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DATA MANAGEMENT

RELEASE 8.4

FUNCTIONAL REQUIREMENT SPECIFICATION

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Chapter 1

Introduction

This document details the requirements of the functions implemented for master data management with PharmaSuite Data Manager. The management includes equipment management and its related objects (page 51) and work center and station management (page 115). Other resource master data like materials (page 121), complementary master data (page 125), and inventory data (page 131) are maintained in PharmaSuite for Production Management.

Each requirement is composed of a name and a unique identifier (e.g. Search Results Panel (SR3071.8.1.2)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g. Data Manager Workbench (SR3071.8+)).

In some cases, additional context information is available, indicated in the document by a frame and a gray background color. This context information is related to the respective requirement, but not part of the formal requirement description.

The revision history (page 145) lists the changes made to the document with PharmaSuite 8.3 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g. status).

Chapter 2

Master Data Management

This section provides an overview of

- the PharmaSuite clients available for master data management (page 3) and
- specific aspects related to equipment management (page 3).

PharmaSuite Clients for Master Data Management

In PharmaSuite, master data is managed in different places.

Data Manager is the client for the management of:

- equipment data and its related objects (page 51),
- work center and station data (page 115).

While the Production Management Client is the tool for the management of:

- resource master data like material (page 121),
- complementary master data like units of measure or risk and safety phrases (page 125),
- inventory data and its related objects (page 131).

Equipment Management

Equipment management supports the creation of specific equipment entities and requirements and to manage each entity's life cycle along with the usage of equipment during execution.

Equipment management includes the management of:

- Equipment classes (page 52)
  They provide a means to bundle and address equipment entities that share a common set of properties and capabilities.
- Template equipment entities (page 63)
  They specify the properties and class assignments that generated equipment entities will have.
- Equipment entities (page 76)
  They represent a physical piece of equipment and its properties.

- Equipment graphs (page 95)
  They specify the statuses an equipment entity can assume while it is used in execution and the transitions between the statuses.
- Property types (page 103)
  They are based on specific data types and define the properties of entities and classes.

While the equipment model is very flexible and allows a data administrator to create any type of equipment object, PharmaSuite supports scales, rooms, and containers as pre-defined equipment types. Specific product phases are designed especially for using equipment objects of these pre-defined equipment types, in order to optimize the user experience during recipe design and execution.

Certain minimum requirements apply to related equipment objects based on their assigned equipment type: **Scale (RS)**, **Room (RS)**, **Container (RS)**, or **Hybrid (RS)**. For details, see **Equipment Type Consistency (SR1099.3.4.5)** error handling (page 89).

Equipment entities can be collected in groups (e.g. assembly), used as an entire group, and separated again. The execution process on the shop floor does not only include the usage of an equipment entity group, but also grouping and separation are usually part of the execution process. For more information on the configuration of the dedicated phases, please refer to "Functional Requirement Specification Equipment Tracking Phases" [A9] (page 143).
All grouping-related actions are tracked within the logbook (if maintained) of the affected equipment entities. In order to support ad-hoc repair use cases, the assignment between parent and child entities can also be updated by authorized users within Data Manager - Equipment. If the grouping is updated while a parent entity is already bound to a unit procedure, the system automatically records the update as an exception in the context of this unit procedure.

Usually, dedicated pieces of equipment such as tools and machines are created once in Data Manager and used during processing afterwards. Other pieces of equipment with a short lifetime such as filter liners or hoses can be generated as approved entities on the shop floor and used immediately. The master for the generated entities is a template equipment entity that is created and validated in Data Manager.

Scales and Their Default Graphs

For scales to be used in the context of PharmaSuite Dispense, Inline Weighing, and Output Weighing (see "Functional Requirement Specification Dispense and Inline Weighing" [A6] (page 143) and "Functional Requirement Specification Output Weighing" [A7] (page 143)), the following properties and graphs must be assigned to a scale.

Property / Graph description	Usage	Data type Content	Purpose	Key (for built-in phase logic)
Equipment type property	Specification	EquipmentType Scale (RS)	n/a	Content
Scale range property	Specification	Ranges (defined per scale)	Scale Ranges (RS)	Purpose
Scale configuration property	Specification	ScaleConfiguration (defined per scale)	n/a	Data type
Scale test and calibration property	Specification	ScaleTestAndCalibration (defined per scale)	n/a	n/a
Work center assignment property	Specification	WorkCenterAssignment (defined per scale)	n/a	Data type
Current load property	Runtime	String (set/cleared during execution)	Current Load (RS)	Purpose
Scale test graph	n/a	n/a n/a	Scale Test (RS)	Purpose
Tested shelflife property	Specification	Duration (defined per scale)	n/a	n/a
Scale calibration graph	n/a	n/a n/a	Scale Calibration (RS)	Purpose
Calibrated shelflife property	Specification	Duration (defined per scale)	n/a	n/a

The **Key** column describes the attributes that are used by Dispense, Inline Weighing, and Output Weighing as a unique key per scale, in order to automatically retrieve or write data during execution. In this context (built-in phase logic), it is not a property identifier that is used as the key.

However, for any reference that is manually built into a recipe, workflow, or graph (process parameter definitions, SFC transitions, graph conditions or actions), based on the **Equipment Property Attribute** function (equipmentPropertyAttribute(arg1, arg2, [arg3, arg4])) function, the property identifier is used as second argument (arg2). Therefore, in order to ensure the consistent definition of property identifiers for a given semantic context across all scales, the same property type must be assigned to all scales of the

semantic context, e.g. for shelflife definition properties or for the property of the **Current Load (RS)** purpose.

As an example scale configuration, PharmaSuite provides the **Scale_RS_1** default class with the following default properties and default graphs assigned to it:

- **Scale Configuration (RS)** property
- **Scale Load (RS)** property
- **Scale Ranges (RS)** property
- **Scale Test and Calibration (RS)** property
- **Scale Type (RS)** property
- **Work Center Assignment (RS)** property
- **ScaleTest_RS_1** graph
- **Scale Test Shelflife (RS)** property
- **ScaleCalibration_RS_1** graph
- **Scale Calibration Shelflife (RS)** property

Scale Test Graph

To avoid breaking the integration of the scale's life cycle management in combination with PharmaSuite' Dispense, Inline Weighing, and Output Weighing, there is a minimum set of requirements that needs to be met for a scale test graph.

Minimum requirements:

- Purpose: Scale Test (RS)
- Statuses (key): TO_BE_TESTED, TESTED
- Triggers (key): TO_BE_TESTED, TESTED, Expired (RS)

As an example test graph, PharmaSuite provides the **ScaleTest_RS_1** default graph.

Statuses of the default scale test graph:

Key	Display text	Initial status	Can expire
TO_BE_TESTED	To be tested	Yes	No
TESTED	Tested	No	Yes

Triggers of the default scale test graph:

Key	Display text
TO_BE_TESTED	To be tested
TESTED	Tested

Key	Display text
Expired (RS)	Expired (RS)

Property types required by the default scale test graph:

Property type	Comment
Scale Test Shelflife (RS)	Specification property (**Duration** data type)
ExpiryDate	Automatically assigned built-in property type (**DateTime** data type)

Triggers and their **transitions** of the default scale test graph
(for applied conditions and actions see the respective table below):

	To status	
From status	**To be tested**	**Tested**
To be tested	To be tested	Tested
Tested	To be tested Expired (RS)	Tested

Applied **conditions and actions** of the triggers:

- An expiry date for the **Tested** status is only calculated if the **Scale Test Shelflife (RS)** property is defined.

Trigger	Condition	Action
To be tested	none	none
Tested	NOT isNull({Scale Test Shelflife (RS)})	set {ExpiryDate} = now() + {Scale Test Shelflife (RS)}
	isNull({Scale Test Shelflife (RS)})	none
Expired (RS)	none	none

Scale Calibration Graph

To avoid breaking the integration of the scale's life cycle management in combination with PharmaSuite' Dispense, Inline Weighing, and Output Weighing, there is a minimum set of requirements that needs to be met for a scale calibration graph.

Minimum requirements:

- Purpose: Scale Calibration (RS)

- Statuses (key): TO_BE_CALIBRATED, CALIBRATED
- Triggers (key): TO_BE_CALIBRATED, CALIBRATED, Expired (RS)

As an example calibration graph, PharmaSuite provides the **ScaleCalibration_RS_1** default graph.

Statuses of the default scale calibration graph:

Key	Display text	Initial status	Can expire
TO_BE_CALIBRATED	To be calibrated	Yes	No
CALIBRATED	Calibrated	No	Yes

Triggers of the default scale test graph:

Key	Display text
TO_BE_CALIBRATED	To be calibrated
CALIBRATED	Calibrated
Expired (RS)	Expired (RS)

Property types required by the default scale calibration graph:

Property type	Comment
Scale Calibration Shelflife (RS)	Specification property (**Duration** data type)
ExpiryDate	Automatically assigned built-in property type (**DateTime** data type)

Triggers and their **transitions** of the default scale calibration graph (for applied conditions and actions see the respective table below):

	To status	
From status	**To be calibrated**	**Calibrated**
To be calibrated	To be calibrated	Calibrated
Calibrated	To be calibrated Expired (RS)	Calibrated

Applied **conditions and actions** of the triggers:

- An expiry date for the **Calibrated** status is only calculated if the **Scale Test Shelflife (RS)** property is defined.

Trigger	Condition	Action
To be calibrated	none	none
Calibrated	NOT isNull({Scale Calibration Shelflife (RS)})	set {ExpiryDate} = now() + {Scale Calibration Shelflife (RS)}
	isNull({Scale Calibration Shelflife (RS)})	none
Expired (RS)	none	none

Rooms and Their Default Graph

For rooms to be used in the context of PharmaSuite Dispense, Inline Weighing, and Output Weighing (see "Functional Requirement Specification Dispense and Inline Weighing" [A6] (page 143) and "Functional Requirement Specification Output Weighing" [A7] (page 143)), the following properties and graph must be assigned to a room.

Property / Graph description	Usage	Data type Content	Purpose	Key (for built-in phase logic)
Equipment type property	Specification	EquipmentType Room (RS)	n/a	Content
Cleaning rules property	Specification	RoomCleaningRules (defined per room)	n/a	Data type
Work center assignment property	Specification	WorkCenterAssignment (defined per room)	n/a	Data type
Room cleaning graph	n/a	n/a n/a	Room Cleaning (RS)	Purpose
Generally cleaned shelflife property	Specification	Duration (defined per room)	n/a	n/a

The **Key** column describes the attributes that are used by Dispense, Inline Weighing, and Output Weighing as a unique key per room, in order to automatically retrieve or write data during execution. In this context (built-in phase logic), it is not a property identifier that is used as the key.

However, for any reference that is manually built into a recipe, workflow, or graph (process parameter definitions, SFC transitions, graph conditions or actions), based on the **Equipment Property Attribute** function (equipmentPropertyAttribute(arg1, arg2, [arg3, arg4])) function, the property identifier is used as second argument (arg2). Therefore, in order to ensure the consistent definition of property identifiers for a given semantic

context across all rooms, the same property type must be assigned to all rooms of the semantic context, e.g. for a shelflife definition property.

As an example room configuration, PharmaSuite provides the **Room_RS_1** default class with the following default properties and default graph assigned to it:

- **Room Cleaning Rules (RS)** property
- **Room Type (RS)** property
- **Work Center Assignment (RS)** property
- **RoomCleaning_RS_1** graph
- **General Clean Shelflife (RS)** property

Room Cleaning Graph

To avoid breaking the integration of the room's life cycle management in combination with PharmaSuite' Dispense, Inline Weighing, and Output Weighing, there is a minimum set of requirements that needs to be met for a room cleaning graph.

Minimum requirements:

- Purpose: Room Cleaning (RS)
- Statuses (key): CLEAN_GENERAL, CLEAN_MAJOR, CLEAN_MINOR, IN_USE, NOT_CLEANED
- Triggers (key): CLEANING_GENERAL, CLEANING_MAJOR, CLEANING_MINOR, REQUIRE_GENERAL_CLEANING, REQUIRE_MAJOR_CLEANING, REQUIRE_MINOR_CLEANING, START_USE, END_USE, Expired (RS)

As an example room cleaning graph, PharmaSuite provides the **RoomCleaning_RS_1** default graph.

Statuses of the default room cleaning graph:

Key	Display text	Initial status	Can expire
CLEAN_GENERAL	Clean (general)	No	Yes
CLEAN_MAJOR	Clean (major)	No	Yes
CLEAN_MINOR	Clean (minor)	No	Yes
GENERAL_CLEANING_REQUIRED	General cleaning required	Yes	No
MAJOR_CLEANING_REQUIRED	Major cleaning required	No	Yes
MINOR_CLEANING_REQUIRED	Minor cleaning required	No	Yes
IN_USE	In use	No	Yes
NOT_CLEANED	Not cleaned	No	Yes

Triggers of the default room cleaning graph:

Key	Display text
CLEANING_GENERAL	Cleaning (general)
CLEANING_MAJOR	Cleaning (major)
CLEANING_MINOR	Cleaning (minor)
REQUIRE_GENERAL_CLEANING	Require general cleaning
REQUIRE_MAJOR_CLEANING	Require major cleaning
REQUIRE_MINOR_CLEANING	Require minor cleaning
START_USE	Start use
END_USE	End use
Expired (RS)	Expired (RS)

Property types required by the default room cleaning graph:

Property type	Comment
General Clean Shelflife (RS)	Specification property (**Duration** data type)
ExpiryDate	Automatically assigned built-in property type (**DateTime** data type)

Triggers and their **transitions** of the default room cleaning graph
(for applied conditions and actions see the respective table below):

	To status							
From status	**Clean (general)**	**Clean (major)**	**Clean (minor)**	**General cleaning required**	**Major cleaning required**	**Minor cleaning required**	**In use**	**Not cleaned**
Clean (general)	Cleaning (general)	---	---	Require general cleaning Expired (RS)	Require major cleaning	Require minor cleaning	Start use	---
Clean (major)	Cleaning (general)	Cleaning (major)	---	Require general cleaning Expired (RS)	Require major cleaning	Require minor cleaning	Start use	---

	To status							
From status	**Clean (general)**	**Clean (major)**	**Clean (minor)**	**General cleaning required**	**Major cleaning required**	**Minor cleaning required**	**In use**	**Not cleaned**
Clean (minor)	Cleaning (general)	Cleaning (major)	Cleaning (minor)	Require general cleaning Expired (RS)	Require major cleaning	Require minor cleaning	Start use	---
General cleaning required	Cleaning (general)	---	---	Require general cleaning	---	---	---	---
Major cleaning required	---	Cleaning (major)	---	Require general cleaning Expired (RS)	Require major cleaning	---	---	---
Minor cleaning required	---	---	Cleaning (minor)	Require general cleaning Expired (RS)	Require major cleaning	Require minor cleaning	---	---
In use	---	---	---	Expired (RS)	---	---	---	End use
Not cleaned	Cleaning (general)	Cleaning (major)	Cleaning (minor)	Require general cleaning Expired (RS)	Require major cleaning	Require minor cleaning	Start use	---

Applied **conditions and actions** of the triggers:

- An expiry date for the **Clean (general)** status is only calculated and passed on if the **General Clean Shelflife (RS)** property is defined.

Trigger	Condition	Action
Cleaning (general)	NOT isNull({General Clean Shelflife (RS)})	set {ExpiryDate} = now() + {General Clean Shelflife (RS)}
	isNull({General Clean Shelflife (RS)})	none
Cleaning (major)	NOT isNull({ExpiryDate})	set {ExpiryDate} = {ExpiryDate}

Trigger	Condition	Action
Cleaning (minor) Require major cleaning Require minor cleaning Start use End use	isNull({ExpiryDate})	none
Require general cleaning Expired (RS)	none	none

Containers and Their Default Graph

For managed containers to be used in the context of PharmaSuite Dispense, Inline Weighing, and Output Weighing (see "Functional Requirement Specification Dispense and Inline Weighing" [A6] (page 143) and "Functional Requirement Specification Output Weighing" [A7] (page 143)), the following properties and graph must be assigned to a container.

Property / Graph description	Usage	Data type Content	Purpose	Key (for built-in phase logic)
Equipment type property	Specification	EquipmentType Container (RS)	n/a	Content
Current tare property	Runtime	MeasuredValue (set/cleared during execution)	Current Tare (RS)	Purpose
Current sublot property	Runtime	String (set/cleared during execution)	Current Sublot (RS)	Purpose
Container cleaning graph	n/a	n/a n/a	Container Cleaning (RS)	Purpose
Generally cleaned shelflife property	Specification	Duration (defined per container)	n/a	n/a

The **Key** column describes the attributes that are used by Dispense, Inline Weighing, and Output Weighing as a unique key per container, in order to automatically retrieve or write data during execution. In this context (built-in phase logic), it is not a property identifier that is used as the key.

However, for any reference that is manually built into a recipe, workflow, or graph (process parameter definitions, SFC transitions, graph conditions or actions), based on the **Equipment Property Attribute** function (equipmentPropertyAttribute(arg1, arg2, [arg3, arg4])) function, the property identifier is used as second argument (arg2). Therefore, in order to ensure the consistent definition of property identifiers for a given semantic context across all containers, the same property type must be assigned to all containers of

the semantic context, e.g. for a shelflife definition property or for the properties of the **Current Tare (RS)** or **Current Sublot (RS)** purpose.

As an example container configuration, PharmaSuite provides the **Container_RS_1** default class with the following default properties and default graph assigned to it:

- **Container Sublot (RS)** property
- **Container Tare (RS)** property
- **Container Type (RS)** property
- **ContainerCleaning_RS_1** graph
- **Container Clean Shelflife (RS)** property

Container Cleaning Graph

To avoid breaking the integration of the container's life cycle management in combination with PharmaSuite' Dispense, Inline Weighing, and Output Weighing, there is a minimum set of requirements that needs to be met for a container cleaning graph.

Minimum requirements:

- Purpose: Container Cleaning (RS)
- Statuses (key): CLEANING_REQUIRED, CLEANED, IN_USE, LOADED
- Triggers (key): CONT_EMPTY, CONT_CLEAN, CONT_ID, CONT_LOADED, CONT_REQUIRE_CLEANING, Expired (RS)

As an example room cleaning graph, PharmaSuite provides the **ContainerCleaning_RS_1** default graph.

Statuses of the default container cleaning graph:

Key	Display text	Initial status	Can expire
CLEANING_REQUIRED	Cleaning required	Yes	No
CLEANED	Cleaned	No	Yes
IN_USE	In use	No	No
LOADED	Loaded	No	No

Triggers of the default container cleaning graph:

Key	Display text
CONT_CLEAN	Clean
CONT_ID	Use
CONT_LOADED	Load
CONT_EMPTY	Unload

Key	Display text
CONT_REQUIRE_CLEANING	Require cleaning
Expired (RS)	Expired (RS)

Property types required by the default container cleaning graph:

Property type	Comment
Container Sublot (RS)	Runtime property (**String** data type) of the **Current Sublot (RS)** purpose
Container Clean Shelflife (RS)	Specification property (**Duration** data type)
ExpiryDate	Automatically assigned built-in property type (**DateTime** data type)

Triggers and their **transitions** of the default container cleaning graph (for applied conditions and actions see the respective table below):

	To status			
From status	**Cleaned**	**Cleaning required**	**In use**	**Loaded**
Cleaned	Clean	Require cleaning Expired (RS)	Use	---
Cleaning required	Clean	Require cleaning	---	---
In use	---	Unload	---	Load
Loaded	---	Unload	---	---

Applied **conditions and actions** of the triggers:

- An expiry date for the **Cleaned** status is only calculated if the **Container Clean Shelflife (RS)** property is defined.
- During status transition from **Loaded** to **Cleaning required**, the **Container Sublot (RS)** property is cleared.

Trigger	Condition	Action
Clean	NOT isNull({Container Clean Shelflife (RS)})	set {ExpiryDate} = now() + {Container Clean Shelflife (RS)}
	isNull({Container Clean Shelflife (RS)})	none
Use	none	none

Trigger	Condition	Action
Load Unload (from **In use** to **Cleaning required**) Require cleaning		
Unload (from **Loaded** to **Cleaning required**)	none	clear {Container Sublot (RS)}
Expired (RS)	none	none

Use Counter Example of an Equipment Entity Group

This section provides an example how equipment graph conditions can result in different target statuses for different equipment entities (based on different **Max_use** definitions) and how graph transition triggers and rule checks during the identification apply to an entire group with all of its entities. For more details, please refer to "Functional Requirement Specification Equipment Tracking Phases" [A9] (page 143).

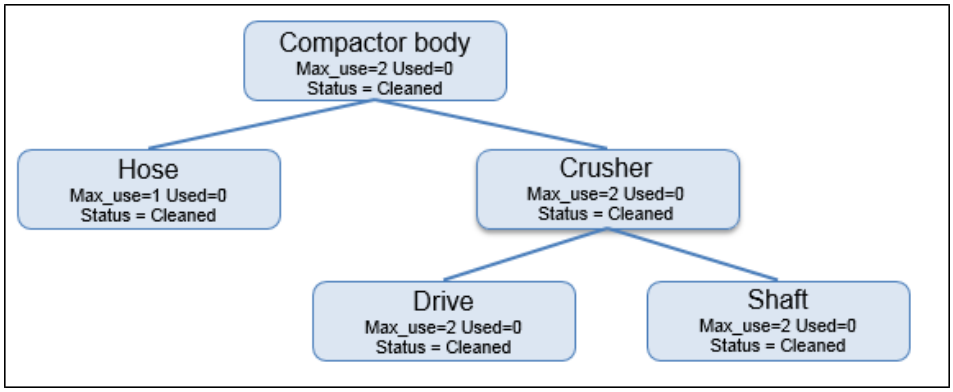

Figure 1: Compactor - example equipment entity group with "use count" runtime properties before first usage

According to the figure above, the example entity group contains a Compactor body as the main parent entity of the group, a Crusher as a sub-parent entity and three more child entities (Hose, Drive, Shaft). For each entity a **Used** counter (runtime property) and a **Max_use** counter (specification property) has been defined.

The following example cleaning graph is assigned to each entity of the group.

Triggers and their **transitions** of the example cleaning graph
(for applied conditions and actions see the respective table below):

	To status			
From status	**Cleaned**	**Cleaning required**	**In use**	**Reusable**
Cleaned	Clean	Require cleaning Expired (RS)	Use	---

	To status			
In use	---	End use	---	End use
Reusable	Clean	Require cleaning	Use	---
Cleaning required	Clean	Require cleaning	---	---

Applied **conditions and actions** of the triggers:

Trigger	Condition	Action
Clean	none	set {ExpiryDate} = now() + {Clean Shelflife (RS)} set {Used} = 0
Use	none	set {Used} = {Used} + 1
End use (from **In use** to **Reusable**)	{Used} <= {Max_use}	none
End use (from **In use** to **Cleaning required**)	{Used} <= {Max_use}	none
Require cleaning	none	none
Expired (RS)	none	none

According to the recipe design, during execution, the **Trigger graph transition** phase manually triggers status transitions, which apply to the main parent entity and to each entity of the group:

- **Use** trigger after successful identification of the Compactor: increases the **Used** counter for each entity of the group.
- **End use** trigger when the Compactor is no longer used for the current batch: for each entity of the group, sets the new target status to **Reusable** (if the **Used** counter is smaller than **Max_use**) or to **Cleaning required** (if the **Used** counter is greater than or equal to **Max_use**).

