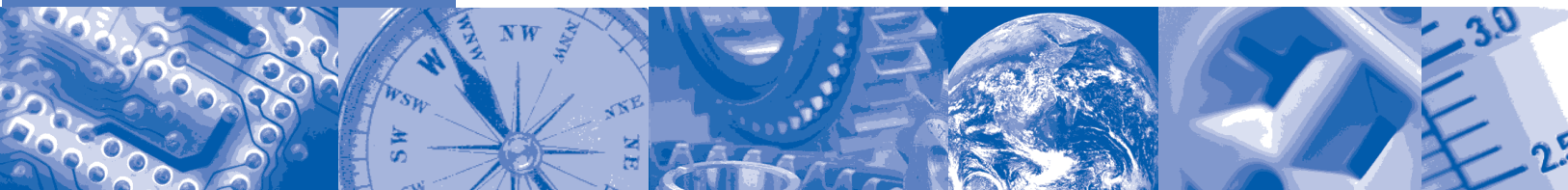


ANSI/ISA-88.00.03-2003



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



**ISA—The Instrumentation,
Systems, and
Automation Society**

Approved 14 March 2003



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

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Preface

This preface, as well as all footnotes and annexes, is included for information purposes and is not part of ANSI/ISA-88.00.03-2003.

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The ISA Standards and Practices Department is aware of the growing need for attention to the metric system of units in general, and the International System of Units (SI) in particular, in the preparation of instrumentation standards. The Department is further aware of the benefits to USA users of ISA standards of incorporating suitable references to the SI (and the metric system) in their business and professional dealings with other countries. Toward this end, this Department will endeavor to introduce SI-acceptable metric units in all new and revised standards, recommended practices, and technical reports to the greatest extent possible. *Standard for Use of the International System of Units (SI): The Modern Metric System*, published by the American Society for Testing & Materials as IEEE/ASTM SI 10-97, and future revisions, will be the reference guide for definitions, symbols, abbreviations, and conversion factors.

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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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This standard was approved for publication by the ISA Standards and Practices Board on 19 February 2003.

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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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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.



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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.

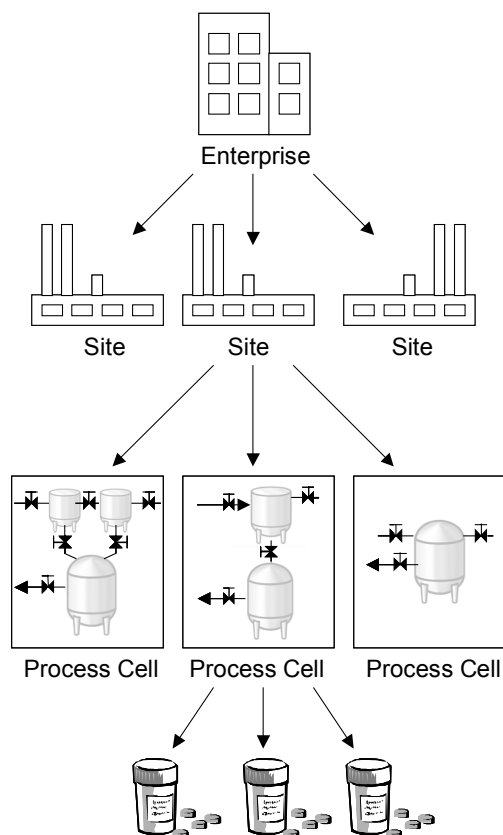
4.2 General and site recipe description

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.

