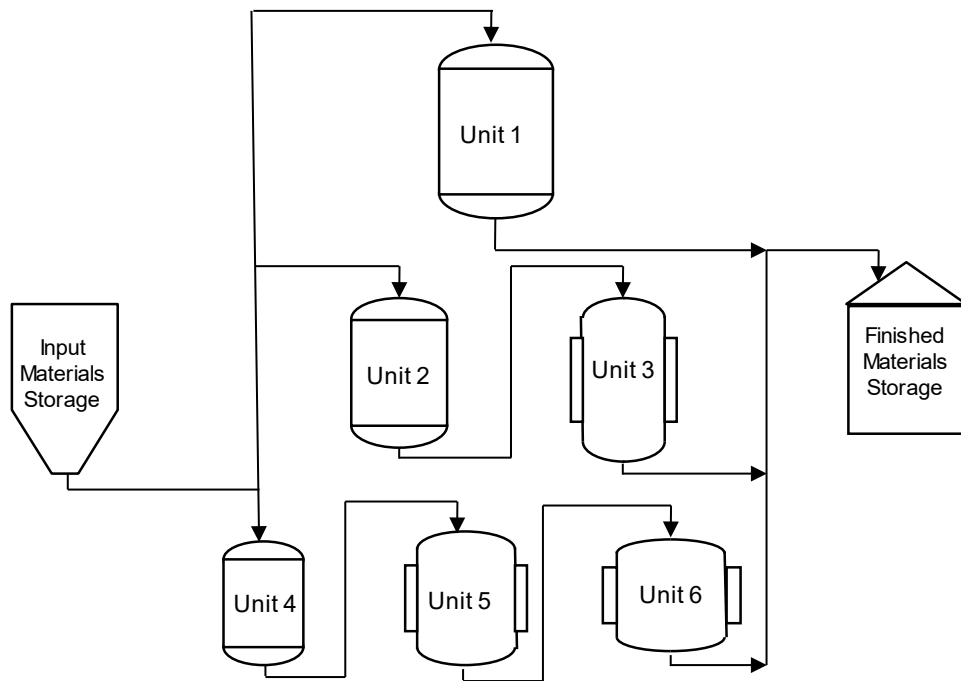
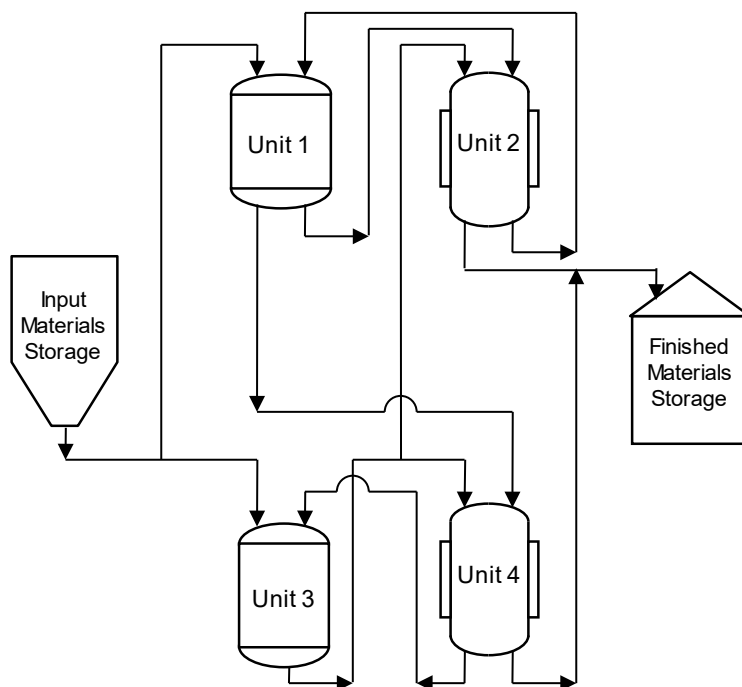


**Figure 7 — Multiple-path structure**

NOTE Input Material Storage and Finished Materials Storage may be multiple locations.

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*.



1300

1301

**Figure 8 — Network structure**

1302 Note Input Material Storage and Finished Materials Storage may be multiple locations.

1303 Actual implementations of these three possible structures for a *process cell* can vary widely. In  
1304 addition, the structure of the *process cell* may include or exclude material storage.

## 1305 **5 Structure for batch control**

### 1306 **5.1 General**

1307 This clause describes the following:

- 1308 • three types of control (*basic control*, *procedural control*, and *coordination control*) typically  
1309 needed to provide *process* functionality and control capabilities for *batch* manufacturing;
- 1310 • the relationship of *equipment entities* to each type of control;
- 1311 • the forms of *coordination control* referred to as *allocation* and *arbitration*;
- 1312 • the relationship of both the *process model* and the *equipment entity model* to the *procedural*  
1313 *control model*.

1314 The controls described may be implemented entirely through automation, through human  
1315 intervention, or through a combination of both.

### 1316 **5.2 Basic control**

#### 1317 **5.2.1 General**

1318 *Basic control* comprises a subset of *equipment control* that is dedicated to establishing and  
1319 maintaining a specific *state* or behaviour of equipment and *process*.

1320 *Basic control*

- 1321 • includes regulatory control, interlocking, monitoring, *exception handling*, and discrete or  
1322 sequential control necessary for establishing or maintaining a specific *state* or behaviour;
- 1323 • may respond to *process* conditions by influencing the control outputs or triggering corrective  
1324 actions;
- 1325 • may be activated, deactivated, or modified by operator commands or by *procedural control*  
1326 or *coordination control*; and
- 1327 • exposes equipment and *process* condition information.

1328 NOTE 1 Regulatory control is dedicated to maintaining a *process* variable or variables at or near some desired value.  
1329 Complex control strategies such as multivariable control, model-based control, and artificial intelligence techniques  
1330 also fit into this category of regulatory control.

1331 NOTE 2 *State-oriented* control refers to setting the *state* of a piece of equipment as opposed to the *state* of a *process*  
1332 variable or variables. *State-oriented* equipment has a finite number of *states* and allowed transitions among them.

1333 NOTE 3 *Basic control* strategies may include *exception handling* logic that is activated when an equipment  
1334 malfunction or abnormal *process* deviation occurs.

1335 The actions of *basic control* in a *batch* environment are in principle no different from the control  
1336 of continuous *processes*. However, in the *batch* environment, there may be higher requirements  
1337 on the ability for *basic control* to receive commands and to modify its behaviour based on these  
1338 commands.

1339 NOTE Annex C.4 further characterises how *basic control* differs from *procedural control*.

#### 1340 **5.2.2 Basic control in equipment entities**

##### 1341 **5.2.2.1 General**

1342 This subclause (5.2.2) describes the role of *basic control* in each level of the *equipment entity*  
1343 *model*.