In the given example, the **Max_use** counter is different for the Hose (**Max_use = 1**, see figure below), compared to the other entities of the group. That means that the first **End use** trigger already sets the status of the Hose to **To be cleaned**, while the cleaning status of all other entities is set to **Reusable** (see figure below).

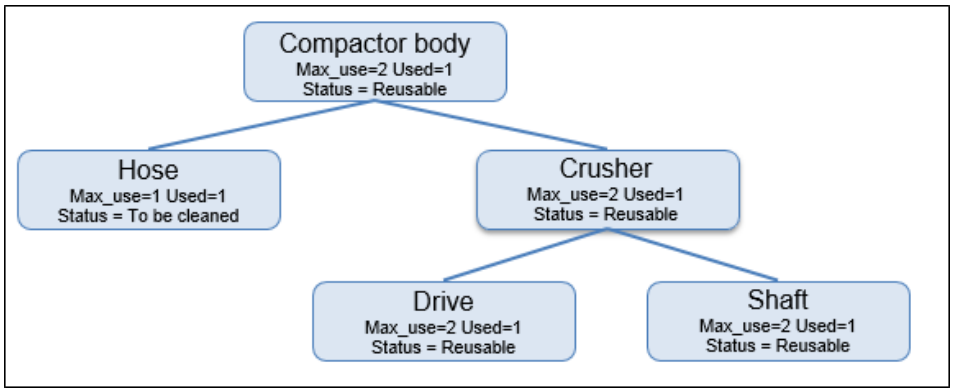

Figure 2: Compactor - example equipment entity group with "use count" runtime properties after first usage

According to the recipe design, the cleaning status of the Compactor is checked to be either **Cleaned** or **Reusable**, when the Compactor is identified in the context of another batch. The **Identify equipment** phase thereby checks the status not only for the main parent entity, but for all entities of the group. However, the respective check will fail if the Hose's cleaning status is still **To be cleaned**.

This means, in the given example, the Hose first has to be disassembled and replaced by a clean Hose, before the Compactor can be used again.

Template Equipment Entity and Generated Equipment Entity

A template equipment entity is a means to generate equipment entities when needed during processing. If generated during processing, the status of a generated entity usually reflects the status of its template entity, which should be **Approved** to generate **Approved** entities that are immediately available for use. Entities that are created manually from template entities in Data Manager are always created in the **Draft** status and need to be moved to the **Approved** status manually.

The template equipment entity acts as a master. All properties with their configured values are available at the generated entity. It is not possible to set a value for a runtime property assigned to a template entity. A runtime property of the generated entity always has its initial value.

A typical use case for generating template-based equipment entities during processing are product or gas filters with a relation to a material and a sublot. Here, the template entity is set up with a specification property of the **Hybrid (RS)** equipment type which ensures that runtime properties of the **Current Sublot (RS)** and **Base Sublot (RS)** purposes are available. This means that when a phase building block generates a product filter from a sublot that should be consumable against the BOM of a processing order at the time of the filter identification, the **Current Sublot (RS)** property is filled with the identifier of the sublot that was generated along with the entity and the **Base Sublot (RS)** property is filled with the identifier of the sublot that was identified and split in order to generate the sublot of the **Current Sublot (RS)** property. The template equipment entity to be used for

the generation of an equipment entity is retrieved from the material of the identified sublot documented afterwards as **Base Sublot (RS)** property.

Using an Empty Container

- For recent changes, see revision history (page 145).

When a clean or reusable container is used for the first time during Dispense or Output Weighing it must be ensured that the container is really empty and does not contain leftover material that all accessories attached during a previous usage have been removed. This is done by checking the container tare.

Containers that are set up with a specification property of the **Container (RS)** equipment type can evaluate the runtime property of the **Reference Tare (RS)** purpose. Each container has a defined weight (tare) which is stored in the **Reference Tare (RS)** property. During execution, the container tare is checked against the stored container tare.

For more information on the configuration of the dedicated phases, please refer to "Functional Requirement Specification Dispense and Inline Weighing" [A6] (page 143) and "Functional Requirement Specification Output Weighing" [A7] (page 143).

Equipment Mass Change

- For recent changes, see revision history (page 145).

During the life time of an equipment entity its characteristics can change due to various reasons. In many cases, this should be reflected by additional properties or a changed behavior of the equipment entity. Reasons for entity changes can be for example a physical extension with a new sensor, a new QA requirement to maintain an additional counter or the expiry date. To apply the changes manually would require the following steps for each affected entity in Data Manager: change the entity's status from **Approved** to **Draft**, update the entity as required, and change its status again to **Approved**.

Changing a large amount of entities manually is a time-consuming and error-prone activity. The equipment mass change process can perform all these activities in an automated way. It is based on the assumption that the entities are assigned to a shared equipment class.

Chapter 3

Data Manager Workbench (SR3071.8+)

Data Manager of PharmaSuite is a graphical workbench for creating and maintaining master data. With its function for change control, it covers the entire life cycle of master data. It is available in two modes. As Data Manager - Equipment, it allows to create and maintain equipment classes, template equipment entities, equipment entities, property types, and equipment graphs and their assignments between one another. As Data Manager - Work Center, it allows to create and maintain work center and station objects and the hierarchical relationship that exists between a work center and its station or stations.

- **UI elements (SR3071.8.1+)** details (page 21)
- **Usability (SR3071.8.2+)** details (page 44)
- **Search capabilities (SR3071.8.3+)** details (page 45)
- **Object operations (SR3071.8.4+)** details (page 46)
- **Access control (SR3071.8.6+)** details (page 49)
- **Technical property types and editors (SR3071.8.7+)** details (page 28)

Change control is only available for equipment classes, entities, and graphs.

Data Manager UI Elements (SR3071.8.1+)

The graphical Data Manager workbench provides several UI elements (e.g. work area (**Search** window with search results panel, **Details** window).

Work Area (SR3071.8.1.1)

The work area (**Search** window) consists of the following panels:

- Search criteria panel (see **Search capabilities (SR3071.8.3+)** UI element (page 45))
- Search results panel (see **Search results panel (SR3071.8.1.2)** UI element (page 21))

Search Results Panel (SR3071.8.1.2)

The search results panel displays all data that matches the filter criteria provided by the data administrator. The data is presented in various views:

- **Mini tiles view (SR3071.8.1.2.7)** UI element (page 22)

- **Tiles view (SR3071.8.1.2.4)** UI element (page 22)
- **Cards view (SR3071.8.1.2.5)** UI element (page 23)

Objects that are open in the **Details** window have their frames highlighted (**Highlighting (SR3071.8.1.2.6)** characteristic (page 23)).

MULTIPLE OBJECTS (SR3071.8.1.2.1)

The search results panel can present data of multiple objects. The objects depend on the defined filter criteria.

HIDE ARCHIVED OBJECTS (SR3071.8.1.2.8)

➢ Does not apply to Data Manager - Work Center.

Smart search (SR1099.10) mode (page 51):

- By default, objects in the **Archived** status are excluded from the search result.
- The inclusion of objects in the **Archived** status can be switched on.

Basic search (SR1099.11) mode (page 51):

- By default, all objects are included in the search result.
- The inclusion of objects in the **Archived** status can be switched off.

SORTING (SR3071.8.1.2.2)

The data in the search results panel is grouped per object type. It is sorted by title.

MULTIPLE SEARCH RESULTS PANELS (SR3071.8.1.2.3)

Multiple search results panels can be open simultaneously along with their related Search criteria panels.

MINI TILES VIEW (SR3071.8.1.2.7)

The Mini Tiles view presents one mini tile per data record. A mini tile displays the title of the data record (e.g. identifier). Upon mouse over, the tooltip of the mini tile represents the **Cards View (SR3071.8.1.2.5)** UI element (page 23).

TILES VIEW (SR3071.8.1.2.4)

The Tiles view presents one tile per data record. A tile displays the title of the data record (e.g. identifier), the short description (in Data Manager - Equipment), the description (in Data Manager - Work Center), and an icon. Upon mouse over, the tooltip of the tile represents the **Cards View (SR3071.8.1.2.5)** UI element (page 23).

The display of the tooltip can be switched off and on.

CARDS VIEW (SR3071.8.1.2.5)

The Cards view presents one card per data record. A card displays the title, up to seven key attributes and properties of the data record, and an icon.

HIGHLIGHTING (SR3071.8.1.2.6)

All objects that are open in the **Details** window have their tile or card frames highlighted in the search results panel. The active object's frame is highlighted in a different color.

In the **Basic search (SR1099.11)** mode (page 51), only the active object is highlighted.

Details Window (SR3071.8.1.3)

The **Details** window displays the data attributes of a data record in detail. Double-clicking a data representation (tile, card) in the **Search results (SR30718.1.2)** panel (page 21) opens the **Details** window.

- An asterisk in the window title is the indicator for unsaved objects.
- An R in the window title is the indicator for read-only objects.

MULTIPLE DETAILS WINDOWS (SR3071.8.1.3.1)

Multiple **Details** windows can be open simultaneously.

TABS IN DETAILS WINDOW (SR3071.8.1.3.2)

The **Details** window can contain multiple tabs in order to organize numerous attributes. Number, order, and contents of tabs is defined in the system per object.

- Tabs can be closed separately.
- All tabs can be closed at one time.

MODES OF DETAILS WINDOW (SR3071.8.1.3.3)

The **Details** window is available in **Edit** mode and in **Read-only** mode. The status of the current data record and the access rights of the logged-in user determine the mode in which a **Details** window is opened.

Expression Editor (Data Manager) (SR3071.8.1.4)

The Expression editor supports:

- References to values of property types assigned to an **equipment graph (SR1099.4+)** object (page 95) (e.g. used for transition conditions and transition actions)
- Operators (see SR3071.8.1.4.3 (page 26))

- Functions (see SR3071.8.1.4.7 (page 27) and SR3071.8.1.4.5 (page 27))

The editor is available for the definition of transition conditions and transition actions within an **equipment graph (SR1099.4+)** object (page 95).
A transition condition determines if the expected circumstances are met so that the transition can be executed.
Transition actions are performed along with the transition.

Intelligent auto-completion feature supports the selection of expression components.

Textual description of a transition condition is displayed as the condition of the transition condition.
Textual description of a transition action is displayed as the description of the transition action.

Concurrent syntax and semantics validation supports the definition of expressions and references.

Property type references consist of the property type identifier.

Blanks, tabs, and line breaks can be used for better readability.

Round brackets can be used to override or clarify an operators' precedence.

Single-line and multi-line comments can be added.

Indicators for errors (red underline of expression, error icon at affected line, global error status marker).

Code folding is supported to enable a clear structuring of large expressions.

EXPRESSIONS FOR TRANSITION CONDITIONS (SR3071.8.1.4.1)

Transition conditions can be defined with the Expression editor.

The expression result must be of the **Boolean** type. If the condition is empty, the result is **true**.

- If the expression result is **true**, the status transition is executed and the actions of the transition are executed.
- In case multiple transitions are defined for a given trigger, only one transition can be executed. If the result of more than one condition expression is **true**, the transition and trigger execution terminates/fails. The reason is provided in the logbook of the entity (if the logbook is maintained).
- If the expression result is **undefined** or an error occurred, the transition and trigger execution terminates/fails. The reason is provided in the logbook of the entity (if the logbook is maintained).
- If the expression result is **false**, the status transition is not executed and the actions of the transition are not executed.
  If there is another transition of the trigger, its condition is processed.

An editor-specific icon indicates the editor's availability.

Expressions for Transition Actions (SR3071.8.1.4.2)

Transition actions related to transition conditions can be defined with the Expression editor.

The Expression editor supports the following commands:

- Manipulate the values of runtime properties of an entity during execution:
  - **set** allows to change the value of a property, either to a constant or to a calculated value.
  - **clear** allows to delete the value of a property, setting it to **undefined**.
- Force the archiving of the current entity:
  - **archive** forces a status transition of the entity to **Archived**.

For each action, exactly one **set**, **clear**, or **archive** commend must be used.
Multiple actions can be defined for one transition.

If the execution of one action expression fails, the transition and entire trigger execution will fail as well. A status transition and already performed actions are rolled back. The reason is provided in the logbook of the entity (if the logbook is maintained).

When an action changes the content of a property, the old content and the final new content (after all actions of the transaction were executed) are provided in the logbook of the entity (if the logbook is maintained).

When the **Archived** status is set with the **archive** command, the new status of the entity is provided in the status history of the entity.

An editor-specific icon indicates the editor's availability.
The data type of the expression result must match the property type's data type.

Expression Editor - Built-in Property Types (SR3071.8.1.4.8)

The Expression editor supports the following built-in property types:

- **ExpiryDate** allows to read and write the expiry date of the current **From** and **To statuses** with the **DateTime** data type.
  - The referenced **From status** of a transition must be set to **Can expire** in order to read an expiry date. The referenced **To status** of a transition must be set to **Can expire** in order to write an expiry date.
  - If the referenced **To status** of a transition is set to **Can expire** and no action of the executed transition sets the expiry date, the expiry date is automatically set to **undefined**.

In case of the **Expired (RS)** system-created trigger (page 97):

- If both **From** and **To statuses** of a transition are set to **Can expire** and the old expiry date is in the past, the new expiry date has to be greater than the old expiry date.
- If both **From** and **To statuses** of a transition are set to **Can expire** and the new expiry date is set to a value in the past, the **Expired (RS)** trigger is called again. This can cause cascading status transitions.

EXPRESSION EDITOR OPERATIONS (SR3071.8.1.4.3)

The Operators tree panel provides the following operators:

- Arithmetic operators: + , - , *, /
- Comparison operators: ==, !=, <, <=, >, >=
- Logical operators: AND, OR, NOT

A special handling applies to the Date and Duration data types:

- Date - Date = Duration
- Date (+, -) Duration = Date
- Duration (*, /) Scalar = Duration

A special handling applies to the Measured value (MV) data type:

- MV (*, /) Scalar = MV
- MV (+, -) MV = MV
- MV (/) MV = Scalar.

EXPRESSION EDITOR LITERALS (SR3071.8.1.4.4)

The following literals are supported:

- Long - integral numbers: e.g. 12345
- Float - floating point numbers (fractional numbers): e.g. 123.45Float
- BigDecimal - floating point numbers (fractional and integral numbers) with greater precision than Float: e.g. 123.45 or 123BDecimal or 12.3e42
- Boolean: true, false
- String: e.g. "This is a string."
- Date and time: e.g. 07/19/2012 9:20:00 AM CEST
- Duration: e.g. 23d1h44min3s
- Measured value: e.g. 23kg

Expression Editor Functions (SR3071.8.1.4.5)

The Functions tree panel provides the following functions:

- Current Date and Time function: now()
  The return value of **now()** is determined when the trigger execution is entered. All calls of **now()** with the conditions and actions of this trigger return this value.
- Convert to Unitless Number function: convertTo(arg1, arg2)
- Convert to BigDecimal function: convertToBigDecimal(arg1)
- Convert to Long function: convertToLong(arg1, arg2)
- Convert to MeasuredValue function: convertToMeasuredValue(arg1, [arg2])
- String Contains function: containsItem(arg1, arg2, [arg3])
- Average function: average(arg1, arg2, ...)
- Minimum function: min(arg1, arg2, ...)
- Maximum function: max(arg1, arg2, ...)

- Null-handling functions: see SR3071.8.4.1.7 (page 27)
- Average function is only supported by Numeric data types.

Expression Editor - Implicit Null Handling (SR3071.8.1.4.6)

The Expression editor implicitly handles NULL markers according to the SQL standard. This leads to the following behavior for expressions including NULL:

- Mathematical expressions result in NULL
  Example: 3 + NULL = NULL
- Aggregation functions eliminate NULL
  Example: MIN(3,NULL,5) = 3
- Comparative expressions result in NULL
  Example: 4 > NULL results in NULL
- Boolean expressions follow the Three-valued logic (3VL).

Expression Editor - Explicit Null Handling (SR3071.8.1.4.7)

The Functions tree panel provides the following functions for the explicit handling of NULL markers:

- Is undefined: isNull(arg1)
- Undefined - one of two: nvl(arg1, arg2)
- Undefined - one of many: coalesce(arg1, arg2, ...)

Technical Property Types and Editors (SR3071.8.7+)

➢ Does not apply to Data Manager - Work Center.

The workbench provides various editors that support data entry.

Technical property type	Usage type and context													
	Specification				Automation			Runtime				Historian		
	Cla	Ent	Gra	Req	Cla	Ent	Req	Cla	Ent	Gra	Req	Cla	Ent	Req
BigDecimal (SR3071.8.7.3) (page 29)	W	W	R	W	(W)	W	X	R	W	R	W	R	W	X
Boolean (SR3071.8.7.4) (page 33)	W	W	R	W	(W)	W	X	R	W	R	W	---	---	X
Duration (SR3071.8.7.16) (page 34)	W	W	R	W	---	---	---	R	W	R	W	---	---	---
Equipment type (SR3071.8.7.10) (page 34)	R	R	X	R	---	---	---	---	---	---	---	---	---	---
Flexible attribute definition (SR3071.8.7.9) (page 35)	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Attributes	---	---	---	---	---	---	---	R	R	R	R	---	---	---
Values	---	---	---	---	---	---	---	R	W	R	---	---	---	---
Flexible tag definition (SR3071.8.7.8) (page 36)	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Tag	---	---	---	---	R	R	X	---	---	---	---	---	---	---
Tag name	---	---	---	---	X	W	X	---	---	---	---	---	---	---
Values	---	---	---	---	X	X	X	---	---	---	---	---	---	---
Measured Value (SR3071.8.7.14) (page 36)	---	---	---	---	---	---	---	X	W	R	W	---	---	---
Ranges (SR3071.8.7.12) (page 37)	W	W	X	X	---	---	---	---	---	---	---	---	---	---
Room cleaning rules (SR3071.8.7.15) (page 37)	W	W	X	X	---	---	---	---	---	---	---	---	---	---
Scale configuration (SR3071.8.7.11) (page 38)	W	W	X	X	---	---	---	---	---	---	---	---	---	---
Scale test and calibration (SR3071.8.7.17) (page 40)	W	W	X	X	---	---	---	---	---	---	---	---	---	---

Technical property type	Usage type and context													
Status model (SR3071.8.7.6) (page 41)	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Graph	---	---	---	---	---	---	---	R	R	X	R	---	---	---
Status	---	---	---	---	---	---	---	X	X	X	X	---	---	---
Semantic property	---	---	---	---	---	---	---	X	X	X	W	---	---	---
String (SR3071.8.7.5) (page 41)	W	W	R	W	(W)	W	X	R	W	R	W	R	W	X
Work center assignment (SR3071.8.7.13) (page 43)	X	W	X	X	---	---	---	---	---	---	---	---	---	---

LEGEND

Cla	Class
Ent	Entity
Gra	Graph
Req	Requirement
W	Write access
(W)	Restricted write access, tag names are read-only
R	Read access
X	Not supported
---	Not applicable

For technical property types and their related editors, there is no difference in the support of equipment entities and template equipment entities except for runtime properties. It is not possible to set a value for a runtime property assigned to a template equipment entity.

BigDecimal Technical Property Type (SR3071.8.7.3)

The system supports the **BigDecimal** technical property type and provides an editor for entering big decimal values or ranges including a unit of measure (engineering unit).

The property type supports the **Specification**, **Automation**, **Runtime**, and **Historian** usage types.

BigDecimal property types of the **Specification** and **Runtime** usage types can be referenced in equipment graphs and thus in their transition conditions and transition actions.

For **BigDecimal** property types of the **Automation** usage type, the **Live Data type** attribute must be defined, which represents the required data type in an automation environment. The following Live Data types are supported:

- Double
- Float

- Integer (signed and unsigned)

BigDecimal editor - Specification and Runtime usage (SR3071.8.7.3.1)

The editor is used for properties of the **Specification** and **Runtime** usage types in the context of

- property type definitions
- equipment class properties (read-only for properties of the **Runtime** usage type)
- equipment entity properties
- equipment requirements of recipes

Property parameter	Comment
Value	■ Read-only for property types ■ Read-only if **Low limit** or **High limit** has been entered
Unit of measure	■ Read-only for class properties, entity properties, and recipe requirements
Low limit High limit	■ Read-only for property types ■ Read-only if **Value** has been entered ■ For the **Runtime** usage type: Read-only and empty for entity properties
Range check type	■ Read-only for property types ■ For class properties, the default setting is **[<>]** (Defined range contains the value/range of the entity). ■ Read-only and empty for entity properties

BigDecimal editor - Automation usage - Tag enabling (SR3071.8.7.3.3)

The editor is used for properties of the **Automation** usage type in the context of

- property type definitions

Property parameter	Comment
Value	■ **Enabled** checkbox

Property parameter	Comment
Low limit	■ **Enabled** checkbox
High limit	■ **Enabled** checkbox
Unit of measure	■ ---

BigDecimal editor - Automation usage (SR3071.8.7.3.2)

The editor is used for properties of the **Automation** usage type in the context of

- equipment class properties
- equipment entity properties

The value, low limit, high limit, and related tag name parameters are only editable if the respective tag has been enabled on property type level.
The low limit, high limit, and related tag name parameters are only visible if at least one of the related check boxes has been enabled on property type level.

Property parameter	Comment
Value	■ ---
Unit of measure	■ Read-only
[Value] Tag name	■ Read-only for class properties
Low limit	■ ---
[Low limit] Tag name	■ Read-only for class properties
High limit	■ ---
[High limit] Tag name	■ Read-only for class properties
Health verification	■ ---
Health indicator tag	■ Read-only for class properties
Simulation verification	■ ---
Simulation indicator tag	■ Read-only for class properties
Maintenance verification	■ ---

Property parameter	Comment
Maintenance indicator tag	■ Read-only for class properties
Default tag update rate [ms]	■ Read-only (from MESConfiguration)
Tag update rate [ms]	■ Overrides default configuration ■ Read-only for class properties

The validity of the defined tag path ("Tag name", "Indicator tag") can be verified by the data administrator.

BigDecimal editor - Historian usage - UoM definition (SR3071.8.7.3.4)

The editor is used for properties of the **Historian** usage type in the context of

- property type definitions

Property parameter	Comment
Unit of measure	■ **Enabled** choice list of unit of measure entries

BigDecimal editor - Historian usage (SR3071.8.7.3.5)

The editor is used for properties of the **Historian** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Point name	■ Name of the Historian data point. ■ Point name can hold up to 80 characters. ■ Point name can contain special characters: _ - / . $ + ( ) (Blank) (German umlauts: ä, ü, ö). ■ Read-only for class properties
Unit of measure	■ Read-only

The validity of the defined tag path ("Tag name", "Point name") can be verified by the data administrator.

Boolean Technical Property Type (SR3071.8.7.4)

The system supports the **Boolean** technical property type and provides an editor for entering a boolean value or null.

The property type supports the **Specification**, **Automation**, and **Runtime** usage types.

Boolean property types of the **Specification** and **Runtime** usage types can be referenced in equipment graphs and thus in their transition conditions and transition actions.

The editor is used for properties of the **Automation** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Value	■ **N/A, No, Yes**
[Value] Tag name	■ Read-only for class properties
Health verification	■ ---
Health indicator tag	■ Read-only for class properties
Maintenance verification	■ ---
Maintenance indicator tag	■ Read-only for class properties
Simulation verification	■ ---
Simulation indicator tag	■ Read-only for class properties
Default tag update rate [ms]	■ Read-only (from MESConfiguration)
Tag update rate [ms]	■ Overrides default configuration ■ Read-only for class properties

The validity of the defined tag path ("Tag name", "Indicator tag") can be verified by the data administrator.

