Critical manufacturing
an ASM PT company

Label Verification and Reconciliation

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In highly regulated environments such as medical device manufacturing, labels are tightly connected to traceability and batch control. On the shop floor, this creates a practical challenge: ensuring that every printed label is accounted for, correctly applied, and reconciled at the end of a production run.

The **Label Verification and Reconciliation** functionality addresses this operational need by providing MES users with clear visibility and control over label quantities throughout the process. It enables tracking of printed labels, monitoring of actual usage, management of reprints and scrap, and reconciliation of totals before closing an order.

Overview

This tutorial will walk you through the setup and usage of the Label Verification and Reconciliation functionality in **Critical Manufacturing MES**. The following topics will be covered:

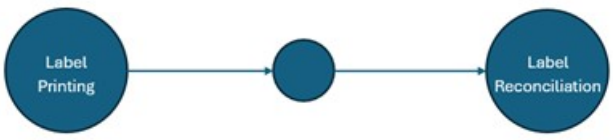
- **Scenarios**
- **Modelling**
  - Configuration Entries
  - Printable Documents
  - Data Collections
  - Exception Management
  - Checklists
- **Execution**

Scenarios

For the purpose of this tutorial, we will consider two simple production processes:

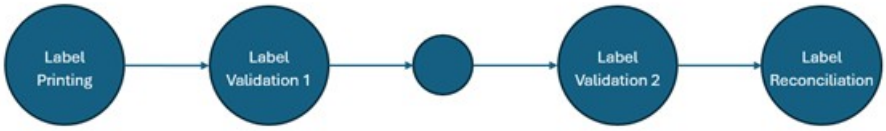
Scenario A

In the first step, 3 labels are printed and applied to each unit. Some additional labels are often printed if replacing them is required downstream.
At the last step of the flow, **Label Reconciliation** is executed to account for all issued labels before the order is closed.



Scenario B

In the first step, 3 labels are printed and applied to each unit. Some additional labels are often printed if replacing them is required downstream. The material then proceeds to the next step, where Label Verification is performed for label 1 and 2. After going through another production step, a second Label Verification is performed now to verify label 3, and to re-validate label 1, which if often damaged during the in-between process. If that is the case, it will be replaced by a new label. Finally, at the last step of the process, Label Reconciliation is executed to account for all issued labels before the order is closed.



Info

While in these scenarios the Label related operations have singularized steps, these operations may be included into regular process steps.

Modeling

This section describes the configuration required to set up the Label Verification and Reconciliation process. It assumes that the base model (Flow, Steps, Services, etc.) has already been created and configured in MES.

Configuration Entries

> /MedDev/LabelReconciliation/EnableLabelReconciliation

- Must be set to “True” for the functionality to be enabled.

> /MedDev/LabelReconciliation/DataCollectionType/

- Defines the Data Collection type expected when creating the Data Collections.

PATH	NAME	VALUE
/MedDev/LabelReconciliation/DataCollectionType/	DataCollectionType	Label Reconciliation
/MedDev/LabelReconciliation/EnableLabelReconciliation/	EnableLabelReconciliation	true

Printable Documents

Although not directly part of the Label Reconciliation functionality, the configuration of Printable Documents with MES-triggered printing is a pre-requisite for its use. For more information on this topic visit the Printable Documents Tutorial.

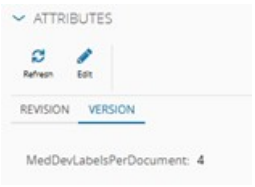
Additionally, the `MedDevLabelsPerDocument` attribute is now associated with each Printable Document. Its objective is to represent when one Printable Document includes multiple instances of the same label.

Info

To be used on the Label Reconciliation process, the Printable Document must have the **"Store Print History"** flag set to TRUE.

Configuration of Printable Documents for Scenarios A & B:

- FrontLabel
- BackLabel (MedDevLabelsPerDocument=4)
- SafetyLabel



Data Collections

Create Data Collections that must be configured as **LongRunningAfterTrackIn**, with the type configured in the above-mentioned configuration entry. Add the relevant parameters for the specific Verification and Reconciliation processes to be represented. It's possible to select several predefined Parameters which are divided into three categories:

- Absolute: Updating these parameters will overwrite the previous count.
- Incremental: Updating these parameters will add to the previous values.
- Calculated: Value is automatically calculated using a Rule.