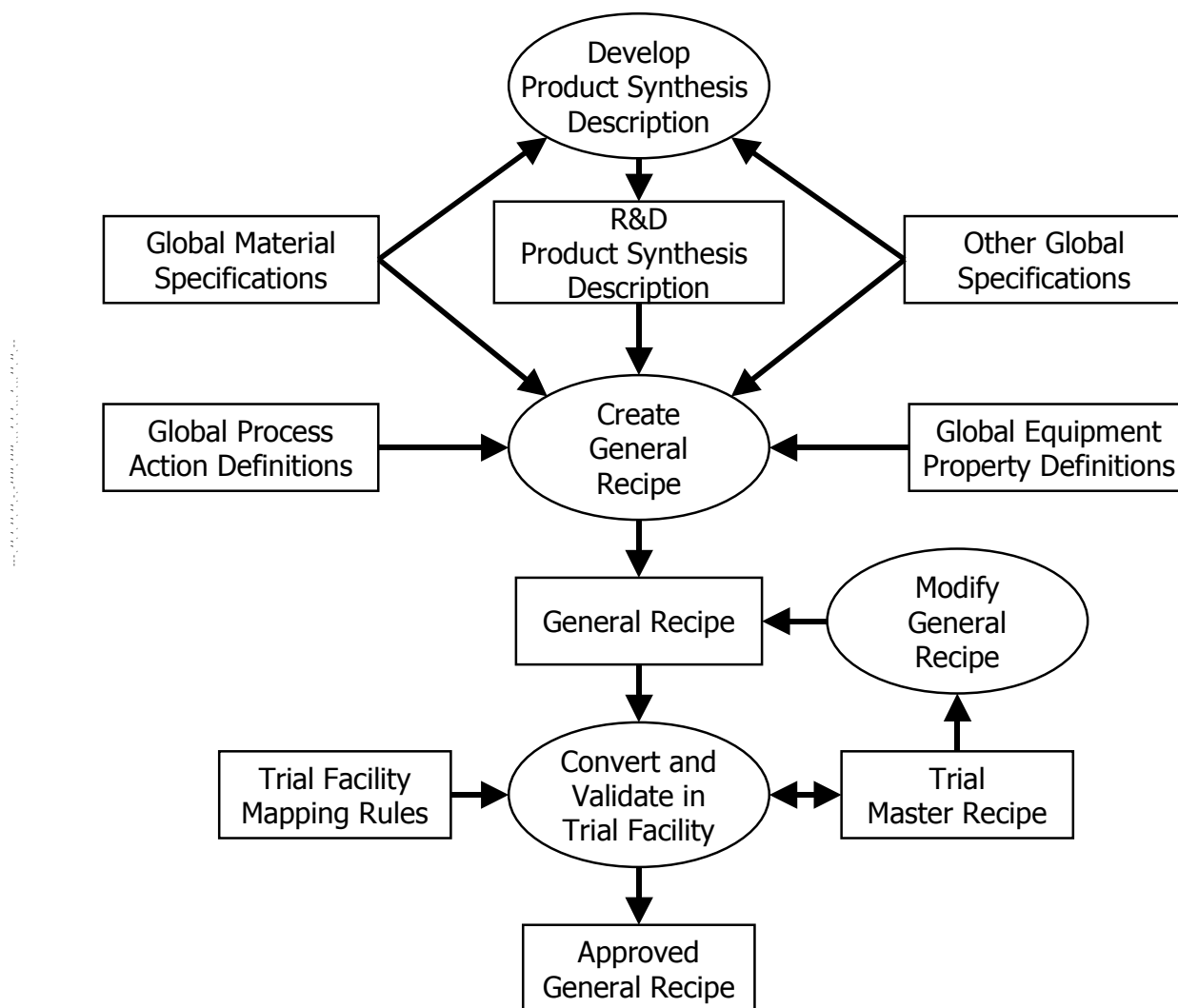


Figure 2 - Pilot plant creation of equipment-independent recipe

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.

