Agile Product Lifecycle Management

Recipe & Material Workspace Recipe Management Guide

v9.3.2

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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 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.

The Oracle Technology Network (OTN) Web site 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.

Note   Before calling Oracle Support about a problem with an Agile PLM manual, please have the full part number, which is located on the title page.

TTY Access to Oracle Support Services

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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.

Agile Training Aids

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

Accessibility of Code Examples in Documentation

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.

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Introduction to Recipe Management

This chapter includes the following:

The Recipe Management module within the Agile PLM Recipe & Material Workspace (RMW) solution provides integrated recipe authoring capabilities that help you to track the development process of a product. 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 Import /Export 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 *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.

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. 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 only communicates processing requirements to multiple manufacturing sites.

▫ **Site Recipe**: A Site Recipe is created directly and takes into consideration the specific conditions or constraints of a particular manufacturing site. The user can select multiple sites for a site recipe. 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 created directly. In this recipe creation, user can select only one recipe. 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 (For example: 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 *Recipe & Material 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.
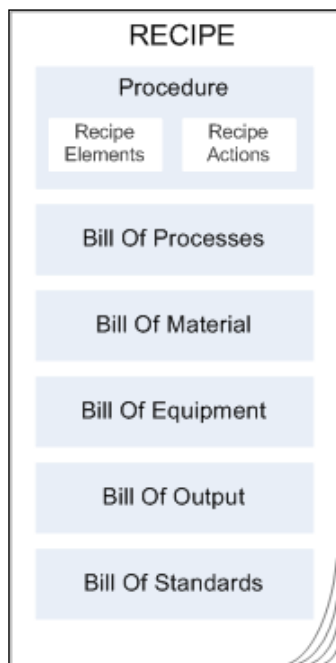
Procedure

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** - an ordered set of operations carried out 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. Unit procedures can contain operations, phases and actions.

▫ **Operation** - an ordered set of phases carried out to completion within a single unit. An operation usually takes 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. Operations can contain phases and actions.

▫ **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 or control

▫ **Second Person Verification** – whether you require electronic signature and second person verification.

- Electronic Signature indicates that an operator completed the task

- Second Person Verification indicates that a second person or automation verified the action or measurement

▫ **Execution mode** – manual or automatic.

Bill Of Processes

A BOP for a target material contains a list of materials, equipment, process steps, standards, control parameters, and measured parameters which may use assays. BOP contains the process of sequential flow of elements and actions. 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).

BOP is composed of one or more recipe elements and/or recipe actions. Recipe elements contain recipe actions which is the lowest level of instruction.

Bill Of Material

A **Bill of Material** (BOM) is an assembled list of all materials and their quantities (with UOM's) required to produce a target/output material 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. When these recipes in the master library are "resolved" by the user, the software automatically generates the BOM for the **Recipe**.

While editing a **Recipe Action** instance in edit **Recipe** page user can add multiple **Material** directly.

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**.

While editing a action instance in edit recipe page, user can add **Equipment** directly.

Bill Of Assays

A **Bill Of Assays** (BOA) is a list of assays that are referenced indirectly from a **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 Standards

A **Bill of Standards** (BOS) is a library of pre-defined statements relating to the safety and caution of a manufacturing process. It comprises of general instructions, guidelines and specifications you have to adhere to while handling equipment, material and processes in the industry and organization. **Standards** are used while authoring Unit Operations and creating **Control Recipes**, **Process Steps** and **Work Requests**.

Output

Quantities of materials or resources, created as a result of the product manufacturing processes define **Output**. The quantity specified for output material at **Recipe** creation level is the planned quantity. Actual quantity will be added only after the output material is added to inventory at Work Request level.

This chapter includes the following:

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 you need to be measure during the process or the actual values that the operator used for the control parameters or measured parameters.

□ **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.
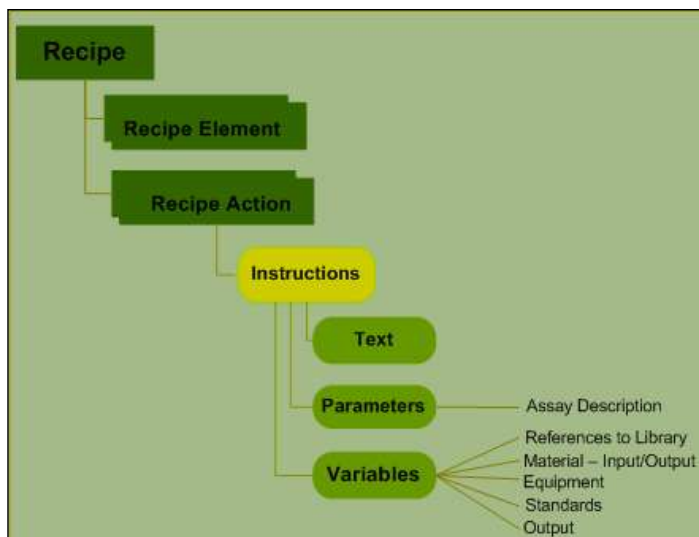
Creating Recipe Action Template

A **Recipe Action** template is a recipe object that defines the procedures to create a recipe. 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. Phase, Operation and Unit Procedures exist as templates and can be re-used in higher level elements/ recipe library. 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 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** - Method of recording 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 instructions in the Text Editor.