Parameter	Description	Type	Used In
MedDevFirstLabelCheck	Boolean validation of the first label of the batch.	Increment	Verification
MedDevGoodLabels	Number of used labels which were validated and considered good.	Increment	Verification
MedDevLastLabelCheck	Boolean validation of the last label of the batch.	Increment	Verification
MedDevScrappedLabels	Number of labels which were scrapped during the current process.	Increment	Verification
MedDevRemainingLabels	Total number of labels that were printed but not used.	Absolute	Verification/Reconciliation
MedDevTotalGoodLabels	Total number of good labels used.	Absolute	Verification/Reconciliation
MedDevTotalScrappedLabels	Total number of scrapped labels.	Absolute	Reconciliation

Parameter	Description	Type	Used In
MedDevFirstLabelCounts	Count of the number of successful first label validations complete during the process.	Absolute	Reconciliation
MedDevLastLabelCounts	Count of the number of successful last label validations complete during the process.	Absolute	Reconciliation
MedDevPrintedLabels	Total Printed Labels Parameter for Reconciliation process. This parameter is populated automatically and should not be changed manually.	Absolute	Reconciliation
MedDevFirstLastDiff	Difference between the count of good first label validations and good last label validations. Requires configuration of Rule **'MedDevPreviewFirstLastDif'** *(MedDevFirstLabelCounts - MedDevLastLabelCounts)*	Calculated	Reconciliation
MedDevMissingLabels	Total number of labels not accounted for. Requires configuration of Rule **'MedDevPreviewMissingLabels'** *(MedDevPrintedLabels - MedDevTotalGoodLabels - MedDevTotalScrappedLabels - MedDevRemainingLabels)*	Calculated	Reconciliation

Info

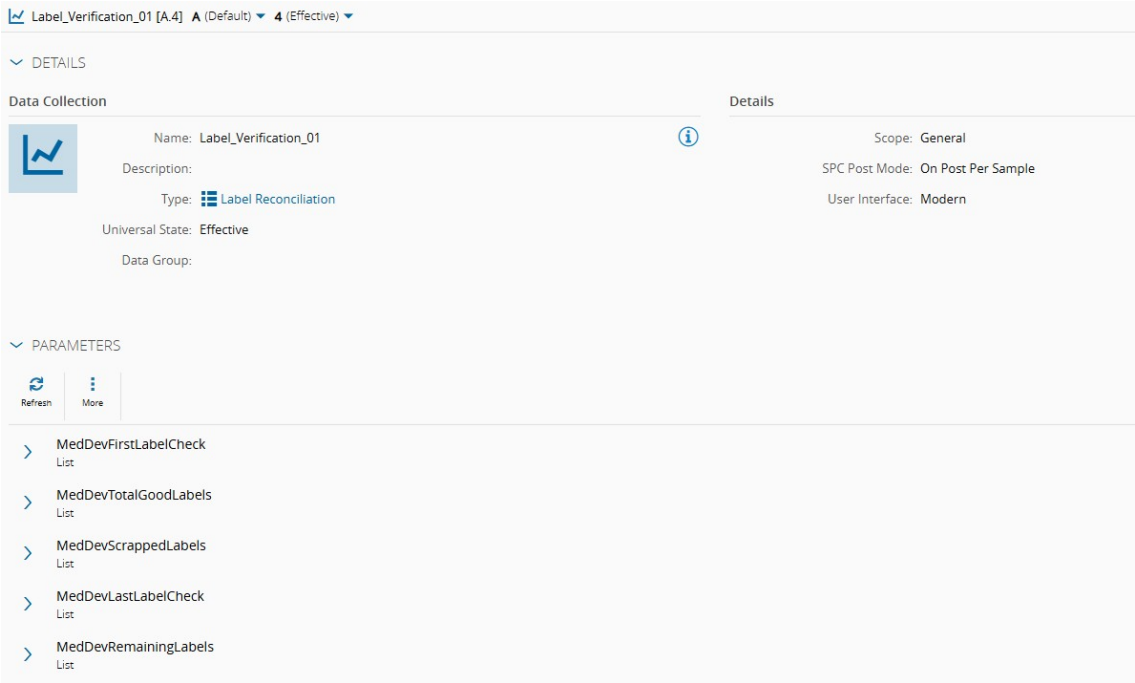
The incremental counting of good labels using the `MedDevGoodLabels` parameter is only meaningful in scenarios where each verification step is responsible for a distinct, non-overlapping subset of labels, and operators clearly understand which subset they must validate. In typical manufacturing workflows, however, label validation is either performed entirely within a single step or, when distributed across multiple steps, all labels are revalidated at each step to ensure consistency and traceability. For this reason, the use of the absolute parameter `MedDevTotalGoodLabels` is generally recommended and expected in most implementations.