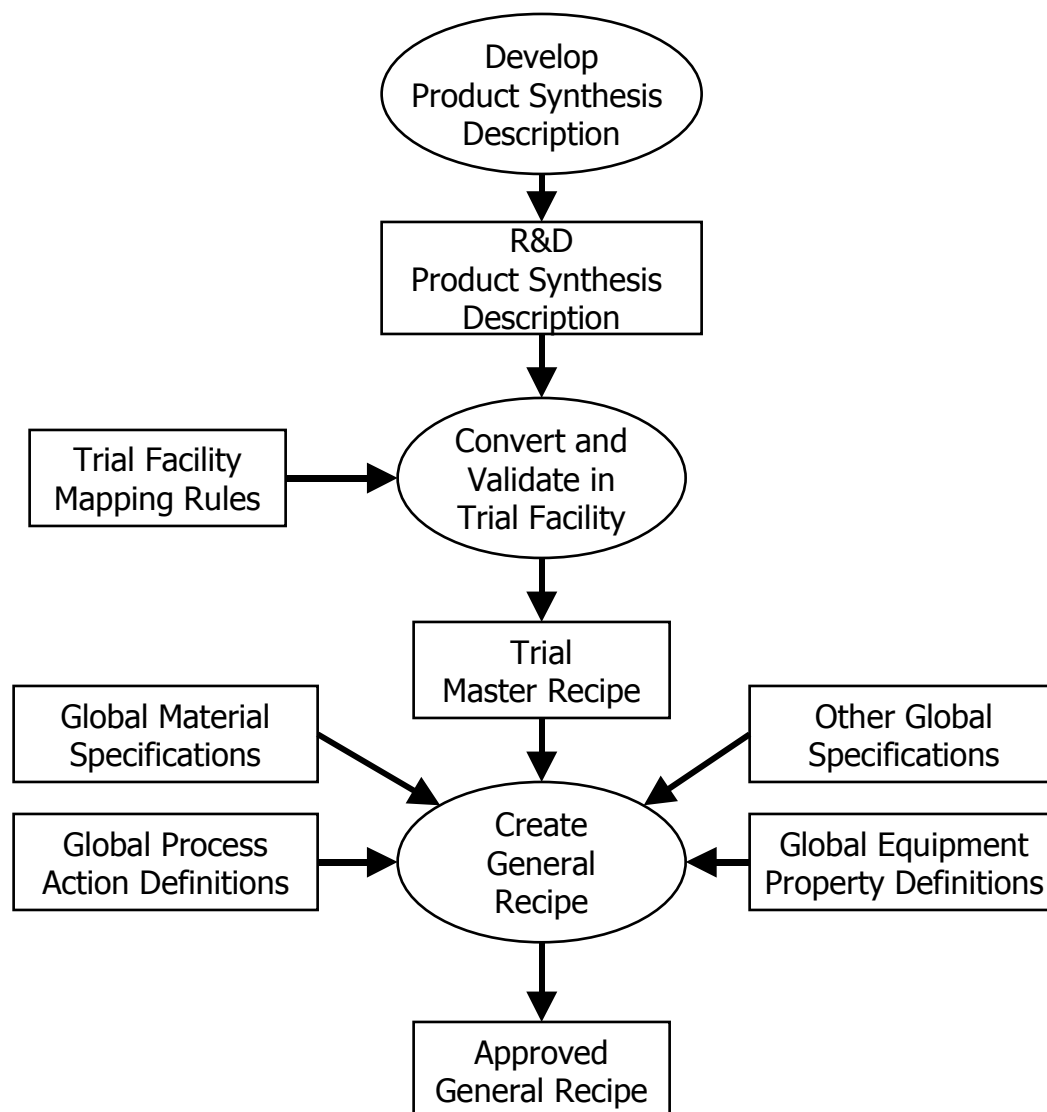


Figure 3 - Equipment-independent recipe from pilot plant development

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.

