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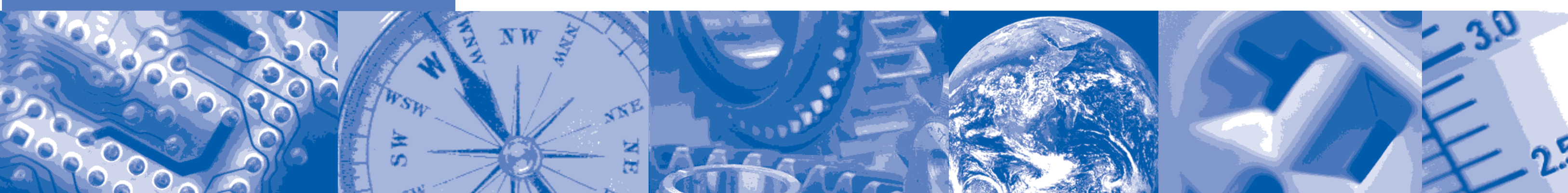


# Batch Control Part 3: General and Site Recipe Models and Representation

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ISA–The Instrumentation, Systems, and Automation Society

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Batch Control Part 3: General and Site Recipe Models and Representation

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# Preface

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

Clause 4, *Recipe Description*, is informative.

Clause 5 is normative. The intent of this clause is to describe the contents of general and site recipes.

Clause 6 is normative. The intent of the clause is to describe an object model of general and site recipes.

Clause 7 is normative. The intent of this clause is to describe a symbolic language for general and site recipe depiction.

Clause 8 is informative. The intent of this clause is to describe some aspects of general or site to master recipe transformation.

The annexes are informative.

This standard is intended for those who are:

a) responsible for defining product processing requirements;

b) involved in designing and/or operating batch manufacturing processes;

c) responsible for specifying controls and the associated application programs for batch manufacturing plants;

d) involved in the design and marketing of products in the area of batch control; or

e) use product information for the purposes of manufacturing or managing the manufacture of product.

The following individuals served as active members of ISA SP88 in preparing this Part 3 standard:

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## Dedicated to Thomas G. Fisher

Almost alone, Tom Fisher initiated the highly visible and successful ISA SP88 batch control standards project, recruiting and energizing diverse committee members, serving as chairman through much of its early work, and continuing in the critical role of project editor until his untimely death. Generous with his time and unstinting in his efforts, Tom provided the leadership, technical expertise, editorial wisdom, and willingness to listen to and give credit to others that have been vital as the ISA 88 series has become a major force throughout the batch processing industries. Although this part of the standard was not finished when he passed away, it bears his imprint. It is dedicated to his memory as one of the giants in the industry.

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# Table of Contents

# Foreword

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

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

In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules insofar as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

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

# Introduction

ANSI/ISA-88.01-1995, Batch Control Part 1: Models and Terminology (referred to as Part 1 throughout this standard) provides models and terminology applicable to batch control. ANSI/ISA88.00.02-2001, Batch Control Part 2: Data Structures and Guidelines for Languages (referred to as Part 2 throughout this standard) addresses data structures and guidelines for languages. This Part 3 standard defines additional information on general and site recipes. Clause 4 of this standard contains definitions of general and site recipes in greater detail than in Part 1. Clause 5 defines detailed description of the contents of general and site recipes. Clause 6 defines a data model that identifies objects and relationships that were addressed in Clauses 4 and 5. Clause 7 defines a method for depiction of general and site recipes that can be used for both simple and complex processing requirements, using both a tabular and a graphical notation. Clause 8 describes some aspects of general or site to master recipe transformation. The annexes provide complementary information.

Although this standard is intended primarily for batch processes, it may have considerable value for other types of processes as well.

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# 1 Scope

This Part 3 standard on Batch Control defines a model for general and site recipes; the activities that describe the use of general and site recipes within a company and across companies; a representation of general and site recipes; and a data model of general and site recipes.

# 2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this Part 3 standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid normative documents.

ANSI/ISA-88.01-1995, *Batch Control Part 1: Models and Terminology* (referred to in this standard as "Part 1").

ANSI/ISA-88.00.02-2001, *Batch Control Part 2: Data Structures and Guidelines for Languages* (referred to in this standard as "Part 2").

IEC 61512-1:1997, *Batch Control — Part 1: Models and Terminology*.

IEC 61512-2: 2001, *Batch Control — Part 2: Data Structures and Guidelines for Languages*.

ANSI/ISA-95.00.01-2000, *Enterprise-Control System Integration Part 1: Models and Terminology.*

ANSI/ISA-95.00.02-2001, *Enterprise-Control System Integration Part 2: Object Model Attributes.*

IEC 60050-351:1998, *International Electrotechnical Vocabulary — Part 351: Automatic Control.*

ISO/IEC DIS 19501-1: *Information Technology—Unified Modeling Language (UML) — Part 1:Specification.*

# 3 Definitions

For the purposes of this Part 3 standard, the following definitions apply. Definitions and concepts expressed in the Part 1 and Part 2 standards apply, except where differences are explicitly stated in this Part 3 standard. Definitions in IEC 60050-351:1998 were also used as a basis.

3.1 equipment-independent recipe:
a super class of a recipe type that is independent of equipment and follows the procedural model of general recipes.

3.2 master recipe transform component:
part of a master recipe that is used in the transformation of an equipment-independent recipe into a complete master recipe.

3.3 process procedure chart (PPC):
a method for the graphical representation of equipment-independent recipes.

3.4 product family:
a set of produced materials that are related by manufacturing business policy.

3.5 product grades:
a collection of similar materials with some variations in properties.

# 4 Recipe description

## 4.1 Recipe types

As defined in the recipe model of the Part 1 standard, a recipe is an entity that contains the minimum set of information that uniquely defines the manufacturing requirements for a specific product. Recipes provide a way to describe products and how those products are produced.

Four types of recipes are defined in Part 1: general recipe, site recipe, master recipe, and control recipe. There are substantial differences between general/site and master/control recipes. General/site recipes describe the equipment-independent processing requirements to make a specific product. Master/control recipes describe the specific actions required with specific equipment to make a batch of product.

Additional information on the four recipe types is defined the Part 1 standard.

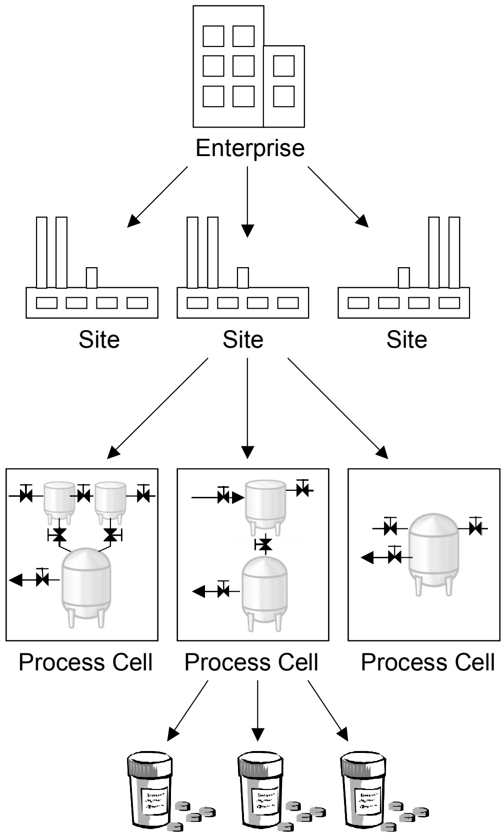
## 4.2 General and site recipe description

### 4.2.1 Manufacturing information

General and site recipes are sources of information for the development of process cell-specific master recipes. Their purpose is to describe manufacturing information without regard to specific manufacturing equipment. They describe, in manufacturing terms, the materials, equipment requirements, chemical transformations, and physical transformations required to manufacture a product.

### 4.2.2 Multiple site definitions

General and site recipes are intended to define processing requirements that can be carried out in differently constructed process cells and that can be valid in multiple areas and multiple sites, as shown in figure 1. In some circumstances, general recipes can even be used to convey product-manufacturing information across multiple enterprises.




One **General Recipe** per produced material, maintained at the enterprise level. For example, 1000 company wide products

One **Site Recipe** per site and produced material, maintained at the site for local materials, language, or segment of production.
For example, 10,000 site recipes for 10 sites

One **Master Recipe** per Process Cell and produced material.
For example, 50,000 master recipes for 5 process cells per site.

One **Control Recipe** per batch.
For example, 1,000,000 batches per year.
Describes the custom options and formula values for one specific batch of product.

**Figure 1 - Recipe hierarchy example**

There are generally fewer general and site recipes in a manufacturing enterprise than master recipes. For example, a small specialty chemical company can have 1,000 general recipes, and 10,000 site recipes for 10 production sites. The company can have 50,000 master recipes, assuming an average of 5 process cells per site that can manufacture the products. Large companies can have thousands of products and millions of master recipes. A single change to a general recipe can result in changes to hundreds of master recipes.

#### 4.2.3 Expansion and collapsing of the recipe type hierarchy

The general and site recipe hierarchy can be expanded or collapsed to meet an enterprise’s needs. For example, a company might only have general recipes and not site recipes. Alternately, a company could include another level of equipment-independent recipes below the site recipe that is specific to an area within a site.

### 4.3 Equipment-independent recipes

#### 4.3.1 Equipment-independent recipe subtypes

General and site recipes are subtypes of a general class of equipment-independent recipes. They have the same structure, information, and display, but they differ by their use within a company, based on company policies.

#### 4.3.2 Activities of equipment-independent recipes

There are multiple possible implementations of equipment-independent recipes within a company. Two commonly used approaches are defined here, one in which equipment-independent recipes are used as input to trial or pilot plant production, another in which equipment-independent recipes are generated as a result of trial or pilot plant production. These approaches are defined for product manufacturing; they do not necessarily apply to other areas of the enterprise, such as research and development (R&D), but the concepts can be beneficial in other areas.

In the examples, the recipes are identified as General Recipes, but they can be any type of equipment-independent recipe.

Development of equipment-independent recipes is typically an iterative process so there will be feedback loops throughout both processes. For simplicity, the multiple feedback loops have not been shown in figure 2 and figure 3.

#### 4.3.3 Input to trial or pilot production

Figure 2 illustrates the activities associated with the generation and use of equipment-independent recipes as an input to trial or pilot plant production.

In this usage scenario, a company generates equipment-independent recipes that are the definitions given to the trial or pilot plant operation. The equipment-independent recipes are converted to master recipes that match the pilot plant equipment layout and the process is scaled up and validated.

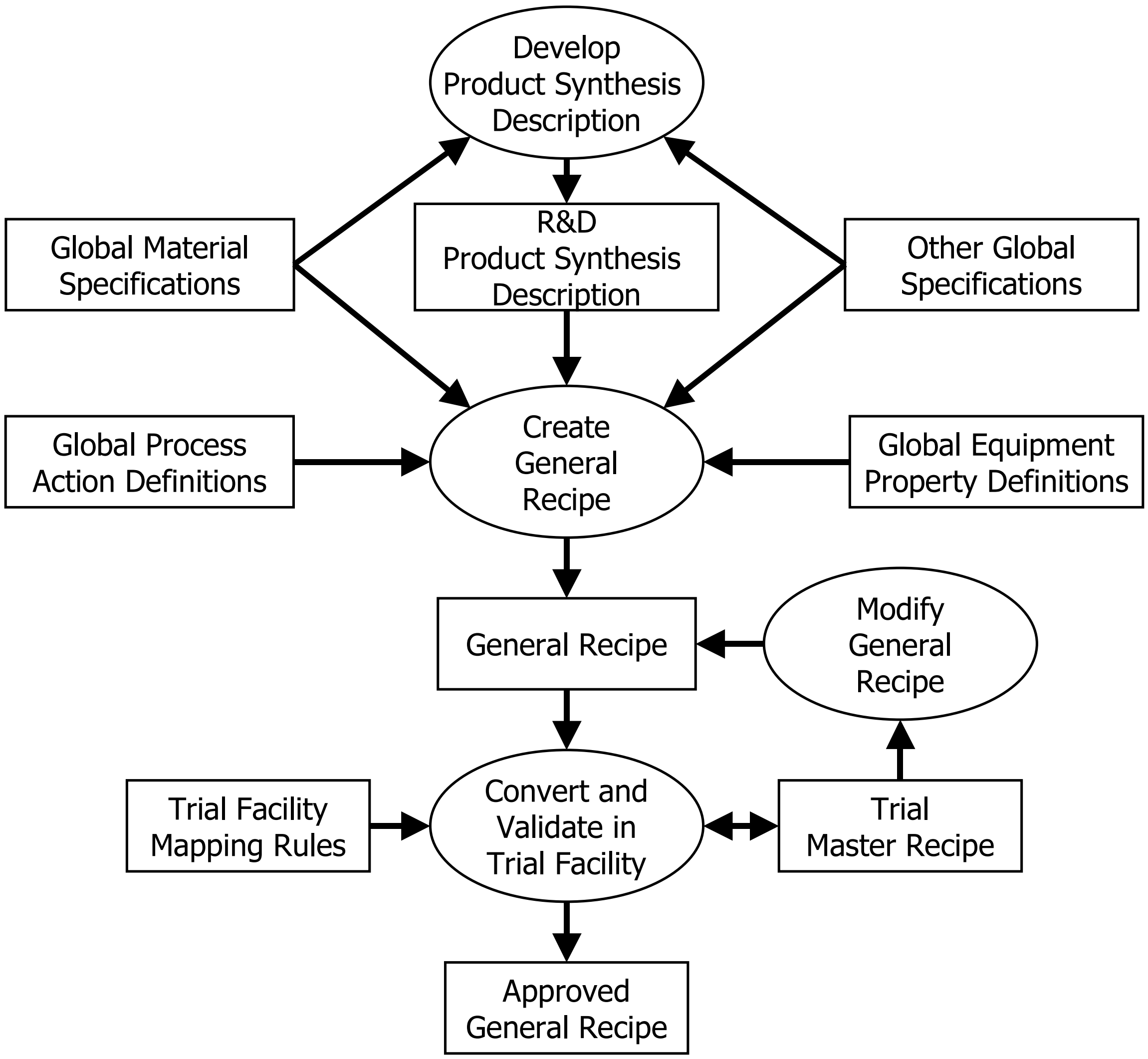



**Figure 2 - Pilot plant creation of equipment-independent recipe**

4.3.4 Output from trial or pilot production

An alternate method for equipment-independent recipes development is the creation of an equipment-independent recipe after the scaleup and verification of the process in a trial or pilot facility, as shown in figure 3. In this model a final equipment-independent recipe is generated after the scale up and verification of the process in a trial or pilot facility. This equipment-independent recipe is usually constructed using the final trial master recipe as the process description.

Note that because of clarity of the process description inherent in formal equipment-independent recipes, it can be advantageous in some circumstances to use the same structure as an input to the pilot plant, even if it is not identified as a recipe.

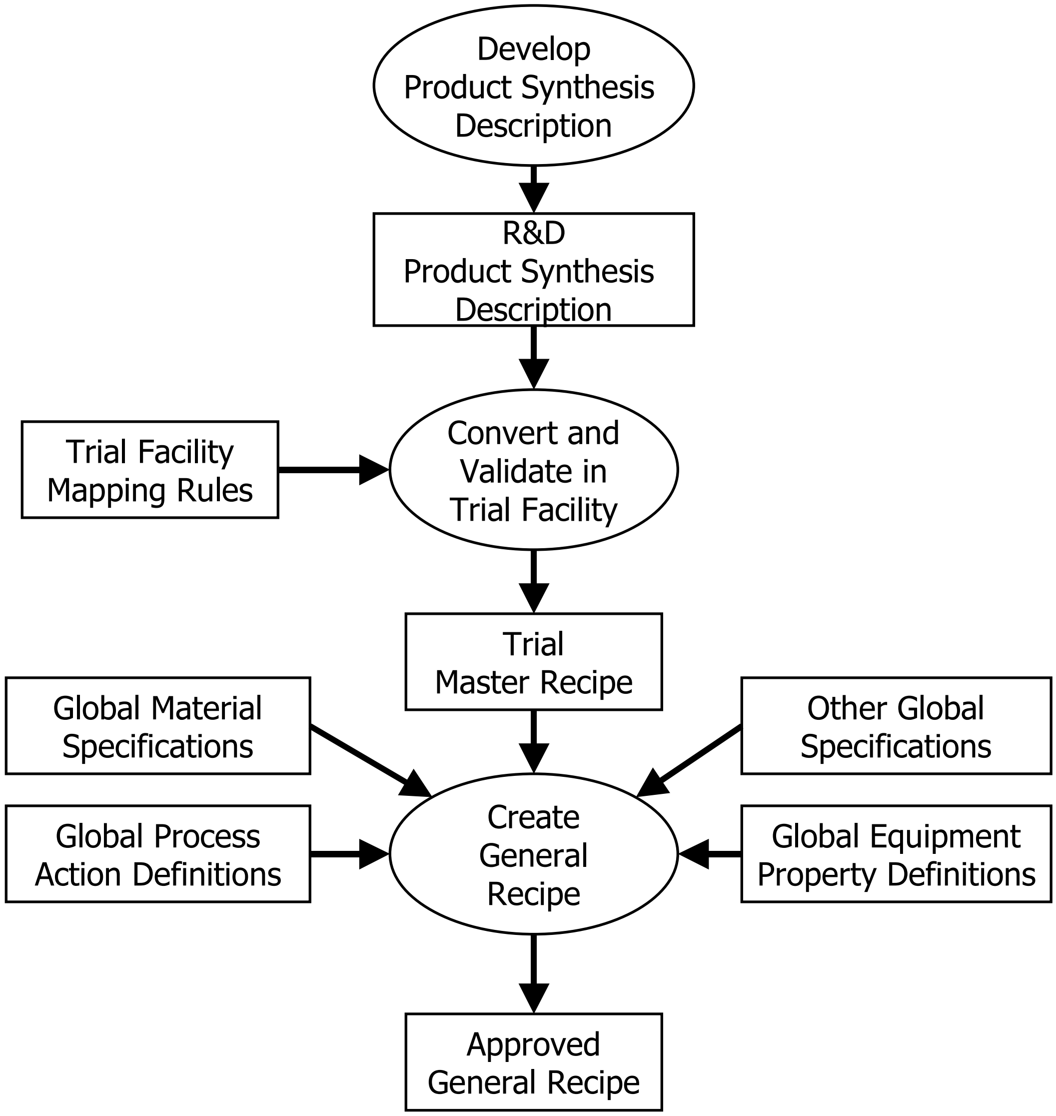



**Figure 3 - Equipment-independent recipe from pilot plant development**

4.3.5 Control of equipment-independent recipes

Equipment-independent recipes are usually tightly controlled because they represent the valuable, proprietary, and unique intellectual capital of a company. It is important that equipment-independent recipes be managed with formal procedures and adequate safeguards for change control.