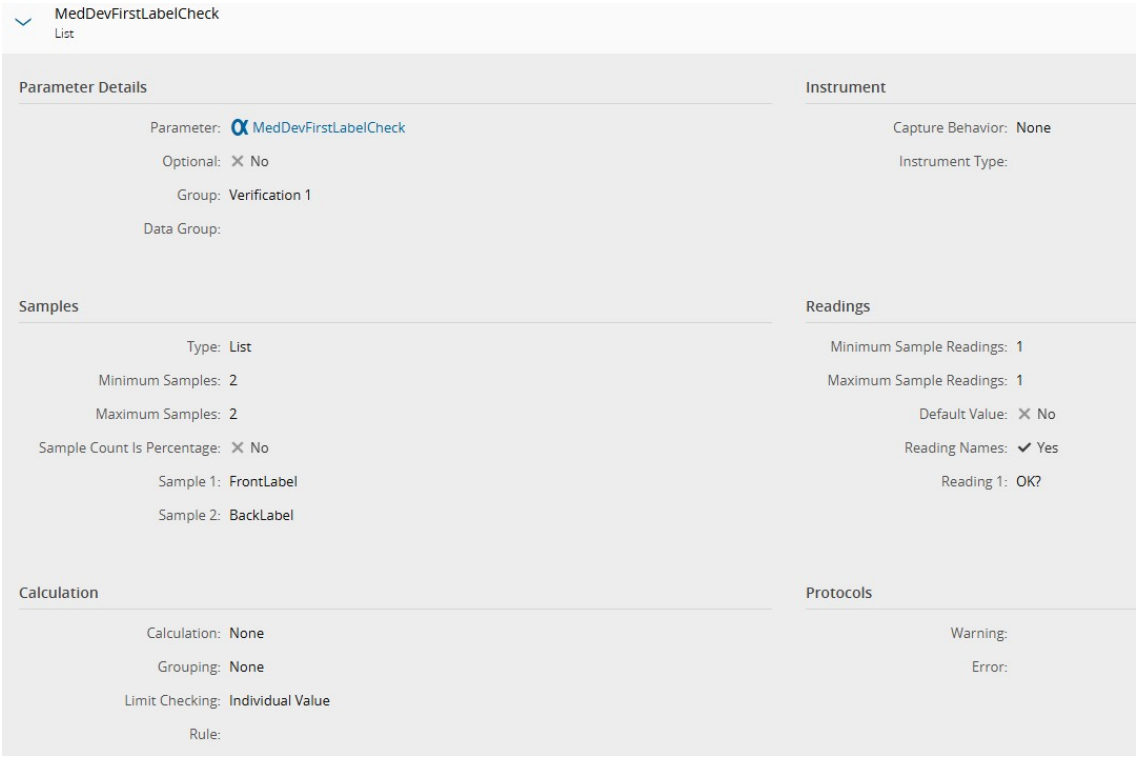
Info

These Parameters will automatically populate the `MedDevMaterialPrintableDocument` relation, based on the link defined in the `MedDevLabelVerificationParameters` Generic Table, under the Verification Property column. It's possible to create new Parameters and link them to the Reconciliation process by adding them to this table, with the additional possibility of configuring them as *Decremental* (will remove from the previous values) or *NoCalculation*.

One or several Label Verification Data Collection can be configured. Each verification step can include validations for all labels or just some, and the same label can be validated more than once in different steps. A single Label Reconciliation step is expected.

These Data Collections may include other Parameters that need to be recorded for the step, without any relation to the Label Reconciliation process, as long as the Reconciliation Data Collection Type is maintained.

> **Configuration of Label Verification Data Collections for Scenario B:**
>
> Create a new Data Collection for **Label Verification 1** with type `Label Reconciliation`, Scope `General` and Post Mode `One Post per Sample`. Include the following Parameters:
>
> - `MedDevFirstLabelCheck`
> - `MedDevTotalGoodLabels`
> - `MedDevScrappedLabels`
> - `MedDevLastLabelCheck`
> - `MedDevRemainingLabels`
>
> 
>
>
> For each Parameter setup the Samples:
>
> - `Type` '**List**'
> - `Minimum & Maximum Samples`: Corresponding to the number of Labels to be verified, in this case 2.
>   - *Optional:* To improve user experience set up a common group for all Parameters.
> - `Minimum & Maximum Readings`: Always 1.
>   - *Optional:* Set the "Reading Names" to True so that it is possible to create a label for that field (e.g. "OK?"; "QTY")
> - On the `Samples and Readings` section, attribute each Sample the name of the Printable Documents it will reflect:
>   - FrontLabel
>   - BackLabel



