



Agile Product Lifecycle Management

Recipe & Material Workspace Recipe Management Guide

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Preface

Oracle's Agile PLM documentation set includes Adobe® Acrobat PDF files. The [Oracle Technology Network \(OTN\) Web site](http://www.oracle.com/technetwork/documentation/agile-085940.html) <http://www.oracle.com/technetwork/documentation/agile-085940.html> contains the latest versions of the Agile PLM PDF files. You can view or download these manuals from the Web site, or you can ask your Agile administrator if there is an Agile PLM Documentation folder available on your network from which you can access the Agile PLM documentation (PDF) files.

Note To read the PDF files, you must use the free Adobe Acrobat Reader version 9.0 or later. This program can be downloaded from the [Adobe Web site](http://www.adobe.com) <http://www.adobe.com>.

The [Oracle Technology Network \(OTN\) Web site](http://www.oracle.com/technetwork/documentation/agile-085940.html) <http://www.oracle.com/technetwork/documentation/agile-085940.html> can be accessed through Help > Manuals in both Agile Web Client and Agile Java Client. If you need additional assistance or information, please contact My Oracle Support (<https://support.oracle.com>) for assistance.

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Readme

Any last-minute information about Agile PLM can be found in the Readme file on the [Oracle Technology Network \(OTN\) Web site](http://www.oracle.com/technetwork/documentation/agile-085940.html) <http://www.oracle.com/technetwork/documentation/agile-085940.html>.

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Go to the [Oracle University Web page](http://www.oracle.com/education/chooser/selectcountry_new.html) http://www.oracle.com/education/chooser/selectcountry_new.html for more information on Agile Training offerings.

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Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

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Introduction to Recipe Management

This chapter includes the following:

▪ About this Guide	1
▪ Recipe & Material Workspace Documentation	1
▪ Recipes in RMW - An Overview	2
▪ Types of Recipes	2
▪ Recipe and Recipe Templates.....	3
▪ Recipe Components	3

The Recipe Management module within the Agile PLM Recipe & Material Workspace (RMW) solution provides integrated recipe authoring capabilities that help you to track the process for a product being developed. In RMW, recipes are integrated with the related Bill of Materials (BOM), Bill of Equipment (BOE), and Bill of Processes (BOP) to maintain a complete and reliable electronic record.

The primary benefits of using RMW for recipe management are:

- Re-usability of recipe objects — once created, each recipe object can be reused in other recipes and experiments or work requests, across multiple sites.
- Recipe and experiment results captured in electronic format — recipes, experiments, and bills need not be created manually (in paper format) for each recipe instance.
- Ability to import and export recipes in XML — eliminates manual errors during tech transfers; the transfer can be completed in a fraction of the usual time.
- Greatly reduced effort in authoring — easy-to-use graphical and text editors simplify and expedite the recipe authoring process.

About this Guide

This guide provides information on all the features and functionality of the RMW Material Management module. It also covers instructions on how to use the various menus and commands available on the RMW User Interface to create and manage material objects. The features that are visible to you on the interface are determined by the access privileges assigned to you by an administrator.

Recipe & Material Workspace Documentation

The complete list of RMW manuals is provided here for the benefit of users and administrators of the RMW solution.

- *Getting Started with Recipe & Material Workspace* — describes common concepts, basic navigation, searches and workflows. Also covers how to work with reports, standards, and
-

environmental conditions.

- *Recipe & Material Workspace Administrator Guide* — describes all administration and configuration information including Agile PLM integration requirements.
- *Recipe & Material Workspace Process Management Guide* — describes the features of the Process module, covering the creation and execution of projects and campaigns, control recipes, and work requests.
- *Recipe & Material Workspace Recipe Management Guide* — describes the features of the Recipe module, covering the authoring and management of recipes and recipe templates.
- *Recipe & Material Workspace Material Management Guide* — describes the features of the Materials module, covering how to work with material requests, inventory, and allocation. Also covers how to manage analytical activities.
- *Recipe & Material Workspace Equipment Management Guide* — describes the features of the Equipment module, covering equipment qualification, loan, lease, and reservation.
- *Recipe & Material Workspace Export/Import Guide* — describes how to export and import RMW business and administrator objects from a source system to a target system.

RMW is accessed only through the Agile PLM user interface. Refer to the *Getting Started with Agile PLM* along with the *Agile PLM Administrator Guide* for a thorough understanding of PLM processes. The complete set of Agile PLM documentation, including RMW documentation, is available on the [Oracle Technology Network \(OTN\) Web site](http://www.oracle.com/technetwork/documentation/agile-085940.html)
<http://www.oracle.com/technetwork/documentation/agile-085940.html>.

Recipes in RMW - An Overview

A Recipe contains the minimum set of information about the developmental requirements of a specific product. Recipes generally include instructions about gathering and combining raw material, the type of equipment to be used, and processes to be followed to create the target product.

In RMW, instructions in a recipe can have embedded variables (placeholders) for generic resource names – for resources such as equipment, material, or standards. This type of authoring ensures that the recipes can be reused as required, with the variables resolved to specific values for each use in a project or campaign.

Within the product development cycle for a target material, as a project or campaign gets underway, the recipe that defines the process of creating that product is attached to a process step within the campaign. Generic recipes are converted to project-specific Control Recipes, and these are in turn used to create Work Requests. Work requests can be completed in an experiment, or logged as a production batch record.

Recipes can be versioned based on feedback from the pilot plant or commercial operations.

Types of Recipes

Recipes are classified into the following types:

- **General Recipe:** A General Recipe is the basis for lower-level recipes and used at the company level. It specifies the raw materials, quantities (of raw material) required and processing information for making the product. It does not include information about the Site/Equipment involved in the manufacture of a product. It only communicates processing requirements to multiple manufacturing sites.
- **Site Recipe:** A Site Recipe is a derived form of a general recipe that takes into consideration the specific conditions or constraints of a particular manufacturing site. It provides the level of detail necessary for site-level, long-term production scheduling.

Site recipes contain information tailored for a target location. These can be modified for local language, local measurements and availability of local raw materials and include information about on-site processing, storage capacity, and constraints. From a general recipe, you can derive multiple site recipes, each covering a part of the general recipe that may be implemented at a specific site.