For properties of the **Specification** and **Runtime** usage type, editing is supported by an inline editor (option list). In this case, no explicit Boolean editor is required. This applies to

- equipment class properties (read-only for properties of the **Runtime** usage type),
- equipment entity properties, and
- equipment requirements of recipes.

DURATION TECHNICAL PROPERTY TYPE (SR3071.8.7.16)

The system supports the **Duration** technical property type and provides an editor for entering a duration value.

The property type supports the **Specification** and **Runtime** usage types.

Duration property types of the **Specification** and **Runtime** usage types can be referenced in equipment graphs and thus in their transition conditions and transition actions.

The editor is used for properties of the **Specification** and **Runtime** usage types in the context of

- equipment class properties (read-only for properties of the **Runtime** usage type)
- equipment entity properties
- equipment requirements of recipes

Property parameter	Comment
Days	---
Hours	---
Minutes	---
Seconds	---
Milliseconds	---

EQUIPMENT TYPE TECHNICAL PROPERTY TYPE (SR3071.8.7.10)

The system supports the **Equipment type** technical property type to support an accurate configuration of equipment entities and classes for the following objects:

- containers,
- rooms, and
- scales.

Additionally, the **Hybrid** equipment type supports the maintenance of template equipment entities that are used to generate entities from a sublot during production.

The property type supports the **Specification** usage type.

Selecting an equipment type is supported by an inline editor (option list). In this case, no explicit Equipment type editor is required. This applies to

- property type definitions.

The minimum requirements of an equipment entity definition depend on its equipment type definition. For details, see **Equipment Type Consistency (SR1099.2.4.4)** error handling (page 59).

Flexible Attribute Definition Technical Property Type (SR3071.8.7.9)

The system supports the **Flexible attribute definition** technical property type and provides an editor for defining the data.

The property type supports the **Runtime** usage type.

Flexible attribute definition property types of the **Runtime** usage type can be referenced in equipment graphs and thus in their transition conditions and transition actions.

The following data types are supported by the property type:

- Boolean
- DateTime
- Duration
- Long
- MeasuredValue
- String

The editor is used for properties in the context of

- property types
- equipment class properties
- equipment entity properties

Property parameter	Comment
Identifier (1..n)	■ Read-only for class and entity properties
Value (1..n)	■ Not visible for property types ■ Read-only for class properties

Property parameter	Comment
[Attribute] Data type (1..n)	■ Read-only for class and entity properties

FLEXIBLE TAG DEFINITION TECHNICAL PROPERTY TYPE (SR3071.8.7.8)

The system supports the **Flexible tag definition** technical property type and provides an editor for defining tag-specific data.

The property type supports the **Automation** usage type.

The editor is used for properties in the context of

- property types
- equipment entity properties

Property parameter	Comment
Attribute name (1..n)	■ Read-only for entity properties
Live Data type (1..n)	■ Read-only for entity properties
Unit of measure (1..n)	■ Read-only for entity properties
Tag name (1..n)	■ Not visible for property types ■ Read-only for class properties
Default tag update rate [ms]	■ Read-only (from MESConfiguration)
Tag update rate [ms]	■ Read-only for property types ■ Overrides default configuration

The validity of the defined tag path ("Tag name") can be verified by the data administrator.

MEASURED VALUE TECHNICAL PROPERTY TYPE (SR3071.8.7.14)

The system supports the **Measured value** technical property type and provides an editor for entering a value with a unit of measure.

The property type supports the **Runtime** usage type.

Measured value property types of the **Runtime** usage type can be referenced in equipment graphs and thus in their transition conditions and transition actions.

The editor is used for properties of the **Runtime** usage type in the context of

- equipment entity properties

Property parameter	Comment
Quantity	---
Scale	---
Unit of measure	---

RANGES TECHNICAL PROPERTY TYPE (SR3071.8.7.12)

The system supports the **Ranges** technical property type and provides an editor for entering up to three ranges.

The property type supports the **Specification** usage type.

The editor is used for properties of the **Specification** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Low	■ Available for **Range 1**, **2**, and **3**
High	■ Available for **Range 1**, **2**, and **3**
Resolution	■ Available for **Range 1**, **2**, and **3**
Unit of measure	■ Available for **Range 1**, **2**, and **3**

ROOM CLEANING RULES TECHNICAL PROPERTY TYPE (SR3071.8.7.15)

The system supports the **Room cleaning rules** technical property type and provides an editor for defining room-specific cleaning demands for each rule.

The property type supports the **Specification** usage type.

The editor is used for properties of the **Specification** usage type in the context of

- property type definitions
- equipment class properties (only activated cleaning rules are displayed)
- equipment entity properties (only activated cleaning rules are displayed)

Property parameter	Comment
Available rules	■ Read-only (from configuration key)
Apply	■ Not visible for equipment classes ■ Not visible for equipment entities ■ At least one cleaning rule must be activated for a property type.
Demand	■ Not visible for property types ■ For class properties: **---**, **None**, **Minor**, **Major**, **General** ■ For entity properties: **None**, **Minor**, **Minor**, **General**

Only one property type of this type can be assigned to an equipment entity or class.

SCALE CONFIGURATION TECHNICAL PROPERTY TYPE (SR3071.8.7.11)

The system supports the **Scale configuration** technical property type and provides an editor for entering scale configuration-specific data.

The property type supports the **Specification** usage type.

The editor is used for properties of the **Specification** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Manual scale	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox ■ Default setting: **No**
Scale driver	■ **Enabled** choice list: **---**, **<Available scale drivers>**
COM port	■ ---
TCP server / port	■ ---
Terminal number	■ ---

Property parameter	Comment
Resolution factor	■ ---
Supported driver features ■ Zeroing	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Manual tare	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Tare	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Weighing	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Get serial number	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Scale keyboard lockable	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Disable scale keyboard	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Send nominal value	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox
■ Calibration with adjustment	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox

Property parameter	Comment
■ Calibration without adjustment	■ For class properties: **N/A**, **No**, **Yes** ■ For entity properties: **Enabled** checkbox

For a **Manual scale**, the configuration of a **Scale driver**, **COM port**, **TCP server / port**, and **Terminal number** is not possible.

For a non-**Manual scale**, either a **COM port** or a **TCP server / port** configuration can be defined.

Only one property type of this type can be assigned to an equipment entity or class.

SCALE TEST AND CALIBRATION TECHNICAL PROPERTY TYPE (SR3071.8.7.17)

The system supports the **Scale test and calibration** technical property type and provides an editor for entering scale test- and calibration-specific data.

The property type supports the **Specification** usage type.

The editor is used for properties of the **Specification** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Test weights ■ #	■ Available for each test weight
■ Position	■ Available for each test weight
■ Expected value	■ Available for each test weight
■ Lower tolerance	■ Available for each test weight ■ 0 is not allowed.
■ Upper tolerance	■ Available for each test weight ■ 0 is not allowed.
■ Unit of measure	■ Available for each test weight
Test comment	■ ---
Calibration comment	■ ---

Only one property type of this type can be assigned to an equipment entity or class.

Up to 20 test weights can be defined.

Status Model Technical Property Type (SR3071.8.7.6)

The system supports the **Status model** technical property type and provides an editor for entering status values (semantic properties) of a specified flexible state model (FSM). The editor only allows to select FSMs of an EQM-specific category.

The property type and editor is only supported for properties of the **Runtime** usage type in the context of

- equipment class properties
- equipment entity properties
- equipment requirements of recipes

Property parameter	Comment
FSM identifier	■ Read-only for class properties, entity properties, and recipe requirements
[FSM] Description	■ Read-only
Status group	■ Read-only for property types, class properties, and entity properties

String Technical Property Type (SR3071.8.7.5)

The system supports the **String** technical property type and provides an editor for entering a string value.

The property type supports the **Specification**, **Automation**, **Runtime**, and **Historian** usage types.

String property types of the **Specification** and **Runtime** usage types can be referenced in equipment graphs and thus in their transition conditions and transition actions.

The editor is used for properties of the **Automation** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Value	■ String format
[Value] Tag name	■ Read-only for class properties
Health verification	■ ---
Health indicator tag	■ Read-only for class properties
Maintenance verification	■ ---
Maintenance indicator tag	■ Read-only for class properties
Simulation verification	■ ---
Simulation indicator tag	■ Read-only for class properties
Default tag update rate [ms]	■ Read-only (from MESConfiguration)
Tag update rate [ms]	■ Overrides default configuration ■ Read-only for class properties

The editor is used for properties of the **Historian** usage type in the context of

- equipment class properties
- equipment entity properties

Property parameter	Comment
Point name	■ Name of the Historian data point. ■ Point name can hold up to 80 characters. ■ Point name can contain special characters: _ - / . $ + ( ) (Blank) (German umlauts: ä, ü, ö). ■ Read-only for class properties

The validity of the defined tag path ("Tag name", "Indicator tag", "Point name") can be verified by the data administrator.

For properties of the **Specification** and **Runtime** usage type, editing is supported by an inline editor (text box). In this case, no explicit String editor is required. This applies to

- equipment class properties (read-only for properties of the **Runtime** usage type),
- equipment entity properties, and
- equipment requirements of recipes.

WORK CENTER ASSIGNMENT TECHNICAL PROPERTY TYPE (SR3071.8.7.13)

The system supports the **Work center assignment** technical property type to support the assignment of a work center to equipment entities.

The property type supports the **Specification** usage type.

Selecting a work center is supported by an inline editor (option list). In this case, no explicit Work center assignment editor is required. This applies to

- equipment entity properties.

The **Work center assignment** property is mandatory for entities with the **Scale (RS)** or **Room (RS)** equipment types. For details, see **Equipment Type Consistency (SR1099.3.4.5)** error handling (page 89).

Other Editors (SR3071.8.8+)

The workbench provides various editors that support data entry. This applies to the various types of input data.

LABEL LAYOUT SELECTION EDITOR (SR3071.8.8.1)

The system provides a Label Layout Selection editor to select a report design (label layout) of a specific category for a (template) equipment entity. The category can be configured.

FURTHER EDITORS

The editors listed in this section are specified in the "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 143).

- Multi-line text editor
  (see **Other Editors (SR3146.9.2.17+)**)
- **Date/Time Picker editor (SR3146.9.2.17.1)**

Data Manager Usability (SR3071.8.2+)

The graphical Data Manager workbench supports usability aspects related to its graphical user interface and general handling. Both are targeted to minimize time to result significantly.

Context Menus (SR3071.8.2.1)

Context menus enhance the usability during the creation and maintenance of data records.

Docking (SR3071.8.2.2)

The docking configuration is available as a default layout and a user-specific layout.

In the default docking configuration the windows are arranged as follows:

- To the right of the work area (**Search** window): **Details window (SR3071.8.1.3)** UI element (page 23).

The following functions are available to maintain the docking configuration:

- Undo last layout changes related to the dockable windows.
- Redo last layout changes related to the dockable windows.
- Save the window layout (user-specific).
- Load the last saved window layout (user-specific).
- Reset the window layout to the default layout.

Tooltips (SR3071.8.2.3)

Tooltips are available for tiles and mini tiles.

References (SR3071.8.2.4)

Whenever references need to be defined within Data Manager, the following mechanisms allow to assign an object in the **Search results (SR3071.8.1.2)** panel (page 21) to an object in the **Details (SR3071.8.1.3)** window (page 23):

- drag and drop and
- context menu functions.

The following conditions apply:

- No object can be assigned to objects that are read-only (e.g. an equipment class in the **Approved** status).
- Any read-only object can be assigned to editable objects (e.g. an equipment entity in the **Draft** status).

A reference is revoked with the **Remove** action located in the Details window's tab of the object from which another object is to be removed.

Examples for references:

- assignment of equipment entities to equipment entities for building an equipment entity group,
- assignment of equipment entities and template equipment entities to equipment classes,
- assignment of property types to equipment entities, template equipment entities, equipment classes, and equipment graphs,
- assignment of equipment graphs to equipment entities, template equipment entities, and equipment classes,
- assignment of stations to work centers.

Data Manager Search Capabilities (SR3071.8.3+)

Data Manager supports a **smart search (SR3071.8.3.1)** capability (page 45), a **basic search (SR3071.8.3.3)** capability (page 45), and a search by **object type (SR3071.8.3.2)** capability (page 46).

Smart Search (SR3071.8.3.1)

Smart search evaluates the following data during searching:

- content of attributes of the objects,
- identifier of properties of the objects,
- content of properties that are visible on the **Cards View (SR3071.8.1.2.5)** UI element (page 23), and
- list of assigned objects (e.g. classes, stations).

The search result is refreshed directly as the smart search expression is defined by the data administrator.

Basic Search (SR3071.8.3.3)

➢ Does not apply to Data Manager - Work Center.

Basic search only evaluates object identifiers.

The search result is refreshed when the data administrator explicitly triggers the search with the RETURN key or the **Refresh** operation.

Search by Object Type (SR3071.8.3.2)

Data Manager allows to define one or multiple specific object types as part of the search criterion. Available object types are:

- Equipment management
  - **Equipment class (SR1099.2+)** objects (page 52),
  - **Template equipment entity (SR1099.5+)** objects (page 63),
  - **Equipment entity (SR1099.3+)** objects (page 76),
  - **Property type (SR1099.1+)** objects (page 103), and
  - **Equipment graph (SR1099.4+)** objects (page 95).
- Work center and station management
  - **Work center (SR1100.1+)** objects (page 115) and
  - **Station (SR1100.2+)** objects (page 117).

Data Manager Object Operations (SR3071.8.4+)

Data Manager supports a range of operations applicable to the maintained objects (equipment classes, template equipment entities, equipment entities, equipment graphs, property types, work centers, and stations).

Basic Operations (SR3071.8.4.1)

The following basic operations are supported:

- Create new
- Save (current or all)
- Edit
- Duplicate without referenced objects (applies to e.g. equipment entity or work center)
- Duplicate with classes (applies to template equipment entity and equipment entity)
- Delete
- Restore
- Refresh (the currently active object in the Details window)
  For equipment entities, this includes the update of all runtime data, such as runtime properties, graph-related data, or grouping situations, which may have changed due to processing activities on the shop floor.

- Close (current or all)

Additional operations:

- Find elements by searching for a specific string.
- Support of zoom in and zoom out.

Status Change Operations (SR3071.8.4.3)

Data Manager provides a status change function for equipment classes, entities, and graphs. This includes:

- Definition of the desired transition (target status).

Consistency Checks (SR3071.8.4.3.1)

The status change checks verify the consistency of a desired status change. In case of conflicts, corresponding messages are displayed.

Export/Import Operations (SR3071.8.4.2+)

The Data Manager workbench allows to export and import objects that are maintained within Data Manager.

Both the source and target systems must be of the same release and build.

Before the import, several checks are performed to avoid data inconsistency.

Supported Objects (SR3071.8.4.2.1)

The following objects can be exported and imported:

- Property types
- Template equipment entities
- Equipment entities
- Equipment classes
- Equipment graphs

The export/import operations are specific per object:

- Property type-specific export/import (SR1099.1.5+) characteristics (page 105)
- Equipment entity-specific export/import (SR1099.3.7+) characteristics (page 91)
- Template equipment entity-specific export/import (SR1099.5.6+) characteristics (page 74)

- Equipment class-specific export/import (SR1099.2.5+) characteristics (page 61)
- Equipment graph-specific export/import (SR1099.4.6+) characteristics (page 102)

Work centers and stations cannot be exported or imported.

EXPORT (SR3071.8.4.2.2)

The following features are supported along with the export of an object:

- Trigger export by means of a context menu option or file menu option
- Export dialog (including definition of zip file and log file names)
- Show log with detailed export results

IMPORT (SR3071.8.4.2.3)

The following features are supported along with the import of an object:

- Trigger import by means of a file menu option
- Import dialog (including selection of zip file and definition of log file name)
- Preview content of zip file to be imported
- Check if content can be imported
- Show log with detailed import results
- In case a change history is maintained, the import action is tracked in the change history.
- Imported equipment classes, template entities, entities, and graphs are in the **Draft** status.

CONFLICT HANDLING (SR3071.8.4.2.4)

The following situations are subject to conflict handling along with the import of an object:

- Dependent object does not exist
  Example: A property type depends on the definition of a flexible state model (FSM) that does not exist in the target system.
- Checksum is violated.
- Version of B2MML schema has changed.

Data Manager Modes (SR3071.8.5+)

Data Manager supports several modes.

Supported Modes (SR3071.8.5.1)

For each of the following use cases, Data Manager provides a separate mode:

- Equipment management
  - **Equipment class (SR1099.2+)** objects (page 52),
  - **Template equipment entity (SR1099.5+)** objects (page 63),
  - **Equipment entity (SR1099.3+)** objects (page 76),
  - **Property type (SR1099.1+)** objects (page 103), and
  - **Equipment graph (SR1099.4+)** objects (page 95).
- Work center and station management
  - **Work center (SR1100.1+)** objects (page 115) and
  - **Station (SR1100.2+)** objects (page 117).

Data Manager Access Control (SR3071.8.6+)

The access control of the Data Manager workbench enables the definition of user-specific access rights.

Access Rights for Editing (SR3071.8.6.1)

Upon user login, the Data Manager workbench checks if a user is authorized to edit data. If not, the user can access the workbench, but is not allowed to edit data. In this case, it depends on the **Access Rights for Viewing (SR3071.8.6.2)** assignments (page 49), if the user is authorized to view data.

The access rights can be configured separately for each of the supported Data Manager modes.

Access Rights for Viewing (SR3071.8.6.2)

Upon user login, the Data Manager workbench checks if a user is authorized to view data. If not, the user cannot view any object within the workbench.

The access rights can be configured separately for each of the supported Data Manager modes.

Chapter 4

Equipment Management (SR1099+)

In PharmaSuite, equipment management is done by means of **Data Manager (SR3071.8+)** workbench (page 21).

Equipment management with Data Manager supports the following use cases:

- **Property type (SR1099.1+)** management (page 103)
- **Equipment class (SR1099.2+)** management (page 52)
- **Template equipment entity (SR1099.5+)** management (page 63)
- **Equipment entity (SR1099.3+)** management (page 76)
- **Equipment graph (SR1099.4+)** management (page 95)

Data Manager - Equipment is available in two modes that differ in their search behavior:

- The **Smart search (SR1099.10)** mode (page 51) provides the full potential of the system's flexible search mechanisms.
- The **Basic search (SR1099.11)** mode (page 51) allows to search for objects with their identifiers as search criterion.

Smart Search Mode (SR1099.10)

This mode applies the **Smart Search (SR3071.8.3.1)** capability (page 45) to display the objects that match the search criteria in the **Search Results (SR3071.8.2)** panel (page 21). The search operates on a limited set of data and only on the data that is cached in the memory to provide the result almost instantly.

In the default configuration, equipment entities that have been generated on the shop floor and that are in the **Archived** status are excluded from the limited set of data. Upon configuration, generated equipment entities can be excluded at all, for example to reduce the number of matches when a large number of generated entities is available.

The data excluded in this mode is accessible in the **Basic Search (SR1099.11)** mode (page 51).

Basic Search Mode (SR1099.11)

This search mode applies the **Basic Search (SR3071.8.3.3)** capability (page 45) to display the objects that match the search criteria in the **Search Results (SR3071.8.2)**

panel (page 21). The search always operates on the full set of data, but on a more restricted set of object values than the **Smart Search (SR1099.10)** mode (page 51).

If the search result exceeds a configurable number of objects, the system displays an appropriate message.

Equipment Classes (SR1099.2+)

An **equipment class** provides a means to bundle and address equipment entities that share a common set of properties and capabilities.
The life cycle of an equipment class is controlled by the **status management of equipment classes (SR1099.2.6+)** feature (page 55).

The following use cases are supported by the means of an equipment class:

- An equipment class can be used as an **equipment requirement**.
  In this case equipment entities are grouped and class properties are defined in light of the required equipment usage within a recipe or workflow.
  During the design of a master recipe or master workflow, equipment requirements are used to define the needs that an equipment entity must provide for a specific process step during execution. During execution, the applied equipment requirement (class) must be in the **Approved** status or in a suitable status as defined in the phase.
- An equipment class can be used as a **template** within Data Manager - Equipment.
  In this case class properties are assigned and defined in order to optimize the re-use of that class as a template for new equipment entities.
- An equipment class can be used for simple **grouping** within Data Manager - Equipment, in addition to grouping per requirement or template.
  Example: grouping of all entities that use a controller of a specific manufacturer.
- Any classes assigned to an entity can be used as the **style class** of the entity in order to define its graphical appearance by way of the settings made on the class' **Style (SR1099.2.1.7)** tab (page 54).

Attributes and Properties (SR1099.2.1+)

Attributes and properties of an equipment class are grouped by the following tabs:

Basic Attributes Tab (SR1099.2.1.2)

Available **Asset** attributes are:

- Identifier (mandatory, unique, insert only)
- Short description
- Description
- Status (read-only)

- [S88] Level (Process cell, Unit, Equipment module, control module)
- Inventory number
- Manufacturer
- Model
- Serial number
- Date of manufacturing
- Disposable (Yes, No, N/A)
- Logbook (defines if equipment has a logbook) (Yes, No, N/A)

Specification Tab (SR1099.2.1.3)

This tab holds the status-related properties and other specification-related properties according to the assignment of property types by the data administrator.

Process Properties Tab (SR1099.2.1.4)

This tab holds process properties according to the assignment of property types by the data administrator.

Engineering Properties Tab (SR1099.2.1.5)

This tab holds engineering properties according to the assignment of property types by the data administrator.

Graph Properties Tab (SR1099.2.1.10)

This tab holds graph properties according to the assignment of equipment graphs by the data administrator.

Entity Assignments Tab (SR1099.2.1.6)

This tab holds the list of (template) equipment entities that have been assigned to the specific equipment class by the data administrator.

Available attributes are:

- Style class (read-only): A flag that indicates if the current class is the style class of the specific equipment entity. This applies to the **Cards View (SR1099.3.2.1)** UI element (page 85) and the **Tiles View (SR1099.3.2.2)** UI elements (page 85) of the equipment entity.
- Equipment identifier
- Short description
- Description
- Status

- Template

STYLE TAB (SR1099.2.1.7)

Available attributes are:

- Image selector (for the icon displayed on the card/tile)
- Background color
- Font color

CHANGE HISTORY TAB (SR1099.2.1.8)

➢ For recent changes, see revision history (page 145).

This tab holds the change history entries of the specific equipment class. The entries can be filtered by time.

Available information is:

- Timestamp
- Action
  - Class created/deleted/imported/migrated
  - (Template) entity assigned/removed
  - Attribute updated
  - Property assigned/removed
  - Property value updated
  - Equipment graph assigned/removed
  - Mass change of assigned (template) entities started
- Affected object
- Old content
- New content
- Signatures with user names and comments (if applicable)
- Logged-in user

STATUS HISTORY TAB (SR1099.2.1.9)

This tab holds the status history entries of the specific equipment class. The entries can be filtered by time.

Available information is:

- Timestamp
- Action

- To status
- Signature
- Comment

Status Management of Equipment Classes (SR1099.2.6+)

Default Statuses for Equipment Classes (SR1099.2.6.1)

➢ For recent changes, see revision history (page 145).