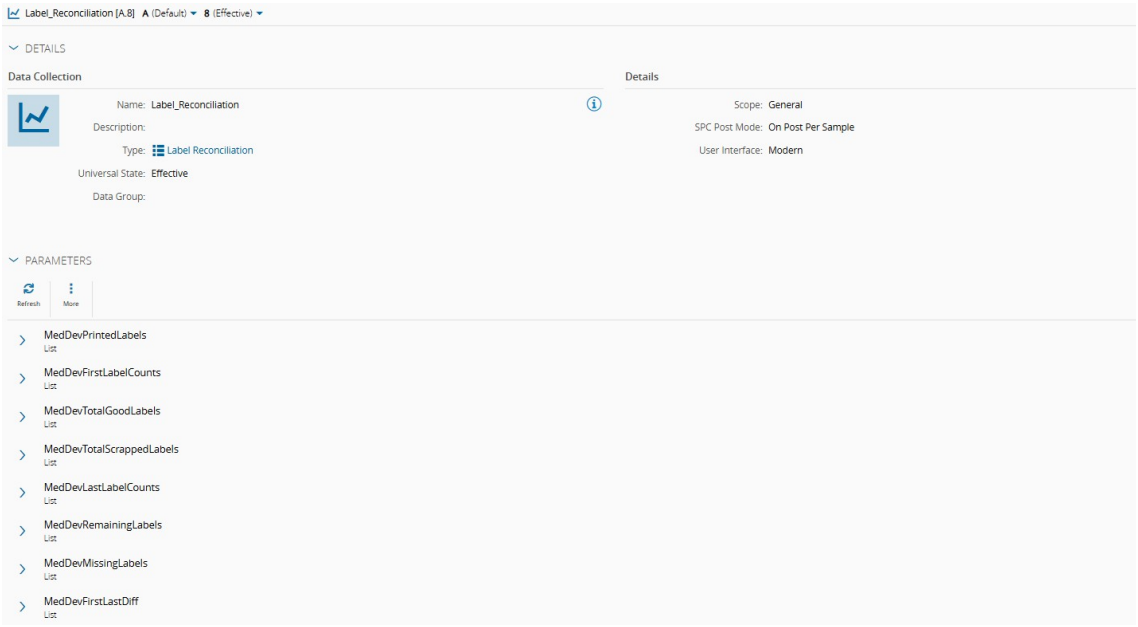
Create a new Data Collection for **Label Verification 2**. This Data Collection can use the same template as created for Label Reconciliation 1, replacing the `BackLabel` with the `SafetyLabel`.

Configure the created Data Collections at the required Steps on the `MedDevMaterialDataCollectionContext` smart table, as **LongRunningAfterTrackIn**.

> **Info**
>
> Verify that the `MedDevMaterialDataCollection` is configured for the `MaterialDataCollectionResolution` on the `ContextResolution` Generic Table.

Configuration of Label Reconciliation Data Collections for Scenarios A & B: For both scenarios it's necessary to create a new Data Collection for **Label Reconciliation** with type `Label Reconciliation`, Scope `General`, Post Mode `One Post per Sample`. Include the following Parameters:

- `MedDevPrintedLabels`
- `MedDevFirstLabelCounts` (only for scenario B)
- `MedDevLastLabelCounts` (only for scenario B)
- `MedDevTotalGoodLabels`
- `MedDevTotalScrappedLabels`
- `MedDevRemainingLabels`
- `MedDevMissingLabels`
- `MedDevFirstLastDiff` (only for scenario B)