4.3.6 Equipment-independent recipe process definition

An equipment-independent recipe defines a single process for the production of an intended, or in some cases, multiple intended materials.

4.3.7 Equipment-independent recipe variants

There can be multiple variants of an equipment-independent recipe for a produced material that describe alternate synthesis paths or alternate formula materials. Each variant is described in a separate equipment-independent recipe. An identification method is usually used to indicate the relationship among the multiple variant recipes for the produced material.

For example, multiple equipment-independent recipes might be used to make a wood- based glue product. Different recipes would be used based on the time of the year or species of trees used. All of the general recipes would specify the same final product, but could be identified by variant.

4.3.8 Source of scheduling information

Equipment-independent recipes, and in particular site recipes, provide a source for scheduling and planning information for a corporation. A site recipe defines all of the processing materials required to make a product, or a portion of a product, at a site. It also contains information about the resources required to make the product; information that can be useful for production and resource scheduling.

Equipment-independent recipes, and in particular site recipes, provide a source for site scheduling and planning information including:

a) information about materials required to make a product, or a portion of a product

b) information about the resources required to make the product

In cases where site recipes are not used (e.g., all sites use the same general recipe), then for purposes of scheduling the general recipe can be considered a site recipe.

Master recipes are needed for detailed scheduling of process cells and units, because these schedules require knowledge of the specific equipment required.

4.3.9 Equipment-independent recipes and business information

Recipes correspond to *product production rules*, as defined in ANSI/ISA-95.00.01-2000. General and site recipes correspond to equipment-independent *product production rules*; master and control recipes correspond to equipment-specific *product production rules*.

Because a site recipe can be defined for many process cells, with different structures, it is often used as a basis for site planning information, as specified in ANSI/ISA-95.00.01-2000.

There is an overlap of the information contained in a site recipe and the Bill Of Materials (BOM) used in business systems to manage and schedule materials. This overlap is identified as a Manufacturing Bill in ANSI/ISA-95.00.01-2000, and is made up of the site recipes' process inputs. The site recipe can be the source of information for the manufacturing bill. See figure 4.

There is an overlap of information in a site recipe and the Bill Of Resources (BOR) used in business systems to schedule production. The overlap is defined as Process and Product Segments in ANSI/ISA-95.00.01-2000 and can correspond to the site recipe's process stages and process operations.

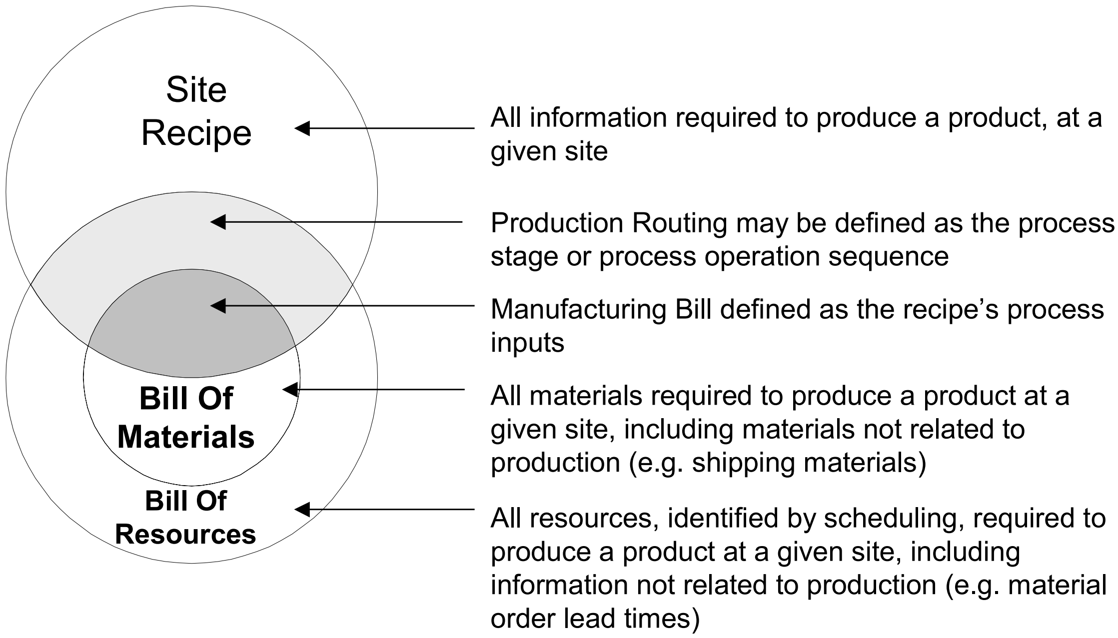



**Figure 4- Site recipe, BOM, and BOR information overlaps**

4.3.10 Equipment-independent recipes for capability comparison

Equipment-independent recipes allow product-manufacturing specifications to be compared with equipment capabilities. The generalized equipment and process requirements contained in an equipment-independent recipe can be matched against definitions of site or process cell equipment capability to determine where a product can be manufactured, to determine where parts of the product can be manufactured, or to determine what additional equipment capability is required to manufacture the product.

4.3.11 Equipment-independent recipes as facility design specifications

Equipment-independent recipes are, by their very nature, a useful component of a facility design specification. Equipment-independent recipes in their native form often are not directly usable as specifications, but they do contain information required for a facility specification in a formal, understandable, and standard format. Examples of the use of equipment-independent recipes for facility design include the following:

a) The collection of equipment-independent recipes formally defines the processing requirements and some of the associated equipment requirements for the facility.

b) The process dependencies are useful in the definition of material flows between units and between process cells.

c) The formulas within the equipment-independent recipes precisely define the materials that are to be handled by the facility.

d) The formulas clearly define the ratios of amounts of materials, including expected yield amount compared to raw material amounts.

e) The process definition can include product-dependent processing times, when these are based on chemistry requirements rather than on equipment size.

f) Recipes and anticipated production schedules, as defined in ANSI/ISA-95.00.01-2000, when combined can be used to determine equipment capacities.

## 4.4 General recipes

### 4.4.1 Enterprise-wide definition

A general recipe defines the manufacturing requirements for a specific product or range of product. It is independent of the actual site or equipment that could be actually used to manufacture the product. A general recipe can be considered as the technical specification of the process to make a product.

A general recipe is an enterprise-wide recipe that serves as the basis for site and master recipes. It is created by people with knowledge of both the chemistry and processing requirements for the product. It identifies raw materials, their relative quantities, the required processing, and order of processing. It defines processing capabilities required, such as cooling or heating, or generalized equipment requirements such as glass-lined reactors. It does not define specific equipment that has to be used to implement processing, but it specifies authorized types of equipment, usually when it is critical to the process described.

The general recipe is suitable across the entire enterprise. It contains the manufacturing requirements for a particular material in terms that can be used by all sites that manufacture that material. It also can serve as input for corporate production planning and standard costing.

### 4.4.2 Purpose of a general recipe

A general recipe is a corporate recipe that defines processing required to manufacture a single uniform product at different manufacturing sites and cells. Possible variations between these manufacturing sites can be in their plant topologies, raw materials, and degree of automation. A general recipe for a product might only be created after a master recipe for the product has been proven in one or more sites.

A general recipe should not be generated by a chemist or formulator based only on their experience in producing a product in a laboratory environment. It should be based on company-accepted definitions of manufacturing capabilities and is often tested in a production environment before it is fully accepted.

### 4.4.3 General recipe information

#### 4.4.3.1 Manufacturing information

General recipes contain manufacturing information, and cannot be complete until the manufacturing process is well defined. They are typically developed during the scale-up verification of manufacturing and process requirements at pilot plants or other process trial or scale-up facilities. General recipes contain references to a company's basic manufacturing capabilities. Development of general recipes can also involve process development as well as product development, as shown in figure 5. The general recipe provides a means for unambiguously communicating processing requirements to multiple manufacturing locations.

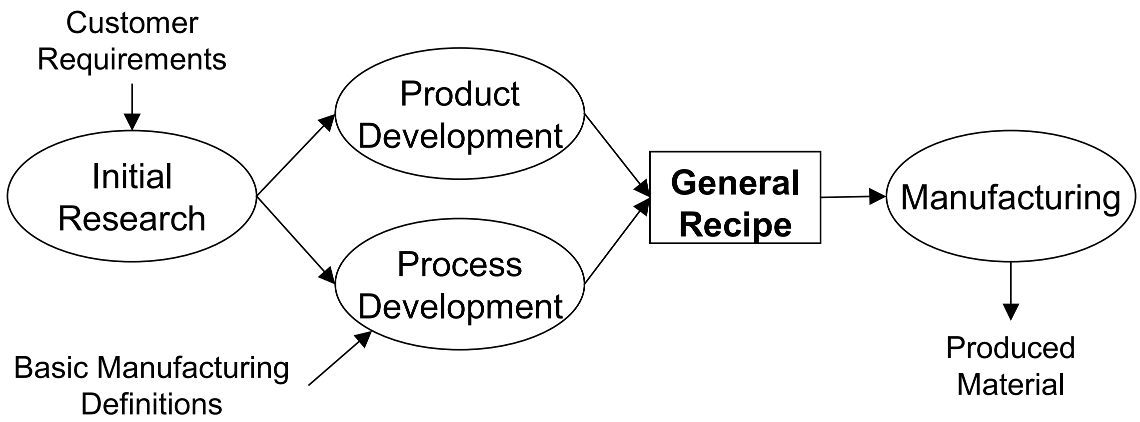



**Figure 5- General recipes in a typical development function**

#### 4.4.3.2 Product development

Product development results in the definition of the product and product specifications. It includes definitions of how to make the product, at least in laboratory scale. It results in basic understanding of the chemistry and processing requirements peculiar to the product. Product development can result in equipment requirements that are described in enough detail to define the type of equipment needed.

#### 4.4.3.3 Process development

Process development results in the definition of the manufacturing processes required to produce the product within product specifications. Process development takes into account the currently defined basic manufacturing process definitions. If additional manufacturing processes are needed, for example because of unique new chemistry that requires new process actions, then process development defines the new process requirements.

## 4.5 Site recipes

### 4.5.1 Site-specific recipes

The site recipe is a type of recipe that is specific to a particular site. A site recipe is the combination of site-specific information and general recipe information. Such things as the language in which it is written or local raw material differences are accommodated as site-specific variances. It is usually not specific to a particular set of process cell equipment.

A site recipe is usually derived from a general recipe to meet the conditions and requirements found at a particular manufacturing location and provide the level of detail necessary for site-level, long-term production scheduling. However, it can also be created directly without the existence of a general recipe.

### 4.5.2 Site recipe definition

A site recipe has the same structure as a general recipe, but the information in the site recipe is tailored for each target location. The site recipe can be modified for the local language (e.g., French, German, or English), the local unit of measure (e.g., English or metric), local requirements and/or local raw material availability. The site recipe can include only a part of the process defined in the general recipe that is actually implemented on the site. For example, a single product can have intermediate materials manufactured at one site that are then shipped to a second site for final processing. In that case, each site recipe would be derived from only the portion of the general recipe actually required for the processing to be done at that site.

Typical reasons for the use of site recipes include:

a) Site recipes can be used to define local variations in the recipe production process or recipe presentation. These variations might include such factors as:

- Local regulations
- Local language
- Local units of measure
- Local materials availability
- Local requirements
- Alternate raw materials

b) When production of a product defined by a general recipe is split across multiple sites, a site recipe may only define the portion of a manufacturing process appropriate for the site.

c) Site recipes can be used to provide a site-level genealogy link to master recipes.

d) Site recipes can be defined locally for materials that are only produced and consumed at the site.

e) Site recipes can be used for site-costing purposes.

f) Site recipes can be used as a source of manufacturing specifications for matching against area and process cell equipment capabilities.

g) Site recipes are a source of information about production requirements, material requirements, and material ratios for the design of a production facility.

#### 4.5.3 Site recipe policies

Site recipes are not always used. Their use is determined by a company's policy. If site recipes are used, then a company should define a policy for control of the recipes. For example, a policy can be defined in which a site generates its own site recipes that are not shared with other sites or corporate management, or a site only receives site recipes generated for the site and never receives general recipes. An alternate policy would allow sites to generate site recipes based on copies of approved general recipes.

### 4.6 Product families and product grades

#### 4.6.1 Product definition

The Part 1 standard uses the term "product" to define the output of a process cell. The definition of a finished or final product is defined at the enterprise level and is often differentiated by things other than the production processes; for example, it can be defined by packaging, brand name, or delivery form. The definition of a final or finished “product” is beyond the scope of this standard. However, the terms "product family" and "product grade" are commonly used to define classifications of products and can apply to both the product of a process cell and/or to final or finished products.

#### 4.6.2 Product families

Sets of produced materials that are related by manufacturing process or business policy are sometimes identified as product families. Examples of product family definitions include:

a) A collection of produced materials that are all manufactured using the same process definition.

b) A collection of produced materials manufactured using the same equipment.

c) A collection of produced materials where the same manufacturing processes are used but different packaging processes are used.

d) A collection of produced materials that are defined by business rules rather than manufacturing rules, such as for forecasting of demand.

#### 4.6.3 Product grades

Product grades are collections of similarly produced materials with variations in properties. Typical implementations of product grades use multiple recipes that all use the same procedure, but have different formula values. In this situation there is one recipe per product grade.

In some cases a single recipe can also produce product grades. In this situation process variability or material property variations produce a range of products that match various product quality specifications.

## 5 Equipment-independent recipe contents

### 5.1 Recipe information

General and site recipes are equipment-independent recipes. Equipment-independent recipes shall contain the same categories of information as master and control recipes: header, formula, procedure, equipment requirements, and other information as defined in the Part 1 standard.

### 5.2 Recipe life cycle states

Equipment-independent recipes shall have an associated life cycle state. The state information is used to define the current state of the recipe definition.

The minimum set of equipment-independent recipe life cycle states that shall be supported is defined in table 7.

There should be an association of the life cycle state of an equipment-independent recipe with the life cycle states of the elements the recipe references (process actions, equipment requirements, and materials). There should be a policy and process in place to ensure the life cycle states are consistent. For example, if the state of a referenced material becomes “Withdrawn,” then the state of all recipes referencing the material are made “Withdrawn.”

### 5.3 Recipe header

The administrative information in an equipment-independent recipe is referred to as the header. Header information in an equipment-independent recipe may include such items as recipe identification, product identification, version number, product family, product grade, originator and life cycle state.

## 5.4 Recipe formula

The formula is a category of equipment-independent recipe information that includes process inputs, process parameters, and process outputs. The process inputs and process outputs identify materials or resources and quantities of materials or resources.

Materials used in equipment-independent recipes shall be identified by material definitions or material classes as defined in ANSI/ISA-95.00.01-2000. Equipment-independent recipes do not use *material lot* definitions (see ANSI/ISA-95.00.01-2000).

Material definitions and material class definitions should be maintained in a material definition library to ensure that only valid material definitions are used in equipment-independent recipes.

A material definition shall have an associated state. The state information is used to define the life cycle status of the material definition, and the life cycle state of equipment-independent recipes using the material definitions.

The minimum set of material definition and material class states that shall be supported are defined in table 7.

## 5.5 Recipe procedure

### 5.5.1 Process model

The procedural part of an equipment-independent recipe is defined according to the process model described in the Part 1 standard.

### 5.5.2 Process hierarchy

An equipment-independent recipe procedure shall define a process as a set of one or more process stages. Stages are comprised of process operations, and process operations are comprised of process actions. Figure 6 illustrates this hierarchy.