- **Master Recipe:** A master recipe is targeted to a processing area and is derived from a site recipe or created directly. Master recipes depend on equipment types or classes, such as a glass-lined reactor or mixing vessel. These recipes can contain product-specific information required for detailed scheduling, such as equipment requirements. But unlike the general and site recipes, S88 batch control requires a master recipe. A master recipe is the template for recipes used to create individual batches. Without this template, no specific batch recipes can be created, and therefore, no batches can be produced.
- **Control Recipe:** A control recipe is used to create a single, specific batch. It starts as a copy of a master/general/site recipe and is modified as necessary to create a batch. The modifications may account for batch size, characteristics of raw materials on-site (e.g., potency), or actual equipment to be used. While several (dozens, hundreds, or thousands of) batches may use the same master recipe, every batch has a single control recipe unique to that batch and that batch alone.

Two control recipes may be identical in ingredients, quantities, or equipment used, but they are identified individually. Control recipes unique to individual batches allow product tracking or genealogy tracking to occur.

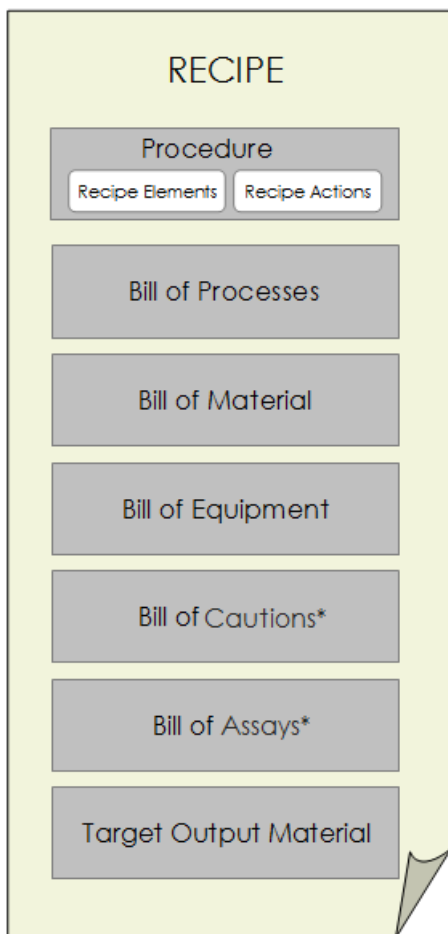
For complete information on Control Recipes, see *Agile Recipe & Materials Workspace Process Management Guide*.

Recipe and Recipe Templates

The difference between a Recipe and a Recipe Template is that templates have unresolved variables and parameters with undefined constraints. A Recipe needs to be complete and ready before you can execute it.

Recipe Components

A Recipe in RMW is a structured compilation of a set of components as shown below. The following sections describe each component.



* Generated only if associated references are available. See [Bill of Cautions](#) on page 6 and [Bill of Assays](#) on page 6.

Procedure

In RMW, a recipe procedure is a structural representation of Recipe Elements, Recipe Actions, and associated objects. The RMW user interface allows you to create Recipe Element Templates and Recipe Action Templates which can then be reused while authoring recipes.

Recipe Elements

A recipe element is a procedural element that is used to represent an entity in procedure function charts. A recipe element can be any of the following:

- **Unit Procedure** - A Unit Procedure is an ordered set of Operations that is carried to completion on a single unit. It is a contiguous production sequence acting on a single unit only. Only one Unit Procedure is allowed to be active on a unit at a time. Multiple Unit Procedures can run concurrently as part of the same procedure, as long as they are active on different units.
- **Operation** - An Operation is an ordered set of Phases carried to completion within a single unit. An Operation usually involves taking the material being processed through some type of physical, chemical, or biological change. Like unit procedures, the standard presumes only one operation is active on a particular unit at a time.
- **Phase** - A phase is the smallest element of procedural control that can accomplish process-oriented tasks. A Phase performs unique and generally independent, basic process-oriented functions, such as charging an ingredient or agitating a tank. All other elements (procedures, unit procedures, and operations) group, organize, and direct the Phases.

Recipe Actions

A Recipe Action contains an instruction to perform a unique and generally independent action related to the manufacturing process. It allows the author to specify the following details:

- **Variables** – resources you can use. For example: Equipment, Material and Standards
- **Parameters** – Parameters you need to measure
- **Second Person Verification** – Whether you require electronic signature and second person verification
- **Execution mode** – manual or automatic.

Bill of Processes

A Work Request for a target material contains a list of all materials, equipments, process steps, and assays. At the heart of the creating a Work Request is a series of steps that go into creating the target material, called the Bill of Process (BOP).

The BOP is composed of one or more Unit Operations each of which is composed of one or more Unit Actions.

Bill of Material

A Bill of Material (BOM) is an assembled list of all materials required to produce a product at a given site, including materials not related to production (For example: Shipping materials, or other consumables required for the overall recipe).

Recipes contain text instructions embedded with variables which act as placeholders for defined material types or categories. Each variable is associated with certain criteria that qualify the material. Also see: [Variables](#) on page 13

When these recipes in the master library are “resolved” by the user, the software automatically generates the Bill of Materials for the Recipe.

Bill of Equipment

A Bill of Equipment (BOE) is the approved list of equipment used in the process of creating a product.

When the equipment-related variables in recipes are resolved by the user, the application generates the BOE for the Recipe.

Bill of Assays

A Bill of Assays (BOA) is a list of assays that are referenced in the recipe. If recipe actions within a recipe contain parameters that have references to defined assays in the system, the application generates a BOA for the recipe.

Bill of Cautions

A Bill of Cautions is a list of standards of the type Caution, associated with a recipe. If recipe actions within a recipe contain associations to defined Standards in the system, and these Standards are categorized as Cautions, a Bill of Cautions is also generated for the recipe.

Targeted Output Material

Quantities of materials or resources, created as a result of the product manufacturing processes defines Output. During recipe creation, you can specify the material that will be produced as output, along with the exact output quantity.

Authoring Recipes

This chapter includes the following:

▪ Creating Recipe Action Template	8
▪ Creating Recipe Element Template	9
▪ Creating a Recipe	10
▪ Working with Recipe Variables and Parameters	13

Recipe authoring involves creation of recipe actions and recipe elements - the essential components of a recipe. Instructions or the procedures for recipe execution are created in recipe action template. These instructions include:

Variables - material, equipment and standards.

Control Parameters - to set the control settings within the Recipe.

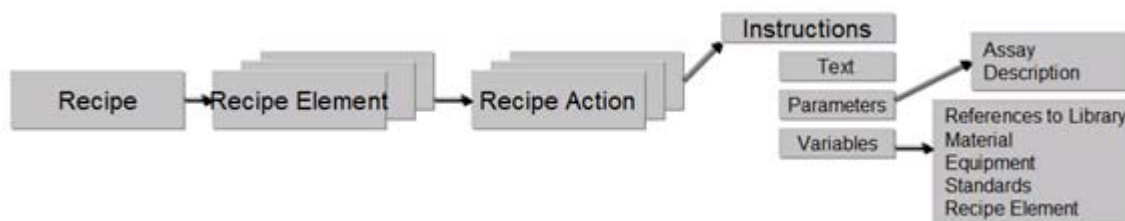
In-process parameters - quality parameters which need to be measured during the process.

