Describing Safety Analysis Items

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Safety Analysis Items should be described in a predefined Risk Table. Since Risk Tables are based on Generic Tables, the toolbar and the Criteria area wo rk in the same manner.

A Risk Table allows you to analyze the safety aspect of your model, and provides a convenient way to fill-in Safety Analysis Item information using a spreadsheet-like tabular format. Each row in a table represents a Safety Analysis Item. Table columns represent the properties Safety Analysis Items. In a Risk Table, you can:

- Create a new Safety Analysis Item directly in a table, or add an existing one.
- Edit the properties of Safety Analysis Items directly in a table.
- Generate a risk analysis report, and export a table into a CSV or HTML file format.

A Risk Table has the following columns:

Table column name	Description
Id	Safety Analysis Item ID.
MHT Reference	The reference to a Master Hazard Table.
FMEA Reference	The reference to an FMEA Item.
Initiating Cause	A short description of a Safety Analysis Item reflecting the cause of a risk.
Hazard	A potential source of Harm.
Sequence of Events	Sequence of Events leading to a Hazardous Situation. Every Sequence of Events can have a default **P1** value assigned as its property. To assign a value, open the Specification window of a Sequence of Events, and set the desired **P1** value. **Adding P1 values** If you add a Sequence of Events with a specified **P1** value to a certain row of a Risk Table for the first time, this value is automatically entered into an appropriate cell of the P1 column. The value is entered even if the cell already has a value specified. You can manually change the P1 value that was automatically added to a Risk Table. This action does not change the default **P1** value assigned to this specific Sequence of Events element.
Hazardous Situation	A situation in which a subject or object of the environment is exposed to one or more Hazards. Every Hazardous Situation can have a default **P2** value assigned as its property. To assign a value, open the Specification window of a Hazardous Situation, and set the desired **P2** value. **Adding P2 values** If you add a Hazardous Situation with a specified **P2** value to a certain row of a Risk Table for the first time, this value is automatically entered into an appropriate cell of the P2 column. The value is entered even if the cell already has a value specified. You can manually change the P2 value that was automatically added to a Risk Table. This action does not change the default **P2** value assigned to this specific Hazardous Situation element.
Harm	Damage to the health of people, damage to property or environment, or both. Every Harm can have a default severity (S) value assigned as its property. To assign a value, open the Specification window of a Harm, and set the desired **Severity** value. **Adding severity values** If you add a Harm with a specified severity value to a certain row of a Risk Table for the first time, this value is automatically entered into an appropriate cell of the S column. The value is entered even if the cell already has a value specified. You can manually change the severity value that was automatically added to a Risk Table. This action does not change the default severity value assigned to this specific Harm element.
S	Severity is the quantitative evaluation of the Harm that is caused if exposed to a Hazard. The valid values of this property are 1 to 4 (lowest to highest severity). Click an appropriate column cell to select its value from a drop-down list.

P1	Probability of a foreseeable Sequence of Events leading to a Hazardous Situation. The valid values of this property are 1 to 5 (lowest to highest probability). Click an appropriate column cell to select its value from a drop-down list.
P2	Probability of a Harm occurring when exposed to a Hazard. The valid values of this property are 1 to 5 (lowest to highest probability). Click an appropriate column cell to select its value from a drop-down list.
P	The function of P1 and P2.
D	Detectability measures the likelihood of discovering and correcting a Hazard prior to Harm occurrence. The valid values of this property are 1 to 5 (highest to lowest detectability). Click an appropriate column cell to select its value from a drop-down list.
C	Correctability is the rate of relative ease of mitigating a certain risk. The valid values of this property are 1 to 5 (lowest to highest correctability). Click an appropriate column cell to select its value from a drop-down list.
PU	Product Utility shows the clinical benefits of a product taking into account the risks it holds. The valid values of this property are 1 to 5 (highest to lowest clinical benefits that outweigh the risks). Click an appropriate column cell to select its value from a drop-down list.
Risk	The function of P and S.
Use Related	The property indicating a Hazard's relation to device usage. The values of this property can be one or multiple Use Cases.

Creating a Risk Table

To keep your model clean and simple, create a Risk Table in the package that contains the Safety Analysis Items to be included in the table.

To create a Risk Table

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1. Do one of the following:
   - Right-click the Package in which you want to create a Risk Table, and select **Create Diagram** from the menu.
   - Select the Package in which you want to create a Risk Table, and click the **Create Diagram** button on the main toolbar.
2. Click **Risk Table** under the **Safety and Reliability Analysis** group.
3. If needed, change the name of the newly created Risk Table.

A new Risk Table is created in the selected Package. Now, you should add Safety Analysis Items to the table, as described in the next section.

Adding Safety Analysis Items to a Risk Table

There are two ways to add Safety Analysis Items to a Risk Table:

- Create new Safety Analysis Items directly in the table.
- Add existing Safety Analysis Items to the table.

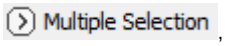
To create a new Safety Analysis Item in a Risk Table

- Do one of the following:
  - Click the **Add New** button on the table toolbar.
  - Press Insert (Cmd+I on Mac OS).

A new row containing the newly created Safety Analysis Item is added at the end of the table. In the model browser, the Safety Analysis Item is placed in the Package containing the related Risk Table. Now you can define the Safety Analysis Item directly in the table by double-clicking an appropriate cell.

Model structure information
To have a clear model structure, create Safety Analysis Items in dedicated Packages.

To add an existing Safety Analysis Item to a Risk Table

1. Do one of the following:
   - Click the **Add Existing** button on the table toolbar.
   - Press Ctrl+Insert (Cmd+E on Mac OS).
2. In the open dialog, select the Safety Analysis Item you want to add to the table. To select multiple elements, click 

, and add the desired Safety Analysis Items to the **Selected elements** area on the right side of the dialog.
3. Click **OK**.

Productivity tip

To make your work quicker, you can add existing Safety Analysis Items to a Risk Table by dragging them directly to the table. Simply select one or more Safety Analysis Items in the model browser, and drag them to a Risk Table. New rows for the added elements are created automatically.

Selected Safety Analysis Item(s) are now added to the Risk Table as new row(s). You can change the properties of the added elements directly in the table by double-clicking an appropriate cell.

Related pages

- Safety analysis
  - Describing reduced risks
  - FMEAs to be analyzed