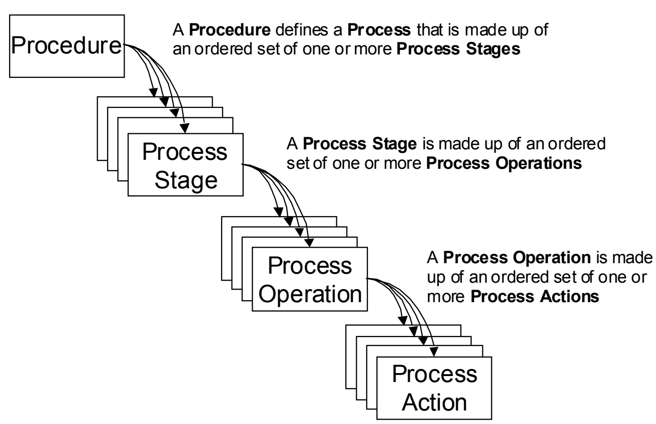



**Figure 6– Equipment-independent recipe procedure definition**

A procedure is made up of process stages; the process stages are made up of process operations, which in turn are made up of process actions.

There is a significant difference between the procedure definition in a master recipe and the procedure definition in an equipment-independent recipe. A master recipe's procedure is focused on specific process-oriented tasks carried out in specific process cell equipment and is often dependent on the organization of a process cell's equipment. An equipment-independent recipe's procedure is focused on the order that materials are processed and the character of the processing required. For example, some materials have to be operated on independently before they are joined, because the materials react or mix to form different materials or unique compounds.

### 5.5.3 Ideal procedure for manufacture

The sequence of process stages, process operations and process actions define an ideal procedure for the manufacture of a successful product. Exception logic or exception conditions are generally not specified in the procedure definition, but can be specified in the recipe's other information.

### 5.5.4 Process stage

A process stage defines a part of a process that usually operates independently and usually results in a planned sequence of chemical or physical changes in the material being processed. Process inputs and process outputs depicted in a recipe should always be identified resources or materials. In the case where a process output from one stage is a process input to another stage, this material is called a process intermediate and does not need to be otherwise identified. Process stages can generate multiple process outputs or process intermediates.

### 5.5.5 Process operation

A process operation is a major processing activity that is defined without specification of the actual target equipment configuration and usually results in a chemical or physical change in the material being processed. Process operations are generally defined based on chemical or physical considerations. Some reasons for process operations are:

a) As a natural organizational structure to identify major processing steps

b) As an identification of possible operation boundaries for subsequently generated master recipes

c) To identify equipment requirements for actions within the operation.

Process operations are presumed to operate in sequence on the material defined in the process stage.

### 5.5.6 Process action

A process action is a minor processing activity, such as grind, cool, heat, delay, test or mix. Many actions are simply the addition of material, removal of material, addition of energy, or removal of energy.

Even the simple addition of a material can be performed through different types of process actions. For example, the addition rate could be fixed or could be controlled by a process variable such as a pressure, temperature, or pH.

There can also be company-specific process actions that define unique processing capabilities of a company, such as separation or packaging. There can also be industry-specific process actions, such as catalytic conversions or property state changes.

Process actions within the operation are presumed to operate on the defined materials in a defined sequence. The sequence of process actions may be serial or parallel and may contain multiple branches.

#### 5.5.7 Definition of equipment requirements

Process elements are equipment-independent, but they may define requirements for the target equipment or production environment, usually when the equipment or environment characteristics influence the chemistry or physics of the production process. For example, in the production of some chemicals for color photography film, the presence of nickel in the process vessels or pipes will fog the resultant film. In this example, the process stage defining the production of the chemical would have an equipment requirement that specifies that all vessel and pipe lining are free of nickel. Another example could be a concern that the material is shear sensitive, and there could be an equipment constraint specifying that any target equipment has low shear properties.

#### 5.5.8 Process stage guidelines

##### 5.5.8.1 Identifying characteristics

This section aids in the identification of process stages. It focuses on the identifying characteristics of process stages and is meant as guidelines for identifying process stages, not as absolute rules.

##### 5.5.8.2 Process-related guidelines

a) A process stage usually describes a major physical or chemical function in a manufacturing process, such as grinding, mixing, chemical synthesizing, fermenting, and packaging.

NOTE: This may even be considered the primary characteristic used in defining a process stage.

b) A process stage can lead to the production of more than one material.

NOTE: For example, a process stage involving separation may produce multiple primary materials.

c) A process stage can usually be associated with some major transformation of the material, and can be identifiable as a way to implement a specific named chemical reaction.

NOTE: This is a secondary defining characteristic, but it does have meaning to chemists who have to interpret general recipes.

d) A process stage deals with a single collection of material.

e) Materials have to be operated on independently.

NOTE: Materials in separate stages can be assumed to be independent (not reacting) with the other materials until the materials are combined through specific process actions.

f) Materials can be operated on asynchronously.

NOTE: Intermediate materials may be pre-made and stored for later use.

g) There are common chemical or physical properties required for the target equipment.

NOTE: Equipment requirements can be applied to an entire stage. This means that any target equipment, for any of the process actions and any intermediate material movement system, meet the equipment requirements.

#### 5.5.8.3 Non-process related definitions

a) Different parts of the processing described in the equipment-independent recipe can eventually be carried out in more than one process cell, requiring the intermediate material to cross cell boundaries with possible intermediate storage.

NOTE 1 — The process stage provides a convenient organizational structure for splitting a general recipe into smaller parts.

NOTE 2 — A process stage defines processing that will likely be implemented in a single process cell.

b) Different parts of the equipment-independent recipe can eventually be carried out on different sites, requiring the intermediate material to be transported between sites.

NOTE: Part of the definition of a site recipe is as the subset of a general recipe that can be implemented on a site. Process stages provide a convenient organization structure for splitting a general recipe into multiple site recipes. One or more stages can then be implemented on each site, and intermediate materials may be shipped between sites.

c) An intermediate material has to be separately inventoried.

NOTE 1 — Intermediate materials possibly have a unique cost, or value, to the company and possibly have to be identified and inventoried for tax or accounting purposes. Many intermediates can also be final products and are either sold or used based on customer demand.

NOTE 2 — Process stage boundaries can be used to identify inventoried intermediates.

d) Intermediate materials can be purchased instead of produced, so that part of the equipment-independent recipe would not need to be transformed into a segment of a master recipe.

NOTE: Process stage boundaries can be used to identify intermediates that can be obtained locally instead of being produced.

e) The same intermediate materials can be used in multiple products or general recipes.

NOTE: A library of process stages can be developed for commonly used intermediate materials. Many companies generate hundreds of products based on a much smaller number of common intermediates.

f) The production of intermediate materials has to be separately planned and scheduled.

NOTE: If the production of intermediates takes significant time, or uses constrained resources, then process stages can be used to identify process breakpoints to balance workload on capacity-constrained equipment.

### 5.5.9 Process operation guidelines

#### 5.5.9.1 Identifying characteristics

Process operations make up process stages. These are major processing events that carry the batch through a chemical or physical transformation. Process operations are closely related to the traditional chemical engineering unit operations.

This section aids in the identification of process operations. It focuses on the identifying characteristics of process operations and is meant as guidelines for identifying process operations, not as absolute rules.

#### 5.5.9.2 Process-related guidelines

a) A process operation can be identified with some physical or chemical change in the material. The change is typically not reversible.

b) There can be different equipment requirements required within a stage; the equipment requirements can be associated with process operations.

c) Process operations can be used to separate process actions that work together to perform a basic function.

d) Process operation boundaries can occur at natural breakpoints in production, when the material being created has readily identifiable characteristics.

e) Process operation boundaries can occur where there are test points or decision points in related master recipes. Test points and decision points are often associated with delays while tests are run. The process operation provides a convenient boundary for test points.

f) Common process operations can be defined and used in multiple recipes.

5.5.9.3 Non-process-related guidelines

a) Process operations can be defined to simplify transformation of an equipment-independent recipe to master recipes. The process operations can be used to define the boundaries of master recipe unit procedures or operations. This can be information used by people generating master recipes, or information used by automated conversion facilities.

b) Process operations can be defined to segment a long process stage. They serve as bookmarks or chapter headings to break up a long series of actions.

c) Process operations can be defined because activity-based cost accounting needs finer granularity than is provided by process stages.

d) Process operations can be defined as a boundary condition so that the resultant target equipment can be reconfigured between master recipe operations.

5.5.10 Process action guidelines

5.5.10.1 Identifying characteristics

This section aids in the identification of process actions. It focuses on the identifying characteristics of process actions and is meant as guidelines for identifying process actions.

5.5.10.2 Process action library

Process action definitions should be maintained in a process action library in order to ensure that only accepted and broadly understood process action definitions are used in equipment-independent recipes. In this context, the term *library* is used to indicate the collection of available process action definitions, and not meant to imply any specific storage or management mechanism.

Before any recipe can be written, the basic building blocks have to be available. For an equipment-independent recipe, the minimal necessary building blocks are the process actions. If these building blocks have not already been defined, their process intentions fully described, and the necessary parameters identified, the author of the recipe will be forced to define his or her own nonstandard action. If this happens there will be confusion over the true intention of the author or just how the parameters are expected to work within the process action. There would also be the likelihood of differences from one recipe to the next and from one author to another.

Process actions are defined and available for use at the time of the recipe's creation. Using pre-defined building blocks not only makes it easier to construct the recipe, but it also standardizes them, making possible a better understanding of their process intent by those who are ultimately responsible for making everything operate in the actual equipment. The effective use of equipment-independent recipes requires that there is a well-defined and documented set of process actions from which all recipes are built.

5.5.10.3 Process action states

Process actions in the process action library shall have an associated state. The state information is used to define the life cycle state of process action definition, and the life cycle state of equipment-independent recipes using the process action.

The minimum set of process action states that shall be supported is defined in table 7.

5.5.10.4 Process action elements

Process actions in the process action library shall have the minimum set of properties defined in table 1.

**Table 1- Process action properties**

| Property | Property Description |
|---|---|
| Unique Identification | Used to identify the specific process action and version of the process action. |
| Functional Description | Used to describe the intent of the action. |
| State | Used to define the life cycle state of the process action definition. |
| Parameters | Used to optionally parameterize each specific use of the process action in a recipe. |

5.5.11 Process action types

5.5.11.1 Environment setting actions

There are process actions that alter processing conditions: the environment within which processing occurs. This environment is typically defined in terms of temperature, pressure, mixing state and other processing conditions. There are at least two alternatives to setting the environment of the process, using either a non-persistent or a persistent model. Whichever model is chosen, it is necessary to unambiguously communicate it to those who interpret the equipment-independent recipe to generate master recipes.

5.5.11.2 Non-persistent actions

The non-persistent model defines process actions that define the environment only when they are active. In this model a mechanism is needed to document the parallel execution of process actions. In the example shown in figure 7 in graphical format, the process actions of HEAT and MIX run in parallel to the CHARGE, WAIT, CHARGE, and TEST actions.

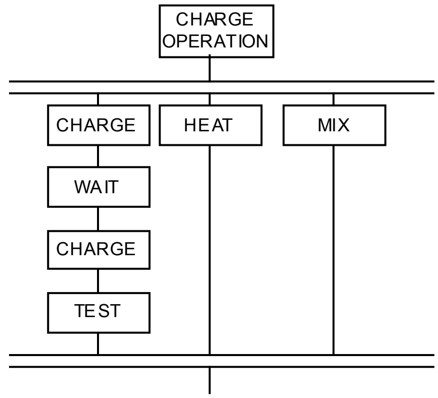



**Figure 7- Non-persistent process actions**

5.5.11.3 Persistent actions

The persistent model defines process actions that set the environmental conditions that are maintained until altered by another process action or external command. In the example shown in table 2, using a table format, the heating and mixing are on during the CHARGE, WAIT, CHARGE, and TEST actions. In this example, the process action “MIX ON” starts mixing and continues mixing until the process action “MIX OFF” is reached, and “HEAT ON” starts heating and continues until the process action “HEAT OFF” is reached.

**Table 2 - Persistent process action table format example**

| Sequence Order | Sequence Path | Process Operation or Process Action | Material |
|---|---|---|---|
| ⇩ | 0 | CHARGE OPERATION | |
| ⇩ | 0 | HEAT ON | |
| ⇩ | 0 | MIX ON | |
| ⇩ | 0 | CHARGE | Material A, 25% |
| ⇩ | 0 | WAIT | |
| ⇩ | 0 | CHARGE | Material A, 75% |
| ⇩ | 0 | TEST | |
| ⇩ | 0 | HEAT OFF | |
| ⇩ | 0 | MIX OFF | |

5.5.11.4 Adding materials

There are process actions that add materials. These can be parameterized and there can be different actions depending on how the material is to be added. Table 3 lists some example process actions for material addition.

## Table 3 – Material addition process action examples

| Process Action Name | Functional Description | Parameters |
| --- | --- | --- |
| Charge | Add the specified material. There is no rate constraint on the material addition. Usually used where there is no expected chemical reaction. | Material To Add<br>Amount to Add |
| ChargeAtRate | Add the specified material at the specified rate and tolerance. Usually used when mixing is required or too fast a rate will cause an undesired chemical reaction. | Material To Add<br>Amount to Add<br>Percent Per Minute<br>% per Minute Tolerance |
| ChargeAtTemperature | Add the specified material so the temperature of the material being produced stays within the specified value. This can require heating or cooling capability. Usually used when an exothermic or endothermic chemical reaction will occur. | Material To Add<br>Amount to Add<br>Maximum Temperature<br>Minimum Temperature<br>Temperature Tolerance |

5.5.11.5 Removing materials

There are process actions that remove materials from the process. These can be parameterized and there can be different actions depending on how the material is to be removed. Table 4 lists some example process actions for material removal.

## Table 4 - Material removal process action examples

| Process Action Name | Functional Description | Parameters |
| --- | --- | --- |
| Dry | Dry the material to remove any water or other safely evaporated materials. | Material To Remove<br>Expected Amount Removed<br>Minimum Temperature |
| EvaporateSolvent | Remove a solvent through evaporation. The solvent is to be retained and not dispersed into the atmosphere. | Material To Remove<br>Expected Amount Removed<br>Evaporation Temperature |
| FilterSolids | Remove solids. | Material To Remove<br>Expected Amount Removed |

5.5.11.6 Adding energy

There are process actions that add energy to the process. These can be parameterized and there can be different actions depending on how the material is to be heated. Table 5 lists some example process actions for energy addition.

## Table 5 - Energy addition process action examples

| Process Action Name | Functional Description | Parameters |
|---|---|---|
| Heat | Induce energy to flow into the material. | Final temperature |
| HeatProfile | Control the rate at which energy is added to the material. There can be one or many sets of parameters for different profiles. | Rate to heat<br>Holding temperature<br>Holding time |

5.5.11.7 Removing energy

There are process actions that remove energy from the process. These can be parameterized and there can be different actions depending on how the heat is removed. Table 6 lists some example process actions for energy removal.

## Table 6 - Energy removal process action examples

| Process Action Name | Functional Description | Parameters |
|---|---|---|
| Cool | Induce energy to flow out of the material | Final temperature |
| CoolProfile | Control the rate at which energy is removed from the material. There can be one or many sets of parameters for different profiles. | Rate to cool<br>Holding temperature<br>Holding time |

## 5.6 Equipment requirements

### 5.6.1 Requirements of final manufacturing equipment

Equipment requirements are a statement of the specific requirements of the final manufacturing equipment necessary to bring about the process activities, as well as to document certain important attributes of the equipment needed in this process.

### 5.6.2 Equipment selection

An important reason for having equipment requirements in the recipe is to assist in selecting suitable equipment sets in which a product is to be manufactured. It is especially useful if the selection process is to be automated. Equipment requirements provide information upon which a comparison of the characteristics and attributes of existing plant equipment can be made in order to determine the suitability of selected equipment.

### 5.6.3 Constraining target equipment

Equipment requirements define the constraints to be placed on target equipment, usually where the constraints impact the chemical or physical processing of the material. For example, the chemistry of a process stage could require that the operations occur in glass-lined reactors and Teflon-lined pipes, because materials being processed will interact with normal steel containers and pipes.

#### 5.6.4 Managing equipment requirement definitions

Equipment requirement definitions should be maintained in an equipment requirement library in order to ensure that only available equipment requirement definitions are used in equipment-independent recipes. In this context, the term *library* is used to indicate the collection of available equipment requirement definitions, and not meant to imply any specific storage or management mechanism.

Equipment requirement definitions in the equipment requirement definition library shall have an associated life cycle state. The state information is used to define the life cycle state of the equipment requirement definition, and the life cycle state of equipment-independent recipes using the equipment requirement definitions.

The minimum set of equipment requirement definition life cycle states that shall be supported is defined in table 7.

### 5.7 Other information

A general recipe is a container of production information required for manufacturing, including the process definition, material identification and amounts, material quality information, and references to test definitions and test standards. Examples of other information often included with equipment-independent recipes are:

a) Spreadsheets detailing known process sensitivity models

b) Complete process models

c) Pictures of good products

d) Pictures of bad products and possible failure reasons

e) References to test methods and test specifications

f) References to material data safety sheets

g) Additional health and safety information

h) Packaging information

### 5.8 Life cycle states

Life cycle states for equipment-independent recipes, process action definitions, equipment requirement definitions, material class, and material definitions are defined in table 7.