   For complete details on how to use the Text Editor, see Working with Text Editor on page 27.

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 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.
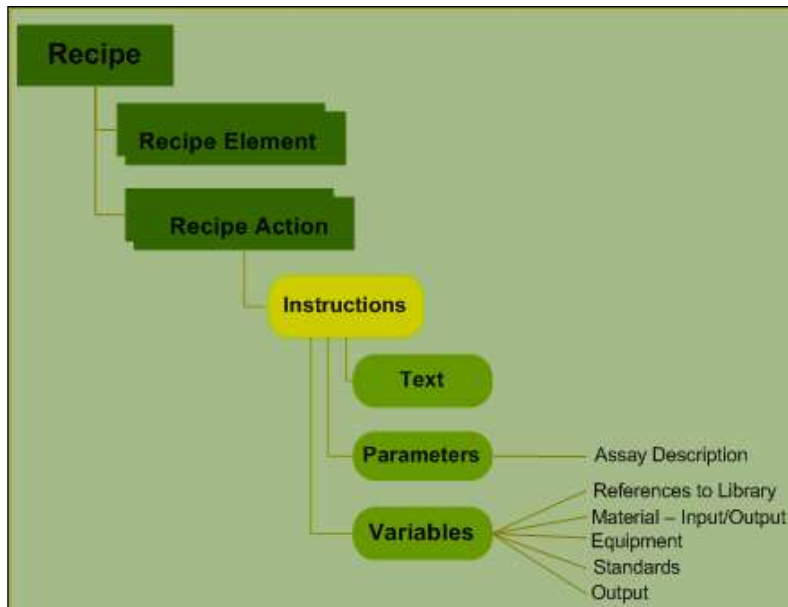
Editing a Recipe Action Template

You can edit a **Recipe Action Template** only when it is in the *Draft* status.

Note	The usage of a Recipe Action in a Recipe is referred to as an Instance, which does not have a status.

To edit a recipe action:

1. Go to **Recipes > Action Template** and run a search. From the results, select a **Recipe Action**.
2. Select a **Recipe Action Template** and click **Edit.** An Edit Action Template page appears.
    1. In the **General** tab, modify fields as required.
    2. In the **Instructions** tab, modify fields as required. You can add new variables, parameters, and edit or delete existing ones.
    3. Click **New Variable** to add a new variable or **New Parameter** to add a new parameter.
    4. In the **Details** tab, you can redefine characteristics and acknowledgments.
3. Click **OK**.

While editing a recipe action instance within a recipe, you can add new **Material, Equipment or Standards** directly to the **BOM, BOE or BOS**, without creating a variable.

To add material to a BOM of a recipe:

1. Go to **Recipes> Library** and run a search.
2. Select a **Recipe** record which is in the *Draft* status and click **Edit**.
3. In the Edit Recipe page, click the **BOP** tab.

1. In the **Instructions** sub-tab, select a Recipe Action and click **Edit**.

2. In the Edit Action page, go to **Instructions** tab click the New Material icon to add material.

3. From the palette, choose the **Material Type** - Input or Output, click **OK**.

4. In the Search Material page, choose criteria and click **Search**.

5. From the search results, select a Material and click **OK**. A variable place button mentioning the Material appears in the Instructions (Text editor) area.

6. Click **OK** button in edit **Recipe Action** page.

7. Click the BOM tab. Material added in edit **Recipe Action** instance page appears under this tab.

8. Click **Save BOM** to save the BOM.

4. Click **OK**.

A message confirms you have updated the recipe successfully. Similarly, you can add **New Equipment** and **New Standard** within a **Recipe Action**.

Changing Lifecycle Phases 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 only from *Submitted* and *Approved* status.

▫ **Submitted** - when the recipe action template is submitted 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. Obsolete status actions cannot be revived for approval.

To change the lifecycle phase of a recipe action template:

1. Go to **Recipes > Action Template** and run a search. Select a recipe action template from the search results.

2. Click **Change > Lifecycle Phase** and select an applicable lifecycle phase.

The lifecycle phase of the RAT appears on the page along with the chosen category.

Creating Recipe Element Template

The sequential flow of recipe actions is created in recipe element template and can include other recipe elements as well. You can further modify the components in the recipe and optionally save the recipe element as a 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.
  Recipe Element levels: Unit Procedure, Operation, and Phase. (A phase contains only

actions. An operation is a combination of phase and actions and Unit Procedure comprises of operation, phase and actions).

- **Life Cycle Point** - The stage of target molecule development.
- **Usage**
  - *Small Molecule* = Chemical Product
  - *Large Molecule* = Biologics
  - *Formulation* = Drug Product
- **Mode** - Method of recording activities.

3. Click **Next.**
4. In the **Instructions** sub-tab under **BOP** tab,
    1. Select the recipe element record and click **Edit SFC**.
    2. In the right pane of the SFC Editor, click on **Start is Complete** and click **Delete** or hit the **Delete** key on your keyboard.
    3. Click **New > Recipe Action From Template** and select a recipe action template.
    4. You can add more than one recipe action template to a recipe element.
    5. Click anywhere in the right pane to insert the recipe action template. The recipe action template(s) appear under the recipe element in the left pane.
    6. Click **Add > Connection** to create the sequence of flow and click **OK**.