The system supports the following default statuses for equipment classes:

- **Initial**: Item is new and has not been saved yet.
- **Draft**: Item is saved and can be modified, including its entity assignment.
- **Verification**: Item is ready for review. If updates are required, a status change back to **Draft** has to be performed.
- **Approved**: Item is ready for use (i.e. assigned entities that are **Approved** can be identified and bound during execution). All of its attributes that are under status control cannot be changed. If updates are required, a status change back to **Draft** has to be performed.
- **Archived**: Item shall no longer be used during the design of a master recipe, master workflow, or building block. For this reason, it is not available in the Universe of Recipe and Workflow Designer [A1] (page 143).

Default Transitions for Equipment Classes (SR1099.2.6.2)

➢ For recent changes, see revision history (page 145).

The system supports the following default transitions for equipment classes:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Draft	---	Automatic transition.
1.2 - Verification » Draft	Status_Trans_ChangeControl_EC_Verification-Draft	---
1.3 - Approved » Draft	Status_Trans_ChangeControl_EC_Approved-Draft	
2.1 - Draft » Verification	Status_Trans_ChangeControl_EC_Draft-Verification	---
3.1 - Verification » Approved	Status_Trans_ChangeControl_EC_Verification-Approved	---
4.1 - Approved » Archived	Status_Trans_ChangeControl_EC_Approved-Archived	---

The diagram illustrates the **S88EquipmentClassStatusGraph** flexible state model.

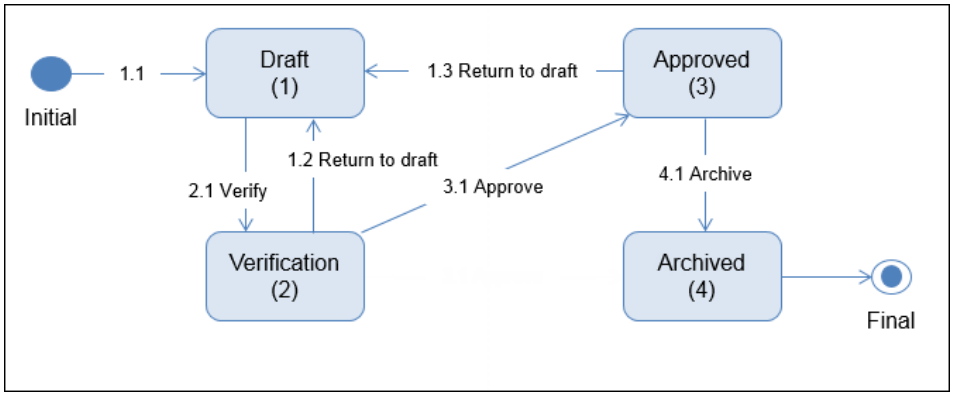

Figure 3: Equipment class - status graph

Definition of Views (SR1099.2.2+)

Equipment classes are presented in their cards view and tiles views.

Cards View (SR1099.2.2.1)

The card displays the following equipment class-related information:

- Icon
- Status
- Identifier
- Short description
- Three asset attributes
- Up to four properties of the **Specification**, **Automation**, **Runtime - Flexible state model**, **Historian** usage types and Equipment graphs (configured by the data administrator)

Tiles View (SR1099.2.2.2)

The tiles display the following equipment class-related information:

- Icon
- Identifier
- Short description

Equipment Class-specific Operations (SR1099.2.3+)

In addition to the general **Object Operations** (SR3071.8.4+) (page 46) of Data Manager, the following operations apply to equipment classes:

Save equipment class as equipment entity (SR1099.2.3.1)

An equipment class can be used as a template to create a new **equipment entity (SR1099.3+)** object (page 76).

The equipment entity is automatically assigned to the class that was used as the template. The class is automatically marked as the style class (see **Style (SR1099.2.1.7)** tab (page 54)).

Save equipment class as a new class (SR1099.2.3.2)

An equipment class can be used as a template to create a new equipment class.

The (template) entity assignments are not copied along with the class.

Save equipment class as template equipment entity (SR1099.2.3.5)

An equipment class can be used as a template to create a new **template equipment entity (SR1099.5+)** object (page 63).

The template equipment entity is automatically assigned to the class from which it was created. The class is automatically marked as the style class (see **Style (SR1099.2.1.7)** tab (page 54)) or the new template equipment entity.

Assign property type with defined purpose (SR1099.2.3.3)

For property types with the same purpose, only one of these property types can be assigned to an equipment class.

Assign equipment graph with defined purpose (SR1099.2.3.4)

For equipment graphs with the same purpose, only one of these graphs can be assigned to an equipment class.

Update assigned (template) entities (SR1099.2.3.6)

➢ For recent changes, see revision history (page 145).

The (template) entities assigned to an equipment class can be updated with the **Equipment Mass Change Process (SR1099.7+)** function (page 108). For the update process,

- the equipment class must not be in a **Retired** state (e.g. **Archived**),
- the equipment class must not be locked by another user,
- at least one (template) entity in a status other than **Archived** must be assigned to the class, and
- there are no unsaved changes for the equipment class.

Compile usage list (SR1099.2.3.7)

➢ For recent changes, see revision history (page 145).

An equipment class can be referenced in master recipes, master workflows, and custom building blocks. The system allows to compile an **Equipment Class Usage List (SR1099.6+)** overview (page 106).

Error Handling (SR1099.2.4+)

As part of the error handling, the system displays messages related to the management of equipment classes.

Entity Assignments (SR1099.2.4.1)

Situation: When the data administrator assigns a (template) equipment entity to an equipment class, when the class is saved, the system checks for property consistency of the class and the (template) entity.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property of the class does not exist in the assigned (template) equipment entity.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on (template) entity level.
- Equipment graphs: A graph of the class does not exist in the assigned (template) equipment entity.

Message category: Warning

Property Consistency (SR1099.2.4.2)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator updates an equipment class or performs a status transition to a read-only status (e.g. **Verification**), the system checks for property consistency based on the already assigned (template) equipment entities that are not in the **Archived** status.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property of the class does not exist in each of the assigned (template) equipment entities.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on (template) entity level.

Message categories:

- Warning, when the class is saved.
- Warning, when the status of the class is transitioned to a read-only status (e.g. **Verification**) while the related (template) entity is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the class is transitioned to a read-only status (e.g. **Verification**) while the related (template) entity is already in a read-only status (e.g. **Approved**).

EQUIPMENT TYPE CONSISTENCY (SR1099.2.4.4)

➢ For recent changes, see revision history (page 145).

When the data administrator updates an equipment class, performs a status transition to a read-only status (e.g. **Verification**), or starts the **Equipment Mass Change Process (SR1099.7+)** function (page 108), the system checks for consistency of the properties and/or attributes required by the assigned equipment type.

The following combinations are supported:

Equipment type	Purpose (property type)	Property type	Purpose (equipment graph)
Container (RS)	Current Tare (RS) Current Sublot (RS)	---	Container Cleaning (RS)
Hybrid (RS)	Current Sublot (RS) Base Sublot (RS)	---	---
Room (RS)	---	Room cleaning rules Work center assignment	Room Cleaning (RS)
Scale (RS)	Scale Ranges (RS) Current Load (RS)	Scale configuration Work center assignment	Scale Test (RS) Scale Calibration (RS)

Message categories:

- Warning, when the class is saved.
- Warning, when the status of the class is transitioned to a read-only status (e.g. **Verification**).
- Error, when the **Equipment Mass Change Process (SR1099.7+)** function (page 108) is started.

GRAPH CONSISTENCY (SR1099.2.4.3)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator updates an equipment class or performs a status transition to a read-only status (e.g. **Verification**), the system checks for graph consistency based on the already assigned (template) equipment entities that are not in the **Archived** status.

Considered issue: A graph of the class does not exist in each of the assigned (template) equipment entities.

Message categories:

- Warning, when the class is saved.
- Warning, when the status of the class is transitioned to a read-only status (e.g. **Verification**) while the related (template) entity is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the class is transitioned to a read-only status (e.g. **Verification**) while the related (template) entity is already in a read-only status (e.g. **Approved**).

PROPERTY OF GRAPH CONSISTENCY (SR1099.2.4.5)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator updates an equipment class, performs a status transition to a read-only status (e.g. **Verification**), or starts the **Equipment Mass Change Process (SR1099.7+)** function (page 108), the system checks for property consistency based on the already assigned equipment graphs.

Considered issue: Properties of the **Specification** and **Runtime** usage type: A property is missing on class level that is a property of at least one of the assigned equipment graphs.

Message categories:

- Warning, when the class is saved.
- Error, when the status of the class is transitioned to a read-only status (e.g. **Verification**).
- Error, when the **Equipment Mass Change Process (SR1099.7+)** function (page 108) is started.

STATUS AND TRIGGER CONSISTENCY (SR1099.2.4.6)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator updates an equipment class and performs a status transition to a read-only status (e.g. **Verification**) or starts the **Equipment Mass Change Process (SR1099.7+)** function (page 108), the system checks for status and trigger

consistency based on the already assigned equipment type and equipment graphs with their purposes.

Considered issue: One or more statuses or triggers are missing in the assigned equipment graphs.

Message categories:

- Warning, when the class is saved.
- Error, when the status of the class is transitioned to a read-only status (e.g. **Verification**).
- Error, when the **Equipment Mass Change Process (SR1099.7+)** function (page 108) is started.

Class and Graph Purpose Consistency (SR1099.2.4.7)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator updates an equipment class and performs a status transition to a read-only status (e.g. **Verification**) or starts the **Equipment Mass Change Process (SR1099.7+)** function (page 108), the system checks for purpose consistency of the already assigned equipment graphs.

Considered issue: There are graphs assigned to the class that have identical purposes.

Message categories:

- Error, when the class is saved.
- Error, when the status of the class is transitioned to a read-only status (e.g. **Verification**).
- Error, when the **Equipment Mass Change Process (SR1099.7+)** function (page 108) is started.

According to the **Assign Equipment Graph with Defined Purpose (SR1099.2.3.4)** check (page 57), graphs that are assigned to a class can only have identical purposes, if a graph itself has been updated.

Equipment Class-specific Export/Import (SR1099.2.5+)

In addition to the general **Export/Import Operations** (SR3071.8.4.2+) (page 47) of Data Manager, the following characteristics apply to the export/import of equipment classes:

Scope of export (SR1099.2.5.1)

The following objects and attributes are included in the export of an equipment class:

- Basic attributes with values except for the **Status**
- Properties of **Specification**, **Automation**, and **Historian** usage types with content

- Properties of **Runtime** usage type without content
- Assigned (template) equipment entity objects

  The export dialog allows to define if the following assigned (template) entities are in the scope of the export:

  - Generated equipment entities
  - (Template) equipment entities in the **Archived** status

  Per default, these (template) entities are excluded from the scope of the export.
- Assigned equipment graph objects (that are assigned directly to the class or to an assigned entity)
- Used property type objects
- Style-related meta data (UI-related)

The following attributes are excluded from the export of an equipment class:

- Status
- Status history
- Change history

Conflict handling during import (SR1099.2.5.3)

The following situations are subject to conflict handling during the import of an equipment class:

- The equipment class exists in the target system and is read-only due to its status (page 55).
  Resolution: The class cannot be imported (regardless whether (template) equipment entities are assigned or not). The import is aborted.

In case template equipment entity objects are in the scope of the import, the **Conflict handling during import (SR1099.5.6.3)** for template equipment entities (page 75) applies in addition, which also may result in the import of the class being aborted.

In case equipment entity objects are in the scope of the import, the **Conflict handling during import (SR1099.3.7.3)** for equipment entities (page 92) applies in addition, which also may result in the import of the class being aborted.

In case equipment graph objects are in the scope of the import, the **Conflict handling during import (SR1099.4.6.3)** for equipment graphs (page 102) applies in addition, which also may result in the import of the class being aborted.

In case property type objects are in the scope of the import, the **Conflict handling during import (SR1099.1.5.3)** for property types (page 106) applies in addition.

Import from external source (SR1099.2.5.4)

The system supports the import of equipment classes from an external system. The following rules apply:

- Checksum-related checks still apply.
- UI-related meta data is not supported.
  All attributes of the imported class that cannot be mapped directly to the basic attributes of the class are mapped to properties of the default tab, which is the **Specification (SR1099.2.1.3)** tab (page 53).

The system also provides an API that allows to import equipment objects from an external source with checksum-related checks being ignored. For details related to the API, see chapter "Importing Equipment Classes and (Template) Entities from an External Source" in "Technical Manual Administration" [A8] (page 143).

Template Equipment Entities (SR1099.5+)

A **template equipment entity** is the data representation of a piece of equipment that is used during processing as a master to generate new equipment entities that are available for immediate use on the shop floor. A generated entity inherits all class assignments, equipment graphs, and properties from its template equipment entity.
Template equipment entities are required for pieces of equipment such as filter liners, hoses, or plastic bags, which are used as equipment during processing and thus need to be tracked. The template entity can be assigned to a material in order to specify the properties that generated equipment entities of the material will have. Template entities without a material reference can be used for components that are not inventoried.
The life cycle of a template equipment entity is controlled by the **status management of template equipment entities (SR1099.5.2+)** feature (page 67).

Attributes and Properties (SR1099.5.1+)

Attributes and properties of a template equipment entity are grouped by the following tabs:

Basic Attributes Tab (SR1099.5.1.1)

Available **Asset** attributes are:

- Identifier (mandatory, unique within template equipment entities and equipment entities, insert only)
- Short description
- Description
- Status (read-only)
- [S88] Level (Process cell, Unit, Equipment module, Control module)

- Inventory number
- Manufacturer
- Model
- Serial number
- Date of manufacturing
- Disposable (Yes, No)
- Logbook (defines if equipment has a logbook) (Yes, No)
- Label layout (default) (read-only)
- Label layout (Report design incl. revision)

Available **Automation** attributes are:

- Automation Integration server name (default) (read-only)
- Automation Integration server name
- Live Data Area path (default) (read-only)
- Live Data Area path

Available **Historian** attributes are:

- Provider (default: PiConnector) (read-only)
- Provider
- Historian access server (default) (read-only)
- Historian access server
- Historian server (default) (read-only)
- Historian server
- Automation Integration server name for Historian (default) (read-only)
- Automation Integration server name for Historian

Available **Entity Barcode** attributes are:

- Barcode prefix character (default) (read-only)
- Barcode prefix source (From configuration key, Template-specific)
- Barcode prefix character (only for **Template-specific** barcode prefix source)
- Identifier prefix (default) (read-only)
- Identifier prefix
- Sequencer length (default) (read-only)
- Sequencer length

Specification Tab (SR1099.5.1.2)

This tab holds the status-related properties and other specification-related properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

Process Properties Tab (SR1099.5.1.3)

This tab holds process properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

Engineering Properties Tab (SR1099.5.1.4)

This tab holds engineering properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

Graph Properties Tab (SR1099.5.1.5)

This tab holds graph properties according to the assignment of equipment graphs by the data administrator.

The system assigns the **Initial statuses** of assigned equipment graphs to the template equipment entity and displays the status and, if a status can expire, the expiry date in square brackets. Both are read-only.

Class Assignments Tab (SR1099.5.1.6)

This tab holds the list of equipment classes to which the specific template equipment entity has been assigned by the data administrator.

Available attributes are:

- Style class (editable): A flag that defines if the respective class is the style class of the current template equipment entity. The style applies to the **Cards View (SR1099.5.3.1)** UI element (page 68) and the **Tiles View (SR1099.5.3.2)** UI elements (page 69) of the template equipment entity. The definition of the style class is done on template entity level.
- Equipment class identifier

- Short description
- Description
- Status

MATERIAL TAB (SR1099.5.1.7)

This tab holds the list of materials to which the specific template equipment entity has been assigned.

Available material-specific information is:

- Identifier
- Short description
- Description

A template entity can only be assigned to a material in the Production Management Client, if it has a property with **Hybrid (RS)** at its equipment type.

CHANGE HISTORY TAB (SR1099.5.1.8)

➢ For recent changes, see revision history (page 145).

This tab holds the change history entries of the specific template equipment entity. The entries can be filtered by time.

Available information is:

- Timestamp
- Action
  - Template entity created/deleted/imported/migrated
  - Class assigned/removed
  - Attribute updated
  - Property assigned/removed
  - Property value updated
  - Tag update rate updated in property
  - Tag name updated in property
  - Equipment graph assigned/removed
  - Status updated
  - Expiry date updated
- Affected object
- Old content

- New content
- Information
  Provides additional information on the circumstances of the action (e.g. "Performed by mass change execution <class>").
- Logged-in user

STATUS HISTORY TAB (SR1099.5.1.9)

This tab holds the status history entries of the specific template equipment entity. The entries can be filtered by time.

Available information is:

- Timestamp
- Action
- To status
- Signature
- Comment

Status Management of Template Equipment Entities (SR1099.5.2+)

DEFAULT STATUSES FOR TEMPLATE EQUIPMENT ENTITIES (SR1099.5.2.1)

➢ For recent changes, see revision history (page 145).

The system supports the following default statuses for template equipment entities:

- **Initial**: Item is new and has not been saved yet.
- **Draft**: Item is saved and can be modified, including its class assignment. The item can be deleted if no equipment entity has been generated during processing using this template. This means that the template equipment entity is not referenced in the **Template used** attribute by any equipment entity.
- **Verification**: Item is ready for review. If updates are required, a status change back to **Draft** has to be performed.
- **Approved**: Item is ready for use (i.e. it can be used to generate entities during execution). All of its attributes that are under status control cannot be changed. If updates are required, a status change back to **Draft** has to be performed.
- **Archived**: Item can no longer be used.

DEFAULT TRANSITIONS FOR TEMPLATE EQUIPMENT ENTITIES (SR1099.5.2.2)

The system supports the following default transitions for template equipment entities:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Draft	---	Automatic transition.
1.2 - Verification » Draft	Status_Trans_ChangeControl_EE_Verification-Draft	---
1.3 - Approved » Draft	Status_Trans_ChangeControl_EE_Approved-Draft	---
2.1 - Draft » Verification	Status_Trans_ChangeControl_EE_Draft-Verification	Only if all of the graphs assigned to the template equipment entity are at least in the **Verification** status.
3.1 - Verification » Approved	Status_Trans_ChangeControl_EE_Verification-Approved	---
4.1 - Approved » Archived	Status_Trans_ChangeControl_EE_Approved-Archived	---

The diagram illustrates the **S88EquipmentEntityStatusGraph** flexible state model used for template equipment entities and equipment entities.

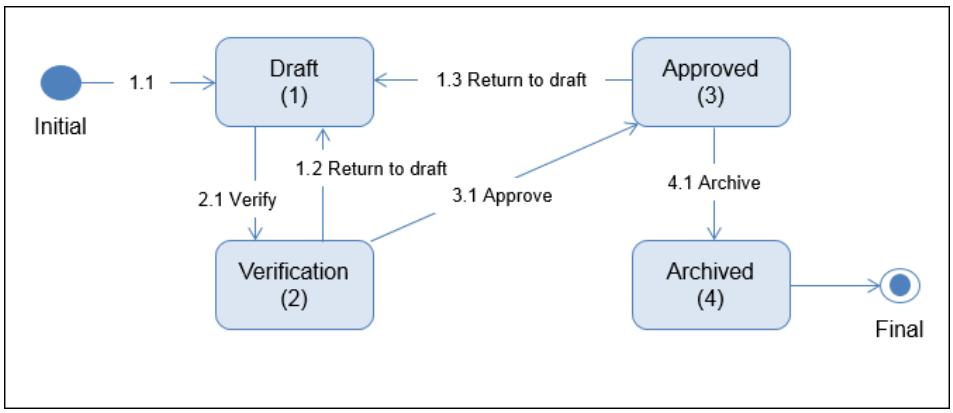

Figure 4: (Template) equipment entity - status graph

Definition of Views (SR1099.5.3+)

Template equipment entities are presented in their cards view and tiles views.

CARDS VIEW (SR1099.5.3.1)

The card displays the following template equipment entity-related information:

- Icon

- Status
- Identifier
- Short description
- Three asset attributes
- Up to four properties of the **Specification**, **Automation**, **Runtime - Flexible state model**, **Historian** usage types and Equipment graphs
  (configured by the data administrator on class level)
  For equipment graphs, the systems displays the status and, if a status can expire, the expiry date in square brackets.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

TILES VIEW (SR1099.5.3.2)

The tiles display the following template equipment entity-related information:

- Icon
- Identifier
- Short description

Template Equipment Entity-specific Operations (SR1099.5.4+)

In addition to the general **Object Operations** (SR3071.8.4+) (page 46) of Data Manager, the following operations apply to template equipment entities:

Save template equipment entity as equipment class (SR1099.5.4.1)

A template equipment entity can be used as a template to create a new **equipment class (SR1099.2+)** object (page 52).

The template equipment entity is not automatically assigned to the class.

Save template equipment entity as new template equipment entity (SR1099.5.4.2)

A template equipment entity can be used as a template to create a new template equipment entity.

- Depending on the operation:
  - The class assignments are copied along with the template equipment entity.
  - The class assignments are not copied along with the template equipment entity.

- The tag paths ("Tag name") defined in the source entity are copied along with the template equipment entity. They are appended by -COPY.
- The assigned graphs are also assigned to the new template entity and the new template entity receives the initial statuses as defined by the respective graphs.

Save template equipment entity as new equipment entity (SR1099.5.4.3)

A template equipment entity can be used as a template to create a new equipment entity.

- The class assignments are copied along with the template equipment entity.
- The tag paths ("Tag name") defined in the source entity are copied along with the template equipment entity. They are appended by -COPY.
- The assigned graphs are also assigned to the new entity and the entity receives the initial statuses as defined by the respective graphs.
- The **Template used** attribute is not set for the new entity. (It is only set when an entity is generated during processing.)

Assign property type with defined purpose (SR1099.5.4.4)

For property types with the same purpose, only one of these property types can be assigned to a template equipment entity.

Assign equipment graphs with defined purpose (SR1099.5.4.5)

For equipment graphs with the same purpose, only one of these graphs can be assigned to a template equipment entity.

Error Handling (SR1099.5.5+)

As part of the error handling, the system displays messages related to the management of template equipment entities.

Class Assignments (SR1099.5.5.1)

Situation: When the data administrator assigns an equipment class to a template equipment entity and saves the template entity, the system checks for property consistency of the class and the template entity.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property is missing on template entity level that is a property of the assigned equipment class.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on entity level.

- Equipment graphs: A graph is missing on template entity level that is a graph of the assigned equipment class.

Message category: Warning

PROPERTY CONSISTENCY (SR1099.5.5.2)

Situation: When the data administrator updates a template equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for property consistency based on the already assigned equipment classes.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property is missing on template entity level that is a property of at least one of the assigned equipment classes.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on entity level.

Message categories:

- Warning, when the template entity is saved.
- Warning, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**) while the related class is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**) while the related class is already in a read-only status (e.g. **Approved**).

EQUIPMENT TYPE CONSISTENCY (SR1099.5.5.3)

Situation: When the data administrator updates a template equipment entity or performs a status transition to a read-only status (e.g. **Verification**), the system checks for consistency of the properties and/or attributes required by the assigned equipment type.

The following combinations are supported:

Equipment type	Purpose (property type)	Property type	Purpose (equipment graph)
Container (RS)	Current Tare (RS) Current Sublot (RS)	---	Container Cleaning (RS)
Hybrid (RS)	Current Sublot (RS) Base Sublot (RS)	---	---
Room (RS)	---	Room cleaning rules Work center assignment	Room Cleaning (RS)

Equipment type	Purpose (property type)	Property type	Purpose (equipment graph)
Scale (RS)	Scale Ranges (RS) Current Load (RS)	Scale configuration Work center assignment	Scale Test (RS) Scale Calibration (RS)

Message categories:

- Warning, when the template entity is saved.
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

EQUIPMENT TYPE AND MATERIAL ASSIGNMENT CONSISTENCY (SR1099.5.5.11)

Situation: When the data administrator saves a template equipment entity or performs a status transition to a read-only status (e.g. **Verification**), the system checks for consistency of any assignment of the template equipment entity to a material.