The life cycle states represent the common minimum set of states. Companies may define additional states as required by business rules.

Transitions between states are not specified. Depending on business rules, it may be possible to enter any state from any other state, such as going directly from *Draft* to *Effective* or going from *Withdrawn* to *Approved*.

**Table 7 - Life cycle states**

| State Name | State Description |
|---|---|
| Draft | Indicates that the element definition is under development or is available for review but is not yet available for use in normal production. Additional substates of "Draft" may be used to indicate work in progress and readiness for approval. |
| Approved | Indicates that the element definition is complete and has been approved by all pertinent authorities. |
| Released | Indicates that the element definition has been approved and has been distributed, but it has not yet become effective. |
| Effective | Indicates that the element definition is available for use. |
| Withdrawn | Indicates that the element definition is no longer effective and is not available for use. |

# 6 Equipment-independent recipe object model



## 6.1 Introduction

This clause defines data models that specify a set of objects, attributes, and their basic relationships that cover the concepts of Clause 4 and Clause 5 of this standard at a high level of abstraction. The models apply to interfaces to recipe management systems in a technology-independent manner. The models are not intended to address the internal system architecture of recipe management systems.

The intended use of these models is to provide a starting point for developing interface specifications for components that address any subset of this standard.

In the cases where the objects and relationships defined in this clause are presented through an interface, then that interface shall use the object names and the relationships of this clause commensurate with the interface technology chosen and the capabilities offered.

## 6.2 Modeling techniques

The models that are described in this clause are based on the Unified Modeling Language (UML) per ISO/IEC 19501-1 (see Clause 2).

## 6.3 Object model

The object model for equipment-independent recipes is shown in figure 8. The main elements are equipment-independent recipes, an equipment requirement library, and a material definition and class definition library.

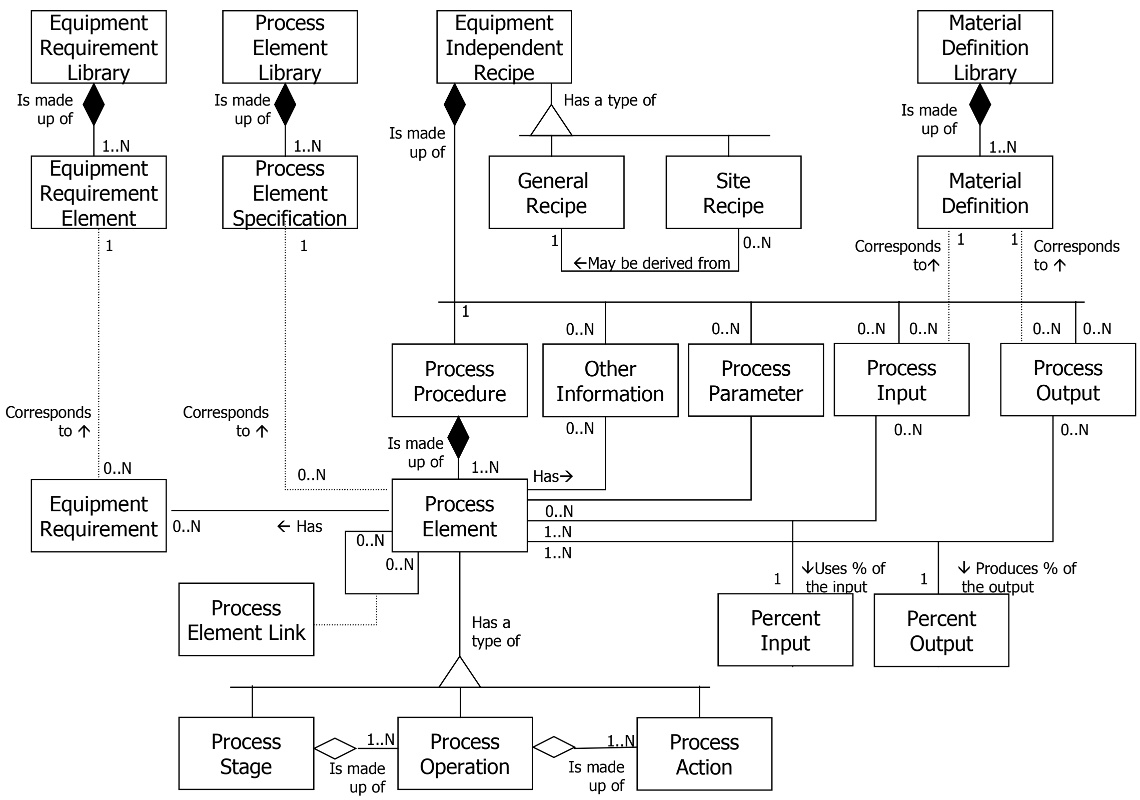



**Figure 8 - Equipment-independent recipe object model**

## 6.4 Object relationships

The object model for equipment-independent recipe entities defines the following relationships:

a) A general recipe is a type of an equipment-independent recipe.

b) A site recipe is a type of an equipment-independent recipe.

c) A site recipe can be derived from all or part of a general recipe.

d) An equipment-independent recipe contains a process procedure definition.

e) An equipment-independent recipe has zero or more sets of other information (e.g., SOP, safety information, exception information, and personnel requirements).

f) An equipment-independent recipe contains one or more process inputs; at least one process input is a material.

g) An equipment-independent recipe contains one or more process outputs; at least one process output is a material.

h) An equipment-independent recipe contains zero or more process parameters.

i) A process procedure contains one or more process elements.

j) A process element defines zero or more equipment requirements.

k) A process element can either be a process action, a process operation, or process stage.

l) A process element corresponds to a process element specification.

m) A process element library is made up of process element specifications.

n) An equipment requirement library is made up of equipment requirement elements.

o) An equipment requirement corresponds to an equipment requirement element. Equipment requirements may be defined and maintained in terms of equipment class properties, as defined in ANSI/ISA-95.00.02-2001.

p) A process element has zero or more percentage of use of a process input.

q) A process element has zero or more percentage of production of a process output.

r) Process inputs and process outputs correspond to material classes or material definitions.

s) The material definition library is made up of material library elements.

t) A process element is linked to zero or more other process elements through a process element link.

## 6.5 Object model elements

### 6.5.1 Attributes

The Part 2 standard defines the attributes for recipe entities. The attributes defined in Part 2 for recipe entities apply to equipment-independent recipes. The attributes defined in Part 2 also apply to the objects in this Part 3 standard.

Each element definition shall have a unique identification consisting of an ID and a version number. Each combination of ID and version number shall be unique.

Typical attributes for element definitions include:

a) Current Status: the current life cycle state of the element definition.

b) Author Name(s) or Initials: an identification of the authors of the element definition.

c) Owner Name or Initials: an identification of the person or position with ownership of the element definition.

d) Approver Name(s) or Initials: an identification of the approving persons for the element definition.

e) Approval Date: the date and time of the final approval of the element definition.

f) Issue Date: the date and time the element definition was released.

g) Effective Date: the date and time the element definition becomes (or became) effective.

h) Withdrawal Date: the date and time the element definition was withdrawn.

i) Replaces Version: the version of the element definition that was replaced when the element definition became effective.

### 6.5.2 Equipment-independent recipe

An equipment-independent recipe is a recipe entity (see the Part 2 standard, Clause 4.3.1) that is a superclass of site and general recipes. An equipment-independent recipe has a life cycle state.

There may be other types of equipment-independent recipes used within a company, but those are outside the scope of this document.

### 6.5.3 Equipment requirement

An equipment requirement defines a constraint to be applied on target equipment.

### 6.5.4 Equipment requirement element

An equipment requirement element is an entry in an equipment requirement library that defines an allowable equipment requirement. An equipment requirement element has a life cycle state.

### 6.5.5 Equipment requirement library

An equipment requirement library is a collection of equipment requirement elements that is used in the construction of an equipment-independent recipe.

#### 6.5.6 General recipe

A general recipe is a type of an equipment-independent recipe that is applied across an enterprise, company, or division. See the Part 2 standard, Clause 4.3.1.

#### 6.5.7 Material definition

A material definition is defined using ANSI/ISA-95.00.01-2000. It may also be a material class as defined in ANSI/ISA-95.00.01-2000. A material definition has a life cycle state.

#### 6.5.8 Material definition library

A material definition library contains material definitions or material classes that are used in the construction of an equipment-independent recipe.

There may be additional material definitions in the material definition library that are not part of the BOM exchanged information defined in ANSI/ISA-95.00.01-2000. For example, a material solution (50% water, 50% caustic) may be defined in the material definition library and used in recipes. The solution can be made up at the sites, and only the components, not the solution, are listed in the Bill Of Material corresponding to the recipe.

#### 6.5.9 Other information

Other information is recipe information that contains support information that is not contained in other parts of the recipe (e.g., regulatory compliance information, materials and process safety information, process flow diagrams, packaging/labeling information).

See the Part 2 standard, Clause 4.3.2 for additional definitions.

#### 6.5.10 Percent input

Percent input defines the percentage of a process input associated with a process element.

Material balancing in a recipe may include a check that the sum of all percent inputs for each material is 100%.

#### 6.5.11 Percent output

Percent output defines the percentage of a process output associated with a process element.

Material balancing in a recipe may include a check that the sum of all percent outputs for each material is 100%.

#### 6.5.12 Process procedure

A process procedure is a definition of the production process for an equipment-independent recipe. It defines a procedure as a hierarchy of process elements.

#### 6.5.13 Process action

A process action causes a physical change to a material within an equipment-independent recipe. Process actions are the basic building blocks of a process procedure.

#### 6.5.14 Process element

A process element is a superclass of process stages, process operations, and process actions. It is a modeling construct used to simplify the object model.

#### 6.5.15 Process element library

A process element library is a collection of process element specifications that is used in the construction of an equipment-independent recipe.

#### 6.5.16 Process element link

A process element link is a link between process elements, usually indicating either a material (in a process or stage diagram) or an action dependency (in a process operation diagram).

#### 6.5.17 Process element specification

A process element specification is an entry in a process element library that defines an allowable process element. A process element specification has a life cycle state.

#### 6.5.18 Process input

A process input defines a material that is used as an input in production of a product.

#### 6.5.19 Process operation

A process operation is an ordered set of process actions.

#### 6.5.20 Process output

A process output defines a material that is produced as a result of production of a product.

#### 6.5.21 Process parameter

A process parameter defines non-material information that is associated with the recipe. See the Part 2 standard, Clause 4.3.2.

#### 6.5.22 Process stage

A process stage is an ordered set of process operations.

#### 6.5.23 Site recipe

A site recipe is type of an equipment-independent recipe that is applicable across a site. See the Part 2 standard, Clause 4.3.1.

## 7 Equipment-independent recipe representation

## 7.1 Process procedure chart

An equipment-independent recipe shall be represented as a process procedure chart (PPC), showing the process input materials, process output materials, and intermediate materials. Process stages are represented by annotated rectangles in the diagram notation. Process operations and process actions may also be represented by rectangles in the diagram notation, or as rows in the table notation.

Annotated lines connecting the annotated rectangles indicate intermediate materials. Annotated lines pointing to the annotated rectangles represent process inputs. Annotated lines leading from the annotated rectangles represent process outputs.

Figure 9 illustrates the stage representation of a sample equipment-independent recipe. The PPC notation is derived from the NAMUR 33 Guideline - Requirements of Systems for Recipe Control (see Annex D reference).

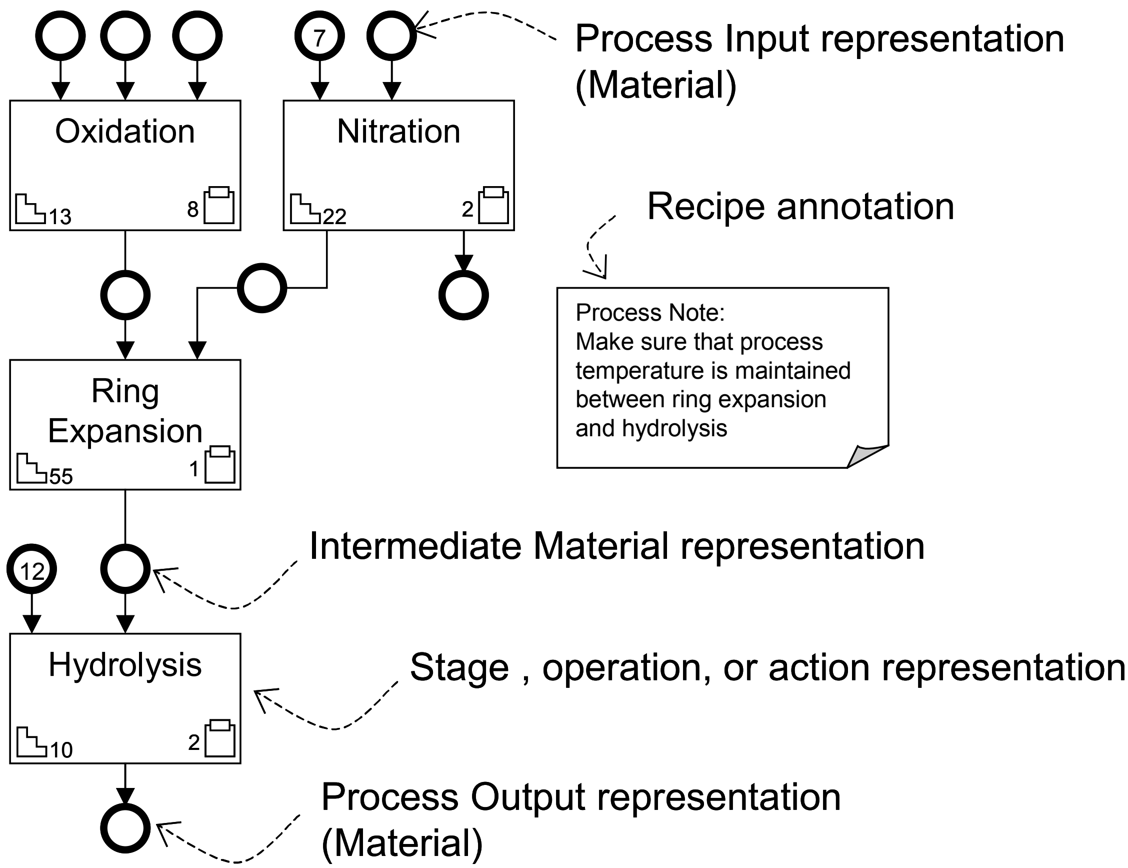



**Figure 9 - Example stage PPC for an equipment-independent recipe**

This clause defines a method for graphical representation of equipment-independent recipes. The representation of the process is called a Process Procedure Chart (PPC). This clause also addresses requirements for representation of formula, equipment requirements, header and other information.

The PPC language as defined in this standard is designed to support recipes with complex processes (e.g., independent stages, parallel actions) that vary from one product to another.

## 7.2 Process procedure chart notation

### 7.2.1 Symbols and links

Process procedure charts depict the dependencies of materials and actions required to manufacture one or more output materials. It uses a series of symbols. The symbols are interconnected by directed links to define the sequencing dependency of the elements.

### 7.2.2 Process procedure chart symbols

#### 7.2.2.1 Symbol types

A process procedure chart is defined by a set of symbols for:

a) Process stages, process operations, and process actions.

b) Process input materials.

c) Intermediate materials.

d) Process output materials.

e) Directed links.

f) Process annotations.

Only the general representation of the symbols is imposed; dimensions and details (e.g., thickness of lines and font of characters) are left to each implementation.

7.2.2.2 Process procedure charts

A process procedure chart represents:

a) A diagram of an equipment-independent recipe’s procedure, consisting of process stages and their dependencies.

b) A diagram of a process stage, consisting of process operations and their sequencing.

c) A diagram of a process operation, consisting of process actions and their ordering and sequencing.

Each diagram shall have an indication of the level the diagram represents, procedure, process stage, or process operation.

7.2.2.3 Stages, operations, and actions

An annotated rectangle shall be used to represent a process stage, a process operation, or a process action. The basic stage symbol is a rectangle with the element name enclosed, as shown in figure 10. The rectangle may be annotated with information indicating additional information about the element.

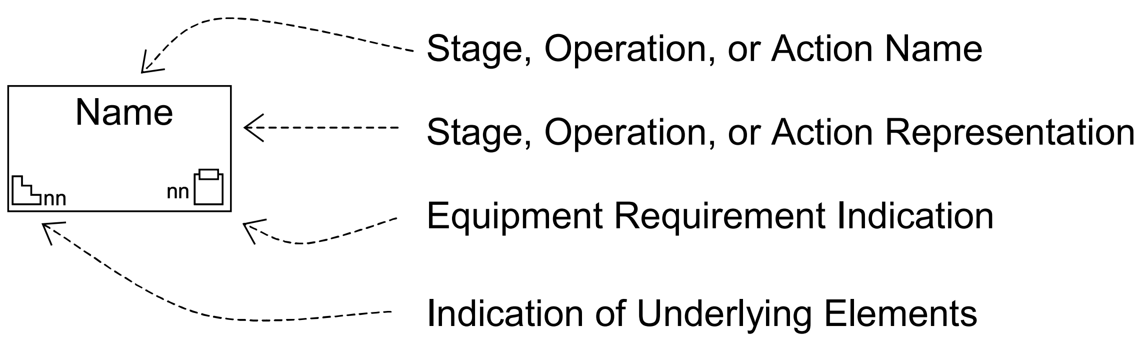



**Figure 10 - Recipe process element symbols**

7.2.2.4 Content indication

An indication may be used within a stage or process operation symbol to indicate that the stage contains procedural elements (process operations or process actions). If an indication is used, then it shall be in the lower left corner of the enclosing symbol. The indication may be numeric, graphical, or a combination. If a graphical figure is used it shall be a step symbol, as illustrated in figure 11. Figure 11 illustrates a content indication annotation comprised of an identifying graphical symbol and a numerical count of underlying elements at the next lower level.