    For more details on how to use the SFC Editor, see Working with SFC Editor on page 27.

    7. To edit a recipe action template, select the recipe action and click **Edit**.
    8. To save the recipe element together with the recipe actions, select the desired records and click **Save As Template**.
    9. Clicking the **Next** button displays the **BOP: Parameters** tab. this tab lists the parameters created for recipe actions. User can edit/ delete these parameters.
    10. Click **Next**. The Target tab is displayed.
5. In the **Targets** tab,
    1. Click **Add Target Material** to select the material from material library.
6. Click **Finish.**

Editing a Recipe Element Template

You can edit a **Recipe Element Template** only when it is in the *Draft* status.

To edit a recipe element:

1. Go to **Recipes > Elelment Template** and run a search. From the results, select a **Recipe Element Template.**
2. Select a **Recipe Element Template** and click **Edit.** An Edit Element Template page appears.
3. In the **General** tab, the Level of the Recipe Element is displayed. Modify fields as required.

    Note Unit Procedure can contain Operation, Phase and Action; while a Phase, which is the lowest element can contain actions.

4. In the **BOP** tab, click the **Instructions** sub-tab.
5. Select a recipe element and click **Edit SFC**. For more details on working with SFC, see Working with SFC Editor on page 27.
6. Click the **Parameters** tab. It displays a list of associated parameters.

7. To edit a parameter, select a parameter row and click **Edit**. For more details, see <u>Parameters</u> on page 23.
8. To delete a parameter, select a parameter row and click **Delete**.
9. Click **OK**.
10. Click the **Target Material** tab.
11. Click the **Add Target Material** sub-tab. Enter a criteria and run a search for Material.
12. From the search results, select a Material and click **OK**. The Material appears in the table.
13. Click **OK**.

A message informs you that you have successfully updated the recipe element template.

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

Recipes instruct you about the processes involved in the manufacture of a product. Creating a recipe involves specifying the purpose, acquiring specific raw material and equipment, the quantities of each raw material, and standards you need to follow.

To create a new recipe:

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

   • **Purpose** - The usage of the recipe - Processing, Cleaning, or Other.

   • **Type** - General, Site, or Master Recipe.

   > **Note** Cleaning or "Other" types of recipes do not target a Target Material.

   > **Note** A Processing type recipe requires an approved raw material in the BOM tab and an approved target material in the Output tab for approval.

3. Click **Next**.
4. In the **General** sub-tab enter the required information for mandatory fields.
   Significant inputs:

- **Operating Mode** – Early or late product development stage.
- **Regulatory Design** – 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**.

Bill of Processes (BOP)

In the **Instructions** sub-tab of the BOP tab, select the recipe record and click **Edit SFC** to create a sequential flow chart of process.

1. In the right pane of SFC Editor, click on **Start Is Complete** and click **Delete**.
2. 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.
3. Select a **Recipe Element Template** and click **OK**.
4. 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 27.

When you add a recipe element template, the recipe action templates associated with it are added automatically. To add more recipe action templates, click **New > Recipe Action Template** and select the desired templates. You can add recipe actions with recipe elements at the same level, as well as have recipe actions within elements.

Recipe Actions and Recipe Elements can be created and filled in while creating a recipe via the BOP and saved as a template.

5. Click **OK**.

In the **Instructions** sub-tab, a table lists recipes and associated recipe elements and recipe actions. The sequence and instructions that you entered in the recipe action template appear in the right column.

7. Click **Next**.

1. In the **Parameters** sub-tab, a table lists parameters that you defined in recipe action template and its results.

- To edit a parameter, select a record and click **Edit**.
- To edit a variable, you first need to edit a recipe action, select the desired record and click **Edit.**

8. Click **Next**.

Bill of Material (BOM)

In the **Materials** sub-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.

Note You can perform a secondary resolution selecting either one of the following options - **All Lots and Containers in the Inventory/Allocated Lots and Containers/ Suitable Lots and Containers** of a **Recipe** in the Draft status with a Material variable primarily resolved.

Note The **Instructions** column of the **BOP** tab displays the Container/Lot information embedded with the instruction.

1. For each material, enter the **Planned Quantity to Consume** and the **Display Order**, in which the items will appear in the recipe list.

2. To view the information of a material sample, select the desired material variable and click **View Sample Information**. The Sample Information page displays the Lot ID, Source Container ID and other details from which the selected material was sampled.

To add new material:

1. Click **More > Add Material**. The Search Material page appears.

2. Select the **Recipe Action** associated with it.

3. Enter a value in any field and run a search. Select a material from the search results and click **OK**.

4. Click **Next**.

    The **Consumables** sub-tab lists consumable material variables. You can resolve the unresolved variables, and also add, delete and edit the variables.

    1. For each material of type **Consumable**, enter the **Planned Quantity to Consume**.

    2. Click **Next**.

    Once you resolve material variables, they appear in the spec plan sub-tab.