Considered issue: The template equipment entity is assigned to a material but a property of the **Hybrid (RS)** equipment type was removed from the template entity.

Message categories:

- Warning, when the template entity is saved.
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

GRAPH CONSISTENCY (SR1099.5.5.4)

Situation: When the data administrator updates a template equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for graph consistency based on the already assigned equipment classes.

Considered issue: A graph is missing on template entity level that is a property of at least one of the assigned equipment classes.

Message categories:

- Warning, when the template entity is saved.
- Warning, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**) while the related class is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

Property of Graph Consistency (SR1099.5.5.5)

Situation: When the data administrator updates a template equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for property consistency based on the already assigned equipment graphs.

Considered issue: Properties of the **Specification** and **Runtime** usage type: A property is missing on template entity level that is a property of at least one of the assigned equipment graphs.

Message categories:

- Warning, when the template entity is saved.
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

Status and Trigger Consistency (SR1099.5.5.6)

Situation: When the data administrator updates a template equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for status and trigger consistency based on the already assigned equipment type and equipment graphs with their purposes.

Considered issue: One or more statuses or triggers are missing in the assigned equipment graphs.

Message categories:

- Warning, when the template entity is saved.
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

Template Entity Target Status and Graph Status Consistency (SR1099.5.5.7)

Situation: When the data administrator performs a status transition to a read-only status (e.g. **Verification**), the system checks for status consistency of the already assigned equipment graphs.

Considered issue: The status of a graph is lower (e.g. **Draft**) than the target status of the template entity.

Message category: Error

Template Entity and Graph Purpose Consistency (SR1099.5.5.8)

Situation: When the data administrator updates a template equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for purpose consistency of the already assigned equipment graphs.

Considered issue: There are graphs assigned to the template entity that have identical purposes.

Message categories:

- Error, when the template entity is saved.
- Error, when the status of the template entity is transitioned to a read-only status (e.g. **Verification**).

ENTITY IDENTIFIER SEQUENCE LENGTH CONSISTENCY (SR1099.5.5.9)

Situation: When the data administrator saves a template equipment entity, the system checks that the specified identifier sequence length for generated equipment entities is within its allowed range.

Message category:

- Error, when the template entity is saved.

Template Equipment Entity-specific Export/Import (SR1099.5.6+)

In addition to the general **Export/Import Operations** (SR3071.8.4.2+) (page 47) of Data Manager, the following characteristics apply to the export/import of template equipment entities:

Scope of export (SR1099.5.6.1)

The following objects and attributes are included within the export of a template equipment entity:

- Basic attributes with values except for the **Status**
- Properties of **Specification**, **Automation**, and **Historian** usage types with content
- Properties of **Runtime** usage type without content
- Assigned equipment class information (no class objects)
- Assigned equipment graph objects
- Used property type objects
- Style-related meta data (UI-related)

The following attributes are excluded from the export of an equipment entity:

- Status
- Status history
- Change history

Scope of import (SR1099.5.6.2)

The import dialog allows to define if the following attributes are in the scope of the import:

- Automation attributes
  - Automation Integration server names
  - Live Data Area paths
  - Tag names of property tags (path information)
- Historian attributes
  - Historian access servers
  - Historian servers
  - Point names of properties
  - Automation Integration server names for Historian

Per default, the attributes are excluded from the scope of the import.

Assignments of template entity to existing classes are established. For conflict situations, see "Conflict handling during import (SR1099.5.6.3)" (page 75).

Conflict handling during import (SR1099.5.6.3)

The following situations are subject to conflict handling during the import of a template equipment entity:

- The template equipment entity was assigned to a class that does not yet exist in the target system.
  Resolution: The assignment cannot be established in the target system.
- A single template equipment entity is imported. The template equipment entity exists in the target system and is read-only due to its status (page 67).
  Resolution: The template equipment entity cannot be imported; the import is aborted.
- A template equipment entity is imported along with the import of its class. The template equipment entity exists in the target system and is read-only due to its status (page 67).
  Resolution: If attributes and properties of the imported template equipment entity are not equal to the existing template equipment entity, the entire import of the class and its template entities is aborted.
  If the attributes and properties of the imported template equipment entity are equal to the existing template equipment entity, the import of this specific template equipment entity is skipped during the class import.

- With the **Work center assignment** property type a work center was assigned to the template equipment entity that does not exist in the target system.
  Resolution: The template equipment entity cannot be imported; the import is aborted.
- The report design assigned as label layout to the template equipment entity does not exist in the target system.
  Resolution: The template equipment entity is imported without label layout assignment. The import results contain an appropriate warning.

In case equipment graph objects are in the scope of the import, the **Conflict handling during import (SR1099.4.6.3)** for equipment graphs (page 102) applies in addition, which also may result in the import of the template entity being aborted.

In case property type objects are in the scope of the import, the **Conflict handling during import (SR1099.1.5.3)** for property types (page 106) applies in addition.

Import from external source (SR1099.5.6.4)

The system supports the import of template equipment entities from an external system. The following rules apply:

- Checksum-related checks still apply.
- UI-related meta data is not supported.
  All attributes of the imported template entity that cannot be mapped directly to the basic attributes of the class are mapped to properties of the default tab, which is the **Specification (SR1099.5.1.2)** tab (page 65).

The system also provides an API that allows to import equipment objects from an external source with checksum-related checks being ignored. For details related to the API, see chapter "Importing Equipment Classes and (Template) Entities from an External Source" in "Technical Manual Administration" [A8] (page 143).

Equipment Entities (SR1099.3+)

An **equipment entity** is the data representation of a physical piece of equipment and its properties. Equipment entities can be derived from an equipment class, a template equipment entity, or from another equipment entity. They can be assigned to all classes whose properties they share.
Additionally, equipment entities can be collected in groups to facilitate scenarios such as a common treatment of otherwise unconnected entities, e.g. sterilization, or a complex piece of equipment that consists of a base entity and several other attached entities, e.g. an assembled machine. A group of entities consists of a parent entity and one or more child entities, which themselves can also be parent to an entity group. Thus a child entity that has children is the sub-parent to a sub-group, which itself belongs to a main group that has its main parent.

The life cycle of an equipment entity is controlled by the **status management of equipment entities (SR1099.3.8+)** feature (page 83).

During execution of a control recipe or workflow, equipment entities in a suitable status as defined in the phase (e.g. **Approved**) can be identified and bound to the respective unit procedure or phase. Based on the configuration of the automation infrastructure, data can directly be downloaded from the control recipe to the equipment entity or uploaded from the equipment entity into the control recipe.

Equipment entities for containers, rooms, and scales require a combination of properties to be fully configured and suitable for use with the Weighing and Dispense phases of PharmaSuite. For details, see **Equipment type consistency (SR1099.3.4.5)** error handling (page 89).

Attributes and Properties (SR1099.3.1+)

Attributes and properties of an equipment entity are grouped by the following tabs:

Basic Attributes Tab (SR1099.3.1.2)

Available **Asset** attributes are:

- Identifier (mandatory, unique within template equipment entities and equipment entities, insert only)
- Short description
- Description
- Status (read-only)
- [S88] Level (Process cell, Unit, Equipment module, Control module)
- Inventory number
- Manufacturer
- Model
- Serial number
- Date of manufacturing
- Disposable (Yes, No)
- Barcode (if created in Data Manager, pre-filled with the configured entity barcode prefix and identifier; if filled, unique)
- Logbook (defines if equipment has a logbook) (Yes, No)
- Template used (read-only)
- Label layout (default) (read-only)
- Label layout (Report design incl. revision)

Available **Automation** attributes are:

- Automation Integration server name (default) (read-only)
- Automation Integration server name
- Live Data Area path (default) (read-only)
- Live Data Area path

Available **Historian** attributes are:

- Provider (default: PiConnector) (read-only)
- Provider
- Historian access server (default) (read-only)
- Historian access server
- Historian server (default) (read-only)
- Historian server
- Automation Integration server name for Historian (default) (read-only)
- Automation Integration server name for Historian

SPECIFICATION TAB (SR1099.3.1.3)

This tab holds the status-related properties and other specification-related properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

PROCESS PROPERTIES TAB (SR1099.3.1.4)

This tab holds process properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

ENGINEERING PROPERTIES TAB (SR1099.3.1.5)

This tab holds engineering properties according to the assignment of property types by the data administrator.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

Graph Properties Tab (SR1099.3.1.11)

This tab holds graph properties according to the assignment of equipment graphs by the data administrator.

The system assigns the **Initial statuses** of assigned equipment graphs to the equipment entity and displays the status and, if a status can expire, the expiry date in square brackets.

Class Assignments Tab (SR1099.3.1.6)

This tab holds the list of equipment classes to which the specific equipment entity has been assigned by the data administrator.

Available attributes are:

- Style class (editable): A flag that defines if the respective class is the style class of the current equipment entity. The style applies to the **Cards View (SR1099.3.2.1)** UI element (page 85) and the **Tiles View (SR1099.3.2.2)** UI elements (page 85) of the equipment entity. The definition of the style class is done on entity level.
- Equipment class identifier
- Short description
- Description
- Status

Grouping Tab (SR1099.3.1.14)

This tab holds the lists of parent and child entities of the specific equipment entity.
An entity can have only one parent and several directly or indirectly assigned children.

Available **Parent** attributes are:

- Identifier
- Short description
- Description
- Status

Available **Children** attributes are:

- Identifier
- Short description
- Description
- Status
- Sub-parent [Identifier]

CONTEXT TAB (SR1099.3.1.13)

This tab holds the context information of the specific equipment entity.
The context information is only updated if an equipment entity is used in the context of an order. It is not updated if the equipment entity is used in the context of a workflow.

Available information is:

- Current order context
  - Batch (product)
  - Material (product)
  - Order
  - Order step
  - Involved material
  - Order step input
  - Order step output
- Previous order context
  - Batch (product)
  - Material (product)
  - Order
  - Order step
  - Involved material
  - Order step input
  - Order step output

LOGBOOK TAB (SR1099.3.1.7)

This tab holds the logbook entries of the specific equipment entity.

- The entries can be filtered by time.
- The logbook can be printed, see **Equipment Entity Logbook Report (SR1099.3.10+)** feature (page 94).

Available information is:

- Timestamp
- Category (e.g.: Binding, Context, Denial, FSM, Graph transition, Grouping, Manual, Phase, Property update)
- Action / Trigger
- Graph (if applicable)

- Property
- Old content (if applicable)
- New content (if applicable)
- Information
  Provides additional information on the circumstances of events of the **Denial**, **Graph transition**, **Grouping**, **Manual**, and **Property update** categories.
- Workflow (if applicable)
- Order (if applicable)
- Product batch (if applicable)
- Product material (if applicable)
- Procedure
- Unit procedure (and instance count, if > 1)
- Operation (and instance count, if > 1)
- Phase (and instance count, if > 1)
- Involved material
- Work center
- Station
- Device
- Signatures with user names and comments (if applicable)
- Logged-in user

Referenced workflows are considered as **Production-relevant**. This affects the **Purge workflow (SR1085.2.11)** operation, see "Functional Requirement Specification Runtime Data Management" [A4] (page 143).

MIGRATED HISTORY TAB (SR1099.3.1.12)

➢ Applies only to scales and rooms that were created within PharmaSuite for Production Management prior to PharmaSuite 8.1 and migrated to Data Manager.

This tab holds the logbook entries and status history entries (calibration and testing) of the specific equipment entity before it was migrated to Data Manager.

- The logbook entries and status history entries can be filtered by time.

Available **Logbook** information is:

- Timestamp
- Old status

- New status
- Context (e.g.: Binding, Unbinding, Status change)
- Batch (product)
- Order step
- Order step input
- Order step output
- Material (product)
- Process order
- User 1
- User 2

Available **Status history** information is:

- Entry time
- Previous status
- Status
- Transition
- Signature
- Comment
- Entry user

CHANGE HISTORY TAB (SR1099.3.1.8)

➢ For recent changes, see revision history (page 145).

This tab holds the change history entries of the specific equipment entity.
The entries can be filtered by time.

Available information is:

- Timestamp
- Action
  - Entity created/deleted/imported/migrated
  - Class assigned/removed
  - Attribute updated
  - Property assigned/removed
  - Property value updated
    Exception: No change history entry is created if runtime data, such as runtime

properties, graph-related data, or grouping situations, is updated. The system updates the logbook accordingly (if maintained).

- Tag update rate updated in property
- Tag name updated in property
- Equipment graph assigned/removed
- Status updated
- Expiry date updated

- Affected object
- Old content
- New content
- Information
  Provides additional information on the circumstances of the action (e.g. "Performed by mass change execution <class>").
- Logged-in user

STATUS HISTORY TAB (SR1099.3.1.10)

This tab holds the status history entries of the specific equipment entity.
The entries can be filtered by time.

Available information is:

- Timestamp
- Action
- To status
- Signature
- Comment

Status Management of Equipment Entities (SR1099.3.8+)

DEFAULT STATUSES FOR EQUIPMENT ENTITIES (SR1099.3.8.1)

➢ For recent changes, see revision history (page 145).

The system supports the following default statuses for equipment entities:

- **Initial**: Item is new and has not been saved yet.
- **Draft**: Item is saved and can be modified, including its class assignment. The item can be deleted if it has never been bound or has not been changed along with its generation during execution.

- **Verification**: Item is ready for review. If updates are required, a status change back to **Draft** has to be performed.
- **Approved**: Item is ready for use (i.e. it can be identified and bound during execution). All of its attributes that are under status control cannot be changed. If updates are required, a status change back to **Draft** has to be performed.
- **Archived**: Item can no longer be used.

The system updates runtime data that reflects the actual activities on the shop floor. To resolve processing exceptions by administrative means, in the **Verification** and **Approved** statuses, the system allows to update runtime data with the **Change Properties of Equipment Entity in Read-only Status (SR1099.3.3.8)** operation (page 87).

Depending on the configuration of the **Identify equipment** phase, equipment entities in the **Verification** status could be identified and thus bound. For those equipment entities, a status transition back to **Draft** is still possible and implies a certain level of risk while the equipment is already used during execution. Therefore, identification of an equipment in the **Verification** status must be handled with care in order to not pose a risk to quality.

Default Transitions for Equipment Entities (SR1099.3.8.2)

The system supports the following default transitions for equipment entities:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Draft	---	Automatic transition.
1.2 - Verification » Draft	Status_Trans_ChangeControl_EE_Verification-Draft	---
1.3 - Approved » Draft	Status_Trans_ChangeControl_EE_Approved-Draft	Only if the equipment entity is neither identified nor bound.
2.1 - Draft » Verification	Status_Trans_ChangeControl_EE_Draft-Verification	Only if all of the graphs assigned to the equipment entity are at least in the **Verification** status.
3.1 - Verification » Approved	Status_Trans_ChangeControl_EE_Verification-Approved	---
4.1 - Approved » Archived	Status_Trans_ChangeControl_EE_Approved-Archived	---

The diagram illustrates the **S88EquipmentEntityStatusGraph** flexible state model used for template equipment entities and equipment entities.

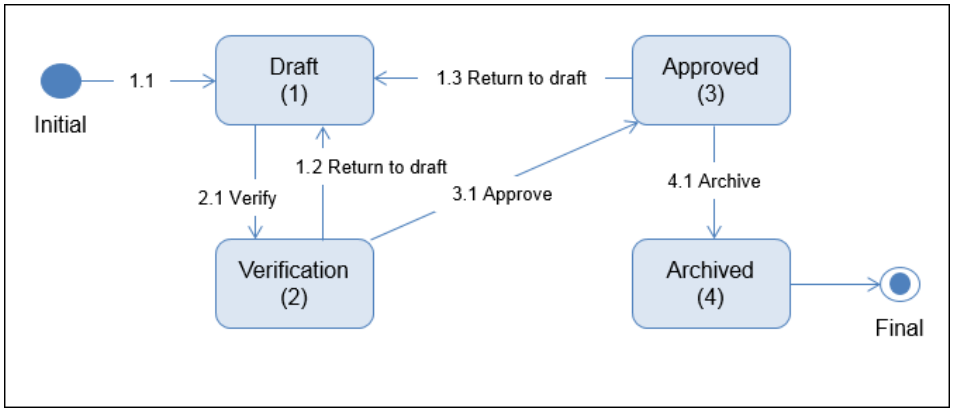

Figure 5: (Template) equipment entity - status graph

Definition of Views (SR1099.3.2+)

Equipment entities are presented in their cards view and tiles views.

CARDS VIEW (SR1099.3.2.1)

The card displays the following equipment entity-related information:

- Icon
- Status
- Identifier
- Short description
- Three asset attributes
- Up to four properties of the **Specification**, **Automation**, **Runtime - Flexible state model**, **Historian** usage types and Equipment graphs
  (configured by the data administrator on class level)
  For equipment graphs, the systems displays the status and, if a status can expire, the expiry date in square brackets.

For properties of the **Automation** and **Historian** usage types, the information whether a tag name is set or not is provided.

TILES VIEW (SR1099.3.2.2)

The tiles display the following equipment entity-related information:

- Icon
- Identifier
- Short description

Equipment Entity-specific Operations (SR1099.3.3+)

In addition to the general **Object Operations** (SR3071.8.4+) (page 46) of Data Manager, the following operations apply to equipment entities:

Save equipment entity as equipment class (SR1099.3.3.1)

An equipment entity can be used as a template to create a new **equipment class (SR1099.2+)** object (page 52).

The equipment entity is not automatically assigned to the class.

Save equipment entity as a new entity (SR1099.3.3.2)

An equipment entity can be used as a template to create a new equipment entity.

- Depending on the operation:
  - The class assignments are copied along with the entity.
  - The class assignments are not copied along with the entity.
- The tag paths ("Tag name") defined in the source entity are copied along with the entity. They are appended by -COPY.
- The assigned graphs are also assigned to the new entity and the entity receives the initial statuses as defined by the respective graphs.
- Any expiry date set in the source entity is undefined in the target entity.
- The **Template used** attribute is not set for the new entity. (It is only set when an entity is generated during processing.)

Assign property type with defined purpose (SR1099.3.3.4)

For property types with the same purpose, only one of these property types can be assigned to an equipment entity.

Assign equipment graphs with defined purpose (SR1099.3.3.5)

For equipment graphs with the same purpose, only one of these graphs can be assigned to an equipment entity.

Change equipment graphs status and expiry date (SR1099.3.3.6)

For equipment entities in the **Draft** status, the status of the entity and, if applicable, its expiry date can be changed according to the statuses defined in the assigned equipment graphs.

Force unbinding an equipment entity (SR1099.3.3.7)

A bound equipment entity can be unbound manually. The action must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A5] (page 143)).

After the electronic signature has been performed successfully, the system automatically records a "unbind equipment entity"-specific exception for the runtime unit procedure of the equipment entity. The risk level of the exception can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A2] (page 143).

Change properties of equipment entity in read-only status (SR1099.3.3.8)

Runtime data, such as runtime properties, graph-related data (e.g. status, expiry date), and grouping situations, of an equipment entity in a read-only status (e.g. **Verification**, **Approved**) can be changed. The action must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A5] (page 143)).
The system updates the logbook accordingly (if maintained).

Only if the equipment entity is bound: After the electronic signature has been performed successfully, the system automatically records a "change runtime data of read-only equipment entity"-specific exception for the runtime unit procedure of the bound equipment entity. The risk level of the exception and the exception text can be configured.

For details, see chapter "Defining the Risk Level for Exceptions" in Volume 2 of the "Technical Manual Configuration and Extension" [A2] (page 143).

Group or separate an equipment entity (SR1099.3.3.9)

An equipment entity or an equipment entity group can be assigned to another entity or the parent entity of an entity group or separated from such a group, i.e. from its parent entity, manually.

A child entity cannot be assigned to a parent entity, when

- the child entity is already a child entity of an equipment entity group,
- the child entity is a main parent entity and the intended parent entity is a member of the child's equipment entity group,
- the child entity is bound to a unit procedure, or
- the child entity has unsaved changes.

If the parent entity is bound to a unit procedure, the same binding context is automatically applied to the child entity when it is assigned to the parent entity.

To separate a child entity from another entity, it must be a direct child of the parent entity and must not be assigned to a sub-parent. If the direct child entity that is separated is a sub-parent entity for other equipment entities, the entire sub-group is separated from the parent group. A separated entity that is bound to a unit procedure is unbound and its binding context is updated.

If one of the equipment entities affected by the grouping or separation is in a read-only status, the action must be confirmed by a signature. If, additionally, the entity is bound, an exception is recorded. For details, see **Change Properties of Equipment Entity in Read-only Status (SR1099.3.3.8)** operation (page 87).

Error Handling (SR1099.3.4+)

As part of the error handling, the system displays messages related to the management of equipment entities.

Class Assignments (SR1099.3.4.1)

Situation: When the data administrator assigns an equipment class to an equipment entity and saves the entity, the system checks for property consistency of the class and the entity.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property is missing on entity level that is a property of the assigned equipment class.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on entity level.
- Equipment graphs: A graph is missing on entity level that is a graph of the assigned equipment class.

Message category: Warning

Property Consistency (SR1099.3.4.2)

Situation: When the data administrator updates an equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for property consistency based on the already assigned equipment classes.

Considered issues:

- Properties of any usage type (**Specification**, **Automation**, **Runtime**, or **Historian**): A property is missing on entity level that is a property of at least one of the assigned equipment classes.
- Properties of the **Specification** usage type: The content of property definitions does not match. If no content of a property is defined on class level, any content is allowed on entity level.

Message categories:

- Warning, when the entity is saved.
- Warning, when the status of the entity is transitioned to a read-only status (e.g. **Verification**) while the related class is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**) while the related class is already in a read-only status (e.g. **Approved**).

Equipment Type Consistency (SR1099.3.4.5)

Situation: When the data administrator updates an equipment entity or performs a status transition to a read-only status (e.g. **Verification**), the system checks for consistency of the properties and/or attributes required by the assigned equipment type.

The following combinations are supported:

Equipment type	Purpose (property type)	Property type	Purpose (equipment graph)
Container (RS)	Current Tare (RS) Current Sublot (RS)	---	Container Cleaning (RS)
Hybrid (RS)	Current Sublot (RS) Base Sublot (RS)	---	---
Room (RS)	---	Room cleaning rules Work center assignment	Room Cleaning (RS)
Scale (RS)	Scale Ranges (RS) Current Load (RS)	Scale configuration Work center assignment	Scale Test (RS) Scale Calibration (RS)

Message categories:

- Warning, when the entity is saved.
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**).

Graph Consistency (SR1099.3.4.4)

Situation: When the data administrator updates an equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for graph consistency based on the already assigned equipment classes.

Considered issue: A graph is missing on entity level that is a property of at least one of the assigned equipment classes.

Message categories:

- Warning, when the entity is saved.
- Warning, when the status of the entity is transitioned to a read-only status (e.g. **Verification**) while the related class is still not in a read-only status (e.g. **Draft**).
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**) while the related class is already in a read-only status (e.g. **Approved**).

Property of Graph Consistency (SR1099.3.4.6)

Situation: When the data administrator updates an equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for property consistency based on the already assigned equipment graphs.

