

	Procedure / Process <b>PRODUCT RECALL</b>	Date: 2024-12-10
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**PRODUCT RECALL**

This process defines what to do if a serious defect (non-compliance with a legal or regulatory requirement) or a risk to the user is identified or suspected.

The same procedure can also be applied in the event of a non-conformity relating to a packaging error (product deviates from that indicated on the packaging).

For the sake of simplicity, the term non-conformity is used in this text.

Note: This procedure does not replace other existing regulations for dealing with non-conformities and handling customer complaints.

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## Recognize non-conformity

The suspected non-conformity that could lead to a product recall can be identified in various ways:

- o internally before delivery
- o from a dealer customer
- o from a user customer

## Inform about non-conformity

As soon as the information about a non-conformity of a department is known to SPPW, the quality department must be notified as soon as possible.

## Analyze non-conformity

Based on the available information and samples, a 2-stage should be performed:

### 1 - Technology:

Analysis of whether there is a technical fault. Under the leadership of QA with the help of the technical department and, if necessary, with the assistance of the production facility.

Objective: Prompt confirmation or non-confirmation of the existence and scope of the problem, particularly with regard to the risk to the user. Search for the causes.

### 2 - Order processing and logistics

Parallel processing by the person responsible for QA in logistics + order processing

Creation of a dossier with as much available information as possible on the following aspects:

- Determine status and location of stocks (internal, subcontractor, consignment, etc ...)
- Create a list of customers who may have been supplied
- Collect identification features (delivery and manufacturing data, traceability elements, etc.)


## Deciding on non-conformity

Based on the analysis, the responsible departments (sales/technology/quality) decide which measures make sense and how they should be implemented:

Depending on the elements collected, the following gradation can be applied:

1. The case will not be pursued after the analysis
2. Only internal corrective and (or) preventive measures are carried out without commercial consequences
3. Customer information, return and exchange of customer stock. Possibly in consultation with the customer,
4. Immediate customer information if the analysis reveals a serious error or user risk.

Attached is a sample letter to be sent to the customer.

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(!) Important: If it turns out that the error poses a significant risk to the safety of users, the responsible supervisory authority (RP Gießen) will be informed and the nature of the problem and the measures taken and planned will be explained.

## Measures in the event of non-conformity


The details of the measures to be taken are determined on a case-by-case basis in view of the situation

## Monitoring and improvement

If a non-conformity has had an impact on the customer (from level 3 above), SPPW's departments must take one or more measures to prevent a recurrence.

It is at least a preventive measure on its own behalf or vis-à-vis a supplier or subcontractor.

In addition, the "product recall" process is reviewed in the light of developments in the case in order to improve its effectiveness where necessary.

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ANNEX: Sample letter to customers in the event of non-conformity

Address

for the attention of

Subject: Non-conformity / defective product <article number

Dear customer,

Our product <product name> has been found to be non-compliant.

We immediately took the following measures.

- a
- b
- c

According to our records, you were supplied with this faulty product.

If you are in possession of a product that does not meet the requirements, please do the following

- To discontinue further sales of the product
- to inform SPPW about the discontinuation of the sale
- To secure the defective products and return them to us

We apologize for the inconvenience this issue has caused and remain at your disposal for further information.

Yours sincerely

SPPW customer service