    3. Select a material row and add new specification plans.

    4. To delete spec plans, select the row and click **Delete**.

5. Click **Next**.

    Bill of Equipment (BOE)

    The **Equipment** sub-tab lists equipment variables. You can resolve the unresolved variables, view disposition of equipment, and also add, delete or edit equipment variables.

    1. To resolve an unresolved equipment variable, select a variable record and click **Resolve Variable**.

    2. To view the disposition of equipment, select an equipment variable record and click View Equipment Disposition. The Equipment Disposition page displays the equipment name, its availability status, etc. It also contains the **OK, Reservations** and **View Last Cleaning Activity** buttons.

    •   Click **OK** to return to the BOE page.

    •   Click **Reservations** to see the reservations made on the equipment. You can create new reservations/ edit reservations from this page.

    •   Click **View Last Cleaning Activity** to see the last cleaning activity performed on the equipment.

    a. To add new Equipment, click **More> Add Equipment**.

    b. In Search Equipment Page, select the **Recipe Action** associated with it.

    c. Enter a value in any field and run a search. Select **Equipment** from the search results and click **OK**.

6. Click **Next**.

    Output

    The **Output** tab, lists output material variables defined in the Instructions tab of recipe action templates. You can edit these variables, add new material variables and resolve the unresolved variables.

    1. To resolve an unresolved output variable, select a variable record and click **Resolve Variable**.

    2. To add material, click **More > Add Material**.

     a.   In the Search Material page, select the **Recipe Action** associated with it.

     b.   Enter a value in any field and run a search. Select a material from the search results and click **OK**.

     c.   Enter **Output Quantity**. Select the appropriate **UOM** from the drop-down list.

     d.   Select the **Type** of the output.

7.   Click **Next**.

Bill of Standards (BOS)

The **BOS** tab lists standards defined in the instructions entered in recipe action templates. You can edit these standards, add new standard variables and resolve the unresolved variables.

   1.   To resolve an unresolved standard variable, select a variable record and click **Resolve Variable**.

   2.   Click **Next.**

The **Cautions** tab displays the caution type standards associated to resolved materials and equipment.

8.   Click **Finish.**

A message confirms the creation of a recipe. The Recipe is ready for publishing.

> **Note**   After you publish a **Recipe** in RMW, the **Recipe BOM** table displays both rows of material and consumables. In Product Collaboration, you can view the UOM details of consumable material. Quantity value displays the Unit of Measurement (UOM) and the quantity column value displays the unit.

Editing a Recipe

While editing a recipe, you cannot save the recipe (root node) as a template; you need to select the children (element/ action) to save as the template.

To edit a recipe:

1.   Go to **Recipes > Library** and run a search. From the search results, select a **Recipe**.

2.   Select a **Recipe** and click **Edit > As New Version.** You can edit a **Recipe in the** *Draft* status as **Current Version**.

3.   Click **Save and Edit**.

4.   Make the necessary modifications in the Edit Recipe page.

5.   **General**

     ▪   Modify required fields and click **OK**.

6.   **BOP**

   1.   In the **Instructions** tab, select a recipe element or recipe action and click **Edit**.

   2.   Modify necessary fields and click **Save BOP** to save the BOP.

   3.   To save the recipe BOP as a template for future use, click **Save As Template**. In the *Save As Template* window, enter a unique **Name** for the recipe template and click **OK**.

   4.   In the **Parameters** tab, you can edit/delete parameters.

   5.   Modify necessary fields and click **OK.**

     You can delete recipe actions /elements only from the SFC editor.

7.   **BOM**

   1.   In the **Material** tab, click the **More** drop-down button.

2. Select **Add Material,** to add a new material to the **BOM.**

3. Select a **Recipe Action** to associate with the Material.

4. In the Search Material page, choose criteria and click **Search**.

5. From the search results, select a **Material** and click **OK**. The Material appears in the BOM table.

6. In the **Consumables** tab, edit and resolve the variables.

7. In the **Specification Plans** tab, add or delete variables.

8. Click **Save BOM** to save the BOM.

8. **BOE**

1. In the **Equipment** tab, click the **More** drop-down button.

2. Select **Add Equipment** to add new Equipment to the **BOE.**

3. Select a **Recipe Action** to associate with the **Equipment**.

4. In the Search Equipment page, choose criteria and click **Search**.

5. From the search results, select **Equipment** and click **OK.** The **Equipment** appears in the BOE table.

6. Click **Save BOE** to save the BOE.

Only if the **Recipe** is of the **Cleaning** type, the **Contaminant** sub-tab lists parameters associated with equipment variables.

9. **BOS**

1. In the **Standards** tab, click **Add Variable** to add a new Standard to the **BOS.**

2. To resolve an unresolved standard variable, select a variable record and click **Resolve Variable**.

Note   While editing a **Recipe Action** instance within a **Recipe**, you can add **Material, Equipment**, and **Standards** directly to the **BOM, BOE and BOS** and save the **BOM, BOE and BOS**.

Creating a Work Request from a Recipe

You can create **Work Requests** only from *Approved* **Recipes**. Once a control recipe moves to the *Approved* status, the application assigns a system-generated **Work Request ID** in the *In Progress* status for the control recipe.