Considered issue: Properties of the **Specification** and **Runtime** usage type: A property is missing on entity level that is a property of at least one of the assigned equipment graphs.

Message categories:

- Warning, when the entity is saved.
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**).

Status and Trigger Consistency (SR1099.3.4.7)

Situation: When the data administrator updates an equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for status and trigger consistency based on the already assigned equipment type and equipment graphs with their purposes.

Considered issue: One or more statuses or triggers are missing in the assigned equipment graphs.

Message categories:

- Warning, when the entity is saved.
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**).

Entity Target Status and Graph Status Consistency (SR1099.3.4.8)

Situation: When the data administrator performs a status transition to a read-only status (e.g. **Verification**), the system checks for status consistency of the already assigned equipment graphs.

Considered issue: The status of a graph is lower (e.g. **Draft**) than the target status of the entity.

Message category: Error

Entity and Graph Purpose Consistency (SR1099.3.4.9)

Situation: When the data administrator updates an equipment entity and performs a status transition to a read-only status (e.g. **Verification**), the system checks for purpose consistency of the already assigned equipment graphs.

Considered issue: There are graphs assigned to the entity that have identical purposes.

Message categories:

- Error, when the entity is saved.
- Error, when the status of the entity is transitioned to a read-only status (e.g. **Verification**).

Binding Status Conflict (SR1099.3.4.3)

Situation: When the data administrator performs a status transition of an equipment entity from **Approved** to **Draft** or to **Archived**, the system checks the binding status of the entity.

Considered issue: The equipment entity is identified or bound to an order or workflow.

Message category: Error

Equipment Entity-specific Export/Import (SR1099.3.7+)

In addition to the general **Export/Import Operations** (SR3071.8.4.2+) (page 47) of Data Manager, the following characteristics apply to the export/import of equipment entities:

Scope of export (SR1099.3.7.1)

The following objects and attributes are included within the export of an equipment entity:

- Basic attributes with values except for the **Status** and **Template used**
- Properties of **Specification**, **Automation**, and **Historian** usage types with content
- Properties of **Runtime** usage type without content
- Assigned equipment class information (no class objects)

- Assigned equipment graph objects
- Used property type objects
- Style-related meta data (UI-related)

The following attributes are excluded from the export of an equipment entity:

- Status
- Status history
- Change history
- Logbook
- Assigned equipment entity information and objects (grouping)

Scope of import (SR1099.3.7.2)

The import dialog allows to define if the following attributes are in the scope of the import:

- Automation attributes
  - Automation Integration server names
  - Live Data Area paths
  - Tag names of property tags (path information)
- Historian attributes
  - Historian access servers
  - Historian servers
  - Point names of properties
  - Automation Integration server names for Historian

Per default, the attributes are excluded from the scope of the import.

Assignments of entity to existing classes are established. For conflict situations, see "Conflict handling during import (SR1099.3.7.3)" (page 92).

Conflict handling during import (SR1099.3.7.3)

The following situations are subject to conflict handling during the import of an equipment entity:

- The equipment entity was assigned to a class that does not yet exist in the target system.
  Resolution: The assignment cannot be established in the target system.

- A single equipment entity is imported. The equipment entity exists in the target system and is read-only due to its status (page 83).
  Resolution: The equipment entity cannot be imported; the import is aborted.
- An equipment entity is imported along with the import of its class. The equipment entity exists in the target system and is read-only due to its status (page 83).
  Resolution: If attributes and properties of the imported equipment entity are not equal to the existing equipment entity, the entire import of the class and its entities is aborted.
  If the attributes and properties of the imported equipment entity are equal to the existing equipment entity, the import of this specific equipment entity is skipped during the class import.
- With the **Work center assignment** property type a work center was assigned to the equipment entity that does not exist in the target system.
  Resolution: The equipment entity cannot be imported; the import is aborted.
- The report design assigned as label layout to the equipment entity does not exist in the target system.
  Resolution: The equipment entity is imported without label layout assignment. The import results contain an appropriate warning.

In case equipment graph objects are in the scope of the import, the **Conflict handling during import (SR1099.4.6.3)** for equipment graphs (page 102) applies in addition, which also may result in the import of the entity being aborted.

In case property type objects are in the scope of the import, the **Conflict handling during import (SR1099.1.5.3)** for property types (page 106) applies in addition.

Import from external source (SR1099.3.7.4)

The system supports the import of equipment entities from an external system. The following rules apply:

- Checksum-related checks still apply.
- UI-related meta data is not supported.
  All attributes of the imported entity that cannot be mapped directly to the basic attributes of the class are mapped to properties of the default tab, which is the **Specification (SR1099.3.1.3)** tab (page 78).

The system also provides an API that allows to import equipment objects from an external source with checksum-related checks being ignored. For details related to the API, see chapter "Importing Equipment Classes and (Template) Entities from an External Source" in "Technical Manual Administration" [A8] (page 143).

Equipment Label Printing (SR1099.3.6+)

Data Manager - Equipment allows to define an equipment entity-specific barcode.

LABEL LAYOUT (SR1099.3.6.1)

The equipment entity label includes the following data:

- Header with logo
- Barcode (Default: 2D barcode)
- Equipment entity identifier: <identifier>
- Footer
  - Printed by: <user name and login>

PRINT LABEL (SR1099.3.6.2)

The system allows to print equipment entity-specific labels. In case the label layout is not defined with the **Label layout** entity attribute (page 77), the default layout is used as defined in the system configuration.

Equipment Entity Logbook Report (SR1099.3.10+)

The equipment entity logbook report represents the equipment entity logbook in a printable way.

PRINT EQUIPMENT ENTITY LOGBOOK REPORT (SR1099.3.10.1)

The system allows the user to print an equipment entity logbook report.

EQUIPMENT ENTITY LOGBOOK REPORT HEADER (SR1099.3.10.2)

The header of the equipment entity logbook report includes the following data:

- Placeholder for a customer logo
- Equipment entity identifier
- Equipment entity short description
- Equipment entity description

EQUIPMENT ENTITY LOGBOOK REPORT FOOTER (SR1099.3.10.3)

The footer of the equipment entity logbook report includes the following data:

- Rockwell Automation logo
- Printed by: <user name and login>

- Printed from: <station/work center>
- Database: <database name>
- Printed on: <local time and server time>
- Page x of y

EQUIPMENT ENTITY LOGBOOK REPORT SECTIONS (SR1099.3.10.5+)

The equipment entity logbook report includes the following sections:

Equipment entity logbook report - Equipment entity logbook (SR1099.3.10.5.2)

The equipment entity logbook section displays the change events that have occurred during the selected date range and the date range itself.

Section for the logbook entries, which includes:

- Timestamp
- Category / Action
- Old content / New content
- Property type / Graph
- Information
- Involved material
- Order / Workflow
- Product batch / Product material
- Logged-in user / Signature
- Procedure / Unit procedure / Operation / Phase / Work center / Station / Device

Equipment Graphs (SR1099.4+)

An **equipment graph** specifies the statuses an equipment entity can assume while it is used in execution, the triggers that affect the entity's status, as well as the transitions between the statuses, their conditions, and actions.

A typical example of an equipment graph is a cleaning graph with statuses such as **Clean** and **Unclean** statuses and a trigger such as **Cleaning expired**.
For more examples, please refer to section "Equipment Management" (page 3) in chapter "Master Data Management" (page 3).

Attributes and Properties (SR1099.4.1+)

Attributes and properties of an equipment graph are grouped by the following tabs:

Basic Attributes Tab (SR1099.4.1.1)

Available **Basic** attributes are:

- Identifier (mandatory, unique, insert only)
- Display text
- Short description
- Description
- Status
- Purpose (mandatory)

  Purposes that are used by the built-in logic of the system:

  - Container Cleaning (RS)
  - Room Cleaning (RS)
  - Scale Calibration (RS)
  - Scale Test (RS)

  Further alternative purposes that can be assigned to a graph:

  - Calibration
  - Cleaning
  - Installation
  - Maintenance
  - Sterilization
  - Testing
  - Usage

Property Type Tab (SR1099.4.1.2)

This tab holds the property type properties according to the assignment of allowed property types by the data administrator.

Allowed property types are:

- **Specification** usage type
  - **BigDecimal**, **Boolean**, **Duration**, **String** technical property type
- **Runtime** usage type
  - **BigDecimal**, **Boolean**, **Duration**, **Flexible attribute definition**, **Measured value**, **String** technical property type

Status/Trigger Tab (SR1099.4.1.3)

This tab holds the lists of graph statuses and triggers which are defined for the specific equipment graph.

Available **Status** attributes are:

- Key (unique)
- Display text
- Description
- Initial status (mandatory) (Yes, No)
  The system allows exactly one status as initial status.
- Can expire (Yes, No)
  The system automatically creates the **Expired (RS)** expiry trigger when the first status is set to **Can expire**; the system automatically removes the **Expired (RS)** expiry trigger when the trigger is not used by a transition and there is no status with **Can expire**.

Available **Trigger** attributes are:

- Key (unique)
- Display text
- Description

System-created Trigger (SR1099.4.1.3.1)

The system creates the following triggers automatically:

- Expired (RS)
  The first status of a graph is set to **Can expire**.

Transition Tab (SR1099.4.1.4)

This tab holds the list of transitions, their conditions, and actions which are defined for the specific equipment graph.

Available attributes are:

- Trigger (triggers defined in the **Status/Trigger (SR1099.4.1.3)** tab (page 97))
- From status (statuses defined in the **Status/Trigger (SR1099.4.1.3)** tab (page 97))
- To status (statuses defined in the **Status/Trigger (SR1099.4.1.3)** tab (page 97))
- Condition (editable with the **Expression editor (SR3071.8.1.4)** UI element (page 23))
- Number of actions (read-only)
- Action attributes:

- Description
- Action (mandatory, editable with the **Expression editor (SR3071.8.1.4)** UI element (page 23))
- [Action] ID (read-only)

- [Transition] ID (read-only)

TIP

In case several actions are defined for a transition, the actions are executed according to their sequence in this tab. All actions of a transition are executed.
In case several transitions are defined for a trigger, all conditions and source statuses are evaluated during execution. If there is no unique match and no transition can be executed, the respective phase will record the **Status transition failed** user-triggered exception.

STYLE TAB (SR1099.4.1.5)

Available attributes are:

- Background color
- Font color

CHANGE HISTORY TAB (SR1099.4.1.6)

This tab holds the change history entries of the specific equipment graph.
The entries can be filtered by time.

Available information is:

- Timestamp
- Action
  - Graph created/deleted/imported/migrated
  - Status added/updated/removed
  - Trigger added/updated/removed
  - Transition added/updated/removed
  - Transition action added/updated/removed
  - Property type assigned/removed
  - Attribute updated
  - Status updated
- Affected object
- Old content

- New content
- Logged-in user

STATUS HISTORY TAB (SR1099.4.1.7)

This tab holds the status history entries of the specific equipment graph.
The entries can be filtered by time.

Available information is:

- Timestamp
- Action
- To status
- Signature
- Comment

Status Management of Equipment Graphs (SR1099.4.5+)

DEFAULT STATUSES FOR EQUIPMENT GRAPHS (SR1099.4.5.1)

The system supports the following default statuses for equipment graphs:

- **Initial**: Item is new and has not been saved yet.
- **Draft**: Item is saved and can be modified.
- **Verification**: Item is ready for review. If updates are required, a status change back to **Draft** has to be performed.
- **Approved**: Item is ready for use. All of its attributes that are under status control cannot be changed.
- **Archived**: Item shall no longer be used.

DEFAULT TRANSITIONS FOR EQUIPMENT GRAPHS (SR1099.4.5.2)

The system supports the following default transitions for equipment graphs:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Draft	---	Automatic transition.
1.2 - Verification » Draft	Status_Trans_ChangeControl_SG_Verification-Draft	Only if all equipment entities to which the graph is assigned are also in the **Draft** status.
2.1 - Draft » Verification	Status_Trans_ChangeControl_SG_Draft-Verification	---

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
3.1 - Verification » Approved	Status_Trans_ChangeControl_SG_Verification-Approved	---
4.1 - Approved » Archived	Status_Trans_ChangeControl_SG_Approved-Archived	---

The diagram illustrates the **S88StatusGraphChangeControl** flexible state model.

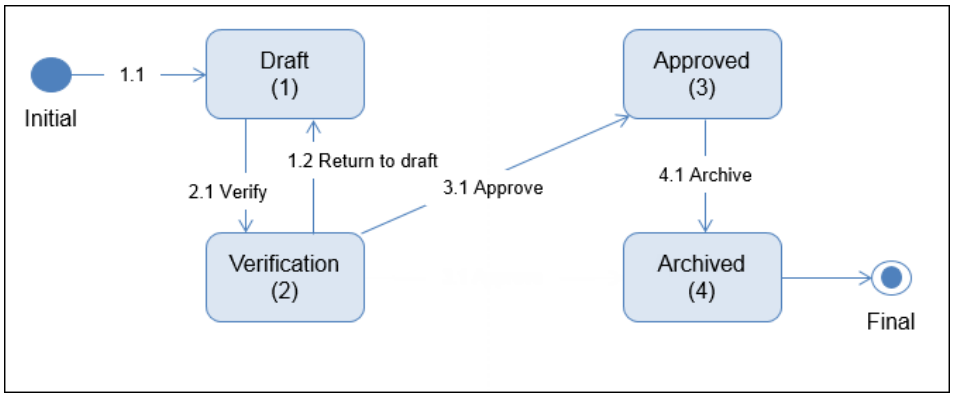

Figure 6: Equipment graph - status graph

Definition of Views (SR1099.4.2+)

Equipment graphs are presented in their cards view and tiles views.

Cards View (SR1099.4.2.1)

The card displays the following equipment graph-related information:

- Identifier
- Short description
- Display text
- Purpose
- Up to four properties of the allowed types (see **Property type (SR1099.4.1.2)** tab (page 96))

Tiles View (SR1099.4.2.2)

The tiles display the following equipment graph-related information:

- Identifier
- Short description

Equipment Graph-specific Operations (SR1099.4.3+)

In addition to the general **Object Operations** (SR3071.8.4+) (page 46) of Data Manager, the following operations apply to equipment graphs:

Assign equipment graph to equipment entity or equipment class (SR1099.4.3.1)

Equipment graphs with unsaved changes cannot be assigned to an **equipment entity (SR1099.3+)** object (page 76) or **equipment class (SR1099.2+)** object (page 52).

Error Handling (SR1099.4.4+)

As part of the error handling, the system displays messages related to the management of equipment graphs.

Expression and Transition Definition (SR1099.4.4.1)

Situation: When the data administrator updates an equipment graph and performs a status transition to a read-only status (e.g. **Verification**), the system checks the transitions of the graph.

Considered issue: An expression is invalid or a transition is incomplete.

Message categories:

- Warning, when the graph is saved.
- Error, when the status of the graph is transitioned to a read-only status (e.g. **Verification**).

Graph Target Status and Entity Status Consistency (SR1099.4.4.2)

Situation: When the data administrator performs a status transition to an editable status (e.g. **Draft**), the system checks for status consistency of the already assigned equipment entities.

Considered issue: The status of an entity is higher (e.g. **Verification**) than the target status of the graph.

Message category: Error

Graph Purpose and Entity or Class Consistency (SR1099.4.4.3)

Situation: When the data administrator saves an equipment graph, the system checks for purpose consistency of the already assigned equipment entities and classes.

Considered issue: The graph is assigned to at least one entity or class that already has a graph of the same purpose assigned.

Message category: Error

Equipment Graph-specific Export/Import (SR1099.4.6+)

In addition to the general **Export/Import Operations** (SR3071.8.4.2+) (page 47) of Data Manager, the following characteristics apply to the export/import of equipment graphs:

Scope of export (SR1099.4.6.1)

The following objects and attributes are included in the export of an equipment graph:

- Basic attributes with values except for the **Status**
- All dependent (sub-)objects of a graph (statuses, triggers, transitions, and transition-related actions)
- Used property type objects
- Style-related meta data (UI-related)

The following attributes are excluded from the export of an equipment graph:

- Status
- Status history
- Change history

Conflict handling during import (SR1099.4.6.3)

The following situations are subject to conflict handling during the import of an equipment graph:

- A single equipment graph is imported. The equipment graph exists in the target system and is read-only due to its status (page 99).
  Resolution: The equipment graph cannot be imported; the import is aborted.
- An equipment graph is imported along with the import of a class or entity. The equipment graph exists in the target system and is read-only due to its status (page 99).
  Resolution: If the imported equipment graph is not equal to the existing equipment graph, the entire import of the class (and its entities and graphs) or the entity (and its graphs) is aborted.
  If the imported equipment graph is equal to the existing equipment graph, the import of this specific equipment graph is skipped during the class or entity import.
- An equipment graph is imported along with the import of an entity. The entity exists in the target system and the entity's graph status is different.
  Resolution: The graph status and the expiry date of the target entity are not updated. If an entity does not exist and is created, the status is set to the **Initial status** of the graph.

In case property type objects are in the scope of the import, the **Conflict handling during import (SR1099.1.5.3)** for property types (page 106) applies in addition.

Import from external source (SR1099.4.6.4)

The system supports the import of equipment graphs from an external system. The following rules apply:

- Checksum-related checks still apply.

Property Types (SR1099.1+)

A **property type** specifies equipment properties and equipment property requirements. Any type is based on a specific **technical property type** (e.g. BigDecimal, String, FSM). It defines the specific properties of **equipment entity (SR1099.3+)** objects (page 76) and the specific property requirements for **equipment class (SR1099.2+)** objects (page 52) and **equipment graph (SR1099.4+)** objects (page 95).

During the design of a master recipe or master workflow, property types can also be used to refine an equipment requirement.

Attributes (SR1099.1.1)

➢ For recent changes, see revision history (page 145).

Attributes of a property type are grouped in the Basic tab.

- Identifier (mandatory, unique, insert only)
- Short description (insert only)
- Description (insert only)
- Usage (mandatory, insert only)
  - Specification (only for the **BigDecimal**, **Boolean**, **Duration**, **Equipment type**, **Ranges**, **Room cleaning rules**, **Scale configuration**, **Scale test and calibration**, **String**, **Work center assignment** technical property types)
  - Automation (only for the **BigDecimal**, **Boolean**, **Flexible tag definition**, **String** technical property types)
  - Runtime (only for the **BigDecimal**, **Boolean**, **Duration**, **Flexible attribute definition**, **Flexible state model**, **Measured value**, **String** technical property types)
  - Historian (only for the **BigDecimal** and **String** technical property types)
- Technical type (mandatory, insert only)
- Live Data type (only for **Automation** usage type) (insert only)

- Attribute data types (only for **Flexible attribute definition** technical property type of **Runtime** usage type) (insert only)
- Purpose (insert only)
  - Base Sublot (RS)
  - Current Load (RS)
  - Current Tare (RS)
  - Current Sublot (RS)
  - Reference Tare (RS)
  - Scale Ranges (RS)
- Content (insert only)

Definition of Views (SR1099.1.2+)

Property types are presented in their cards view and tiles views.

CARDS VIEW (SR1099.1.2.1)

The card displays the following property type-related information:

- Identifier
- Short description
- Technical type
- Usage
- Live Data type (only for **Automation** usage type)
- Attribute data types (only for **Flexible attribute definition** technical property type of **Runtime** usage type)
- Attribute identifiers (only for **Flexible attribute definition** technical property type of **Runtime** usage type)
- Equipment type (only for **Equipment type** technical property type of **Specification** usage type)
- Purpose
- UoM (if applicable)
- Reference (to FSM) (if applicable)

TILES VIEW (SR1099.1.2.2)

The tiles display the following property type-related information:

- Identifier

- Short description

Property Type-specific Operations (SR1099.1.3+)

In addition to the general **Object Operations** (SR3071.8.4+) (page 46) of Data Manager, the following operations apply to property types:

Insert only (SR1099.1.3.1)

Property types can be added to the system, but not edited. They can be deleted as long as they have not been assigned to other objects.

Error Handling (SR1099.1.4+)

As part of the error handling, the system displays messages related to the management of property types.

Property Types with Defined Purpose (SR1099.1.4.1)

➢ For recent changes, see revision history (page 145).

Situation: When the data administrator selects a purpose for a property type and saves the property type, the system checks for the consistency of purpose, usage type, and data type.

- Data type is mandatory.
- The following combinations are supported:

Purpose	Usage type	Data type
Base Sublot (RS)	Runtime	String
Current Load (RS)	Runtime	String
Current Sublot (RS)	Runtime	String
Current Tare (RS)	Runtime	Measured value
Reference Tare (RS)	Runtime	Measured value
Scale Ranges (RS)	Specification	Ranges

Message category: Error

Property Type-specific Export/Import (SR1099.1.5+)

In addition to the general **Export/Import Operations** (SR3071.8.4.2+) (page 47) of Data Manager, the following characteristics apply to the export/import of property types:

Scope of export (SR1099.1.5.1)

The following attributes are included in the export of a property type:

- Basic attributes with values
- Data type-specific content that is editable on property type level

TIP

The export/import of property types requires that the underlying technical property types (data type) exist in both the source and target systems. They are made available along with the deployment, but not with export/import.

Scope of import (SR1099.1.5.2)

The import action results in property types that are not editable in the target system, see also **Attributes (SR1099.1.1)** data (page 103).

Conflict handling during import (SR1099.1.5.3)

The following situations are subject to conflict handling during the import of a property type:

- Property type to be imported already exists (property types cannot be updated).
  Resolution: Import of the property type is skipped.
- Property type to be imported does not match (e.g. attribute value or defined content does not match).
  Resolution: Import is aborted.
- Dependent object is missing (e.g. FSM, UoM)
  Resolution: Import is aborted.

Equipment Class Usage List (SR1099.6+)

➢ For recent changes, see revision history (page 145).

The usage list of an equipment class provides an overview of the objects that reference an equipment class. A typical use case of a usage list is a risk assessment in case an approved equipment class needs to be changed and the **Equipment Mass Change Process (SR1099.7+)** function (page 108) shall run afterwards.

The following object types are supported by the usage list: custom building blocks, master recipes, and master workflows in a status other than **Archived**.

Content (SR1099.6.1)

➢ For recent changes, see revision history (page 145).

The usage list allows to track:

- Usage of an equipment class as equipment requirement
  Equipment classes that are assigned to a phase building block as equipment requirement (class) parameter.
- Usage of an equipment class within an expression that contains the **Equipment is member of class** function
  The function can be used to define equipment requirement rules, transition conditions, or process parameter attributes. The equipment class identifier is the second argument of the function given as string. A class can only be detected for the usage list if the parameter contains the equipment class identifier as one string constant and not as a concatenation of strings or variables.
  The usage can only be tracked in expressions without syntax error.

Objects Information (SR1099.6.2)

➢ For recent changes, see revision history (page 145).

Each object that is listed in the usage list provides the following information:

- Object type (master recipe, master workflow, or custom building block)
- Identifier, version, and status of the object
- Path information of the master recipe, master workflow, or custom building block elements
- Identifier of the low-level object that references the equipment class and its type (parameter or transition)
  - Equipment requirement (class) parameter
  - Equipment requirement (rule) parameter / rule identifier (class used in expression)
  - Process parameter identifier / attribute (class used in expression)
  - Structure level (procedure, unit procedure, operation) / transition identifier

Additionally, the usage list provides a list of changed objects whose objects information cannot be refreshed.

Filter (SR1099.6.3)

➢ For recent changes, see revision history (page 145).