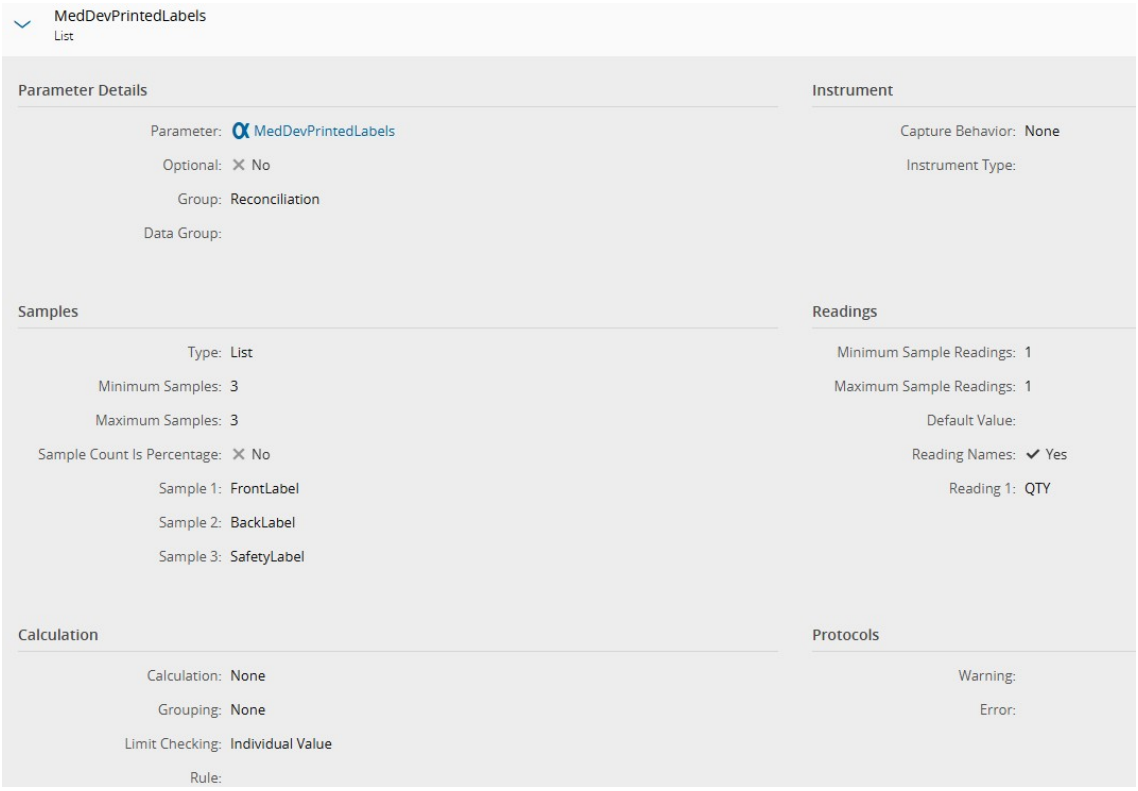


> **Info**
>
> `MedDevFirstLabelCounts` and `MedDevLastLabelCounts` - These parameters display the number of good first and last label validations performed. Since this is not applicable for scenario A, they will not be included in the respective Data Collection. Since the calculated parameter `MedDevFirstLastDiff` needs these for the calculation, it is also not applicable for this scenario and can be excluded.

> **Info**
>
> For both scenarios, `MedDevPrintedLabels` will automatically display the number of printed labels. This value must not be changed manually.

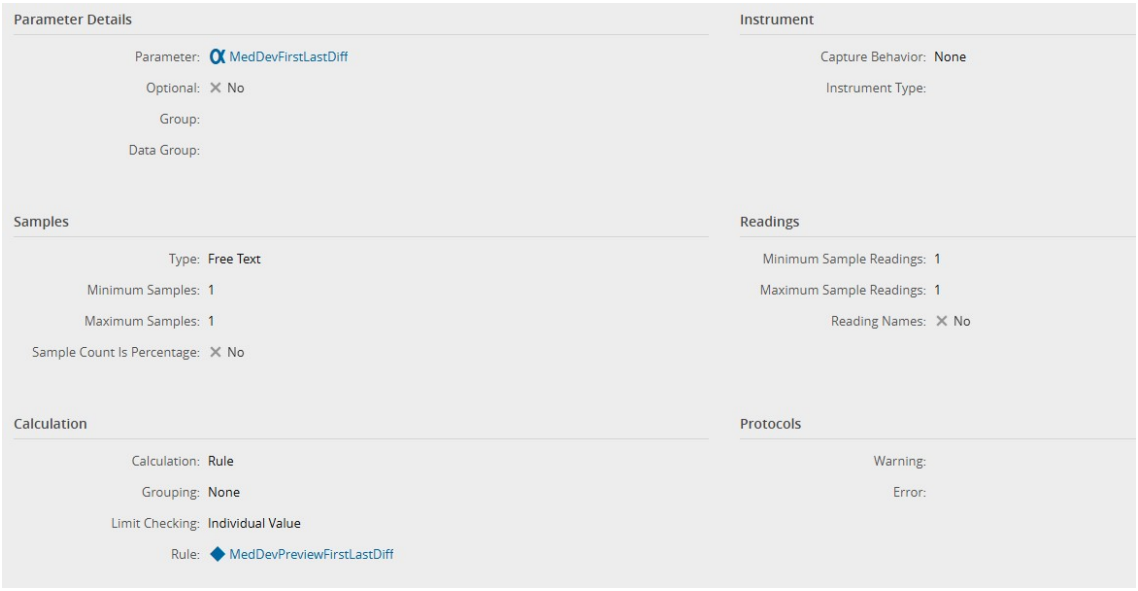
For each Parameter **(except Calculated parameters)** setup the Samples:

- `Type` '**List**'
- `Minimum & Maximum Samples`: Corresponding to the number of Labels to be reconciled, in this case 3.
  - *Optional:* To improve user experience set up a common group for non-calculated Parameters.
- `Minimum & Maximum Readings`: Always 1.
  - *Optional:* Set the “Reading Names” to True so that it is possible to create a label for that field (e.g. “OK?”; “QTY”)
- On the `Samples and Readings` section attribute each Sample the name of the Printable Documents it will reflect.
  - FrontLabel
  - BackLabel
  - SafetyLabel



For each **Calculated parameter** setup the Samples and Calculation:

- `Type` '**Free Text**'
- `Minimum & Maximum Samples`: Always 1.
  - *Optional:* To improve user experience set up a common group for calculated Parameters.
- `Minimum & Maximum Readings`: Always 1.
  - *Optional:* Set the "Reading Names" to True so that it is possible to create a label for that field (e.g. "OK?"; "QTY")
- Set the Calculation field to '**Rule**':
  - `MedDevMissingLabels`: set Rule '**MedDevPreviewMissingLabels**'
  - `MedDevFirstLastDiff`: set Rule '**MedDevPreviewFirstLastDiff**'



Configure the created Data Collections at the required Steps on the `MedDevMaterialDataCollectionContext` smart table, as **LongRunningAfterTrackIn**.

Info

Verify that the `MedDevMaterialDataCollection` is configured for the `MaterialDataCollectionResolution` on the `ContextResolution` Generic Table.