To create a work request:

1. Go to **Recipes > Library** and run a search. Select an **Approved Recipe** from the search results.

2. Select **Create Work Request** from the **More** dropdown list.

3. In the *Create Work Request from Recipe* page, enter the required information.

   Significant inputs:

   - **Project** - Use the **Lookup** icon and select a project 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 and lowering only BOM and Output tab material quantities.
     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.

   - **Criticality** - Indicates the criticality of creating the Work Request.

- **Target Yield** - Net amount of actual produce expected.

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

4. Click **OK.**

Note For more details on 'Creating a **Control Recipe** from a **Process Step**' and 'Creating a **Work Request** from a **Control Recipe**', see the *Recipe & Material Workspace Process Management Guide*.

Batch ML

Planned Work Request details, Recipes, Control Recipes, and Process Steps stored in RMW include:

▫ Routings of recipe actions

▫ Material and Equipment required

▫ Standards you need to follow

▫ Assays and parameters you need to measure within the recipe action.

These details can now be executed in other systems by exporting them as XML files. **BatchML** is an XML using tags specified in S-88. The **Import from BatchML** feature enables you to integrate Master Recipes authored in RMW with external systems.

Listed below are some of the ways you can use Master Recipes.

1. Details in **Work Requests, Recipes, Control Recipes** and **Process Steps** can be executed in other systems by exporting them as XML files. The results of the execution will be imported back from external sources into RMW directly as a work request. Based on the context of the work request, the import program attaches it to the appropriate campaign/process step.

2. Converting the contents of a recipe into XML files and sending them to Manufacturing Execution Systems (MES) increases commercial production of material on a large scale.

3. Working jointly with partners, CMO's, CRO's these files can be outsourced as a collaboration item to companies to manufacture material.

Note The **Import/Export BatchML** feature is available through Web Services and application User Interface.

Comparing Work Requests

A feature comparing work requests and recipes is supported in Agile 9.3.2. Comparing work requests is achieved by the co-relation view. This compares all the output sample results, BOM quantities used, BOM sample parameter results, BOE and Recipe Action texts.

Comparison of recipes can only be general and not in detail.

Working with Recipe Variables and Parameters

This chapter includes the following:

Variables

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

Variables are of two types:

- **Input Variables** – Input variables are the resources required to make a material or perform tasks during the development of a material.

- **Output Variables** – Provides flexibility in case there are by-products being made which are still unknown.

Note   Variables and parameters are defined in **Instructions** which appear in the Recipe Action Template. For more details, see Creating Recipe Action Template on page 8.

Formulation of a Variable

In the **Instructions** tab, you specify the material, equipment and standards that you will use as input for producing the product and also specify the material that will be the result of the recipe.

For example, you may write the following instruction:

This instruction contains the following objects 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 object, the object names are replaced by variable objects and appear as shown below:

On clicking Next button, BOP: Parameters tab will be displayed, this tab list the parameters created for recipe actions, User can edit/ delete these parameters.
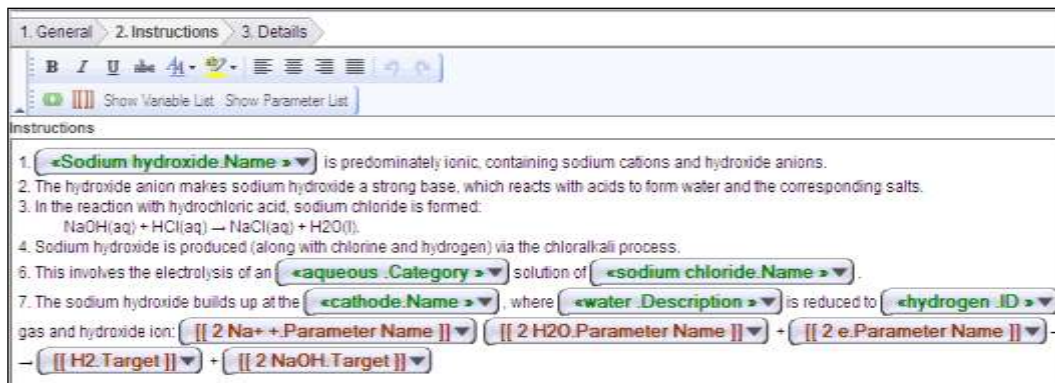
The variable you create consists of two parts:

□ **Variable Name** - A unique name defined for variable. For example, var_H2O.

□ **Label** - A Label represents the attribute of the object to which a variable is resolved. These are:

- **ID** - Object ID, for example, 'Material_Water_001'.
- **Name** - Object name, for example, 'Pure Water'.
- **Description** - Complete description of the object, for example, 'Condensed vapors from solar desalination plant'.
- **Category** - Object category, for example, 'Chemical'.

Example: In `«hydrochloric acid.Current Resolution »▼` **hydrochloric acid** is the variable name and **Current Resolution** is the default label.