The usage list supports the following filter options:

- Include non-approved artifacts

Copy to Clipboard (SR1099.6.4)

➢ For recent changes, see revision history (page 145).

The usage list can be copied to the clipboard to save its content in a text file.

Equipment Mass Change Process (SR1099.7+)

➢ For recent changes, see revision history (page 145).

The complete equipment mass change process consists of several manual and automated steps:

- Identify the shared equipment class of the entities to be changed.
- Define the required changes.
- Determine and check a possible impact on existing master recipes and workflows with the **Equipment Class Usage List (SR1099.6+)** function (page 106).
- If the shared equipment class is in a read-only status, change its status to **Draft**.
- Adapt the equipment class as required.
- Start the update of the entities with the **Update assigned (template) entities (SR1099.2.3.6)** class-specific operation (page 57). This includes the following automated sub-steps:
  - Collect differences between the equipment class and its (template) entities
  - Perform consistency checks
  - Compile an update list
  - Perform the mass change (when triggered by the user)
  - Display the update result list
- Repeat the update of the entities with the **Update assigned (template) entities (SR1099.2.3.6)** class-specific operation (page 57) until all (template) entities have been updated according to the changes applied to the class.
- Approve the adapted equipment class.

Differences between an Equipment Class and its Entities (SR1099.7.1)

➢ For recent changes, see revision history (page 145).

Not all changes that were applied to an equipment class can be propagated with the mass change process to its (template) entities. Excluded are for example:

- The deletion of a property on class level.
- A change of the class status.

The following differences between an equipment class and its (template) entities are propagated:

Equipment property added (SR1099.7.1.1)

➢ For recent changes, see revision history (page 145).

An equipment property that has been added to the equipment class is added to its (template) entities during mass change execution. The values of the equipment property are set as if the (template) entity was created from a class.

The system updates the change history of the (template) equipment entity accordingly. It is visible that the update was done by the mass change process and from which equipment class it was triggered.

Equipment transition graph added (SR1099.7.1.2)

➢ For recent changes, see revision history (page 145).

An equipment transition graph has been added to the equipment class. For each (template) entity of the equipment class, the following applies: If the purpose of this equipment transition graph is not assigned to any equipment transition graph of the (template) entity, the equipment transition graph is added to the (template) entity during mass change execution. The following graph-related data is set accordingly:

- The status of the (template) entity is set to the initial status of the graph.
- An expiry date is neither calculated nor set.

The system updates the change history of the (template) equipment entity accordingly. It is visible that the update was done by the mass change process and from which equipment class it was triggered.

In relation to the updated status, the system updates the logbook of the affected (template) equipment entities accordingly (if maintained). It is visible that the update was done by the mass change process and from which equipment class it was triggered.

Equipment transition graph replaced (SR1099.7.1.3)

➢ For recent changes, see revision history (page 145).

An equipment transition graph of the equipment class has been replaced by another equipment transition graph. For each (template) entity of the equipment class, the following applies: If the purpose of the (new) equipment transition graph is assigned to an equipment transition graph of the (template) entity, the equipment transition graph of the (template) entity is replaced by the equipment transition graph of the class during mass change execution. The following graph-related data is set accordingly:

- The current status of the (template) entity according to the replaced transition graph must be available at the new transition graph and remains unchanged. If this is not the case, the transition graph is not replaced.
- The current expiry date of the entity according to the replaced transition graph remains unchanged if the status of the new transition graph can expire as well. If the current status of the entity according to the replaced transition graph cannot expire, the expiry date according to the new graph is neither calculated and nor set.

The system updates the change history of the (template) equipment entity accordingly. It is visible that the update was done by the mass change process and from which equipment class it was triggered.

In relation to the possibly updated status and expiry date, the system updates the logbook of the affected (template) equipment entities accordingly (if maintained). It is visible that the update was done by the mass change process and from which equipment class it was triggered.

Equipment property value changed (SR1099.7.1.4)

➢ For recent changes, see revision history (page 145).

An equipment property value of the equipment class has been updated to a value that differs from the property value of the assigned (template) entities. The value of an entity's property is updated to the value of the class' property if the following preconditions are fulfilled:

- The property is of the **Specification** usage type and one of the following technical property types: **BigDecimal**, **Boolean**, **Duration**, or **String**.
- The value of the equipment class' property is neither undefined nor empty.
- The value of a **BigDecimal** technical property type does not define a range.

The system updates the logbook of the affected (template) equipment entities accordingly (if maintained). It is visible that the update was done by the mass change process and from which equipment class it was triggered.

Equipment Class-specific Consistency Checks (SR1099.7.2)

➢ For recent changes, see revision history (page 145).

Before the update list with the potential changes on the affected entities is compiled, the equipment class from which the update operation is triggered has to pass the following consistency checks:

- **Equipment type consistency (SR1099.2.4.4)** check (page 59)
- **Property of graph consistency (SR1099.2.4.5)** check (page 60)
- **Status and trigger consistency (SR1099.2.4.6)** check (page 60)

- **Class and graph purpose consistency (SR1099.2.4.7)** check (page 61)

Compiled Update List for Mass Change (SR1099.7.3)

➢ For recent changes, see revision history (page 145).

After all **equipment class-specific consistency checks (SR1099.7.2)** checks (page 110) have passed successfully, the system compiles the update list with all changes to be applied to the (template) equipment entities that are assigned to the class and are not in the **Archived** status.

The update list provides the expected changes for each (template) equipment entity grouped by update category. An entity is displayed in one of the categories with its identifier, short description, status, and template attributes.

- Will be updated (number of entities)
  Per entity, the list provides the following information for each expected change:
  - Action (Property added, Property updated, Graph added, Graph replaced)
  - Object (if applicable), e.g. property or graph identifier
  - New (if applicable), e.g. graph identifier
  - Old (if applicable) , e.g. graph identifier
- Will be skipped - no change required (number of entities)
  All equipment properties and equipment transition graphs of the class are already available at the entity.
- Will be skipped - bound (number of entities)
  The entity is bound on the shop floor and will not be updated by the mass change process.
  The system provides the corresponding work center, order/workflow, procedure, unit procedure, operation, and phase for a selected entity in the details.
- Will be skipped - locked (number of entities)
  The entity is locked by another user or changed and not yet saved by the same user in Data Manager and cannot be updated by the mass change process.
  The system provides the user and client name who locked the entity for a selected entity in the details.

The compiled update list provides the following actions:

- Copy the compiled update list to the clipboard to save its content in a text file.
- Apply the changes to the entities with the **Execute Mass Change (SR1099.7.4)** operation (page 112).
- Close the compiled update list without any further action.

Execute Mass Change (SR1099.7.4)

➢ For recent changes, see revision history (page 145).

The operation must be confirmed by a signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A5] (page 143)). The system adds the action and the signature data to the change history of the equipment class.

The system propagates the changes to all (template) equipment entities that are assigned to the class and are not in the **Archived** status as defined with the **Differences between an Equipment Class and its Entities (SR1099.7.1)** function (page 108).

All (template) equipment entities that need to be updated, independent from their status, are checked according to the entity-specific **Error Handling (SR1099.3.4+)** feature (page 88). For the mass change, all issues are reported as errors.

All changes and the error information are provided in the **Update Result List (SR1099.7.5)** view (page 112).

Update Result List (SR1099.7.5)

➢ For recent changes, see revision history (page 145).

The update result list provides the executed changes grouped by result category. An entity is displayed in one of the categories with its identifier, short description, status, and template attributes.

- Updated successfully (number of entities)
  Per entity, the list provides the following information for each executed change:
  - Action (Property added, Property updated, Graph added, Graph replaced)
  - Object (if applicable), e.g. property or graph identifier
  - New (if applicable), e.g. graph identifier
  - Old (if applicable) , e.g. graph identifier
- Skipped - no change required (number of entities)
  At the time of the update, all equipment properties and equipment transition graphs of the class were already available at the entity.
- Skipped - bound (number of entities)
  At the time of the update, the entity was bound on the shop floor and was not updated by the mass change process.
  The system provides the corresponding work center, order/workflow, procedure, unit procedure, operation, and phase for a selected entity in the details.
- Skipped - locked (number of entities)
  At the time of the update, the entity was locked by another user or changed and not yet saved by the same user in Data Manager and could not be updated by the mass change process.

The system provides the user and client name who locked the entity for a selected entity in the details.

- Processed with errors (number of entities)
  - Action (Property added, Property updated, Graph added, Graph replaced)
  - Object (if applicable), e.g. property or graph identifier
  - New (if applicable), e.g. graph identifier
  - Old (if applicable) , e.g. graph identifier

  The system provides the failure reason for a selected entity in the error details. All entities of this category remain unchanged.

The update result list provides the following actions:

- Copy the update result list to the clipboard to save its content in a text file.
- Close the update result list without any further action.

Chapter 5

Work Center and Station Management (SR1100+)

In PharmaSuite, work center and station management is done by means of **Data Manager (SR3071.8+)** workbench (page 21).

Work center and station management with Data Manager supports the following use cases:

- **Work center (SR1100.1+)** management (page 115)
- **Station (SR1100.3+)** management (page 117)

Work Centers (SR1100.1+)

A work center can be characterized as a suitably equipped location or area within the operational system where personnel utilizes machines, tools, and devices. A work center can comprise one or more stations.

During the design of a master recipe or master workflow, work centers can be assigned to unit procedures.

Attributes and Properties (SR1100.1.1+)

Attributes and properties of a work center are grouped by the following tabs:

Basic Attributes Tab (SR1100.1.1.1)

Available **Basic** attributes are:

- Identifier (mandatory, unique, insert only)
- Description
- Type (Dispense) (mandatory)
- Storage area

Stations Tab (SR1100.1.1.2)

This tab holds the stations according to the assignment by the data administrator.

Change History Tab (SR1100.1.1.3)

This tab holds the change history entries of the specific work center.
The entries can be filtered by time.

Available information is:

- Timestamp
- Action
  - Work center created/deleted
  - Station assigned/removed
  - Attribute updated
  - Storage area changed
- Affected object
- Old content
- New content
- Logged-in user

Definition of Views (SR1100.1.2+)

Work centers are presented in their cards view and tiles views.

Cards View (SR1100.1.2.1)

The card displays the following work center-related information:

- Icon
- Identifier
- Description
- Type (Dispense)
- Assigned storage area

Tiles View (SR1100.1.2.2)

The tiles display the following property type-related information:

- Icon
- Identifier
- Description

Error Handling (SR1100.1.3+)

As part of the error handling, the system displays messages related to the management of work centers.

STATION ASSIGNMENTS (SR1100.1.3.1)

Situation: When the data administrator assigns an additional station to a work center of the **Dispense** type, the system checks if only one station is assigned when saving the work center.
Message category: Error
Issue: The execution of Dispense orders requires a fixed relation of a single station to one Dispense work center. Assigning multiple stations to a work center of the **Dispense** type is an invalid configuration.

Stations (SR1100.3+)

A station represents an operator's access point to execution activities with PharmaSuite at a work center. To actually perform execution activities, an operator uses a stationary or mobile device registered at the station. It is possible to register more than one device at a station.

During the design of a master recipe or master workflow, stations can be assigned to operations.

Attributes and Properties (SR1100.3.1+)

Attributes and properties of a work center station are grouped by the following tabs:

BASIC ATTRIBUTES TAB (SR1100.3.1.1)

Available **Basic** attributes are:

- Identifier (mandatory, unique, insert only)
- Description
- Barcode (pre-filled with the configured station barcode prefix and identifier; if filled, unique)
- Access privilege
- Work center (read-only)

CHANGE HISTORY TAB (SR1100.3.1.2)

This tab holds the change history entries of the specific station.
The entries can be filtered by time.

Available information is:

- Timestamp

- Action
  - Station created/deleted
  - Attribute updated
- Affected object
- Old content
- New content
- Logged-in user

Station Label Printing (SR1100.3.2+)

Data Manager - Work Center allows to define a station-specific barcode.

Label Layout (SR1100.3.2.1)

The station label includes the following data:

- Header with logo
- Barcode (Default: 2D barcode)
- Station identifier: <identifier>
- Footer
  - Printed by: <user name and login>

Print Label (SR1100.3.2.2)

The system allows to print station-specific labels.

Definition of Views (SR1100.3.3+)

Stations are presented in their cards view and tiles views.

Cards View (SR1100.3.3.1)

The card displays the following station-related information:

- Icon
- Identifier
- Description
- Assigned access privilege
- Assigned work center

TILES VIEW (SR1100.3.3.2)

The tiles display the following station-related information:

- Icon
- Identifier
- Description

Chapter 6

Resource Master Data (SR3146.1)

The system supports the definition and management of resource master data.

In addition to the data available in Data Manager, the management of recipes and workflows requires more resource master data objects. They are available in PharmaSuite for Production Management.

Materials (SR3146.1.1)

The system allows the recipe author to manage materials including basic operations like create, update, delete, and copy.

Materials are defined as all substances that are directly or indirectly related to or utilized in the manufacturing process, that are relevant to the pharmaceutical production process, and must thus be taken into consideration for all planning purposes.

Types (SR3146.1.1.1)

The system supports different material types and related property sets.

Examples of material types:

- A raw material is defined as each substance used during the manufacturing of a drug that is not a packaging material.
- An auxiliary substance is a component of a drug. Auxiliary substances do not have a therapeutical effect but are used as flavor or to improve a product's stability.
- A bulk material is defined as the finished but not yet packaged pharmaceutical product, such as loose, uncounted tablets, that is used in producing finished goods, e.g. blistered and packaged tablets. In this sense, a bulk material is a specific case of a semi-finished good.
- Semi-finished goods are materials that are yet unfit for sale or shipment. They can either be produced internally or purchased externally and are usually utilized in further production phases for manufacturing other products - typically finished goods.

- Finished goods (also known as finished products) are all products that are ready for shipping. A variety of different starting materials and/or semi-finished goods is typically involved in the production of finished goods.
- Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product (e.g. blisters vs. folding cartons).
- Secondary packaging materials are all materials used for outer packaging, such as folding cartons, brochures, package leaflets, films, etc.
- Auxiliary packaging materials are materials that are required for additional packaging of trade packs, such as wrapping film, adhesive tape etc.
- Intermediate goods are partially processed materials that must go through additional production stages before they become semi-finished goods, such as tablet bodies prior to coating.

Attributes (SR3146.1.1.8)

➢ For recent changes, see revision history (page 145).

The system supports the following basic attributes for materials:

- [Material] Identifier (unique)
- [Material] Description
- Material type (see **Types (SR3146.1.1.1)** requirement (page 121))
- [Material] Short description
- Comment
- Access privilege (recipe) (copied into newly created master recipes when the material is used as material (product))
- Unit of measure (see **Units of Measure and Conversions (SR3146.2.1)** requirement (page 125))
- Template Equipment Entity (see **Template Equipment Entities (SR1099.5+)** requirement (page 63))
  - Only those template equipment entities are available for assignment that have a property with **Hybrid (RS)** as its equipment type and that are not **Archived**.
- GHS
  - Signal word (Danger, Warning, None)
  - Up to nine hazard pictograms

- ECB hazard classes
  In the default configuration, the usage of ECB hazard classes is deactivated. GHS signal words and hazard pictograms are used.
  - NFPA fire
  - NFPA health
  - NFPA reactivity
  - NFPA special
  - Hazard class 1...4
  - Hazard symbol 1...4
- Default weighing method (see **Pre-defined Weighing Method (SR3146.1.1.3)** requirement (page 123))
- Allowed weighing methods
- Lower and upper tolerances (absolute or relative, non-symmetrical, with UoM) (see **Weighing Tolerances (SR3146.1.1.4)** requirement (page 124))
- Hazard Statements, Precautionary Statements (see **Hazard Statements and Precautionary Statements (SR3146.2.4)** requirement (page 128))
- Risk and Safety Phrases (see **Risk and Safety Phrases (SR3146.2.2)** requirement (page 129))
  In the default configuration, the usage of risk and safety phrases is deactivated. GHS hazard and precautionary statements are used.
- UoM conversion-related attributes (see **Units of Measure and Conversions (SR3146.2.1)** requirement (page 125))
- Packaging Levels
  - L0 Meaning
  - L1 Contained number
    L1 Meaning
  - …
  - L5 Contained number
    L5 Meaning

Pre-defined Weighing Method (SR3146.1.1.3)

The system allows the recipe author to define a default weighing method on material level.

On S88 material parameter level, a default weighing method and allowed weighing methods can be defined as **material input parameter (SR3146.9.5.1.1)** for the execution (see "Functional Requirement Specification Recipe and Workflow Management" [A1] (page 143)).

Weighing Tolerances (SR3146.1.1.4)

The system allows the recipe author to define weighing tolerances on material item level. This includes lower and upper tolerances (absolute or relative, non-symmetrical).

Audit Trail (SR3146.1.1.5)

The system supports audit trail for materials.

Materials Are Not Version-controlled (SR3146.1.1.6)

In the standard configuration, materials are not version-controlled.

ERP Properties (SR3146.1.1.8.1)

The system supports pre-defined ERP attributes for materials.

- ERP01...ERP10 (ERP gateway-related placeholder)

The attributes are read only.

Chapter 7

Complementary Master Data (SR3146.2)

The system supports the definition and management of complementary master data.

In addition to the data available in Data Manager, the management of recipes and workflows requires complementary master data objects.

Units of Measure and Conversions (SR3146.2.1)

The system allows the system administrator to manage units of measure and conversion factors.

They are maintained in Process Designer.

Units of Measure (UoM) (SR3146.2.1.4)

The system supports the following standard units of measure:

- SI weight:
  - kg (kilogram)
  - g (gram)
  - mg (milligram)
- SI length:
  - m (meter)
- SI volume:
  - l (liter)
  - ml (milliliter)
  - cm3 (cubic centimeter)
  - m3 (cubic meter)
- Imperial weight:
  - lb (pound)
  - oz (Avoirdupois ounce)

- International length:
  - in (inch)
  - ft (foot)
- US volume:
  - gallon (US liquid gallon)
  - quart (US liquid quart)
  - fl oz (US fluid ounce)
- Other scalar:
  - % (percent)
  - IU (international unit)
  - ea (each)

ATTRIBUTES (SR3146.2.1.4.1)

For an administrator, the system supports the following attributes for units of measure:

- Full name
- Symbol (as usually represented in the UI)
- Type (for grouping by compatible dimensions)
- UoM System (parameter for different measurement systems)

MANAGE UNITS OF MEASURE BY SYSTEM INTEGRATOR (SR3146.2.1.4.2)

The system allows a system integrator to add, update, and delete units of measure according to customer specification, e.g. through data pre-loading.

DEFAULT UNIT OF MEASURE FOR MATERIAL (SR3146.2.1.4.4)

The system allows a recipe author to assign a single unit of measure to a material (without quantity), so that it can be used as a default.

Conversion Factors (SR3146.2.1.1)

The system converts units of measure automatically.
The following assumption applies: a data object contains the value including the scale of the value and the UoM.

Example: 1.1 kg + 1200 g =2300 g

Attributes (SR3146.2.1.1.2)

For an administrator, the system supports the following attributes for conversion factors:

- Source unit
- Conversion factor
- Target unit

Linear Conversion (SR3146.2.1.1.1)

The system supports linear conversions according to the general formula:
value [source unit] * conversion factor = value [target unit]

Examples:

Source	Target
1,000 g	1 kg
1 carat	200 mg
1 gal(US)	3.78541 l
Metric system	**Avoirdupois system**
1 gr (grain)	1/7000 lb
1dr (dram)	1/16 oz
1 oz (ounce)	1/16 lb
1 lb (pound)	0.453592 kg

Scale-related Conversion Factors (SR3146.2.1.1.1.1)

For Dispense, the system converts the material's unit of measure into the scale's unit of measure.

Consumption-related Conversion Factors (SR3146.2.1.1.1.2)

The system allows an operator to define a target unit of measure during material consumption.

Multi-step Conversion (SR3146.2.1.1.3.1)

The system supports multi-step conversions between units of measures in order to minimize the number of conversion factors to be maintained.

Manage Conversion Factors by System Integrator (SR3146.2.1.1.4)

The system allows a system integrator to add, update, and delete conversion factors according to customer specification, e.g. through data pre-loading.

Material-related Conversion Factors (SR3146.2.1.2+)

The system supports a material-specific conversion factor such as specific weight (density).

Sublot-specific conversion factors are not supported.

MANAGE MATERIAL-RELATED CONVERSION FACTORS (SR3146.2.1.2.1)

The system allows an operator to maintain material-specific conversion factors including basic operations like create, update, and delete.

Calculation of Quantities - Involve Units of Measure (SR3146.2.1.3)

When the system calculates quantities it always takes into account the corresponding units of measure.

- Example (used throughout the requirement):
  1 kg + 1 g "is not equal to" 2 "a unit of measure"
- When a respective conversion factor is available, the conversion is executed automatically.
  Example: 1 kg is converted into g and then added to the g quantity to get 1,001 g.
- The system minimizes the overall accumulated error.
  Example: The kg quantity is converted into g and not vice versa.
- If a conversion is not possible, the calculation is interrupted and the error condition is reported (missing UoM conversion).
- If a different target UoM is defined for the calculation result, the above rules apply to the conversion into the target UoM.
- This also applies to material- and batch-related conversion factors.

CONVERSION FACTORS AND ROUNDING (SR3146.2.1.3.1)

The system does not round numbers during the conversion. Rounding takes place based on the final result.
For more information, please refer to "Technical Description - Number Handling" [A4] (page 143) and "Technical Description - Quantity Calculations" [A5] (page 143).

Hazard Statements and Precautionary Statements (SR3146.2.4)

➢ For recent changes, see revision history (page 145).

The system allows the recipe author to manage multiple hazard statements and precautionary statements on material level including basic operations like create, update, delete, and copy.

Hazard statements and precautionary statements are maintained in PharmaSuite for Production Management.

Attributes (SR3146.2.4.1)

➢ For recent changes, see revision history (page 145).

The system supports the following basic attributes for hazard statements and precautionary statements.

- Identifier (unique)
- Type (hazard or precautionary)
- Statement

Risk and Safety Phrases (SR3146.2.2)

➢ For recent changes, see revision history (page 145).

In the default configuration, the usage of risk and safety phrases is deactivated. GHS hazard and precautionary statements are used.

The system allows the recipe author to manage multiple risk and safety phrases on material level including basic operations like create, update, delete, and copy.

Risk and safety phrases is a system of hazard codes and phrases for labeling dangerous chemicals and compounds.
Risk phrases specify hazards arising from dangerous properties of a material. Safety phrases give advice on necessary precautions that need to be taken during handling of the material, such as indicating the required protective gear.
They are maintained in PharmaSuite for Production Management.

Attributes (SR3146.2.2.1)

The system supports the following basic attributes for risk and safety phrases.

- Identifier
- Type
- Phrase

Chapter 8

Inventory Management (SR3071.3.3)

PharmaSuite provides specific features to support inventory-related data management.

In addition to the data available in Data Manager, the management of inventory requires batches, sublots, devices, warehouses, storage areas, and storage locations. They are available in the Production Management Client of PharmaSuite.

Batches and Sublots (SR1076.3)

The system supports batches and sublots.

A batch is a quantity of substance, packaging materials, or product manufactured during one step or in a series of steps that is expected to be homogeneous.
In the pharmaceutical industry it refers to pharmaceuticals that are produced and packaged during the same production sequence with identical raw materials.
Batches are used to control material flow, starting at goods receipt, in the production process. To ensure the proper quality of materials, batches typically go through several statuses, such as **Blocked** or **Quarantined**, before they are **Released** and can be used for production.