Exception Management

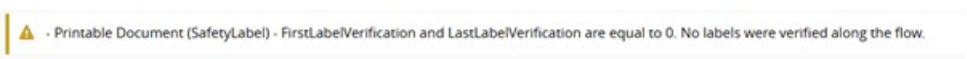
MES allows the configuration of actions to handle cases where the Reconciliation is not successful.

Using Data Collection Attributes:

- **MedDevPreventTrackOutOnLabelCountMismatch**: When set to TRUE, MES will not allow Track-Out if the Reconciliation quantity does not match the Printed quantity OR the number of First Label Validations does not match the number of Last Label Validations.
- `MedDevPrintedLabels` – `MedDevTotalGoodLabels` - `MedDevTotalScrappedLabels` - `MedDevRemainingLabels` = 0 is required

- `MedDevFirstLabelCounts` = `MedDevLastLabelCounts` is required

- **MedDevShow FirstLast labels verification warning**: When set to TRUE, if both the `MedDevFirstLabelCounts` and the `MedDevLastLabelCounts` value is equal to 0, MES will display a warning that no first or last label was validated. To be used in cases where at least one label validation (being it either to the First or Last label) is expected during the process.



Using Data Collection Limit Sets:

- For each Parameter of the Data Collection, it's possible to define warning and error limits using a Data Collection Limit Set. Additional information can be found here: Create a Data Collection Limit Set Tutorial.
- Then, when configuring the Data Collection, setup Protocols to be triggered for each calculated Parameter (`MedDevMissingLabels` and `MedDevFirstLastDiff`), when the obtained value is other than 0.

Configuration of Exception Management for Scenario A:

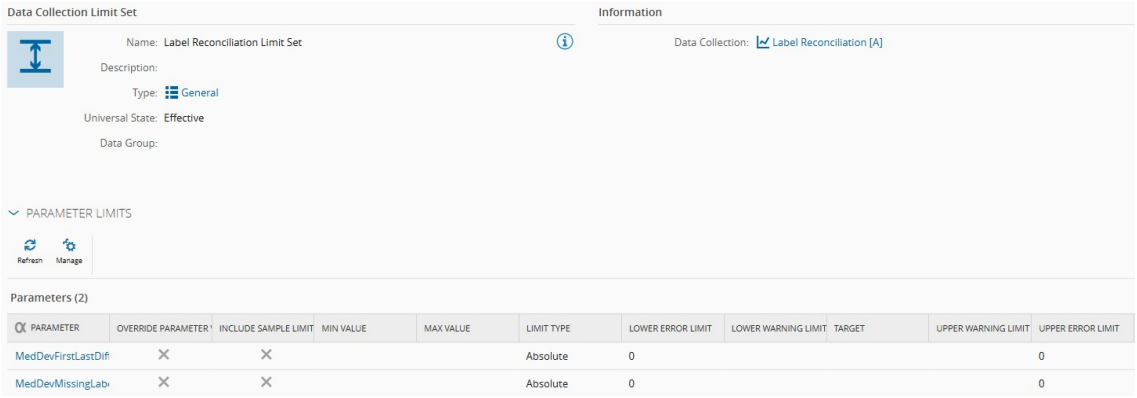
Set the `MedDevPreventTrackOutOnLabelCountMismatch` attribute to True.

Configuration of Exception Management for Scenario B:

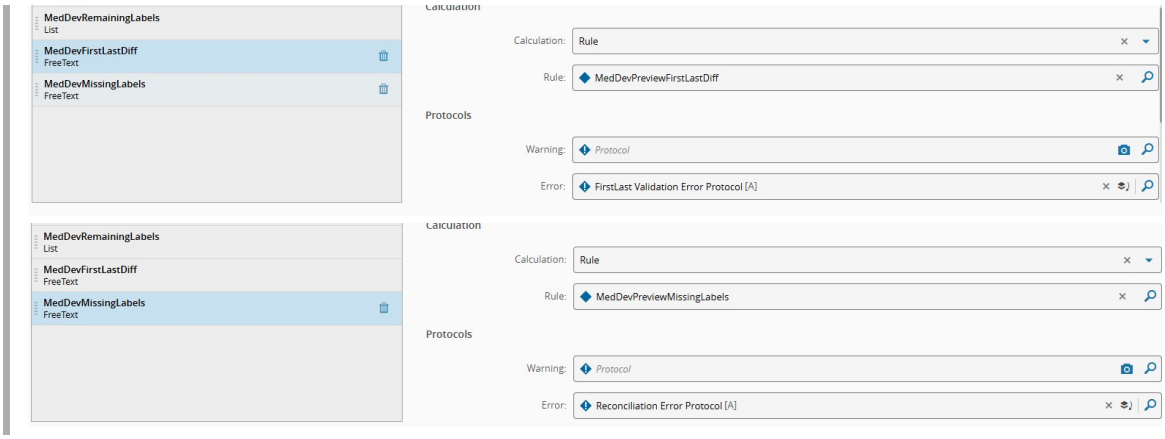
Set the 'MedDev Show FirstLast labels verification warning' attribute to True.