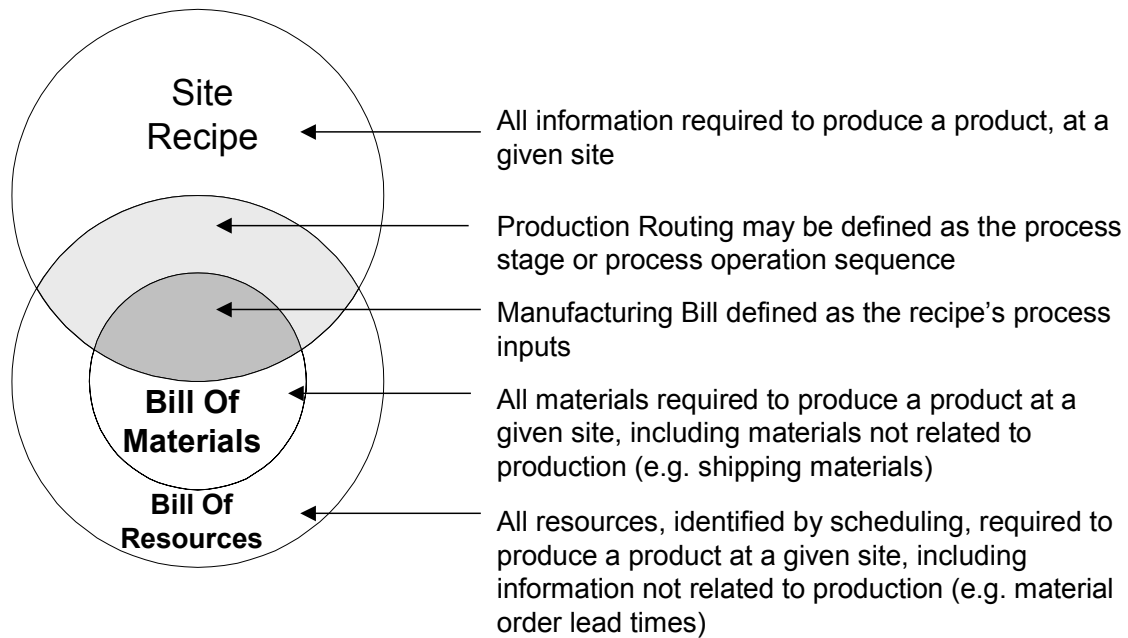


Figure 4- Site recipe, BOM, and BOR information overlaps

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:

- The collection of equipment-independent recipes formally defines the processing requirements and some of the associated equipment requirements for the facility.
- The process dependencies are useful in the definition of material flows between units and between process cells.
- The formulas within the equipment-independent recipes precisely define the materials that are to be handled by the facility.
- The formulas clearly define the ratios of amounts of materials, including expected yield amount compared to raw material amounts.
- 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.

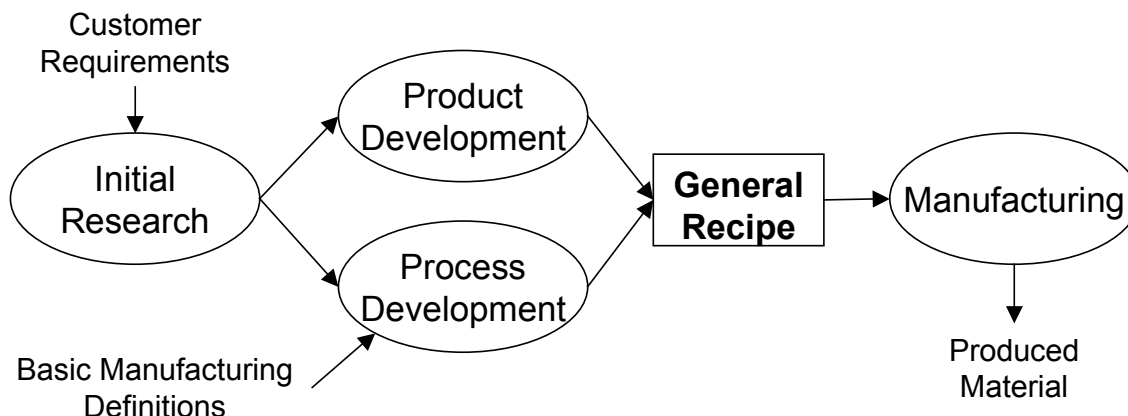


Figure 5- General recipes in a typical development function

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.