A sublot is the smallest material unit in a PharmaSuite-controlled warehouse. It can assume various statuses, such as **Blocked**, **Released**, or **Quarantined**, which are inherited from the batch to which the sublot belongs. It can be necessary to update the quantity of a sublot. One reason for a quantity update, for example, can be that material was lost during transport or was damaged.

Batch and Sublot Identifier (SR1076.3.1)

The system provides a configurable generator for batch and sublot identifiers. A system integrator can configure the identifiers with configuration keys.

For details related to the identifiers, see chapter "Changing Number Generation Schemes" in Volume 2 of the "Technical Manual Configuration and Extension" [A2] (page 143).

Batch Identifier - Prefix (SR1076.3.1.1)

The batch identifier generator supports different prefixes for regular batches and for intra material-specific batches.

Example: BX for finished products and IX for intra materials

BATCH IDENTIFIER - LENGTH (SR1076.3.1.2)

The batch identifier generator supports a variable length.

Example A10 as in ERP systems

BATCH IDENTIFIER - LEADING ZEROS (SR1076.3.1.3)

The batch identifier generator can be configured to support either leading zeros or non-leading zeros.

Example: BX00011 or BX11

BATCH IDENTIFIER - MONOTONICALLY INCREASING (SR1076.3.1.4)

The batch identifier generator supports strictly monotonically increasing batch identifiers.

Example: BX1, BX2, BX3, BX5, ...

BATCH IDENTIFIER - NON-UNIQUENESS (SR1076.3.1.5+)

The system supports non-unique batch identifiers.

UNIQUE BATCH PER MATERIAL - IDENTIFIER (SR1076.3.1.5.1)

The system can be configured to support internal batch identifiers that present a concatenation of the logical batch identifier and the material identifier.

UNIQUE BATCH PER MATERIAL - BATCH IDENTIFIER ONLY (SR1076.3.1.5.2)

In case of an internally concatenated batch identifier, the system allows to retrieve only the batch identifier to be presented on the UI, on labels, and on reports.

UNIQUE BATCH PER MATERIAL - SCANNING (SR1076.3.1.5.3)

The system supports a two-step-barcode reading of batch identifier and material identifier in case only the concatenated key is unique in the system.

Maintenance of Batch-related Data

BATCH ATTRIBUTES (SR1076.3.11)

The batch object supports the following attributes:

- Read-only
  - Batch identifier
  - Material identifier, description
- Modifiable by a supervisor, during execution by an operator, or automatically by the system
  - Status
  - Potency, including UoM

- Expiry date
- Retest date
- Production date
- Comment

Changes performed with the **Change batch attributes** action must be confirmed by a single signature (see **Electronic Signatures (SR1095.50.2)** in "Functional Requirement Specification Non-functional Requirements" [A5] (page 143).

Status Management of Batches (SR1076.3.12)

The system supports the maintenance of batch-related data, incl. batch status.

Status Graph for the QC Status of Batches (SR1076.16)

The system provides a pre-defined status graph for managing the quality status of batches according to cGMP.

Statuses for the QC Status of Batches (SR1076.16.1)

The system supports the following statuses:

- Quarantined
- Released
- Blocked

Default Transitions for the QC Status of Batches (SR1076.16.2)

The system supports the following default transitions for batches:

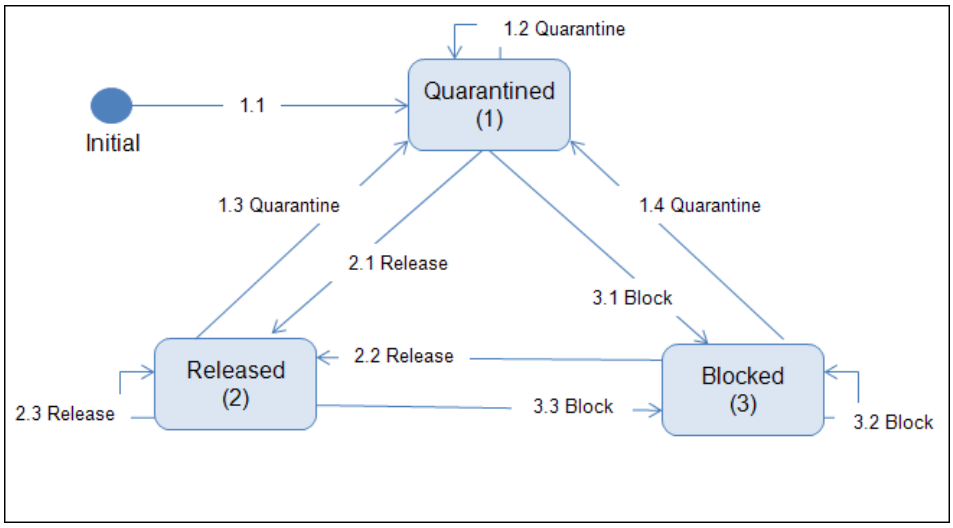

Figure 7: Batch - status graph

The diagram illustrates the **BatchQuality** flexible state model.

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Quarantined	---	Automatic transition.
1.2 - Quarantined » Quarantined	---	---
1.3 - Released » Quarantined	---	Automatic transition if retest date has passed.
2.1 - Quarantined » Released	---	---
2.3 - Released » Released	---	---
3.1 - Quarantined » Blocked	---	Automatic transition if expiry date has passed.
3.2 - Blocked » Blocked	---	---
3.3 - Released » Blocked	---	Automatic transition if expiry date has passed.

For the **1.4 - Blocked » Quarantined** and **2.2 - Blocked » Released** transitions, see the **Additional Transitions for the QC Status of Batches (SR1076.16.2)** requirement (page 134).

ADDITIONAL TRANSITIONS FOR THE QC STATUS OF BATCHES (SR1076.16.3)

The system supports the following additional transitions for batches:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.4 - Blocked » Quarantined	---	---
2.2 - Blocked » Released	---	---

Batch- and Sublot-related Operations

SUBLOT DELETION (SR1076.3.3)

Sublots with a logical quantity of zero are not automatically deleted.

If it is confirmed by the user that a sublot/container is empty (sublots with a physical quantity of zero), the sublot is not automatically deleted either. It is still in the system but marked for deletion (logically deleted) and therefore no longer visible as part of the inventory management.

Target Batch and Sublot Creation (SR1076.3.6)

The system can always provide the content of each sublot (material and batch, not always the quantity).

Target batches and sublots are created as soon as all the necessary information is available. In this sense, the target batch/sublot creation can be considered as a "safe-point" following as close as possible the point of no return in the physical process (e.g. mixing of two different materials cannot be undone).

Batch UoM - Taken from Material (SR1076.3.6.1)

At its creation, a batch inherits the unit of measure of its related material.

Batch UoM - Change of Material UoM (SR1076.3.6.2)

In case the unit of measure of a material is changed, already existing batches of this material keep their unit of measure.

Batch UoM - Stability (SR1076.3.6.3)

The system prevents that the unit of measure of an existing batch can be changed.

Sublot UoM - Taken from Batch (SR1076.3.6.4)

A sublot inherits the unit of measure of its related batch.

Sublot UoM - Stability (SR1076.3.6.5)

The system prevents that the unit of measure of an existing sublot can be changed. All sublots of a batch have the same unit of measure.

Sublot - Creation of Sublot Label (SR1076.3.7)

The system can always provide the content of each sublot (material and batch, not always the quantity).

Target batches and sublots are created as soon as all the necessary information is available. In this sense, the target batch/sublot creation can be considered as a "safe-point" following as close as possible the point of no return in the physical process (e.g. mixing of two different materials cannot be undone).

Atomic Dispensing Transactions (SR1076.3.9)

To ensure consistency, the operations of dispensing a material are performed altogether or not at all:

- Consume material from the source sublot. If the consumed quantity is greater than the logical quantity of the source-sublot, an inventory correction operation must be performed first.
- Create a target sublot if it does not yet exist.

- Add material to the target sublot by changing its quantity.
- Delete (logically) the source sublot if its quantity has been consumed completely or the operator decided that the remaining quantity is waste.
- Adapt the status of the source and target sublots if necessary.

Transactions (SR1076.4)

➢ For recent changes, see revision history (page 145).

The system allows to define an access privilege for the protection of master recipes from unauthorized access. Subsequently, it shall only allow to select order-related data whose master recipe's access privilege matches the access privilege of the logged-in user.

The system supports inventory transactions for tracking purposes.

Transaction history stores data on any events that result in modifying the properties of batches, sublots, and devices in their life cycles. It helps to trace material-related activities on the batch and sublot level, such as the batch creation, change of potency, change of batch status, generation and consumption of sublots, goods issue, etc.
In PharmaSuite, all inventory transactions are recorded in the transaction history.

BATCH - CREATION (SR1076.4.1)

The creation of a batch is an inventory transaction.

See also **Atomic Transactions and Traceability (SR1094.8)** in "Functional Requirement Specification Execution Framework" [A3] (page 143).

BATCH - INITIAL POTENCY (SR1076.4.1.1)

The system sets the initial potency to 0%.

BATCH - CHANGE POTENCY (SR1076.4.1.1.1)

The system allows a supervisor to modify the potency of a batch.

BATCH - INITIAL STATUS (SR1076.4.1.2)

The system sets the initial batch status to **Quarantined**.

SUBLOT - CHANGE QUANTITY (SR1076.4.2)

Changing the quantity of a sublot is an inventory transaction.

See also **Atomic Transactions and Traceability (SR1094.8)** in "Functional Requirement Specification Execution Framework" [A3] (page 143).

SUBLOT - SPLIT (SR1076.4.3)

Splitting a sublot is an inventory transaction.
A sublot split results in n new sublot(s) of the same batch. The source sublot's quantity is adjusted (reduced) according to the quantity of the new sublot.

The system calculates the quantities according the following formula:
Batch A, Sublot A1 (quantity=X) =
Batch A, Sublot A1 (quantity=X-Y) + Batch A, Sublot A2 (quantity=Y)

Any material waste resulting from a split is not taken into account.
The system rounds down the new quantities to avoid a potential creation of new sublots after a subsequent merge.

See also **Atomic Transactions and Traceability (SR1094.8)** in "Functional Requirement Specification Execution Framework" [A3] (page 143).

SUBLOT - CREATION (SR1076.6)

Creating a sublot is an inventory transaction.

Sublots always belong to one batch.

See also **Atomic Transactions and Traceability (SR1094.8)** in "Functional Requirement Specification Execution Framework" [A3] (page 143).

Devices (SR1076.5)

The system supports devices.

Device Identifier (Serial Number) (SR1076.5.1)

The system provides a configurable generator for serial numbers of devices. A system integrator can configure the serial numbers with configuration keys.

For details related to the identifiers, see chapter "Changing Number Generation Schemes" in Volume 2 of the "Technical Manual Configuration and Extension" [A2] (page 143).

BASIC FORMAT (SR1076.5.1.1)

The basic format of a serial number covers the following items:

- Prefix:
  The serial number generator supports one prefix of two characters.
  Example: SN

- Length:
  The serial number generator supports a variable length.
  Example SN10
- Leading zeros:
  The serial number generator can be configured to support either leading zeros or non-leading zeros.
  Example: SN00011 or SN11

MONOTONICALLY INCREASING (SR1076.5.1.2)

The serial number generator supports strictly monotonically increasing serial numbers.

Example: SN 1, SN 2, SN 3, SN 5, ...

UNIQUENESS (SR1076.5.1.3)

Serial numbers are unique per material.

SERIAL NUMBER BARCODE (SR1076.5.1.4)

The system can be configured to support different barcode formats, including a concatenation of the logical serial number and the material identifier.

Device Attributes (SR1076.5.2)

The device object supports the following attributes:

- Read-only
  - [Device] Serial number
  - [Device] Production date
  - Batch identifier, status
  - Sublot identifier, quantity
  - Material identifier, description
  - Storage location
  - Storage area
  - Warehouse
- Modifiable automatically by the system
  - [Device] Status

Status Management of Devices (SR1076.5.3)

The system supports the following default transitions for discrete devices:

Transition (ID - From » To)	Signature (Access privilege, according to FSM)	Additional information
1.1 - Initial » Pending	---	Automatic transition.
2.1 - Pending » Produced	---	Automatic transition after a device order was finished (see "Status Management of Orders and Workflows (SR1084.4)" in "Functional Requirement Specification Runtime Data Management" [A4] (page 143)).
3.1 - Pending » Annulled	---	Automatic transition after a device order was annulled or canceled (see "Status Management of Orders and Workflows (SR1084.4)" in "Functional Requirement Specification Runtime Data Management" [A4] (page 143)).

The diagram illustrates the **DiscreteDeviceStatus80** flexible state model.

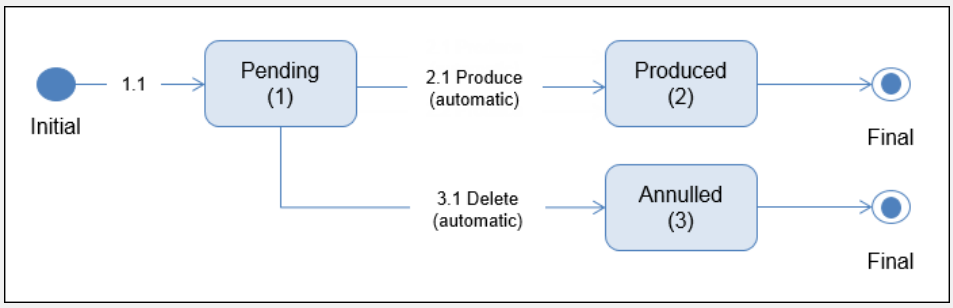

Figure 8: Discrete device - status graph

Logistical Topology Management (SR1076.7)

The system allows to define the logistical topology.

Warehouses (SR1076.7.3)

A warehouse is a physical location, in which materials and goods used in the production process are stored and managed. It is the highest level in the inventory structure.

The system allows the supervisor to define and manage warehouses.

Storage Areas (SR1076.7.5)

A storage area defines a physical area in a warehouse and is relevant to goods receipt and goods issue transactions. It occupies the middle level in the physical hierarchy of a PharmaSuite-controlled inventory.
Each storage area consists of a specified number of storage locations. This number depends on the warehouse type (e.g. high-rack warehouse).

The system allows the supervisor to define and manage storage areas.

Storage Locations (SR1076.7.7)

A storage location is identified by topological data, which defines the exact spatial position of the storage location in the warehouse. It occupies the lowest level of the physical hierarchy in a PharmaSuite-controlled inventory.

The system allows the supervisor to define and manage storage locations.

Relation between Storage Location and Storage Area (SR1076.7.9)

One **storage location (SR1076.7.7)** object (page 140) belongs exactly to one **storage area (SR1076.7.5)** object (page 140).

Relation between Storage Area and Warehouse (SR1076.7.10)

One **storage area (SR1076.7.5)** object (page 140) belongs exactly to one **warehouse (SR1076.7.3)** object (page 140).

Adding Topological Objects (SR1076.7.12)

The system allows the system administrator to add new **warehouse (SR1076.7.3)** objects (page 140), **storage area (SR1076.7.5)** objects (page 140), and **storage location (SR1076.7.7)** objects (page 140) to an operational system.

Deleting Topological Objects (SR1076.7.13)

The system allows the system administrator to delete **warehouse (SR1076.7.3)** objects (page 140), **storage area (SR1076.7.5)** objects (page 140), and **storage location (SR1076.7.7)** objects (page 140) from an operational system, as long as there are no sublots stored on the related inventory structure. In case there are sublots stored on the related inventory structure, the system displays an appropriate error message.

Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM008E-EN-E
A2	PharmaSuite Technical Manual Configuration & Extension - Volume 2	PSCEV2-GR008E-EN-E
A3	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM004E-EN-E
A4	PharmaSuite Functional Requirement Specification Runtime Data Management	PSFRSRT-RM004E-EN-E
A5	PharmaSuite Functional Requirement Specification Non-functional Requirements	PSFRSNF-RM001E-EN-E
A6	PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM006E-EN-E
A7	PharmaSuite Functional Requirement Specification Output Weighing	PSFRSOW-RM002E-EN-E
A8	PharmaSuite Technical Manual Administration	PSAD-RM008E-EN-E
A9	PharmaSuite Functional Requirement Specification Equipment Tracking Phases	PSFRSET-RM004E-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

The following documents are available upon request.

No.	Document Title	Part Number
A4	Technical Description - Number Handling	106721
A5	Technical Description - Quantity Calculations	106806

Appendix A

Document Information

The document information covers various data related to the document.

Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Martin Dittmer	Product Manager
Steffen Landes	Development Manager
Martin Irmisch	Test Manager

In addition, the electronic document approval via DMS is confirmed by a handwritten signature of all approvers in the Quality Document when the release is completed. The Quality Document summarizes the quality-related planning activities and results of a PharmaSuite release.

Version Information

Object	Version
PharmaSuite	8.4
Functional Requirement Specification	1.0

Revision History

The following table describes the history of this document.

Changes related to the document:

Object	Description	Document
---	---	---

Changes related to "Master Data Management" (page 3):

Object	Description	Document
Using an Empty Container (page 19)	New PharmaSuite supports to check the tare value of a container against a reference value.	1.0
Equipment Mass Change (page 19)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0

Changes related to "Data Manager Workbench" (page 21):

Object	Description	Document
---	---	---

Changes related to "Equipment Management" (page 51):

Object	Description	Document
Attributes (SR1099.1.1) (page 103)	Update New purpose to check the tare value of a container against a reference value.	1.0
Property Types with Defined Purpose (SR1099.1.4.1) (page 105)	Update New purpose to check the tare value of a container against a reference value.	1.0
Change History Tab (SR1099.2.1.8) (page 54)	Update The start of a mass change of assigned (template) entities is a new action that is added to the change history. For actions that request a signature, the given signatures with user names and comments are available.	1.0
Update Assigned (Template) Entities (SR1099.2.3.6) (page 57)	New New operation to update (template) entities of an equipment class with the **Equipment Mass Change Process (SR1099.7+)** function.	1.0
Compile Usage List (SR1099.2.3.7) (page 58)	New New operation to compile a list of all master recipes, master workflows, and custom building blocks in which the equipment class is referenced.	1.0
Property Consistency (SR1099.2.4.2) (page 58)	Update (Template) entities in the **Archived** status are excluded from the property consistency checks related to an equipment class.	1.0

Object	Description	Document
Graph Consistency (SR1099.2.4.3) (page 60)	Update (Template) entities in the **Archived** status are excluded from the graph consistency checks related to an equipment class.	1.0
Equipment Type Consistency (SR1099.2.4.4) (page 59)	Update The equipment type consistency check is also performed when the **Equipment Mass Change Process (SR1099.7+)** function is started. In case of an issue, the system displays an error message.	1.0
Property of Graph Consistency (SR1099.2.4.5) (page 60)	Update The property of graph consistency check is also performed when the **Equipment Mass Change Process (SR1099.7+)** function is started. In case of an issue, the system displays an error message.	1.0
Status and Trigger Consistency (SR1099.2.4.6) (page 60)	Update The status and trigger consistency check is also performed when the **Equipment Mass Change Process (SR1099.7+)** function is started. In case of an issue, the system displays an error message.	1.0
Class and Graph Purpose Consistency (SR1099.2.4.7) (page 61)	Update The class and graph purpose consistency check is also performed when the **Equipment Mass Change Process (SR1099.7+)** function is started. In case of an issue, the system displays an error message.	1.0
Default Statuses for Equipment Classes (SR1099.2.6.1) (page 55)	Update The system allows a status transition from **Approved** to **Draft**.	1.0
Default Transitions for Equipment Classes (SR1099.2.6.2) (page 55)	Update The system allows a status transition from **Approved** to **Draft**.	1.0
Change History Tab (SR1099.3.1.8) (page 82)	Update The **Information** column provides additional information related to the action (e.g. mass change on entities).	1.0
Default Statuses for Equipment Entities (SR1099.3.8.1) (page 83)	Editorial The system allows a status transition from **Approved** to **Draft**. No change of code.	1.0
Change History Tab (SR1099.5.1.8) (page 66)	Update The **Information** column provides additional information related to the action (e.g. mass change on entities).	1.0
Default Statuses for Template Equipment Entities (SR1099.5.2.1) (page 67)	Editorial The system allows a status transition from **Approved** to **Draft**. No change of code.	1.0

Object	Description	Document
Equipment Class Usage List (SR1099.6+) (page 106)	New Data Manager allows to compile a usage list of an equipment class.	1.0
Content (SR1099.6.1) (page 107)	New Data Manager allows to compile a usage list of an equipment class.	1.0
Objects Information (SR1099.6.2) (page 107)	New Data Manager allows to compile a usage list of an equipment class.	1.0
Filter (SR1099.6.3) (page 107)	New Data Manager allows to compile a usage list of an equipment class.	1.0
Copy to Clipboard (SR1099.6.4) (page 108)	New Data Manager allows to compile a usage list of an equipment class.	1.0
Equipment Mass Change Process (SR1099.7+) (page 108)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Differences between an Equipment Class and its Entities (SR1099.7.1) (page 108)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Equipment Property Added (SR1099.7.1.1) (page 109)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Equipment Transition Graph Added (SR1099.7.1.2) (page 109)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Equipment Transition Graph Replaced (SR1099.7.1.3) (page 109)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Equipment Property Value Changed (SR1099.7.1.4) (page 110)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Equipment Class-specific Consistency Checks (SR1099.7.2) (page 110)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Compiled Update List for Mass Change (SR1099.7.3) (page 111)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0

Object	Description	Document
Execute Mass Change (SR1099.7.4) (page 112)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0
Update Result List (SR1099.7.5) (page 112)	New Data Manager allows to perform a mass change on entities that share an equipment class.	1.0

Changes related to "Work Center and Station Management" (page 115):

Object	Description	Document
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Changes related to "Resource Master Data" (page 121):

Object	Description	Document
Attributes (SR3146.1.1.8) (page 122)	Update GHS signal words and hazard pictograms replace ECB hazard classes. In the default configuration, the usage of ECB hazard classes is deactivated. Hazard and precautionary statements replace risk and safety phrases. In the default configuration, the usage of risk and safety phrases is deactivated. New attributes (L0 Meaning, L1 Contained number, L1 Meaning, ..., L5 Container number, L5 Meaning) to define packaging levels on material level. New attribute: Access privilege (recipe). PharmaSuite supports the concept of confidential objects to protect the intellectual property of recipes, workflows, orders, and related data from unauthorized access.	1.0

Changes related to "Complementary Master Data" (page 125):

Object	Description	Document
Risk and Safety Phrases (SR3146.2.2) (page 129)	Update In the default configuration, the usage of risk and safety phrases is deactivated. GHS hazard and precautionary statements are used.	1.0

Object	Description	Document
Hazard Statements and Precautionary Statements (SR3146.2.4) (page 128)	New Hazard and precautionary statements replace risk and safety phrases. In the default configuration, the usage of risk and safety phrases is deactivated.	1.0
Attributes (SR3146.2.4.1) (page 129)	New Hazard and precautionary statements replace risk and safety phrases. In the default configuration, the usage of risk and safety phrases is deactivated.	1.0

Changes related to "Inventory Management" (page 131):

Object	Description	Document
Transactions (SR1076.4) (page 136)	Update PharmaSuite supports the concept of confidential objects to protect the intellectual property of recipes, workflows, orders, and related data from unauthorized access.	1.0

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