As a Pre-Requisite, create two Protocols to be open in case of limits violation. A Data Collection Limit Set must also be created to define the limits which will trigger the Protocols and configured on the `MedDevMaterialDataCollectionContext` smart table. For the present scenario, the Limit Set will contain for both parameters a **Lower & Upper Error Limit** of 0.

To prevent repeated validations from opening duplicated Protocol Instances for the same Material or Continuous Flow group, enable the `MedDevIgnoreInstanceCreationIfAlreadyAssigned` attribute on the Protocol used by the warning or error violation.



Set Error Protocols for the limit set violation of Parameters `MedDevFirstLastDiff` and `MedDevMissingLabels`. These calculated Parameters will generally be the ones used to trigger exception management.



Checklists

In order to guide the user through the Verification or Reconciliation process, it's possible to embed the Data Collection Parameters within checklists. These can also be used to request and save photos of the labels. Additional information on how to do this can be found here: Data Collection Parameters within Checklists

Execution

Common

Material with qty 100 is In-Process at the `Label Printing` step. As per the described scenario, 100 labels of each are required. User prints additional labels to be used as replacements, if needed:

- 120 FrontLabel
- 100 BackLabel
- 110 SafetyLabel

MES automatically populates the relation with the printed quantities:

MedDevMaterialPrintableDocument

PRINTABLE DOCUMENT	DESCRIPTION	ENTITYPICTURE	FIRSTLABELVERIFICATIONCOUNT	LASTLABELVERIFICATIONCOUNT	PRINTEDLABELS	REMAININGLABELS	TOTALGOODLABELS	TOTALSCRAPPEDLABELS
BackLabel [B.3]					100			0
FrontLabel [B.2]					120			0
SafetyLabel [A.3]					110			0

Scenario A

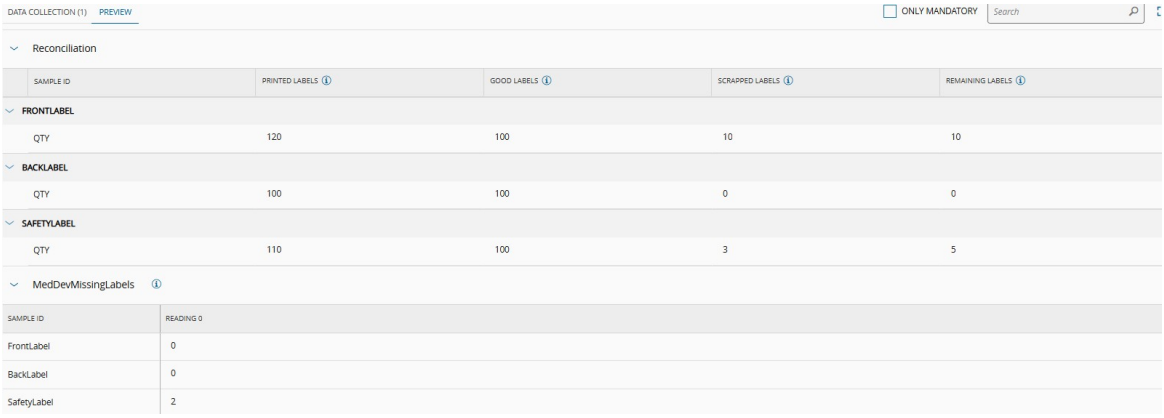
When the Material reaches the `Label Reconciliation` step, a new Instance of the Data Collection is opened. Posting the data, only the Printed Labels field is automatically filled. User must complete the remainder of the Data Collection.

Reconciliation (4 Parameters / 3 Samples)

No active input.

SAMPLE ID	* PRINTED LABELS	* GOOD LABELS	* SCRAPPED LABELS	* REMAINING LABELS
	* QTY	* QTY	* QTY	* QTY
* FrontLabel	120		0	
* BackLabel	100		0	
* SafetyLabel	110		0	

User must manually fill the total number of Good, Scrapped and Remaining Labels. Then, if the **Preview** option is pressed, the user is able to check if the calculated parameters are ok (value must be equal to 0).



In this example, in the case of the *SafetyLabel*, the sum of Good, Scrapped and Remaining Labels does not reach the value of total Printed Labels. Therefore, according to the Exception Management scenario configured, the Track-Out is not allowed:

The user must return to the Data Collection, correct the posted data, ensure all labels are accounted for and the calculated parameter value is 0. The Track-Out is then authorized.

Scenario B

When the Material reaches the first `Label Verification` step, the user must complete the Data Collection referring to the *FrontLabel* and *BackLabel*. In this case, *5 FrontLabels* were scrapped and the *BackLabel* last label validation was not performed.