**Figure 11 - Annotation for stage or operation elements**

7.2.2.5 Equipment requirement indication

An indication may be used within a stage or process operation symbol to indicate how many equipment requirements the stage contains. If an indication is used, then it shall be in the lower right corner of the enclosing symbol. The indication may be numeric, graphical, or a combination. If a graphical figure is used it shall be a clipboard symbol, as illustrated in figure 12. Figure 12 illustrates an equipment requirement indication annotation comprised of an identifying graphical symbol and a numerical count of requirements.

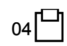



**Figure 12 - Equipment requirement indication**

7.2.2.6 Process annotation

An annotation may be used to include additional process, equipment, or other information of importance. If a process annotation is used then the annotation shall be associated with an object or with the encapsulating process definition. Figure 13 illustrates an example process annotation that could be placed on a process definition diagram.

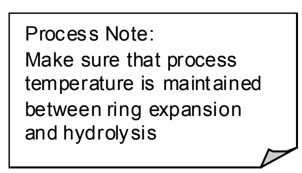



**Figure 13 - Example process annotation indication**

7.2.2.7 Process input

A process input (as defined in the Part 1 standard) shall be represented by the symbol show in figure 14.

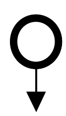


**Figure 14 - Process input symbol**

A process input symbol may be annotated with the identification of the consumed resource, material definition, or material class.

A process input symbol may be annotated with an indication of the scaled or relative amount of material, properties of the material, and/or information about the specific use of the material (e.g. minimum lot size, maximum lot size). Figure 15 illustrates a process input symbol with an optional material identification.

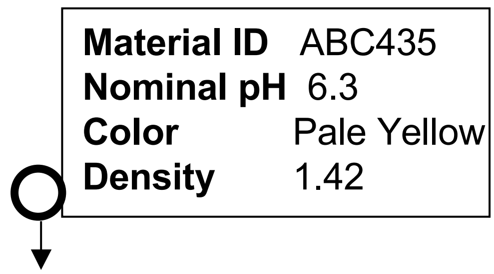



**Figure 15 - Process input symbol with material identification**

For cases where large numbers of process inputs are required, a process input symbol may represent more than one material. If more than one material is represented, then the number of materials represented is indicated inside the process input symbol. The same symbol annotation may be used for process intermediates and process outputs symbols.

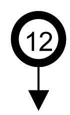



**Figure 16 - Sample process input symbol representing multiple materials**

7.2.2.8 Identified intermediate

An identified process intermediate shall be represented by the symbol shown in figure 17.

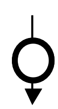


**Figure 17 - Process intermediate symbol**

An intermediate symbol may be annotated with the identification of the produced and consumed resource name, material definition or material class. A process intermediate symbol may be annotated with an indication of the scaled or relative amount of material, properties of the material, and/or information about the specific use of the material (e.g., minimum lot size, maximum lot size).

For cases where large numbers of process intermediates are required, the process intermediate symbol may represent a list of materials.

7.2.2.9 Unidentified intermediate or sequencing dependency

On a procedure and a process stage diagram, an unidentified process intermediate shall be represented as a line with an arrowhead, as shown in figure 18.

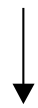


**Figure 18 - Unidentified intermediate material symbol**

7.2.2.10 Process output

A process output (as defined in the Part 1 standard) shall be represented by the symbol shown in figure 19.

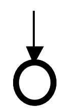


**Figure 19 - Process output symbol**

A process output symbol may be annotated with the identification of the produced resource, material definition, or material class. A process output symbol may be annotated with an indication of the scaled or relative amount of material, properties of the material, and/or information about the specific use of the material (e.g. minimum lot size, maximum lot size). Figure 20 illustrates a process output symbol with an optional material identification and material property information.

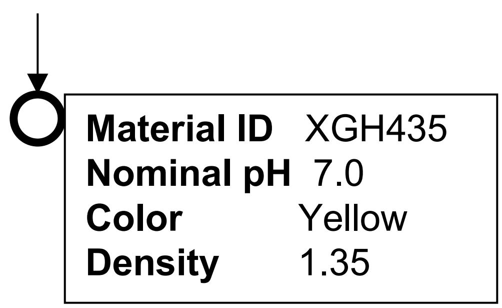



**Figure 20 - Process output symbol with material information**

For cases where large numbers of process outputs are required, the process output symbol may represent a list of materials.

7.2.3 Link types

7.2.3.1 Order of execution sequence

On a process operation diagram, an order of execution sequence definition shall be represented as a line between actions with an arrowhead, as illustrated in figure 21. The action at the tail of the arrow is completed before the action at the head of the arrow starts.

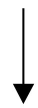


**Figure 21 - Order of execution symbol**

7.2.3.2 Start of parallel execution

On a process operation diagram, when parallel actions are required, the start of parallel execution shall be indicated by arrowheads that point to a double horizontal line, with a line for each parallel sequence leading from the double horizontal line. The action at the tail of the arrow pointing to the double horizontal line is completed before the action at the head of the arrows start.

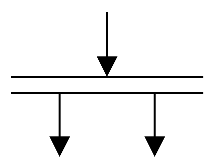


**Figure 22 - Start of parallel execution symbol**

7.2.3.3 End of parallel execution

On a process operation diagram, when parallel actions are required, lines leading to a double horizontal line, and a single line leading from the double horizontal line shall indicate the end of parallel execution. The actions at the tails of the arrows pointing to the double horizontal line are completed before the action at the head of the arrow starts.

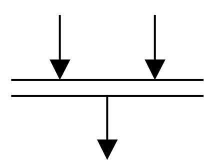


**Figure 23 - End of parallel execution**

7.2.3.4 Start of optional parallel execution

On a process operation diagram, when it is optional for actions to be executed either in parallel or in series, the start of such a sequence of actions shall be indicated by arrowheads that point to a dashed double horizontal line with a right pointing arrowhead and a line for each possible parallel sequence leading from the double horizontal line. The action at the tail of the arrow pointing to the double horizontal line is completed before the actions at the head of the following arrows start. The optional parallel symbol is shown in figure 24.

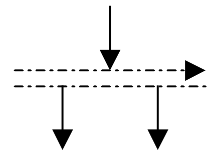


**Figure 24 - Start of optional parallel execution symbol**

Each separate path under the optional parallel symbol may operate as a standard parallel, or each path may operate in series, in order from left to right in the diagram, as illustrated in figure 25.

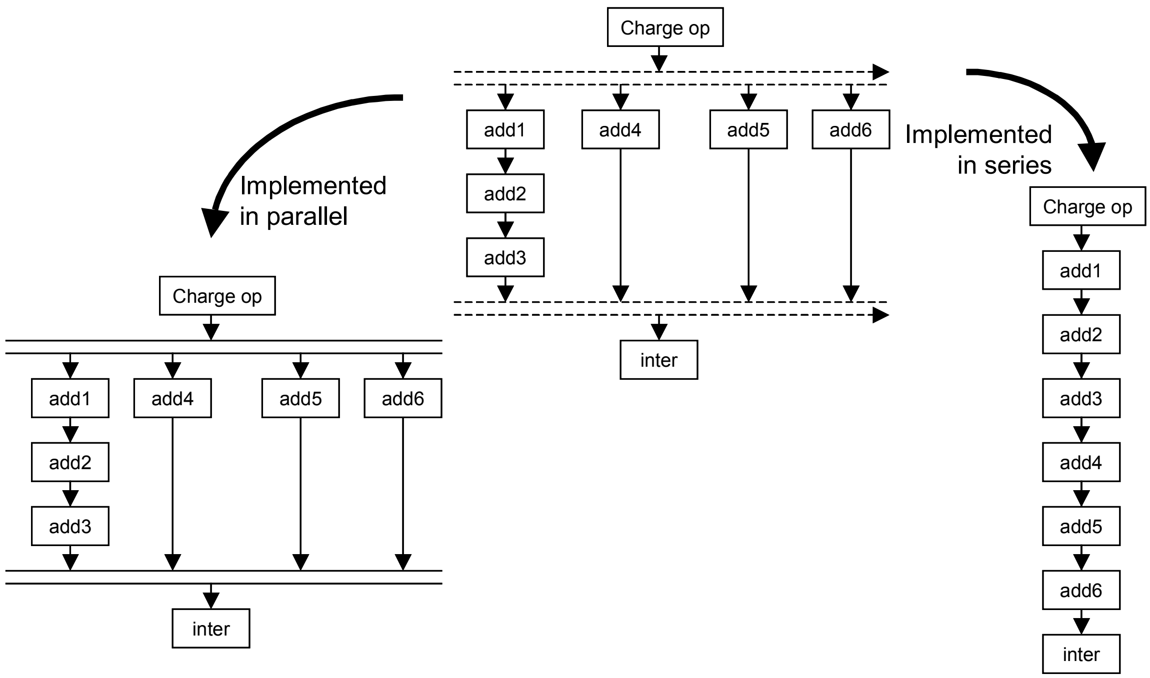



**Figure 25 - Alternate execution paths for optional parallel execution**

7.2.3.5 End of optional parallel execution

On a process operation diagram, when optional parallel actions are defined, lines leading to a dashed double horizontal line with a right pointing arrowhead, and a single line leading from the double horizontal line shall indicate the end of optional parallel execution. The actions at the tail of the arrows pointing to the double horizontal line are completed before the action at the head of the following arrow starts. The end of optional parallel symbol is shown in figure 26.

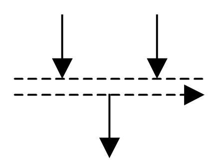


**Figure 26 - End of optional parallel execution**

### 7.2.4 Rules for valid PPCs

#### 7.2.4.1 Single network

All of the elements in a PPC shall be connected.

NOTE: Valid PPCs only have a single network of material flows.

#### 7.2.4.2 Process inputs

Valid PPCs shall start with one or more process inputs.

#### 7.2.4.3 Process outputs

Valid PPCs shall end with one or more process outputs.

#### 7.2.4.4 No loop dependency

Valid PPCs shall have no loops of material dependencies. For example, a process output from a process element cannot also be a direct input to the same or a previous element. When recirculation is needed it can be accomplished through the use of process inputs and process outputs identifying the same resource or material.

Because a PPC defines ideal production, a loop in a PPC would imply that a material needed for generation of a material is actually one of the materials generated. There is no starting point in the recipe in this situation. When this is needed in practice it is usually done by feeding part of one batch into the next batch. In this case the material definition may be the same, but the material lots are usually different. In a PPC this is documented by the use of the same material as a process input and a process output.

## 7.3 Process hierarchy

### 7.3.1 Process operation and process action depiction

Process operations and process actions may be represented in a graphical format, as shown in figure 27 and in figure 29, or in a tabular format, as shown in table 8. Complex definitions, with significant parallel sequences, are usually best represented graphically. Definitions that are primarily sequential are frequently represented in the table format. The table format supports the definition of limited parallelism and sequences within parallels.

In the graphical representation, process operations have similar representations as process stages.

In the graphical representation, process actions have similar representations as process stages, but without the equipment requirement annotations.

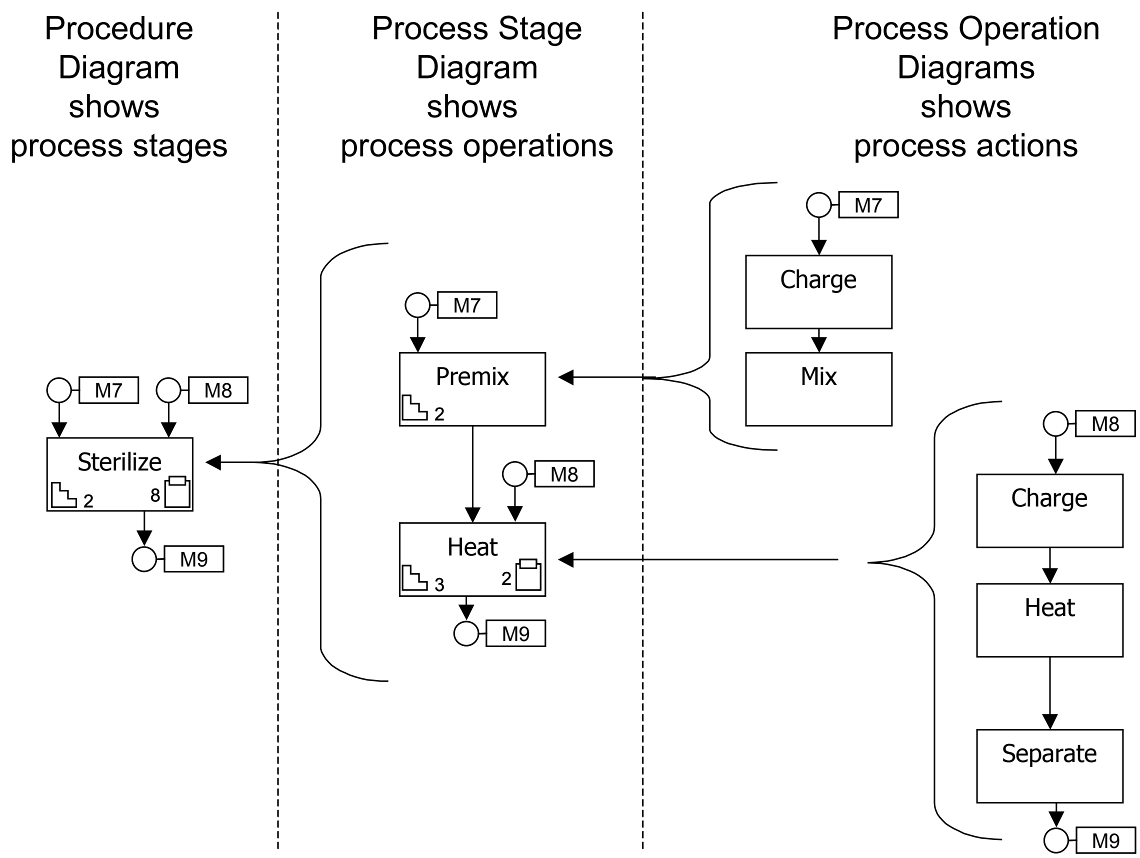



**Figure 27 - Graphical representation example**

7.3.2 Table representation

7.3.2.1 Tabular format

The process operations and process actions within a process stage may be represented in a tabular format, as shown in table 8.

## Table 8 - Table format for process operations and process actions

| Sequence Order | Sequence Path | Operations & Actions | Material Definition |
|---|---|---|---|
| | 0 | PREMIX OPERATION | |
| | 0 | CHARGE | Material M7 |
| | 0 | MIX | |
| | 0 | HEAT OPERATION | |
| | 0 | CHARGE | Material M8 |
| | 0 | HEAT | |
| | 0 | SEPARATE | Material M9 |

This table representation also allows the definition of sequential and parallel paths through annotation of each row.

7.3.2.2 Table position and sequence order column

The order of execution shall be from top to bottom, unless modified by the sequence order symbol and sequence path value. The sequence order symbol indicates sequential execution, parallel branches, or sequential execution under parallel branches. The sequence order symbols shall be indicated as shown by figure 28. The use of symbols within the table format allows simple parallel constructs to be quickly interpreted. Table representation of complex sequences of parallels and nested parallels are not defined in this standard.

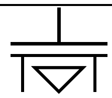
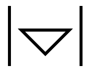
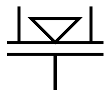
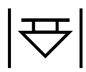
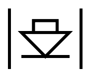
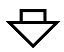
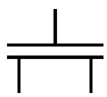
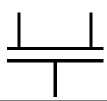
| | |
|---|---|
|  | First in first series under a parallel (first action in first path) |
|  | Action in middle of series under a parallel (not first or last in path) |
|  | Last in last series of actions under a parallel (last action in last path) |
|  | First in a series of actions under a parallel (first action in path) |
|  | Last of series of actions under a parallel (last action in path) |
|  | Action not under a parallel |
|  | Single action at start of a parallel (only action in path) |
|  | Single action under a parallel (only action in path) |
|  | Single action at end of parallel (only action in path) |

**Figure 28 - Sequence order annotations for table representation**

7.3.2.3 Sequence path

The sequence path column shall indicate the sequence within a set of parallel sequences. Sequences should be numbered sequentially, starting from the left. All actions under the same sequence path execute sequentially.

7.3.2.4 Operations and actions

The operations and action column shall contain the name of the corresponding process operation or process action, one row per operation or action.

7.3.2.5 Material definition

A column may be included to contain a material definition for those operations or actions that correspond to process inputs, process outputs, and process intermediates.

7.3.3 Graphical and table view equivalence

The process stage table representation allows moderately complex representations to be represented in a table. For example, the graphical representation of a process operation is shown in figure 29.