Results - analytical result measurements for the sample taken from the material being made.

Since recipe actions are embedded in the elements of a recipe, the recipe author adjusts the recipe action template to suit the requirements of each recipe. Phases can also exist as templates and can be reused.

The sequential flow of recipe actions is created in recipe element template. This flow can include other recipe elements as well. You can further modify these components in the recipe and then later optionally save a recipe element as a template.

A recipe is authored by creating a sequential flow of recipe elements and the recipe actions embedded within, and added externally, if required. The instructions defined in recipe actions become bill of processes. The resources associated with the variables form bills of material, equipment and cautions (standards). All tests associated with recipe elements form the bill of assays.



Creating Recipe Action Template

A Recipe Action Template is a recipe object that defines the procedures to create a recipe. These procedures are a set of actions, called instructions, and include:

- Variables - can be material, equipment and standards.
- Control Parameters - to set the control settings within the Recipe.
- In-process parameters - quality parameters which you need to measure during the process.
- Results - analytical result measurements for the sample taken from the material being made.

Since Recipe Actions are embedded in the elements of a recipe, the recipe author adjusts the Recipe Action template to suit the requirements of each given Recipe. Phases can also exist as templates and can be reused. When the Phase or Recipe Action template objects are included in a Recipe, the contents are copied into the Recipe.

The author can further modify these components in the Recipe and then later optionally save the element as a template.

To create a recipe action template:

1. Go to Create New menu, select Recipes > Action Template.
2. In the General tab, enter the required information.

Significant inputs:

- Mode - The method of recording the activities.
- Second Person Verification Required - If you require another person to verify the recipe actions.
- Category - The group of resources, such as material, to which this recipe action template belongs.

3. Click Next.
4. In the Instructions tab, enter the instructions in the Text Editor.

For complete details on how to use the Text Editor, see Appendix: [Working with Text Editor](#) on page 21.

5. Click Next.
6. In the Characteristics sub-tab under the Details tab, enter the required information.
7. Click Next.
8. In the Acknowledgments sub-tab under the Details tab, enter the required information.

You can define the acknowledgments to ensure that proper procedure is followed during recipe execution. This allows the recipe author to add an acknowledgment that will be required by the operator to acknowledge the instructions/statements while executing the current recipe action. You can also specify if this acknowledgment requires a second person verification or electronic signature.

Changing Lifecycle Phase of Recipe Action Template

A recipe action template goes through the following phases in its lifecycle:

- Draft - the lifecycle phase of a newly created recipe action template. You can roll back a template to the draft state from any other lifecycle phase.
- Submitted - when the recipe action template is sent for approval.
- Approved - when the recipe action template is approved.
- Rejected - not accepted for use.
- Obsolete - not valid for execution, however, can be used for reference purposes. You can also revive it for approval.

Note Editing of a recipe action template is allowed only when it is in Draft status.

To change the lifecycle phase of a recipe action template:

1. Go to Recipes > Action Template and run a search. From the search results, select a recipe action template.
2. Click Change > Lifecycle Phase and select an applicable lifecycle phase.

Creating Recipe Element Template

To create a recipe element template:

1. Go to the Create New Menu, select Recipes > Element Template.
2. In the General tab, enter the required information.

Significant inputs:

- Recipe Element Level - The level identifying the position of a Recipe object in the Recipe hierarchy, as prescribed by ISA-88.
 - Life Cycle Point - The stage of target molecule development.
 - Usage
 - *Small Molecule* = Chemical Product
 - *Large Molecule* = Biologics
 - *Formulation* = Drug Product
 - Mode - The method of recording the activities.
3. Click Next.
 4. In the Instructions sub-tab under BOP tab, select the recipe element record and click Edit SFC.
 5. In the right pane of the SFC Editor, click on Start is Complete and click Delete or hit the Delete key on your keyboard.
 6. Click New > Recipe Action From Template and select a recipe action template.

Note You can add more than one recipe action templates to a recipe element.

7. Click anywhere in the right pane. The recipe action template object is inserted. You also see the added recipe action template(s) under the recipe element name in the left pane.
8. Click Add > Connection to create the sequence of flow and click OK.
For complete details on how to use the SFC Editor, see *Appendix: [Working with SFC Editor](#)* on page 21.
9. To edit a recipe action template, select the recipe action and click Edit.
10. To save the entire recipe element together with some or all the recipe actions, select the desired records and click Save As Template.
11. Click Next.
12. In the Resources sub-tab under BOP tab, you can edit or delete the recipe element components listed under recipe action template. These components are extracted from the variables and parameters defined in instructions given in the recipe action template.
13. Click Next.
14. In the Targets tab, click Add Target Material to select the material from material library.
15. Click Finish.

Changing Lifecycle Phase of Recipe Element Template

A recipe action template goes through the following phases in its lifecycle:

- Draft - the lifecycle phase of a newly created recipe element template. You can roll back a template to the draft state from any other lifecycle phase.
- Submitted - when the recipe element template is sent for approval.
- Approved - when the recipe element template is approved.
- Rejected - not accepted for use.
- Obsolete - not valid for execution, however, can be used for reference purposes. You can also revive it for approval.

Note You can edit a recipe element template only when it is in the Draft status.

To change the lifecycle phase of a recipe element template:

1. Go to Recipes > Element Template and run a search. Select a recipe element template from the search results.
2. Click Change > Lifecycle Phase and select an applicable lifecycle phase.

