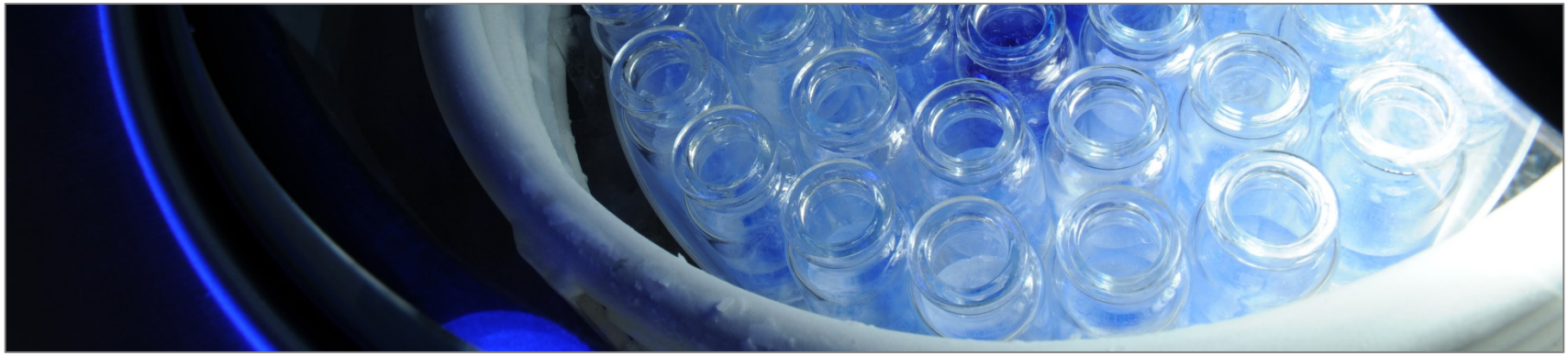
Practice 10, PDA-Seminar

Maintenance and fault correction

2018 PDA Europe
Freeze Drying in Practice



Outline

CHAPTER I: Introduction to a preventive maintenence concept

- What is & Why maintenance ?
- PM, CM, PdM
- Responsibility

CHAPTER II: Introduction to the most frequently occuring faults

- Diagnosis, causes, correction
- Failure report
- Presentation of examples of def. Components with explanation of causes

CHAPTER III: Documents

- Overview
- AMC, Maintenace Plan, Checklist, Protocol
- Spare parts

Introduction to a preventive maintenance concept

What is Maintenance?

- **Definition**: „*Activities required or undertaken to conserve as nearly and as long as possible the original condition of an asset or resource while compensating for normal wear and tear.”*
- **Important**: *Maintenance is the combination of all technical and associated administrative actions intended to retain an item in, or restore it to, a state in which it can perform its required function*. → Responsibility

- Types of Maintenance:

  ! Note that there is a difference between the European standard EN31051 and EN13306! DIN EN 13306 does not explicitly name or define these basic measures like DIN 31051, instead it is structured in maintenance types which differ concerning the time and place of execution. Manufacturers and industrial-supply companies often refer to “MRO” (maintenance, repair and overhaul) which also includes different planned measures and actions to keep equipment in working order.

  Generally there are two commonly known types of maintenance in use:

  - Preventive and scheduled maintenance – before breakdown or other problems
  - Corrective maintenance – after wear, malfunction or breakdown

Why Maintenance?

- Maintenance is required to …
  - …assure faultless operation
  - …prevent large and costly repairs
  - …avoid time consuming failure analysis in case the root cause is not obvious
  - …prevent downtime and therefore production loss
  - …avoid (hazardous) risk to operators
  - …set a defined (validated) status of equipment as per protocol

Compare different maintenance tasks as a single or combined action
Which of below measure is a appropriate maintenance concept?