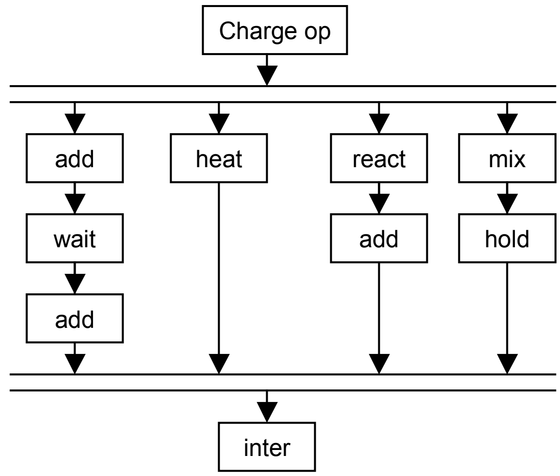



**Figure 29 Sample process operation as graphic**

The sequential paths defined in figure 29 are identified by the circled paths shown in figure 30.

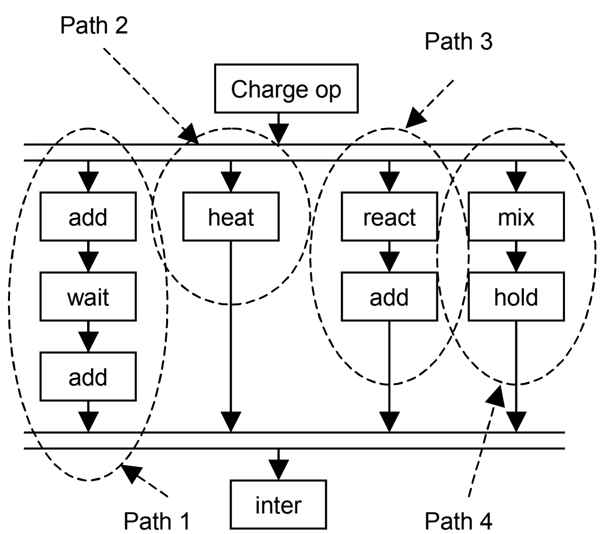
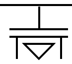
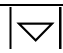
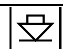
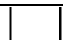
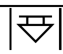
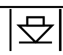
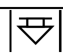
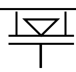
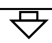



**Figure 30 - Sample graphic showing sequential paths**

This same process operation can be represented in a table as shown in table 9.

## Table 9 - Sample process operation in table

| Sequence Order | Sequence Path | Operations & Actions | Material Definitions |
|---|---|---|---|
|  | 0 | CHARGE OPERATION | |
|  | 1 | ADD | Material M7 |
|  | 1 | WAIT | |
|  | 1 | ADD | Material M6 |
|  | 2 | HEAT | |
|  | 3 | REACT | |
|  | 3 | ADD | Material M9 |
|  | 4 | MIX | |
|  | 4 | HOLD | |
|  | 0 | INTER | |

### 7.3.4 Non-procedural equipment-independent recipe information

All other information that is part of an equipment-independent recipe shall be related to a specific element or symbol in the equipment-independent procedure.

This standard purposely does not specify how that relationship or reference is implemented. In a pencil and paper implementation, for example, the reference might be accomplished with something similar to a footnote, or the information might be written alongside the procedural element in question. In an electronic implementation, pop-up boxes or some other mechanism that is not yet invented might be the implementation of choice. However, if used the relationship should be clearly indicated, and it should be consistent within each application.

### 7.3.5 Equipment-independent recipe formula

Formula information consists of process inputs, process parameters, and process outputs. The formula information may be represented in its entirety (e.g., associated with a recipe procedure), in parts (e.g., process inputs only or for a specific process stage), or as a summary of lower-level formula as appropriate for the context and intended use. When depicted, the formula shall be associated with a process element.

### 7.3.6 Material balance

The recipe depiction should include the ability to show material balances for defined materials. This should include the summation of all uses of a material in all process actions to ensure that the amount of material specified in the formula is actually produced or consumed in the recipe.

### 7.3.7 Equipment requirements

The representation should provide a method for the user to view the equipment requirements that are associated with each process element individually or for all elements in aggregate.

### 7.3.8 Header and other information

Header information and the “other information” category of recipe information can be related to the recipe in general (e.g., recipe ID, regulatory status) or to specific recipe procedural entities (e.g., protective equipment requirements, hazards of chemicals information). All header and ‘other information’ should be able to be represented in its entirety or associated with the procedural entity to which the information is related.

# 8 Transformation of equipment-independent recipes to master recipes

## 8.1 Source of information for master recipes

Process engineers use the information from an equipment-independent recipe to construct one or more master recipes for each process cell. This transformation takes the process definition defined in the equipment-independent recipe and maps it to the specific equipment available in the process cell. The equipment-independent recipes provide the basic information that is required to build master recipes.

Transformation is performed as a set of engineering tasks, usually with formal definitions and processes. Transformation can be an entirely manual process, a partially automated process, or an entirely automated process depending on the availability of formal definitions and appropriate tools.

## 8.2 Element mapping

In some cases there is a one-to-one correspondence between a process stage and a unit procedure, a process operation and an operation, and a process action and a phase. However, many other mappings are possible. For example, a single process could be accomplished in multiple units or process cells, through multiple unit procedures or master recipes, based on the availability of the required processing on actual equipment. Likewise, multiple process stages could be combined into a single unit procedure during transformation to a master recipe. In some circumstances a single process action results in the generation of a complete master recipe. These transformation options are based on the element mapping into target equipment.

## 8.3 Stage-to-unit procedure mapping

Figure 31 illustrates some of the complexity of transformation for a simple equipment-independent recipe, showing only unit procedure boundaries that could result in the mapping of stages to units. In the figure, the shaded areas indicate unit procedure boundaries (identified as UPx, x=1...5) and the rounded rectangles in the shaded area correspond to stages. A full representation would also include the possibility of splitting the stages into operations in multiple units. The final selected master recipe would be dependent on the process input material flows into units, material transfer capability between units, and the matching of general recipe equipment requirements against unit equipment characteristics.

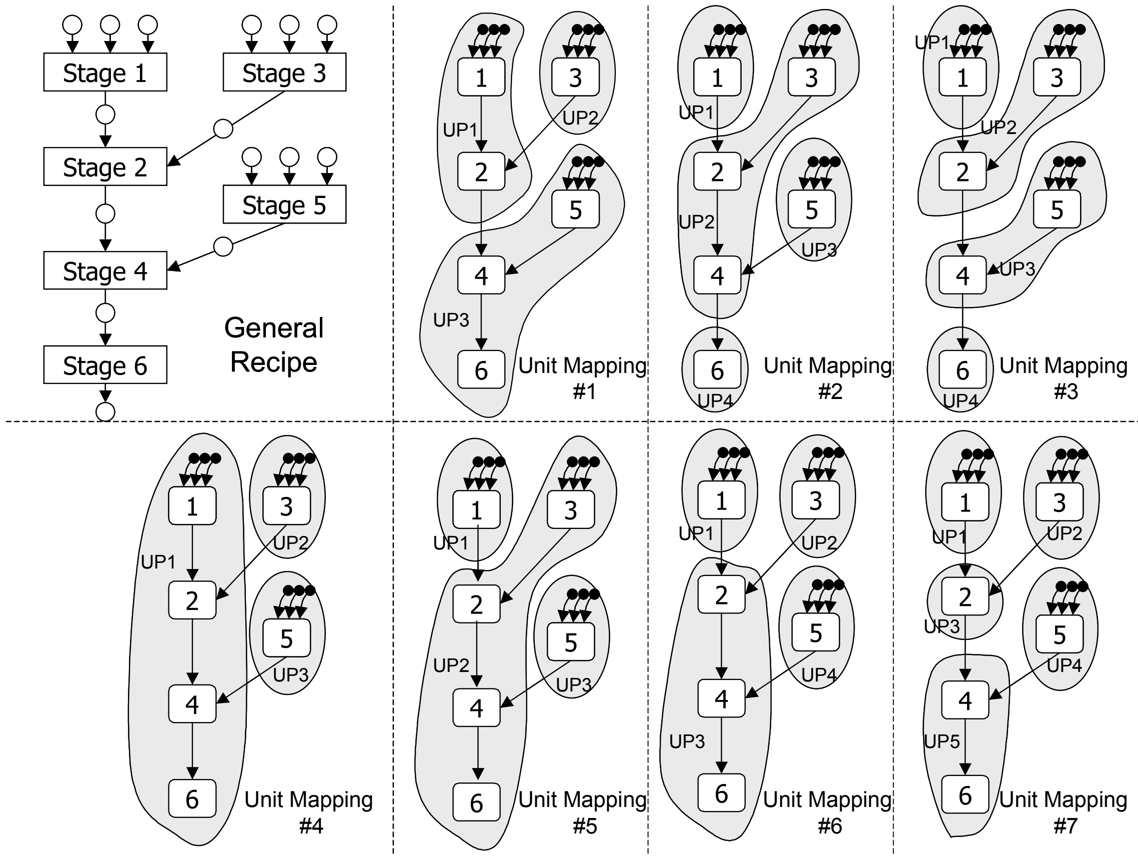



**Figure 31 - Possible general-to-master recipe mappings**

8.4 Transform components

8.4.1 Master recipe component

The first step in formalizing the transformation process is the definition of transform components. A transform component is a component of a master recipe, made up of a specifically ordered set of recipe phases and/or recipe operations, that define a way to implement a single process action on a single class (or instance) of equipment. There should be a library of transform components that can document the best practices for implementing process actions on specific equipment. Multiple possible transform components can be defined for a given process action to be implemented using an equipment element, but some defining characteristics, such as execution time or cost, can be used to select the appropriate transform component.

8.4.2 Transform components for material transfers

Additional transform components can be defined that document the best practice for acceptable material transfer between units. There are no material transfers defined in general recipes. Material transfers have to be merged into the created master recipe. A library of transform components for material transfers between units can be used to ensure consistent handling of material transfers in created master recipes.

8.4.3 Unit startup and shutdown components

Transformation often requires that units be prepared before use (such as washed or heated). Units often also require finishing after use (such as washed or byproducts removed).

Master recipe transform components should be defined for units that require preparation before use or actions after use. These master recipe transform components should then be merged into the generated master recipe at the appropriate point in the unit procedure to ensure their execute at the right time.

#### 8.4.4 Alternate master recipe transform components

There can be multiple master recipe transform components for a given process element in a process cell. These can use alternate sets of equipment and different optimizing criteria, such as minimum number of transfers, lowest cost of use, or least energy use. Transformation can include a selection of the best master recipe transform component that meets the production requirements for the final master recipe (such as lowest cost, fastest batch, or least energy).

## 8.5 Transformation tasks

### 8.5.1 Equipment determination

Once master recipe transform components are available, the next tasks in transformation are the determination of the equipment that can:

a) Perform the process action (there is a transform component defined for the equipment).

b) Meet the equipment requirements defined in the encapsulating process stage or process operation.

c) Meet the material entry requirements of the action, operation, or stage (there is a means to get the material into the equipment selected to perform the action).

d) Meet the material exit requirements of the action, operation, or stage (there is a means to get the material out of the equipment selected to perform the action).

These result in the selection of equipment paths that (a) meet the above requirements, and (b) have valid material transfer paths between the units. These tasks also involve selection of one of the material paths and can be based on various optimization information sets known about the equipment or process.

### 8.5.2 Using non-procedural information in transformation

Non-procedural recipe information includes process parameters, equipment requirements, process input information, process output information, percent input information, or percent output information. This information is usually required in creation of master recipes. For example, the input and output material identifications from the equipment-independent recipe will typically be mapped to master recipe parameters or formula values.

Transformation thus involves taking non-procedural information from the equipment-independent recipe and merging it into master recipe parameters such as material definitions, setpoints or limits. The non-procedural information used in the mapping should be associated with the *master recipe transform component*, not with the *equipment-independent recipe*. There is usually no way to know all of the various options that will be available in the *master recipe transform components* when the *equipment-independent recipe* is built. For example, a *master recipe transform component* element can define a parameter value as an equation (mathematical formula) that references *equipment-independent recipe* information. This equation would be resolved at the time the master recipe is created to set the actual parameter value.

Mapping of non-procedural information can include optional definitions and default values. These could be used if the necessary information is not available from the equipment-independent recipe. This can be required where the same master recipe transform component is used in transformation of many different equipment-independent recipes.

#### 8.5.3 Creating the master recipe

The last tasks involve the creation of one or more master recipes by replacing the actions with the recipe transform components, defining the master recipe operation boundaries using the process operation definitions as a guide, collecting the master recipe operations that deal with the same equipment in the same material dependency path, into master recipe unit procedures, and then adding material transfer master recipe segments to move the materials between units. There can be additional tasks required to initialize units before their first use, and tasks to finalize, clean, or sterilize units after material is transferred.

### 8.6 Transformation mapping

#### 8.6.1 Multiple possible mapping levels

Transformation of equipment-independent recipes to master recipes can be performed at any level of the equipment-independent recipe procedural hierarchy. The mapping could occur at different levels, such as a process operation to a master recipe phase, or a process action to a master recipe operation.

#### 8.6.2 Process action to master recipe phase mapping

Transformation can be done through the lowest level, the process actions, as shown in figure 32. In this case the process actions correspond to an ordered collection of master recipe phases that are merged into a final master recipe. This can be the simplest case of transformation where there is a one-to-one or one-to-many association from a process action to phases.

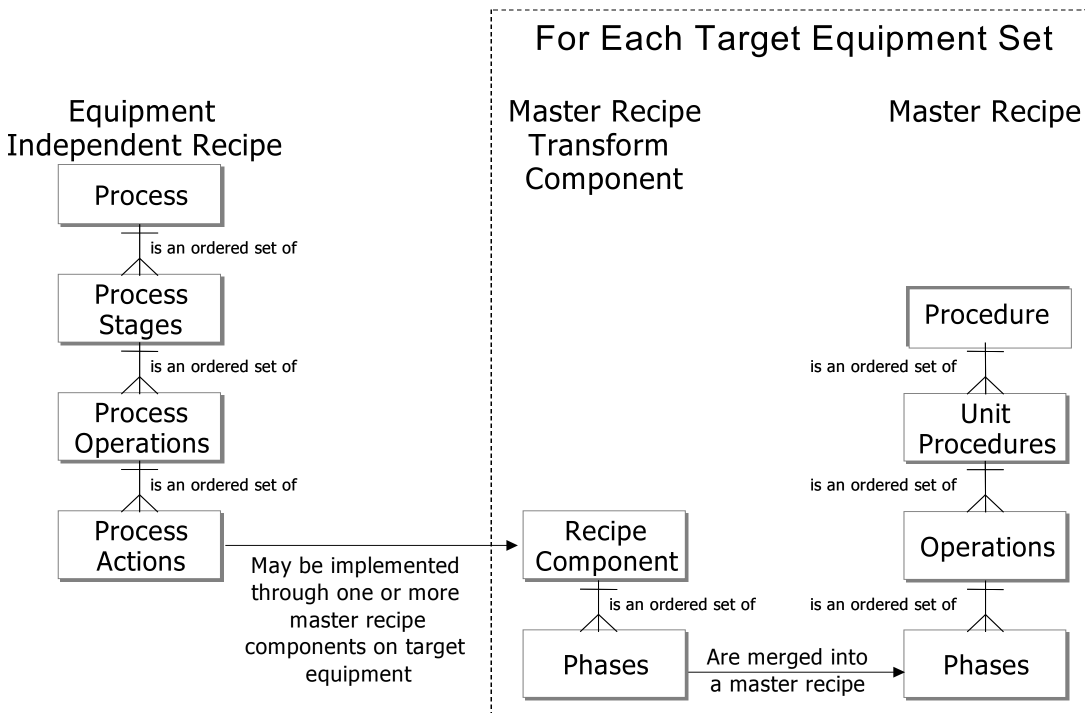



**Figure 32 - Transform through process actions**

### 8.6.3 Process action to master recipe operation mapping

A transform component can define one or more operations, such that one or more complete operations are required to implement a process action. Figure 33 illustrates a transform component that contains one or more operations. These operations are then merged into the generated master recipe for the target equipment.