Creating a Recipe

To create a recipe:

1. Go to Create New menu, select Recipes > Library.
 2. In the Preface tab, select the following:
-

- Purpose - The usage of the recipe.
 - Type - General, Site or Master Recipe.
3. Click Next.
 4. In the General sub-tab under the General tab, enter the required information.
Significant inputs:
 - Operating Mode – For clinical trials or for actual product development.
 - Target Material – The final output after the execution of the recipe.
 - Regulatory Designation – Indicating if it is starting, penultimate or final material.
 5. Click Next.
 - If you selected Site or Master as the Type of recipe in the Preface tab, the Sites tab appears. Use the Lookup icon and select the Site of Execution of this recipe.
 - If you selected General as the Type of recipe in the Preface tab, the Company tab appears. Use the Lookup icon and select the Company where this recipe will be executed.
 6. Click Next.
Recipe Instructions
 7. In the Instructions sub-tab under BOP tab, select the recipe record and click Edit SFC to create a sequential flow chart of process.
 8. In the right pane of *SFC Editor*, click on the *Start Is Complete* object and click Delete.
 9. Click New > Recipe Element from Template.
You can also right-click in the right pane of the editor and select the same option from the menu.
 10. Select a Recipe Element Template and click OK.
 11. Click anywhere in the right pane to add the recipe element object.
For complete details on how to use SFC Editor, see [Working with SFC Editor](#) on page 21.
When you add a recipe element template, the recipe action templates associated with it are added automatically. If you wish to add more recipe action templates, click New > Recipe Action Template and select the desired templates.
 12. Click OK.
In the Instructions tab, a table listing the recipe and associated recipe elements and recipe actions appear. The instructions that you entered in the recipe action template appear in the right column.
 13. To edit a recipe element template or a recipe action template, select the desired record and click Edit.
 14. If you wish to save the recipe BOP as a template for future use, click Save As Template.
 15. In the *Save As Template* window, enter a unique Name for the recipe template and click OK.
 16. Click Next.

Variables and Parameters

Also see: [Working with Recipe Variables and Parameters](#) on page 13.

In the Resources sub-tab under BOP tab, a table appears displaying the list of recipe elements and associated recipe actions, along with the list of variables and parameters that you defined in recipe action template.

Here, you can edit the variables and parameters, delete the variables and parameters that you wish to exclude and resolve Standards variables.

Note The Material and Equipment variables and parameters can be resolved only from BOM and BOE tabs, respectively.

17. To edit a variable or a parameter, select the desired record and click Edit.
18. To resolve a General variable, select the desired record and click Resolve Variable.
19. Click Next.

Bill of Material

In the Materials sub-tab under the BOM tab, the list of material variables appears. You can resolve the unresolved variables, view sample information of the material to which a variable is resolved. You can add, delete and edit the variables.

20. For each material, enter the Planned Quantity to Consume and the Display Order, in which the items will appear in the recipe list.
21. To view the information of a material sample, select the desired material variable and click View Sample Information.

The *Sample Information* page appears, displaying the Lot ID and other details from which the selected material was sampled.

22. To add a new material variable, click More > Add Material Variable.
23. Click Next.

In the Consumables sub-tab under the BOM tab, the list of consumable material variables appears. You can resolve the unresolved variables, and add, delete and edit the variables.

24. For each consumable material, enter the Planned Quantity to Consume.
25. Click Next.

In the Specification Plans sub-tab under the BOM tab, a list of specification plans associated with the recipe appear. You can delete the unwanted plans or add new specification plans.

26. Click Next.

Bill of Equipment

In the Equipment sub-tab under the BOE tab, the list of equipment variables appears. You can resolve the unresolved variables, view disposition of equipment, and add, delete or edit equipment variables.

27. To resolve an unresolved equipment variable, select a variable record and click Resolve Variable.
28. To view the disposition of equipment, select an equipment variable record and click View Equipment Disposition.

The *Equipment Disposition* information page appears, displaying the equipment name, its availability status, etc. You can view the equipment reservation status by clicking Reservations. You can also view the equipment cleaning activity by clicking View Last Cleaning Activity.

29. Click Next.

Targeted Output

In the Output tab, a list of output material variables, which you defined in the instructions entered in recipe action templates, appears. You can edit these variables, add new material variables and resolve the unresolved variables.

30. Click Finish to save the recipe.

Creating Work Request from Recipe

You can create a work request only from an approved Recipe. When you create a work request from a recipe, the application automatically creates a control recipe, assigns a system-generated control recipe ID and approves it internally.

To create a work request:

1. Go to Recipes > Library and run a search. Select a Recipe from the search results.
2. In the *Create Work Request from Recipe* page, enter the required information.

Significant inputs:

- Project - The ID of the project that you wish to associate with the work request.
- Scale Factor - Denotes the factor by which the quantities in recipe will be scaled for production purposes. This is required for raising material and equipment requests. For example, for a recipe action, if the quantity of the material, Sodium Hydroxide, is given as 10 gms, the scale factor of 5 will make the quantity to 50 gms.

Note If the recipe is for Cleaning purpose, the Target Yield field does not appear:

- Target Yield - Net amount of actual produce expected.

Note The application generates the Work Request ID.

Working with Recipe Variables and Parameters

Note Variables and parameters are defined in Instructions entered in the Recipe Action Template. For more details, see [Creating Recipe Action Template](#) on page 8.

Variables

Variables in recipes are links to various resources (objects) in the application such as material, equipment and standards. Since these resources can vary with geographical location, availability, restrictions or standards, a variable helps in picking up a qualified resource for successful execution of a recipe. The qualified resource value depends on the restrictions that you have formulated. Thus, variables provide flexibility to a recipe to adapt to multiple environments and conditions.

Variables are of two types:

- Input Variables – The resources that are used for carrying out development or clinical trial/study of the final product.
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- **Output Variables** – Only the material resources that are result of recipe execution. This can be the final product, by-product or penultimate product.

Resources

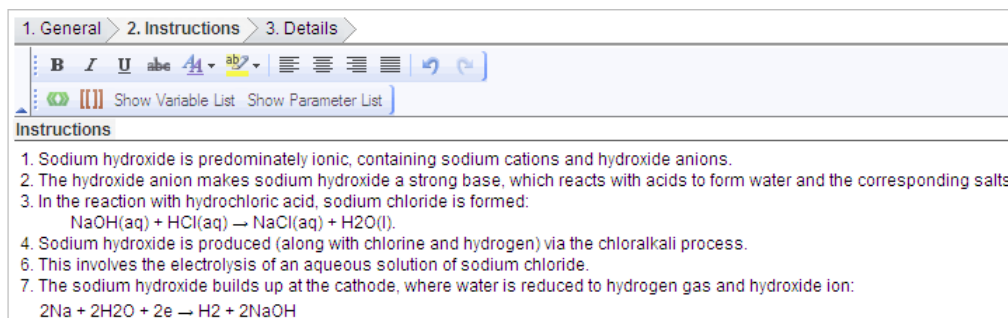
In the RMW application, Resources refer to the equipment, material and standards used in recipe.

- **Equipment** – When you create a variable for Equipment. The variable is associated to a *Category* in the Equipment Library, such as Blender, etc. At the time of its resolution, the variable will search only the selected equipment category to let you pick the desired equipment. If you wish to associate the variable to the whole Library, you need not select a specific category under it.
- **Material** – When you create a variable for Material. The variable is associated to a *Category* in the Material Library, such as, Chemical. At the time of its resolution, the variable will search either the entire material library or only the chemical materials to let you pick the desired material.
- **Standards** – When you create a variable for a Standard. The variable is associated to a *Category* in the Standards list. At the time of its resolution, the variable will search only the selected standard category to let you pick the desired equipment. You can associate the variable to the whole library.