Maintenance concepts

preventive maintenance	scheduled maintenance	Corrective maintenance	Predictive maintenance

PM: Preventive maintenance

- The primary goal of PM is to avoid consequences of failure of equipment.
- This may be by preventing the failure before those actually occur or turn into major defects by following actions:
  1. Daily systematic check-ups & inspection
  2. Calibration, measurements & adjustments
  3. Planned shutdowns or
  4. Annual maintenance as per „maintenance protocol“ or „checklist“
     - replace gaskets, o-rings, membranes
     - replace or refill liquids
     - grease, paint, insulate,…

PM = relies on average and expected life statistics to predict when maintenance will be required.

CM: Corrective maintenance

- CM is a maintenance task performed to identify, isolate, and rectify a fault so that the failed equipment, machine, or system can be restored to an operational condition within the tolerances or limits

- A corrective action to bring back to system into an operational state by
  - replacing defective components
  - repair damage or defective components or modules

- Negative impact:
  - is the time delay (down time of machine)!
  - Lead time for planning, spare parts and manpower
  - Especially within a GMP environment not acceptable approach.

CM = Restore systems functionality after occuring failures.

PdM: Predictive maintenance

- PdM techniques are designed to help determine the condition of in-service equipment in order to predict (forecast) when maintenance should be performed.

- For PM it is necessary to permanent collect data from the actual condition of the equipment.
  - Compare batch records for abnormalities (i.e aging effects)
  - Frequency of actuations or switching frequency (i.e. valves)
  - Running times of equipment and stress analysis

- Positive: right action in the right time. Cost efficient.

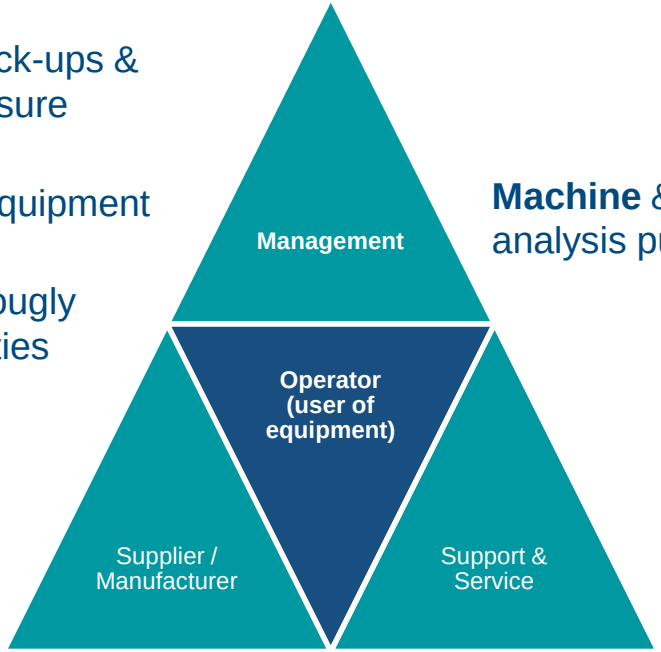
PdM = differs from PM because it relies on actual condition of equipment. PM relies on average and expected life statistics.

Responsibility - Maintenance is not a one man show!

Maintenance is an administrative responsibility! It is a **management** issue to provide resources, money and time to plan maintenance

Operator follow Daily systematic check-ups & inspections recommendations and assure availability of peripheral media: PM

- Operators are responsible for equipment (DGUVV3) (EN378)
- Operators are responsible thorougly documentation towards authorities



Machine & **Operator** collect data for analysis purpose: PdM

Suppliers provide documents (Maintenance-Plan) acc. to OEM documentation and detailed lifetime considerations (Failure reports).