Creating a Variable

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

To create a new input variable:

1. Click the **New Variable** 〈0〉 icon. Alternatively, you can also create a new variable from the **Show Parameter List**.
2. In the *New Variable* window, enter a unique **Variable Name.**
3. Depending upon your requirement, select one of the variable categories – Equipment, Material or Standards.
4. Click **OK**.

Using the above steps, you cannot set the variable resolution criteria and can only create input

variables for different types of objects – 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. For more details, see the *Recipe & Material Workspace Administrator Guide.*

To create a new input or output variable:

1. Click the **New Variable** icon.
2. In the *New Variable* window, click **More Variable Info.**
3. Select one of the variable categories from Equipment, Material or Standards.
4. Click **Next.**
5. 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** - 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.

6. Click **Next.**
7. In the **Criteria** tab, click **New** to select the variable resolution criteria.

    The *Define Criteria* page appears.

    In the **General** tab, the application generates a name for the criteria.

8. Click **Next**.
9. In the **Criteria** tab, click **Show Possible Resolutions** to select the material to which the variable will be resolved.

    1. Select a record and click **Load Selection into Criteria.**

    If you select multiple records as possible resolution for the variable, a *Compare Records* window appears. The criteria of the selected records is loaded in the search criteria. You can compare the attributes of the materials and decide on a suitable material.

    2. Once you compare and decide the material you wish to associate to the material variable, select that material's column and click **Copy to Criteria Value**. The values appear under the column **Criteria Value**.
    3. Modify the values, if required.
    4. Click **OK**.
    5. Click **Finish**. The criteria appear in the **Criteria** tab.

10. Click **Finish** to save the variable.

Managing Variables

To insert an existing variable from the variable list, click **Insert at Cursor**. It appears at the location of the cursor in the instructions area. Click the **Variable** button to edit or delete the variable, or change its label.

To change the label of a variable:

1. Click the **Variable** button.
2. From the dropdown menu, select **Change Label** and choose an appropriate label.

   See <u>Formulation of a Variable</u> on page 19 for label descriptions.

Variable List

The Variable List contains variables that you create. To see all the variables available in RMW click **Show Variable List** in the **Instructions** tab. To hide the list, click **Hide Variable List**, which appears when the variable list is open.

Resolving Variables

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

▫ Raw Material variable and Consumable Material variable, of the type I**nput**, can be resolved only from the **Materials** and **Consumables** sub-tabs of **BOM** tab, respectively. Material variables can further be resolved to lots and containers through secondary resolution.

▫ Material variable of the type **Outpu**t can be resolved from the **Output** tab.

▫ Equipment variable can be resolved only from the **BOE** tab.

▫ Standard variable can be resolved from **Standards** sub-tab of BOS tab.

When you create a variable, it is associated to a *Category* in the library. At the time of its resolution, the variable will search only the selected equipment category to let you pick the desired equipment. You can associate the variable to the whole library or to a specific category under it.

For example, when you create a variable for **Equipment,** the variable is associated to a *Category* in the **Equipment** library, such as Blender.

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 **As New Version**.
3. Based on the type of variable you wish to resolve, go to the corresponding tab. Select a record of an *unresolved* variable.

   Note   You can also resolve a resolved variable to a new object.

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

   The *Criteria* edit page appears.

   During variable creation, or variable edit, if you define the variable resolution criteria in the **Criteria** tab; the application automatically populates those criteria components.

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

   The object appears in place of *unresolved* variable.

Merge Variables

You can name variables with the same name across two or more Recipe Actions, and the system auto-merges them to be the same resource.

Parameters

Parameters can be settings used to control or measure conditions during the execution of the recipe and can be used to define Quality, Process, Safety or Efficacy of a recipe.

For example, in a recipe action, a material variable *Glucose* can be further referenced by its *pH value*. *pH* is the parameter which is eventually measured, in order to control the work request.

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

Creating Parameters

Parameters define the attributes for a variable. For example, if you choose an **Oven** as the variable, the parameter you set is **50 degree Celsius**.

To create a new parameter:

1. In the **Instructions** tab, enter instructions.
2. Select the text that you wish to parameterize.
3. Click the **New Parameter** [I] 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 parameters used in the specification plan.
   - **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** - 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.**
   4. Click **OK**.

Using the steps given above, you can create only the parameters but cannot specify its constraints or associate it to a variable. To 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 instructions.
2. Select the text you wish to parameterize.
3. Click the **New Parameter** [I] icon.
4. In the *New Parameter* window, click **Enter 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 this parameter is critical in processing of the recipe.
- **Forward Processing Parameter** - Whether the value of this parameter will match the 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 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** - 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 allows you to 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 you can record. For example, if the parameter for volume is set 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. 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. These are sent to an execution system in case the recipe is being executed by an MES system. These values determine what you need to do while processing the recipe.

    Significant inputs:

    - **Allow Range Results** - option to record only a data value from 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 dropdown list.
    - **Take Measurements in Time Window (plus or minus %)** - specify the allowed deflection in measurement time, in percent.

12. Click **Finish.**

Managing Parameters

Once created, use the **Parameter** button to edit, delete the variable, or change label.