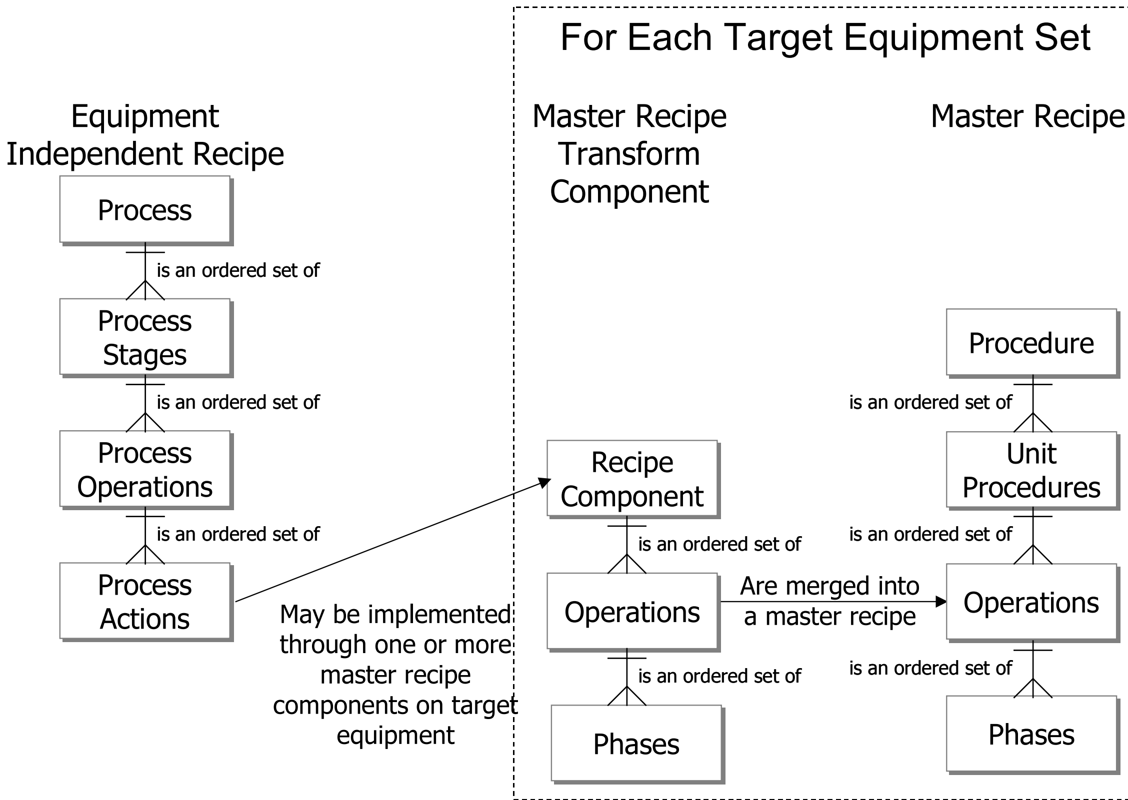



**Figure 33 - Mapping of a process action to one or more operations**

8.6.4 Process action to master recipe unit procedure mapping

A transform component can define one or more unit procedures that implement a process action. For example, this occurs when the process action requires a material mixture that is prepared in a separate unit on the target process cell. Figure 34 illustrates this example. In this case the unit procedures are merged into the generated master recipe, usually including any required material transfers between the units.

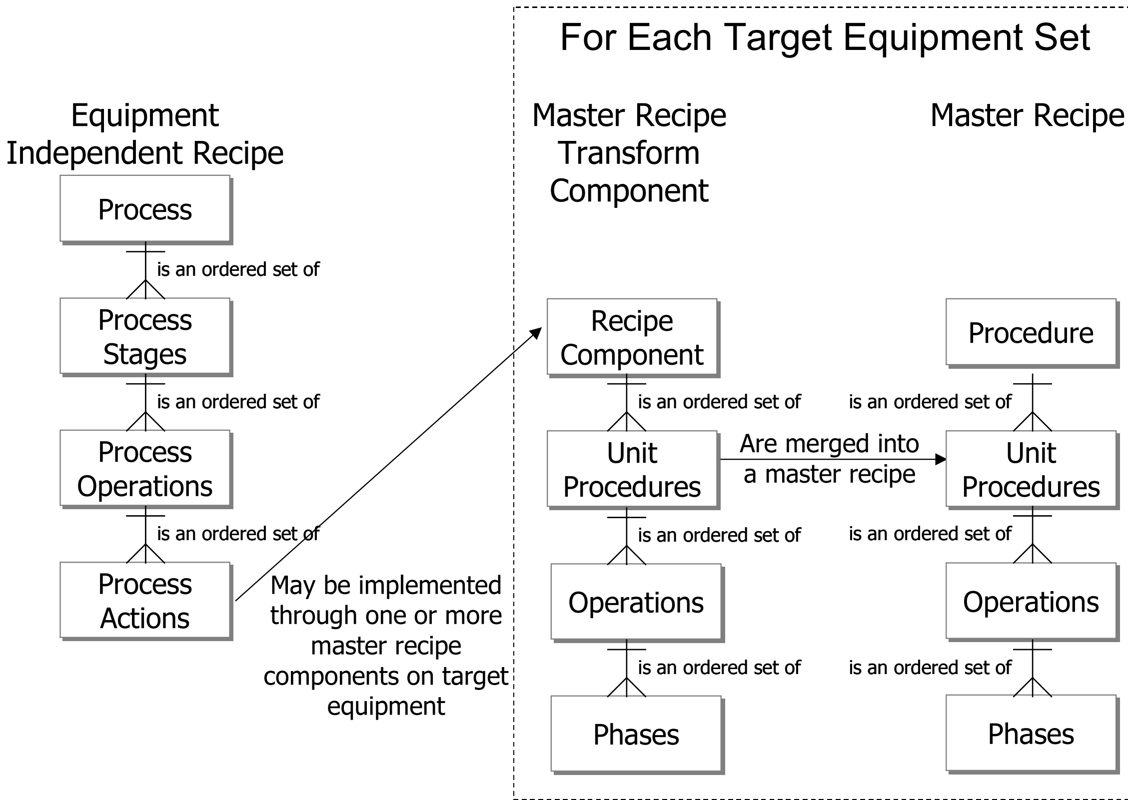



**Figure 34 - Mapping of a process action to one or more unit procedures**

8.6.5 Transformation through process operations

The process hierarchy of an equipment-independent recipe can be collapsed, and transformation can occur at any level. Figure 35 illustrates the mapping of a process operation to a master recipe transform component. In this example, the equipment-independent recipe does not contain any process actions, and the transform component defines one or more operations. In this case, the equipment-independent recipe is constructed from a library of process operations

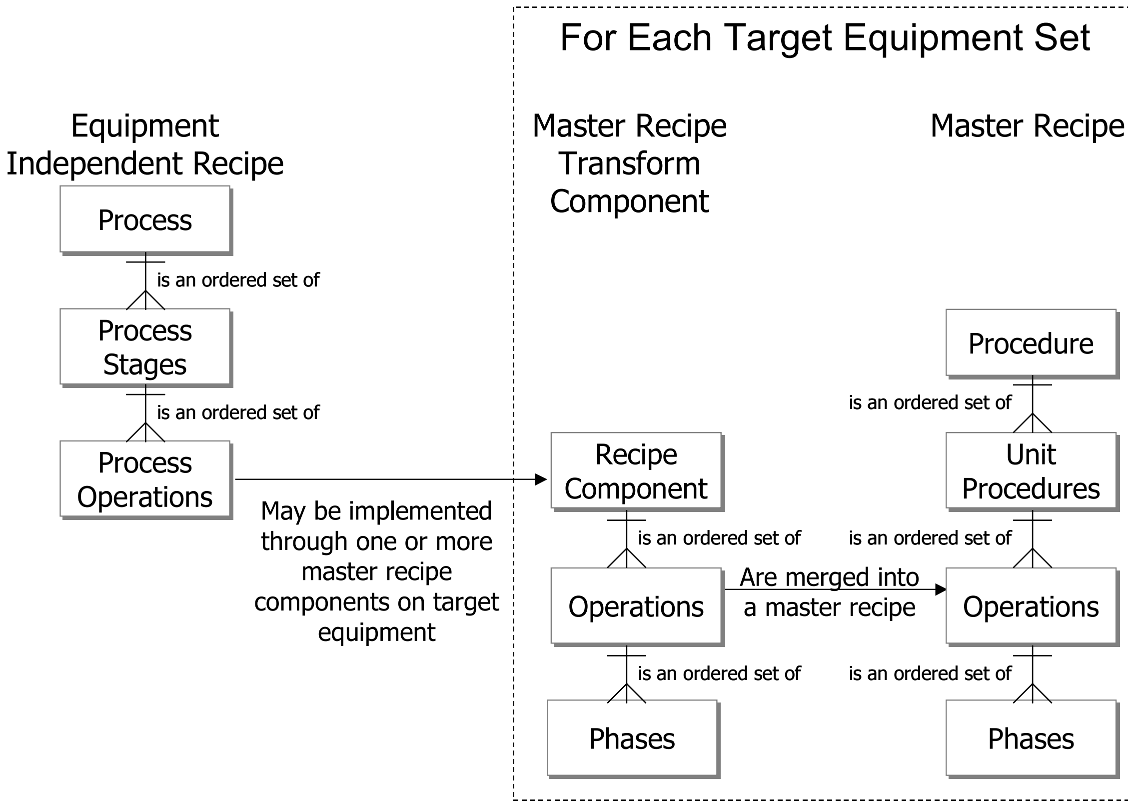



**Figure 35 - Mapping of a process operation to one or more operations**

### 8.6.6 Transformation through process stages

Transformation can be accomplished through process stages, such that an equipment-independent recipe is constructed from a library of process stages. In this case there would be a transform component defined for a process stage. Figure 36 illustrates the transformation mapping where a process stage is implemented through one or more unit procedures.

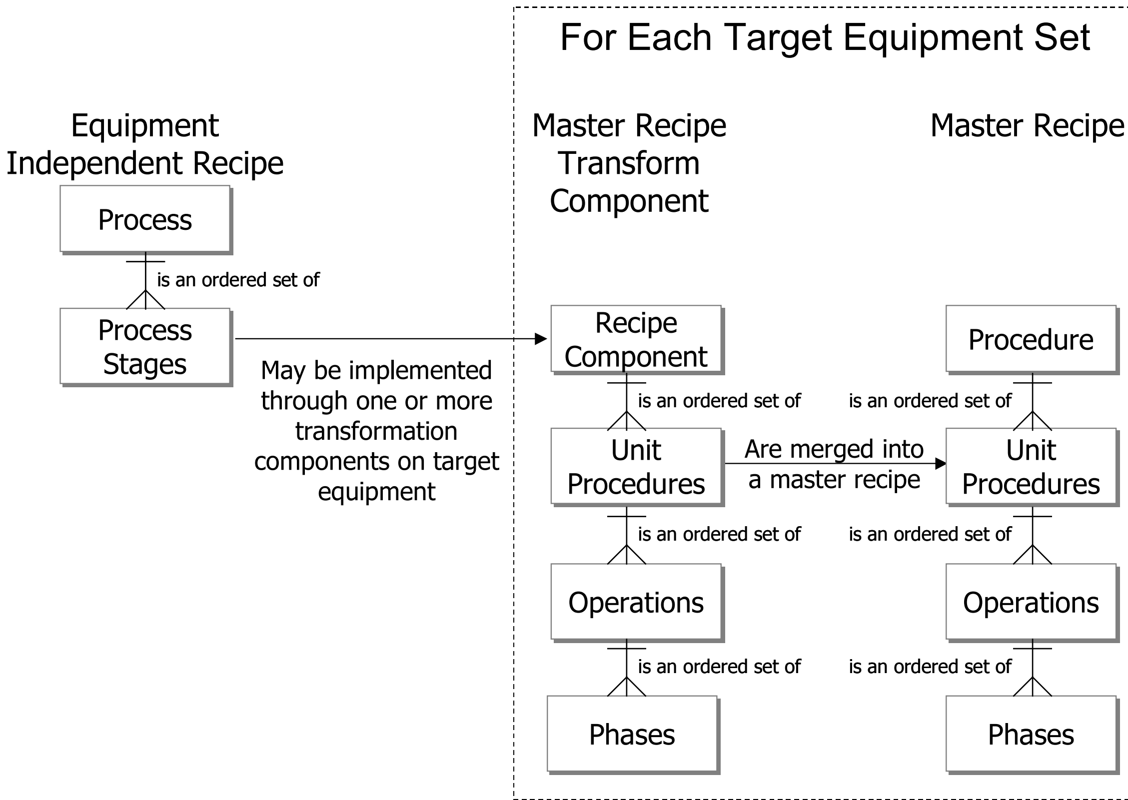



**Figure 36 - Mapping of a process stage to one or more unit procedures**

# Annex A (informative) - General and site recipe benefits

General recipes bring the following benefits to enterprises:

They provide a uniform format for description of all products. This allows all parts of an enterprise that are involved in new product development and introduction (NPD&I) processes to share a common definition of a product. This reduces errors, conflicts, and misunderstandings in the NPD&I processes.

They provide a uniform presentation of recipes, allowing pilot, trial, and production facilities to operate from the same definition. In addition, general recipes provide an unambiguous way to disseminate comprehensive processing requirements to multiple plants worldwide.

They provide a common object model for the entire business, allowing easier integration with business ERP (enterprise resource planning) systems, supply chain management (SCM) systems, Product Life Cycle Management (PLM) systems, and production execution systems.

The formal definition of product definitions, process actions, and equipment requirements allows for a reduction of cycle time between conversions of general recipes to master recipes.

A standard representation minimizes languages differences when recipes must be exchanged across country and language boundaries.

General recipes provide faster technology transfer from research and development (R&D) to manufacturing, and from pilot to production due to unambiguous information definitions. General recipes will allow faster introduction of modifications into production, with associated cost savings because of ability to substitute materials quicker.

The common definition allows parts of the general recipe (formula, material definitions, processing requirements) to be reused.

The formal definition of product definitions, process actions, and equipment requirements allows for a programmatic or standard translation to master recipes. This also makes site determination easier, by allowing automated determination of suitability for manufacturing. Site capabilities can be quickly matched against production requirements to determine where a product is capable of being made, where parts (stages) are capable of being made, or what additional production capabilities are needed to allow production.

General recipes facilitate consistent manufacturing models and metrics across all facilities. This allows comparison of costs, time and quality at process stage and process operation boundaries. This results in reduced plant-to-plant variability and lower cost sourcing.

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## Annex B (informative) – General and site recipes in the enterprise

The recipe model defined in the Part 1 standard has been widely accepted as the preferred method for implementing flexible manufacturing within the manufacturing industries. This success has caused the same model to be applied in more areas of a company than it was originally designed to accommodate. While the model has been found to fit other areas, there has been a confusion regarding naming and functionality. This has been particularly apparent in the integration of ERP and scheduling systems with batch automation systems. To avoid future confusion, this annex defines the relationship of general and site recipes to other information sets used in a manufacturing enterprise.

The recipes described in the standard define manufacturing information. However, the information contained in these recipes must often be mirrored in other information sets required to operate a manufacturing enterprise. Figure B1 illustrates the concept that information may be obtained from a general recipe for use in multiple other business processes.

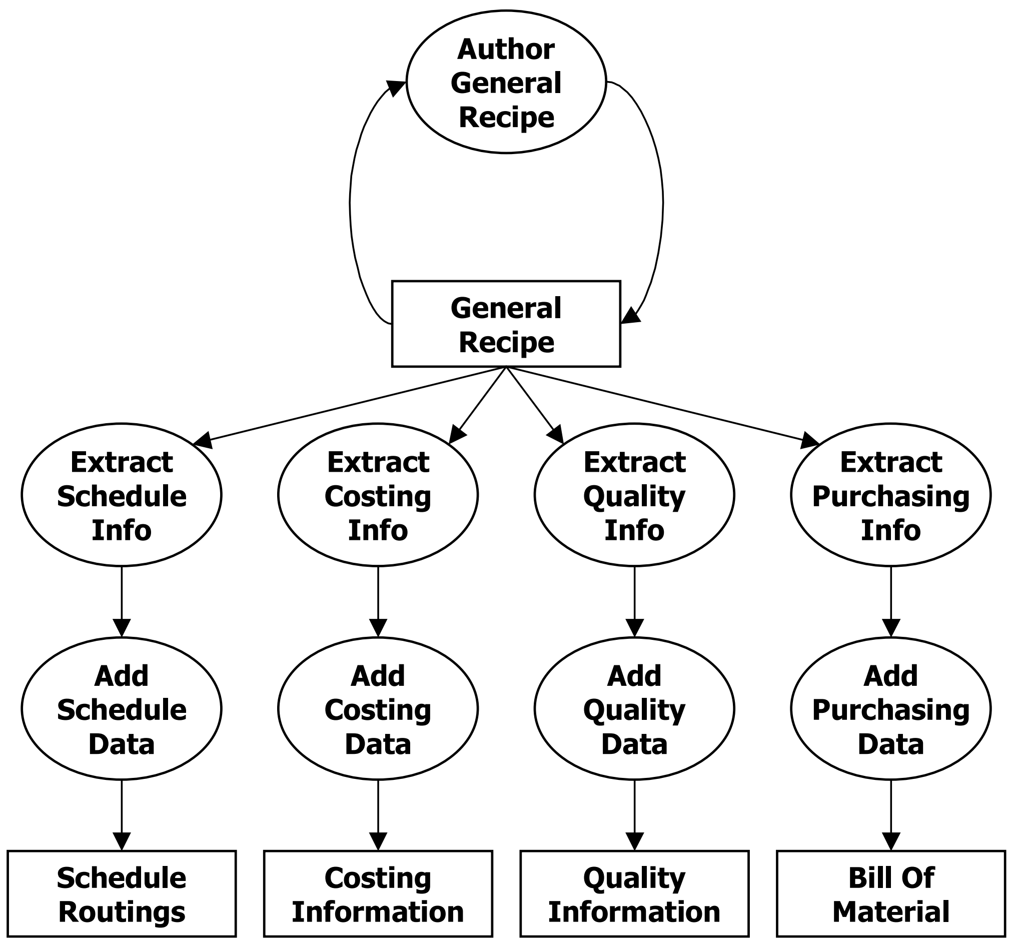


**Figure B1 - Information sets in a manufacturing enterprise**

Some manufacturing information must be mirrored in a scheduling system in order for valid planning and scheduling activities to occur. If information about a product used for planning purposes is not in conformance with information used for production, then generated schedules will be invalid. For example, if a production material changes in a production recipe (e.g., a master or site recipe), and this change is not reflected in planning data, then wrong material will be ordered and delivered to production. If information is not correctly synchronized, then wrong materials may be ordered or delivered or wrong equipment (e.g. site or plant) may be scheduled for use in production. Information in the data sets must be kept in sync, even though it is used by people in different departments with widely different applications of the information.