Support provides service according to Maintenance-Checklist/Protocol: PM

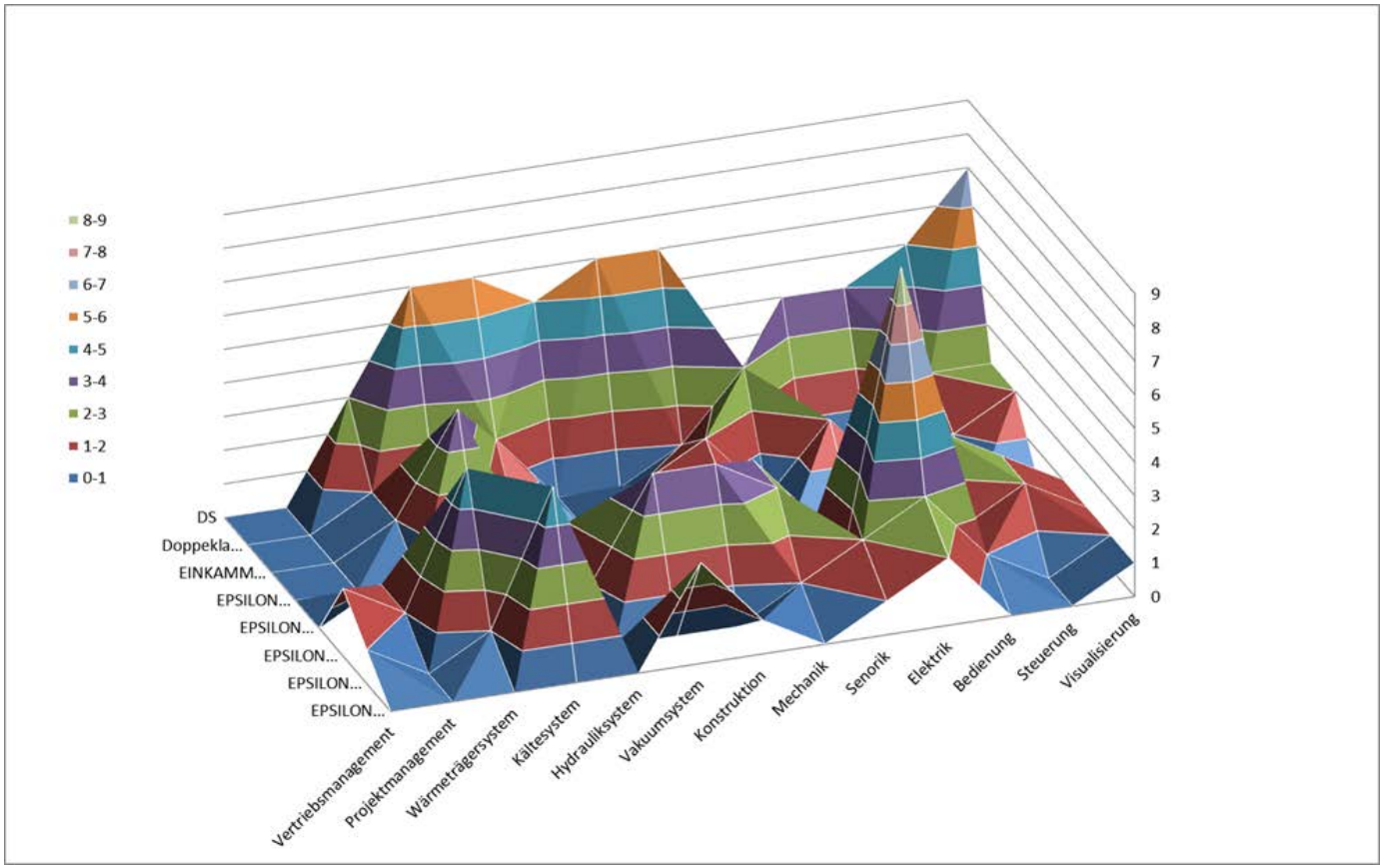
Maintenance conclusion

- A appropriated maintenance concept is based on a maintenance plan
- A maintenance plan (individually adapted) provides required information and based on that a maintenance protocol is generated
- The maintenance protocol provides requirements and recommendations for the user and operator to assure and increase availability of the equipment and helps to discover wear and tear in defined intervals.
- Supplier or distributors provide maintenance contracts (AMC). This should include a mixture of inspection and replacement of wear parts. Advantage: Customer are always on the safe side as suppliers latest finding (weak point analysis, improvements) can be considered during PM.
- Critical items/parts are stored near the machine to reduce lead time for order and shipping.