To change the label of a parameter:

1. Click the **Parameter** button.
2. From the dropdown menu, select **Change Label** and click the appropriate label.

Parameter List

The Parameter List stores the parameters you create. 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 edit and delete variables from variable list or save it as a template using the **Parameter > Save As Template** option**.**

Recipe Editors

This Appendix includes the following:

Working with Text Editor

Instructions for **Recipe Actions** are written using the inbuilt **Text Editor**. These appear under the **Instructions** tab in the **Recipe Action Template**.
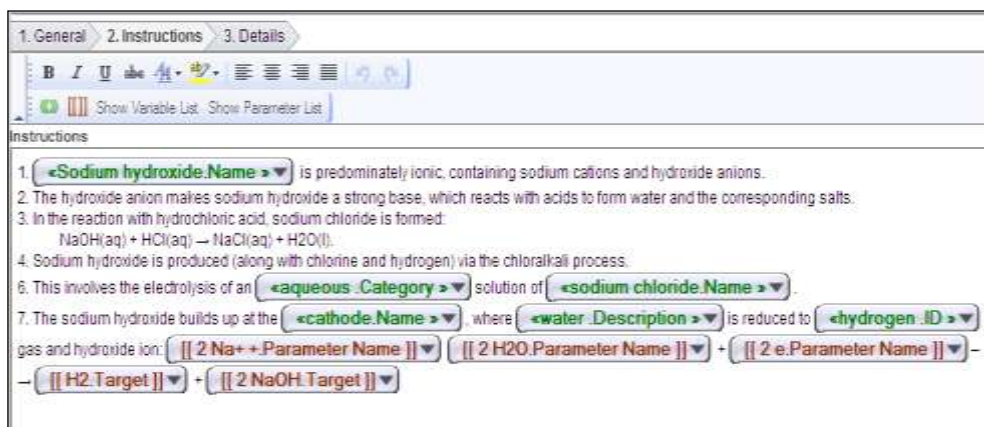
The **Text Editor** allows you to type in any text and use formatting commands to format the entered text. The editor supports the following functionalities:

▫ 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 Chart (**SFC) **Editor** is a tool for creating and editing the process flow of Recipes and Recipe Elements. The **SFC** editor will have nodes that represent an action, a phase or an operation. 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.
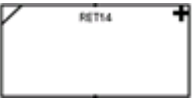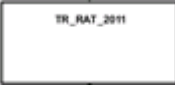
With **SFC Editor**, you can:

▫ Add multiple Recipe Actions in a Recipe Element.

▫ Add multiple Recipe Elements in a Recipe.

▫ Add multiple Recipe Actions in a Recipe.
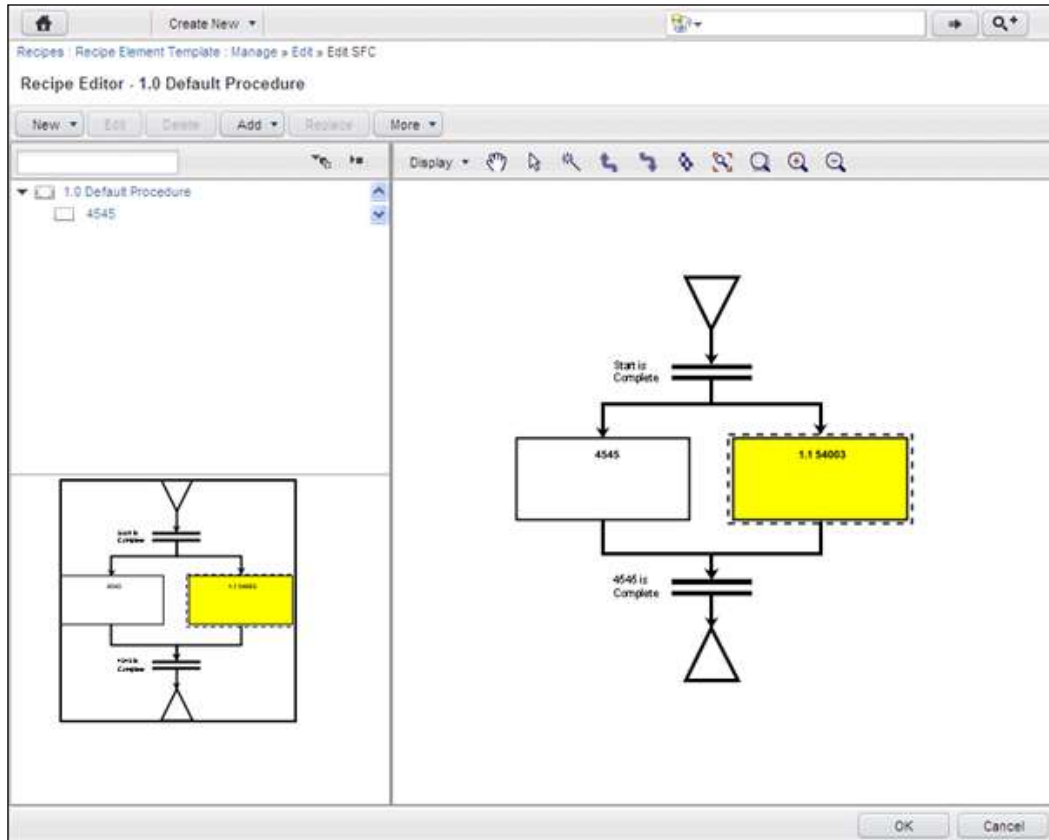
Components of SFC

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

| Name	Description
	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 a recipe, or while editing them.