Formulation of a Variable

When you write instructions, you specify the material, equipment and standards that will be used as input for producing the product. You also specify the material that will be the result of the recipe.

For example, you may write the following instruction:



1. General 2. Instructions 3. Details

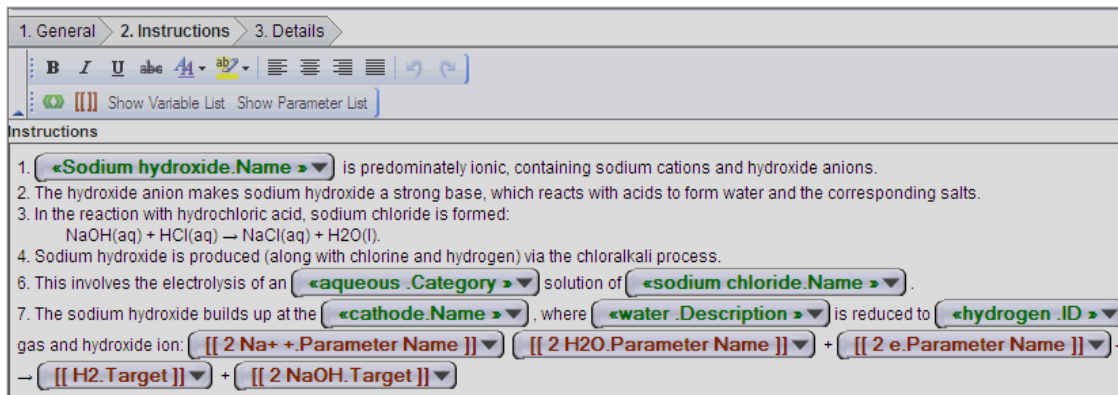
Instructions

1. Sodium hydroxide is predominately ionic, containing sodium cations and hydroxide anions.
2. The hydroxide anion makes sodium hydroxide a strong base, which reacts with acids to form water and the corresponding salts.
3. In the reaction with hydrochloric acid, sodium chloride is formed:
$$\text{NaOH(aq)} + \text{HCl(aq)} \rightarrow \text{NaCl(aq)} + \text{H}_2\text{O(l)}$$
4. Sodium hydroxide is produced (along with chlorine and hydrogen) via the chloralkali process.
6. This involves the electrolysis of an aqueous solution of sodium chloride.
7. The sodium hydroxide builds up at the cathode, where water is reduced to hydrogen gas and hydroxide ion:
$$2\text{Na} + 2\text{H}_2\text{O} + 2\text{e}^- \rightarrow \text{H}_2 + 2\text{NaOH}$$

This instruction contains the following resources whose variables need to be created:

- **Material**
 - Input - sodium chloride, water, hydrogen
 - Output - Sodium hydroxide
 - **Equipment** – cathode
 - **Standards** – none
-

After you create the variables for the resources, the resource names are replaced by variable objects and appear as shown below:



The variable you create consists of two parts:


- Variable Name – A unique name defined for variable. For example, var_H2O.
- Label - A Label represents the attribute of the resource to which a variable is resolved. These are:
 - ID – Resource ID, for example, 'Material_Water_001'.
 - Name – Resource name, for example, 'Pure Water'.
 - Description – Complete description of the resource, for example, 'Condensed vapors from solar desalination plant'.
 - Category – Resource category, for example, 'Chemical'.

Example: In **<hydrochloric acid.Current Resolution>** hydrochloric acid is the variable name and Current Resolution is the default Label.

Creating Variables

You create variables during the creation of Instructions in Recipe Action Template. You can also create them when you edit a recipe element template or a recipe action template.

To create a new input variable:

1. In the Instructions tab, enter instructions.
2. Select a resource.
3. Click the New Variable  icon.

In the *New Variable* window, the Variable Name field automatically fills the resource name you selected.


For example, if you selected a resource 'H2O', the variable name field is filled with H2O. You may modify this variable name to a unique name, say, var_H2O.

4. You can also create a new variable from the variables list.
 1. Click Show Variable List.

2. In the Variables table, click New.
3. Enter a unique Variable Name.
5. Depending upon your requirement, select one of the variable categories – Equipment, Material or Standards.
6. Click OK.

Using the above steps, you cannot set the variable resolution criteria and can only create input variables for different types of resources – equipment, material and standards. To set the variable resolution criteria and create any input or output variable for Material, use More Variable Info feature in the *New Variable* window.

To create a new input or output variable:

1. In the Instructions tab, enter the instructions.
2. Select a resource.
3. Click the New Variable  icon.
4. In the *New Variable* window, click More Variable Info.
5. In the Preface tab, select one of the variable categories from Equipment, Material or Standards.
6. Click Next.
7. In the General tab, enter the required information.

Significant inputs:

- Variable Name – A unique name for the variable.
- Critical Processing Variable – If the variable is critical in arriving at the end results in recipe execution.
- Variable Resolution Criteria – For this release of RMW, the variables can only be resolved manually.

The following additional fields appear only when you create a material variable:

- Variable Type – Input or output.
- Is Consumable – If the material is used as raw material for producing the end product or is a consumable.

8. Click Next.
9. In the Criteria tab, click New to select the variable resolution criteria.

The *Define Criteria* page appears.

In the General tab, the criterion Name is generated by the application, from the variable name. You can modify it.

10. Click Next.
11. In the Criteria tab, click Show Possible Resolutions to select the material to which the variable will be resolved.
12. Click Load Selection into Criteria.

If you select more than one material record as possible resolution for the variable, a *Compare Records* window appears. You can compare the attributes of the materials and decide on a

suitable material.

1. Once you compare and decide the material you wish to associate to the material variable, select that material's column by clicking Copy to Criteria Value. The values appear under the column Criteria Value.
 2. Modify the values if required.
 3. Click OK.
13. Click Finish.

The criteria appear in the Criteria tab.

14. Click Finish to save the variable.

Managing Variables

Once you create a variable, it is inserted at the location of the cursor in the instructions. You can click on the variable button to edit or delete the variable, or change its label.

To change the label of a variable:

1. Click on the variable button.
2. From the drop-down menu, select Change Label and an appropriate label.

See [Formulation of Variable](#) on page 14 for label descriptions.

