

Design and development and risk management is not effective because evidence of a controlled process could not be demonstrated.

Statement of the problem

1. The risk management process VM3COP27.11 includes a scale of 1-4 for severity and occurrence, but does not identify how to determine the boundary/limits between scales.

Root cause

1.
We have not provided a clear definition of how to distinguish between the boundary/limits of the scale for severity and occurrence of the risk management process VM3COP27.11.
Our existing scale is based on levels 1-4, which is not in line with newer expectations which are based on levels of 1-5 Levels of risk.

1.

Immediate Action

We will initiate a review to look at what we have in place to determine the boundary/limits of the scale for severity and occurrence of risk.

To implement a scale of 1-5 Levels of risk.

Risk boundary limits per scale will be updated in each technical file individually.

Corrective Action

To make accessible and clear a definition of how to distinguish between the boundary/limits of the scale for severity and occurrence of risk.

The Risk Analysis Policy Definitions is being re-written in line with the current risk management process. With attention to EN 14971:2012

To review the implementation of the scale of 1-5 Levels of risk.

Risk boundary limits per scale need updating in each technical file individually and address probability scales. We will include the approach to routine component failure.