You can add multiple Recipe Action objects and create a sequential flow. The flow includes parallel and conditional branching between recipe actions.
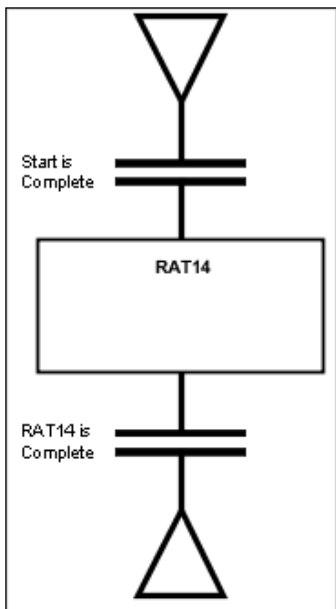
To add a recipe action using the SFC Editor:

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.
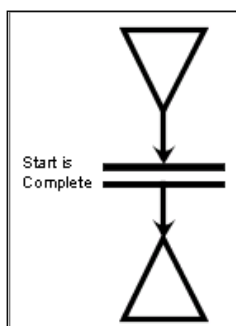
3. Click the Nodes Connector and press **Delete** key, or click **Delete** on the SFC Editor's menu bar. The Nodes Connector disappears, leaving the Process Start and Process End nodes.
4. Click **New > Recipe Action From Template**.
5. From the *Recipe Action Templates* list, select a recipe action template and click **OK**.
6. Click anywhere in the right pane to insert the recipe action object.
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 and a sequential flow is established.


Adding Recipe Elements

You can add recipe elements to a recipe using the **SFC Editor**. You can do so, either during the creation of the recipe or while 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.
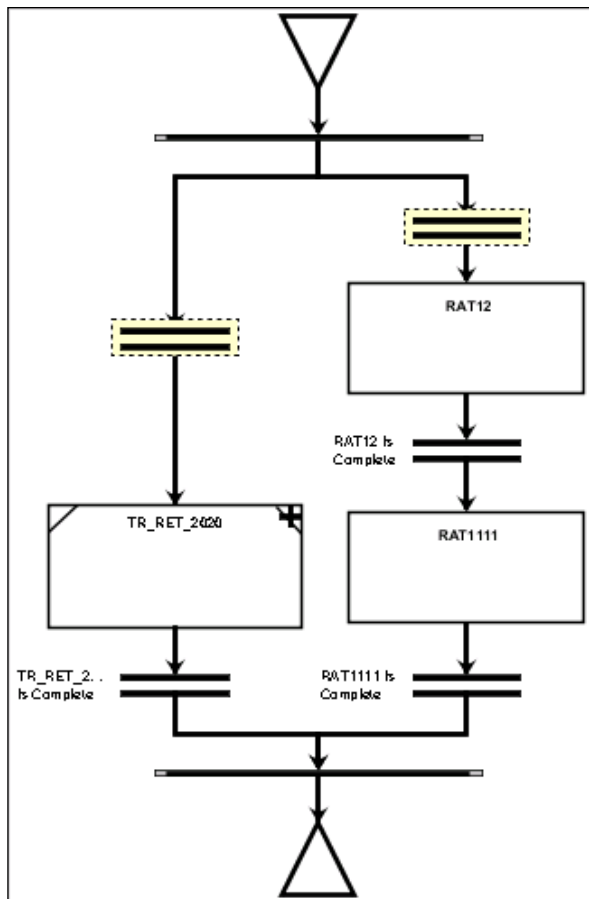

To create a conditional branching:

1. Hold the **Ctrl** key and 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.
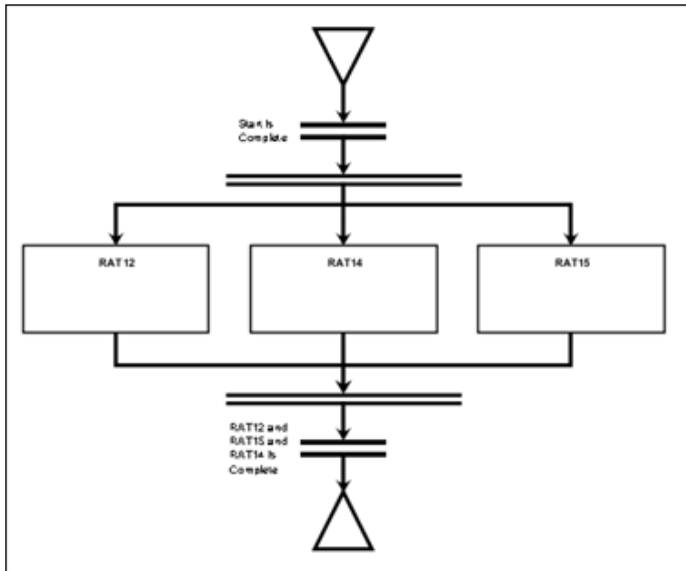
To create a parallel branch:

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

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