Variable List

The variables that you create are stored in Variable List. You can see all the variables available in RMW by clicking Show Variable List in the Instructions tab. To hide the list, click Hide Variable List, which appears when the variable list is open.

You can insert an existing variable from the variable list into the instructions by clicking Insert at Cursor. You can edit and delete variables from the variable list.

Resolving Variables

A recipe can be executed only when all its variables are resolved to the actual resources. You can resolve them in the recipe.

- General Variables can be resolved only from Resources sub-tab under BOP tab. For example: Standard variables
- Raw Material Variables and Consumable Material Variables, of the type Input, can be resolved only from the Materials and Consumables sub-tabs under BOM tab, respectively. Material Variables of the type Output can be resolved only from the Output tab.
- Equipment Variables can be resolved only from the BOE tab.

To resolve a variable:

1. Go to Recipes > Library and run a search. From the search results select a Recipe.
 2. Click either Edit > Current Version or New Version.
 3. Based on the type of variable you wish to resolve, go to the corresponding tab.
-

4. Select a record of an *unresolved* variable.

You can also resolve a resolved variable to a new resource.

5. Click Resolve Variable.
6. In the *Resolve Variable* window, click OK.

The *Criteria* edit page appears.

If during variable creation, or variable edit, you defined the variable resolution criteria in the Criteria tab; those criteria components will be populated.

7. Click Search.
8. From the list of Possible Resolutions, select a resource that meets your requirements and click OK.

The resource appears in place of *unresolved* variable.

Parameters

Parameters are constants values or constant definitions associated with recipe resources. These are used in campaign, equipment procedural elements and can be referenced by recipe variables.


A parameter is used for defining the Quality, Process, Safety or Efficacy of a recipe resource.

For example, in a recipe action, a material variable *Glucose* can be further referenced by its *pH value*. The *pH value* here is the Parameter that specifies a particular property of the material.

Similarly, when a parameter, such as *Oven temperature of 160 deg celsius* is assigned to an equipment, it substantiates the equipment condition.

Creating Parameters


To create a new parameter:

1. In the Instructions tab, enter the instructions.
 2. Select the text that you wish to parameterize.
 3. Click the New Parameter  icon.
 4. In the *New Parameter* window, choose one of the following:
 - Use Parameter Template – to copy parameter and its attributes from a parameter template defined for material analysis.
 - Copy Specification Plan Parameter – to copy the entire specification plan, this includes parameter definitions.
 - Copy Recipe Parameter – to copy a parameter from another recipe.
 5. Select one of the following:
 - Parameter Name – to specify a name of your choice.
 - Use Original Name – if you wish to retain the original name of parameter. This option is applicable when you copy a recipe parameter.
 6. You can also create a new variable from Parameter List.
-

1. Click Show Parameter List.
2. In the parameters table, click New.
3. Enter a unique Parameter Name.
7. Click OK.

Using the steps given above, you can create only the parameters but cannot specify its constraints or associate it to a variable. If you want provide complete details of a parameter, use the More Info feature in the *New Parameter* window.

To create a new parameter and set its details:

1. In the Instructions tab, enter the instructions.
2. Select the text that you wish to parameterize.
3. Click the New Parameter  icon.
4. In the *New Parameter* window, click More Info.
5. In the General tab, enter the required information.

Significant inputs:

- Associated Variable from Action – The variable to which this parameter acts as additional constraint.
- Critical Processing Parameter – Whether or not this parameter is critical in processing of the recipe.
- Forward Processing Parameter – Whether the results of this parameter are criteria to go forward in the processing.
- Parameter has Constraints – If you select Yes, the Constraints sub-tab appears in the Details tab.
- Assay Reference – Reference ID of the assays that you wish to associate with the parameter.

6. Click Next.
7. In the Data Definition sub-tab under Details tab, enter the required information.

Significant inputs:

- Data Type – The type of data that will be captured during execution.
- Float Precision – A decimal level precision of data values. Enter the number of digits allowed after the decimal place. This field is active only when you select Float as the Data Type.
- UOM Group – The unit of measurement group that is used for carrying out data conversion. For example, the *Currency* group let you carry out conversions between two defined currencies.
- Compound Tested For – Indicates if the parameter is used for measurements on experiments done for compounds. For example, the parameters could be % contaminant, % of salt, % of water. This parameter would be testing for the presence or absence of certain materials.
- Entry Field Size – The length of the data value that can be recorded. For example, if you set a parameter for volume to 3, the system will not accept a value more than 999.

8. Click Next.
-

9. In the Constraints sub-tab under Details tab, specify the following:
 - Value UOM – The applicable unit of measurement of the data value. The results recorded in any UOM other than that set in this field will not be accepted by the application.
 - Constraints – Select the constraints that will be applied to the variable. If the constraint is a constant, specify its value in Constant. Select appropriate Operand to define the constraint limits.
10. Click Next.
11. In the Results sub-tab under Details tab, enter the required information.

Significant inputs:

 - Allow Range Results – Option to record only a data value from a given range limits.
 - Measurement Frequency – if you select At Set Interval, fill the time value in the Take Measurements Every field and select a time unit from the drop-down list.
 - Take Measurements in Time Window (plus or minus %) – Specify the allowed deflection in measurement time, in percent.
12. Click Finish.

Managing Parameters

Once you create a parameter, it is inserted at the location of the cursor in the instructions. You can click on the parameter button to edit or delete the variable, or change its label.

To change the label of a parameter:

1. Click on the parameter button.
2. From the drop-down menu, select Change Label and appropriate label.

Parameter List

The parameters that you create are stored in Parameter List. To see all the parameters available in RMW, click Show Parameter List in the Instructions tab. To hide the list, click Hide Parameter List, which appears when the parameter list is open. To insert an existing parameter from the parameter list into the instructions, select the parameter and click Insert at Cursor. You can also edit and delete the variables from variable list.

Parameter can be saved as a template using Parameter > Save As Template option.