Introduction to the most frequently occurring faults

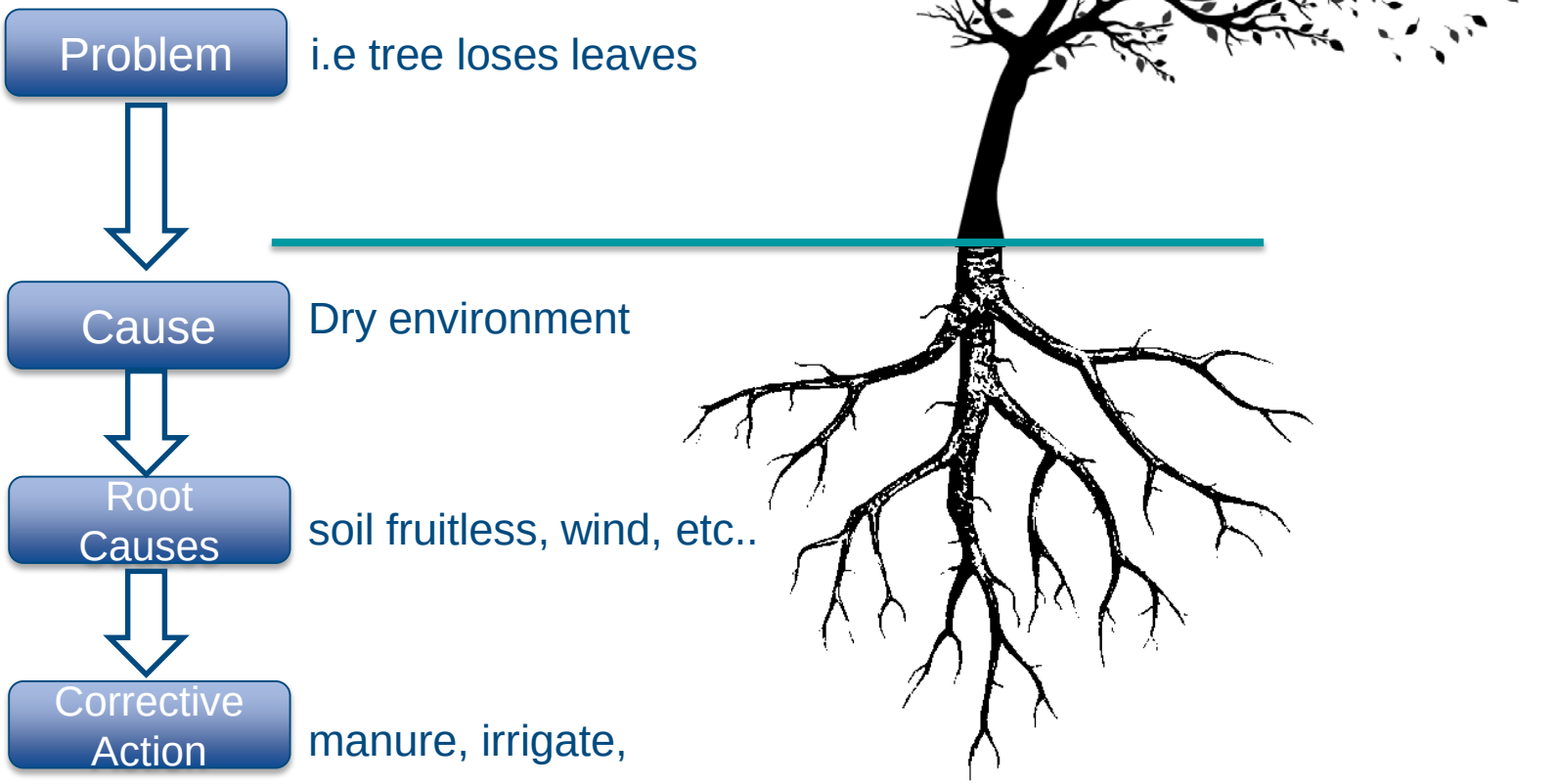
Failure and fault report

- Definition of fault: „a defect, imperfection or wrongful act“ -> abnormality
- A database of failures can help to trace weak points and help to generate remedial actions (graphic shows peaks and valleys)