The production and scheduling information must also be mirrored in costing systems for valid business costing to occur. Errors will also occur if the costing recipe information is not in conformance with the production recipe. For example, invalid costing information may mean that profitable products are dropped and unprofitable products are retained.

## B.1 Scheduling information

Scheduling information may be maintained in a hierarchy of definitions, corresponding to enterprise-wide routing information, site-wide routing information, and area-wide routing information.

### B.1.1 Enterprise routing information

Enterprise routing information contains site-independent definitions of the materials and resources required for production of a product. This includes information required for planning or optimization that is not directly related to the materials and resources of a General Recipe. The Process Inputs and Process Outputs defined in a General Recipe usually must also be reflected in the scheduling information. While the General Recipe does not specify exact equipment, it does specify requirements on equipment that can correspond to resources available to the enterprise.

There may be many General Recipes for a single enterprise route, because there may not be a one-to-one correspondence between planned products and produced material. For example, there may be a single enterprise route for a company's end product. There may be several General Recipes for intermediate materials, a General Recipe for the final product, and another General Recipe for packaging of the product.

A single General Recipe may also be associated with multiple enterprise routes. For example, an intermediate used in many products would have a single General Recipe that is associated with many products' enterprise routes.

An enterprise route contains information that can be used for long-range corporate planning and production capability planning. A definition of long-range capacity and capability planning is outside the scope of this standard, but enterprise-wide planning does require knowledge of what materials and processing capability are required to manufacture a product and what sites are capable of manufacturing a product.

### B.1.2 Site routing information

Site routing information is an equipment-independent definition of what is required to manufacture a product, or part of a product at a site. Site Recipes are used for site-level scheduling activities such as material allocation because they define the site-specific materials and subset of the general recipe actually produced at a site.

The Site Recipe may be used to identify the local Bill of Materials (BOM) for a product. The BOM is the critical information required for planning and costing. The BOM defines all materials required to produce a product at a given site, including materials not related to production, such as shipping materials and documentation. The Bill of Resources is a combination of the BOM, the production routing, and other information required for scheduling. A site route may be considered as an equipment-independent Bill of Resources.

There may be multiple Site Recipes for a single site route, for the same reasons listed above for general recipes.

## B.2 Costing information

Planning and costing information may be combined in integrated ERP systems, or costing may be handled separately. Either way, the information needed for costing must be synchronized with the information used in production and the information used in scheduling. The costing information is generally much less detailed than the production information.

Costing information deals with the cost of production and can be used either in determining the lowest cost cell or unit for production, or to analyze actual production. It can form the basis of decisions on which products are profitable, and decisions on capital investments or optimization efforts.

Many different levels of costing information may exist, mirroring the levels of abstraction in production recipes.

## B.3 Quality information

Quality information is information about quality assurance testing on the product and possible intermediates in order to determine conformance to specifications.

## B.4 Purchasing information

Purchasing information contains information about the cost and delivery of materials from suppliers. Purchasing information can start with the list of process inputs defined in a general or site recipe.

## B.5 Information elements

Table B1 lists the elements of general and site recipes and how that information relates to the other information sets used in a manufacturing enterprise. While each category requires the same basic information components, they use the elements for different purposes, and they require different information with the elements.

### Table B1 - Information elements

| Component | General and Site Recipe | Scheduling Information | Costing Information | Quality Information | Purchasing Information |
|---|---|---|---|---|---|
| Materials | Used for material balance. Used to ensure that the proper amount of materials is added in the right process operations.<br>Concerned with physical properties of materials (pH, density, components). | Used for purchasing or scheduling delivery of materials. Concerned with suppliers, and inventory. | Used to track material cost/expense and production amount/inventory. Concerned with cost. | Used to confirm the quality of materials, raw, intermediate, and final. | Used to identify materials and their properties so they may be correctly purchased. |
| Resources | Resources are implicitly part of the process requirements, since resources are needed to perform the processing actions. | Used to schedule production so as not to overuse resource capacity. | Concerned with the available cost of the resource. | Generally not relevant. | Generally not relevant, unless associated with the possible purchasing of outsourced production capability. |
| Production Stages | Used to determine safe or identifiable boundaries in the production of the product. Concerned with chemical boundaries. | May relate to process stages used in schedule route. | May relate to process stages used in activity costing. | May relate to QA tests on intermediate or raw materials for a stage. | Generally not relevant, unless production is long and raw material delivery dates are relevant. |
| Equipment Requirements | Define the requirements on any final target equipment | Generally not relevant. | Generally not relevant. | Generally not relevant. | Generally not relevant. |
| Other Information | Process safety and operations planning information is typically included. | Vendor information is typically included. | Internal costing and overhead rates. | Information about specific test, procedures, lab equipment, or other information required. | Supplier and delivery information, legal agreements, and other business information. |
| Authors | Development and manufacturing engineering staff. | Administrative staff. | Administrative staff. | QA staff. | Administrative staff. |
| Users | Production execution staff. | Production planning staff. | Accounting staff and management. | QA staff and labs. | Purchasing staff. |

## B.6 Recipe used in planning

The American Production and Inventory Control Society (APICS, www.apics.org) has published guidelines for production planning. The guidelines define the types of planning requirements necessary to obtain an operation schedule. The guidelines use a top down hierarchical process, which shifts responsibility from the management of the enterprise to the management of the site operations. Table B2 lists the APICS levels of plans and/or schedules and the correspondence to the recipes defined in this standard.

**Table B2 - Planning levels and recipes**

| APICS Level | Recipe Type |
|---|---|
| Business Plan | <not applicable> |
| Marketing Plan | <not applicable> |
| Production Plan | Built From General Recipe |
| Master Production Schedule (MPS) | Built From General or Site Recipe |
| Material Requirements Plan (MRP) | Built From Site Recipe |
| Operations Schedule | Built From Site or Master Recipe |

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# Annex C (informative) - Usage questions

**Question 1:** Are general and site recipes required?

**Answer 1:** The Part 1 standard does not impose these two particular recipe levels; the recipe model is both expandable and collapsible. The user is encouraged to implement the model that fits the need. Information contained within these recipes may be introduced at the different levels according to this model.

Master recipes are mandatory to make a product, using specific process cells. Use of higher level recipes depends on business drivers such as enterprise R&D, planning and supply chain environment, and costing methods.

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**Question 2:** When creating a General Recipe for the first time, do you start from an R&D formulation (top down) or from a control recipe created and modified during pilot production (bottom up)?

**Answer 2:** Either way is reasonable, and it depends on corporate culture, the expertise of the pilot plant engineers, and if there are tools in place to automatically generate a master recipe from a general recipe. Many believe that the first pass general recipes must come from R&D, but they may be “tweaked” by the pilot plant during scale up.

---

**Question 3:** What is meant by the recipe type hierarchy being collapsible and extensible?

**Answer 3:** A company may decide to implement general recipes, general and site recipes, or only site recipes. This collapses the recipe-type hierarchy. A company may also define additional levels, such as an Area Recipe, which has the same structure as an equipment-independent recipe, but is scoped to an area within a site. In this case the stage definitions could be split or combined so that they correspond to process cell boundaries, allowing the Area Recipe to be used for scheduling of production at process cells.

---

**Question 4:** Do you maintain a library of pre-defined process actions and process operations?

**Answer 4:** Yes, in order for general recipes to be successfully used, there must at a minimum be a library of process actions. This library defines the ‘contract’ between the pilot plant and the rest of manufacturing. All general recipes will be delivered using the available process actions, and the sites can determine their best method for implementing the actions.

---

**Question 5:** How do you ensure that the general recipe is not equipment dependent?

**Answer 5:** In order for the General Recipe to apply to multiple sites, and even to different process cells within the same site, it must be written without regard to specific equipment or equipment configurations. This is sometimes very difficult to do. It is natural for the author of a General Recipe to have a mental picture of the processing equipment as he or she begins to describe a manufacturing process. But, if not careful, that perceived equipment arrangement may influence the recipe to the point it does not apply across all possible manufacturing locations.

For example, consider a process that requires the removal of a solvent from the batch. Perhaps conditions are such that pumping the batch through an evaporator operated at the appropriate temperature and pressure, and receiving the stripped batch in another vessel could accomplish this. Or, perhaps the solvent removal could be done by pulling a vacuum on the reactor, while heating it to the appropriate temperature, and holding the batch under these conditions until the solvent has been removed.

The point is, if either method is appropriate, the General Recipe should be written to generically describe the process, without regard to the equipment that may be used to accomplish it.

In some cases, however, certain process requirements may dictate specific equipment configurations. An example might be that for a certain temperature-sensitive material, stripping should be done using a wiped film evaporator. In addition, a company may wish to have the General Recipe reflect its specific equipment standards. In these cases, the General Recipe should reflect the specific process equipment to be used. For example, a general recipe in a specific company might call for solids separation to be accomplished specifically by filtration, even though other methods, therefore different equipment, could be used. This is because filtration is the standard for solids removal within the example company.

---

**Question 6:** What is other information?

**Answer 6:** This information category within the general recipe captures recipe-dependent requirements for data collection and reporting as well as the recipe author's comments concerning safety and/or compliance issues. These comments are held to only those that pertain to the particular recipe of which this information category is a part. For example, stating that mercaptans have an obnoxious odor is not done here. That is a property of the group of chemical materials, mercaptans, and not any particular recipe. Stating that an obnoxious odor may be given off if the batch is overheated during the Reaction operation is a valid comment for this category. (Of course, this information would also be reflected by specifying the appropriate value for the maximum temperature limit of the appropriate Process Actions.)

Comments on safety entered here are not a substitute for Material Safety Data Sheets (MSDS). In the first place, MSDS pertain to chemical materials rather than to the recipe itself. The need to provide MSDS and the way in which they are provided is up to the governing authorities and individual companies, and is not covered in this example.

Data collection and reporting requirements are only stated here when they are above and beyond the standard practice established within a company. For example, if it is the normal practice to record temperature every hour during a reaction, but it is necessary to record the temperature every ten minutes for this product, then that requirement would be found in “other information.” (Record here refers to entering it into the batch end report. Temperature may actually be reported to the batch journal at a much shorter interval, depending on the plant site and particular manufacturing train.)

---

**Question 7:** What are equipment requirements?

**Answer 7:** By no means is it practical to load an equipment-independent recipe with sufficient information to design the equipment for a process operation. Therefore, the requirements for the equipment listed in a recipe must be practical and meet the needs of the individual company in their implementation of a recipe system. A company may wish to employ some type of overall requirements classification system, rather than listing individual requirements. That is, a Class I equipment requirement might be a 304 stainless steel reactor with circulating pump, agitator, steam heat, water cooling, an overhead condenser and a distillate receiver. Class II would be something else, and so on. In this case, the equipment requirements in the recipe would appear as one value for each process operation.

In this example, the following approach was taken:

1. Implicit requirements need not be stated.

2. Process results expected to be brought about by the equipment are stated.

3. Certain necessary equipment attributes are stated.

Containment of the batch during manufacturing is a task of the equipment. However, that is needed and expected for all batches, and is therefore implied in every recipe. It is not necessary to state that a reactor is required for a reaction process operation. On the other hand, the equipment's ability to heat, cool and mix are deemed to be important and differentiating requirements in this implementation. In addition, the equipment's material of construction, or its specific corrosion resistance, is deemed to be an important attribute.

To assure a common understanding of the equipment requirement values, a system of "types" may be developed. Only these types may be used in the recipe. For "Material of Construction," categories could be used rather than stating an actual metallurgy.

Equipment requirements are associated with process stages or process operations. When a process stage or operation is used in a recipe, its equipment requirements are brought with it. The recipe author will then assign values to the appropriate Equipment Requirements. These values must be of the permitted value set established in the library.

---

**Question 8:** What are some examples of equipment requirements based on types?

**Answer 8:** Some examples of equipment requirements related to heating are listed below. Heating may be required within a process operation to take the batch from one temperature to a higher temperature, or to put thermal energy into the batch at or near the same temperature, as in boiling off a liquid component or during an endothermic reaction. If heating is required during the process operation with which this requirement is associated, the equipment involved must then have the means of heating the batch. This may be a vessel jacket, internal coils, an external heat exchanger or some other arrangement. The heating media may be whatever is appropriate for the range of temperatures involved, e.g., steam, thermal fluid, hot water, etc. Although there are important engineering design considerations, they should not matter to the product, and, therefore, do not matter to the recipe. In the rare cases where they may make a difference--say the media may have a profound effect on product quality should there be a leak--the preference may be made in the recipe. Appropriate values for this equipment requirement could be, "Type 1," "Type 2," and "Type 3."

**TYPE_1 -** Type 1 heating is low temperature heating, up to 200° F. It can be accomplished with low pressure steam, hot water, or other circulating liquid heat transfer media.

**TYPE_2 -** Type 2 heating is medium temperature heating, up to 320° F. It can be accomplished with medium pressure steam or other circulating liquid heat transfer media.

**TYPE 3 -** TYPE 3 heating is high temperature heating, above 320° F. It usually requires a circulating heat transfer media, which has been heated by a fired heater.

Other equipment requirements based on types could be:

**Reaction -** The collection of process actions that carry out a chemical reaction. This will involve actions such as charging ingredients, heating or cooling, and holding.

**Stripping -** The collection of process actions that will cause a component or components to be vaporized and removed from a batch of material. These components, e.g., solvent, water, etc., may be collected for reuse or discarded.

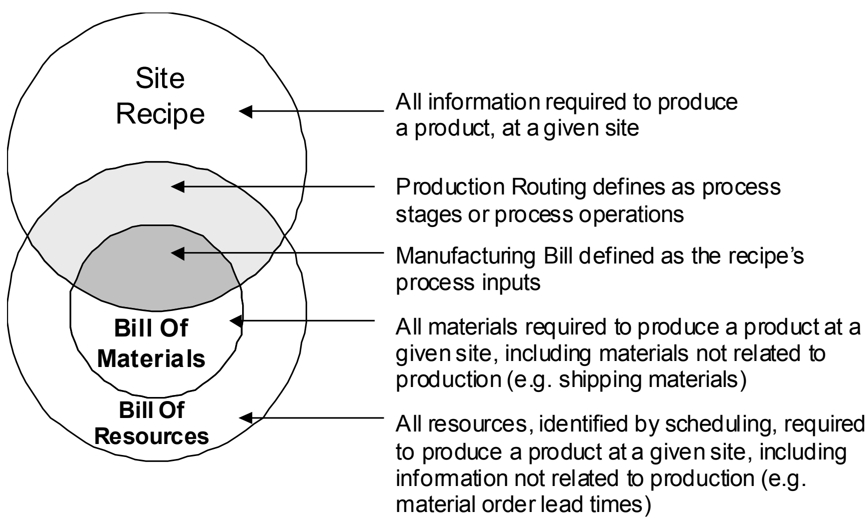
**Solid removal -** The collection of process actions that cause the removal of undesirable solids from a batch of liquid material. This is most commonly done by filtration.

**Finishing -** The collection of Process Actions that finish the batch for storage, use or sale. They will usually consist of sampling, adjusting and discharging the batch from the manufacturing train.

---

**Question 9:** Why is the overlap between Site Recipes and the Bill of Resources important?

**Answer 9:** The following figure illustrates the overlap of information between a site recipe, a bill of material, and bill of resources required to make a product. This overlap is important because, if a material in a site recipe changes or processing steps change, they must be reflected in the bill of materials and scheduler's bill of resources. Otherwise, any production schedules and material inventory scheduling will not line up with actual production.




For example, assume that it is discovered that the efficiency of a catalyst is greater than originally expected. This would require a change in the amount of catalyst in the general recipe and the related site recipes. This must be reflected in an equivalent change in the bill of materials for the product. If the change is not reflected, then too much catalyst would be purchased for each batch, and money would be wasted. If the same change meant that there were fewer processing steps, such as elimination of a filtration stage, then this would need to be reflected in the bill of resources. If this change is not reflected, then the schedule would schedule a filtration system that was not needed, preventing the filtration system from being used by another batch. Unless the information used by the scheduling system and the production system is consistent, any schedule is unrealistic. The schedule would either over commit the resources or under utilize the resources.

**Question 10:** Does the life cycle state model imply a progression of states?

**Answer 10:** There is no defined standard state model. Valid life cycle state transitions are usually defined by company policy. In addition, life cycle states of elements may be related. For example, a change to an equipment requirement definition state to “Withdrawn" may require changes to the life cycle states of all recipes using the definition. This should be defined by corporate policy. Moving in reverse, for example from “Withdrawn” to “Effective,” should also be considered. Systems that implement the life cycle states should take into account interdependencies and reversals of states.

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# Annex D (informative) - Bibliography

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