Appendix A

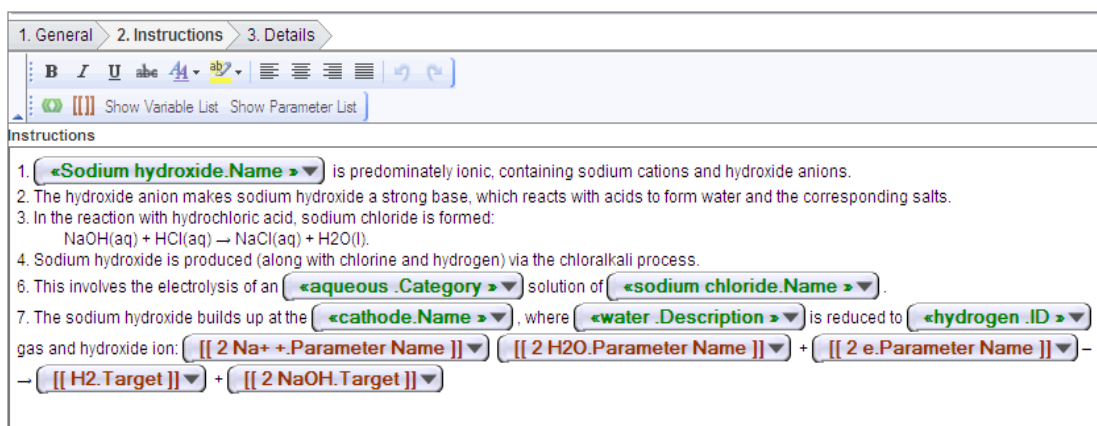
Recipe Editors

This Appendix includes the following:

- Working with Text Editor..... 21
- Working with SFC Editor..... 21

Working with Text Editor

The instructions for Recipe Actions are written using the inbuilt Text Editor. This appears under Instructions tab in the Recipe Action Template.



The Text Editor allows you to type in any text and use formatting commands to format the entered text. A “Node” in the text editor represents an action, a phase or an operation depending on what is being edited. The editor supports the following functionalities:

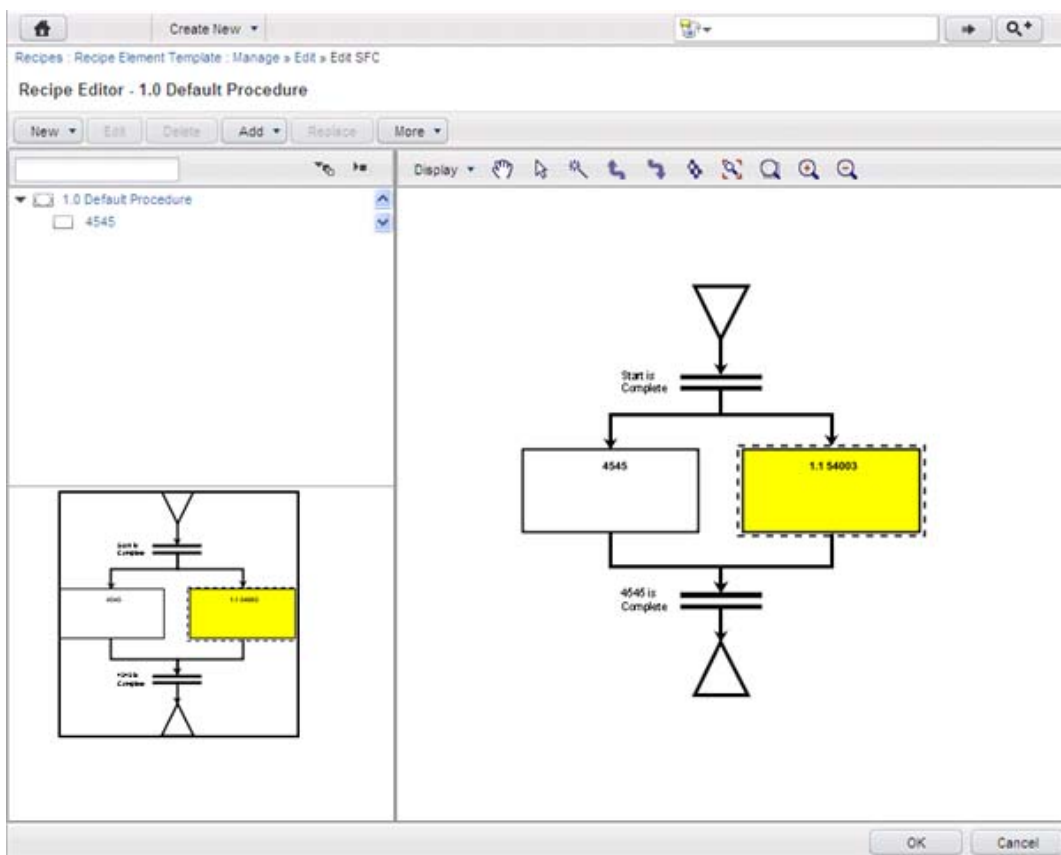
- Format the text such as bold face, italicized, or changing the color of the text.
- Inserts variables or parameters as part of the instruction.
- Select/highlight a portion of the text words keyed in and convert it into either a variable or a parameter
- Repeat a set of instructions until a condition is met.
- Support a context-sensitive menu upon selection of a variable or a parameter in the text editor

Working with SFC Editor

A Sequential Flow Editor is a tool for creating and editing the process flow of Recipes and Recipe Elements. It provides a graphical way to create a Bill of Processes. You can add and organize multiple actions and elements into a series of steps with a distinct start and stop.











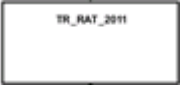
With SFC Editor, you can:

- Add multiple Recipe Actions in a Recipe Element.
- Add multiple Recipe Elements in a Recipe.
- Add multiple Recipe Actions in a Recipe.



Components of SFC

A number of tools are used to create these actions. The table below lists and describes tools that help you in creating a Sequential Flow Chart.

Name	Description
 Add connection	Helps you establish a connection between multiple nodes.
 Traverse up	In an object from selection, traversing from the lower element to the upper element.
 Traverse down	In an object from selection, traversing from the upper element to the lower element.
 Automatic layout	Automatically fits the nodes in the SFC canvas
 Fit in canvas	Fitting the nodes in the SFC canvas
	Start of the Process node
	End of the Process node
	Nodes Connector
	Conditional Nodes Connector
	Recipe Element node To expand and view the SFC in the Recipe Element, click the Plus sign on top right corner. Once expanded, the Plus sign changes into minus sign. To collapse the SFC view of the recipe element, click the minus sign.
	Recipe Action node

Adding Recipe Actions

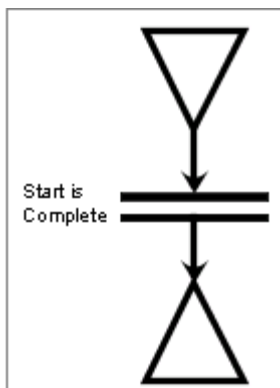
You can add recipe actions in a recipe element or a recipe using the SFC Editor. You can do so either during the creation of recipe element template or recipe, or by editing them.

You can add multiple Recipe Action objects and create a sequential flow. The flow includes parallel and conditional branching between recipe actions.