Verification 1 (5 Parameters / 2 Samples)

Remaining Labels / Remaining Labels Parameter for Verification/Reconciliation process

SAMPLE ID	* FIRST LABEL CHECK		* GOOD LABELS	* SCRAPPED LABELS	* LAST LABEL CHECK		* REMAINING LABELS
	* OK?		* QTY	* QTY	* OK?		* QTY
* FrontLabel	Yes	No	100	5	Yes	No	15
* BackLabel	Yes	No	100	0	Yes	No	0

MES automatically populates the relation:

MedDevMaterialPrintableDocument

PRINTABLE DOCUMENT	DESCRIPTION	ENTITYPICTURE	FIRSTLABELVERIFICATIONCOUNT	LASTLABELVERIFICATIONCOUNT	PRINTEDLABELS	REMAININGLABELS	TOTALGOODLABELS	TOTALSCRAPPEDLABELS
BackLabel [B.3]			1	0	100	0	100	0
FrontLabel [B.2]			1	1	120	15	100	5
SafetyLabel [A.3]					110			0

When Material reaches the second `Label Verification` step, user must complete the Data Collection referring to the *FrontLabel* and *SafetyLabel*. Good and Remaining *FrontLabel* values are carried over from the previous verification.

Verification 1 (5 Parameters / 2 Samples)

No active input.

SAMPLE ID	* FIRST LABEL CHECK		* GOOD LABELS	* SCRAPPED LABELS	* LAST LABEL CHECK		* REMAINING LABELS
	* OK?		* QTY	* QTY	* OK?		* QTY
* FrontLabel	Yes	No	100		Yes	No	15
* SafetyLabel	Yes	No			Yes	No	

User will post the data for both labels. In this case, 7 additional *FrontLabels* were scrapped and replaced, and so the number of Good labels did not change, however the number of remaining labels was inadvertently not reduced. The first and last label check for the *SafetyLabel* was not performed.

Verification 1 (5 Parameters / 2 Samples)

Last Label Check / Last Label check Parameter for Verification process

SAMPLE ID	* FIRST LABEL CHECK		* GOOD LABELS	* SCRAPPED LABELS	* LAST LABEL CHECK		* REMAINING LABELS
	* OK?		* QTY	* QTY	* OK?		* QTY
* FrontLabel	Yes	No	100	7	Yes	No	15
* SafetyLabel	Yes	No	100	0	Yes	No	10

MES automatically updates the relation:

MedDevMaterialPrintableDocument

PRINTABLE DOCUMENT	DESCRIPTION	ENTITYPICTURE	FIRSTLABELVERIFICATIONCOUNT	LASTLABELVERIFICATIONCOUNT	PRINTEDLABELS	REMAININGLABELS	TOTALGOODLABELS	TOTALSCRAPPEDLABELS
BackLabel [B.3]			1	0	100	0	100	0
FrontLabel [B.2]			2	2	120	15	100	12
SafetyLabel [A.3]			0	0	110	10	100	0

After completing the verification, the Material will reach the Reconciliation process. When posting the data for the Reconciliation, the user is presented with a summary of validation processes. The user reviews the data and makes corrections if needed before completing the process.

Reconciliation (6 Parameters / 3 Samples)

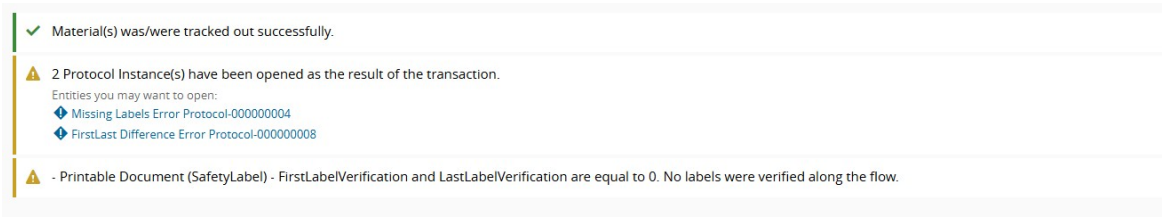
No active input.

SAMPLE ID	* PRINTED LABELS	* FIRST LABEL COUNTS	* LAST LABEL COUNTS	* GOOD LABELS	* SCRAPPED LABELS	* REMAINING LABELS
	* QTY	* QTY	* QTY	* QTY	* QTY	* QTY
* FrontLabel	120	2	2	100	12	15
* BackLabel	100	1	0	100	0	0
* SafetyLabel	110	0	0	100	0	10

If the 'Preview' option is selected, its possible to check the results for the calculated parameters and understand in advance if the data is showing an inconsistency.

If the Track-Out is executed without any changes to the reconciliation values, it will be allowed, however MES applies the following actions according to the configured exception management scenarios:

- Protocol Instance open due to the limit set violation of the `MedDevMissingLabels` parameter (*FrontLabel*)
- Protocol Instance open due to the limit set violation of the `MedDevfirstLastDiff` parameter (*BackLabel*)
- Warning shown due to no first or last label validation being recorded as successful (*SafetyLabel*)



Info

For more information on Label Verification & Reconciliation, see Label Verification and Reconciliation in the User Guide.

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