To add a recipe action using the SFC Editor:

1. In the Instructions sub-tab under the BOP tab, select a Recipe Element.
2. Click Edit SFC.

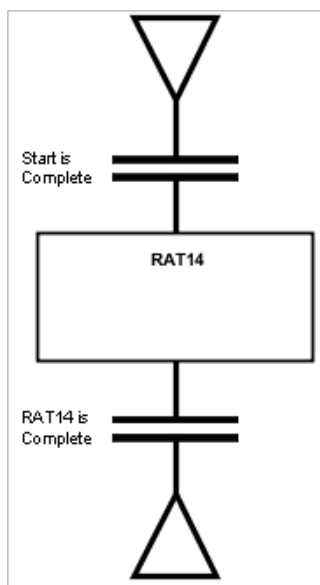
The SFC Editor opens with a basic flow chart in right pane.



3. Click the Nodes Connector and press Delete key, or click Delete on the SFC Editor's menu bar.
The Nodes Connector disappears, leaving the Process Start and Process End nodes.
4. Click New > Recipe Action From Template.
5. From the *Recipe Action Templates* list, select a recipe action template and click OK.
6. Click anywhere in the right pane.
The recipe action object is inserted.
7. Click the Add Connection action button or on the menu bar, select Add > Connection.
8. Place the cursor on the Process Start node, press the left mouse button and drag the mouse to the desired recipe action object.
9. Release the mouse button.
The Process Start node is connected to the recipe action object.
10. Place the cursor on the recipe action object, press the left mouse button and drag the mouse to the Process End node.
11. Release the mouse button.

The recipe action object is connected to the Process End node.

The sequential flow is established.



Adding Recipe Elements

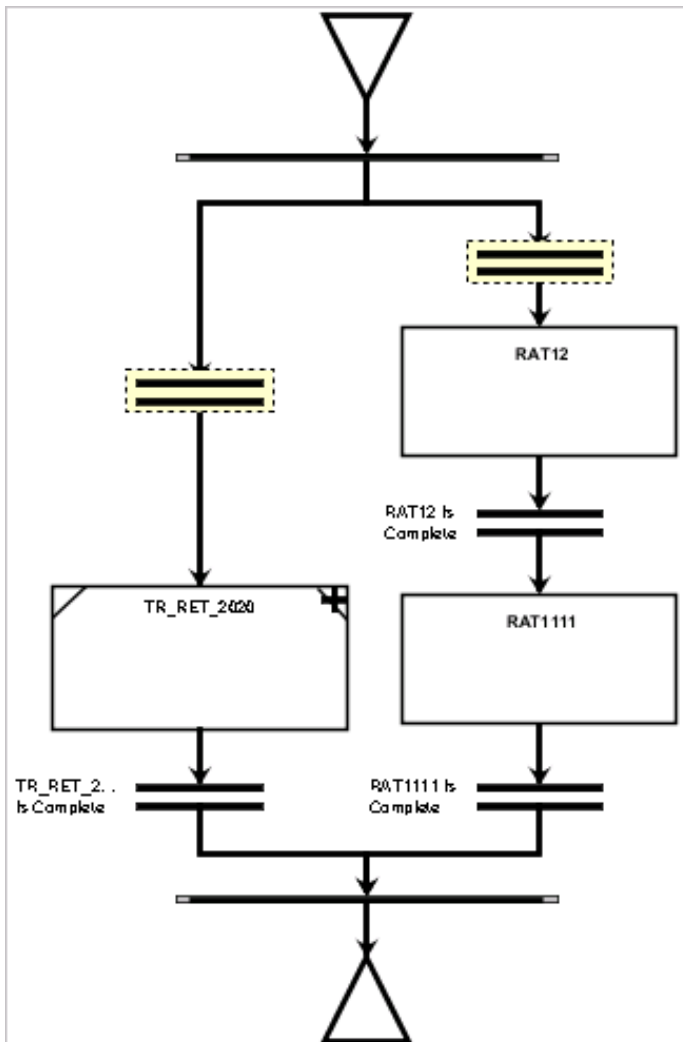
You can add recipe elements and recipe actions in a recipe using the SFC Editor. You can do so either during the creation of the recipe or by editing it.

The steps to add a recipe element are same as that for adding a recipe action, except that you must select Add > Recipe Element from Template option.

Conditional Branching

You can create conditional branching between various objects - Actions to Actions, Actions to Elements or Elements to Elements, and vice-versa.

Conditional branching helps in meeting the IF-THEN-ELSE requirements in a sequence of events.



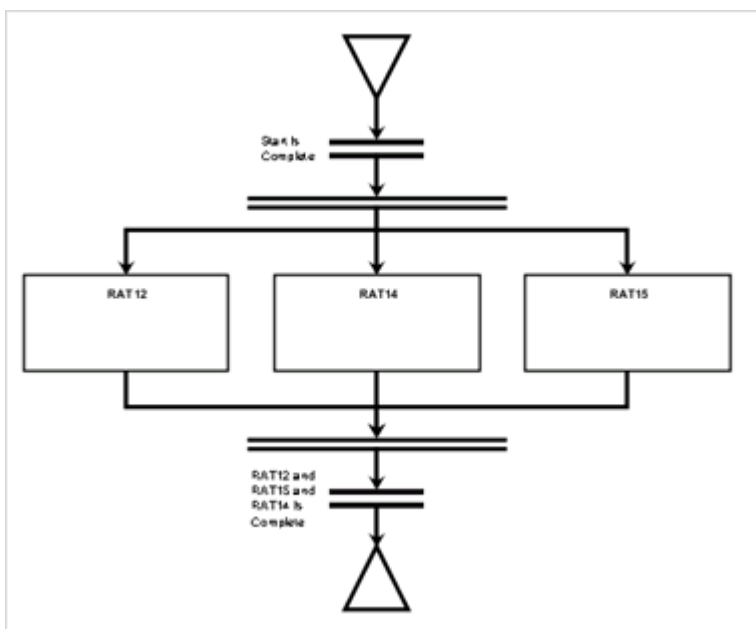
To create a conditional branching:

1. Holding the Ctrl key, click on two or more objects to select them.
2. Click Add > Conditional Branch.

Parallel Branching

When you require parallel processing between Actions, Elements or Actions and Elements, you can use the parallel branching feature of the SFC Editor.

Parallel branching helps in simultaneous processing of events, which meets the AND Boolean condition.



To create a parallel branch:

1. Hold the Ctrl key and click on two or more objects to select them.
2. Click Add > Parallel Branch.

Traversing between the Recipe Elements and Actions

To ascertain the flow of events between the intermediate recipe Actions and Elements, you can traverse the sequence. You can traverse upwards or downwards from any stage in the sequence.