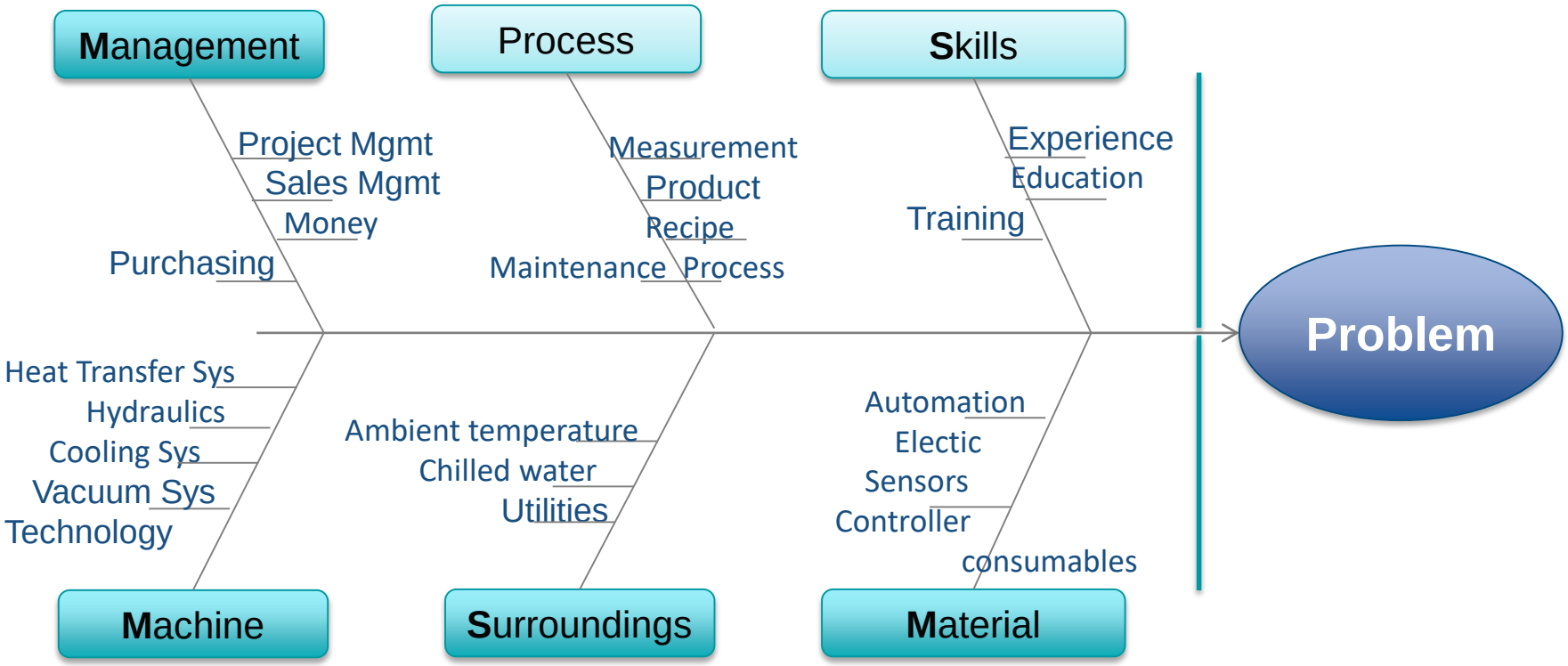
Diagnosis, causes, correction

Each failure (effect) has a source of different causes.
We are trying to find the *root cause* of a problem



Diagnosis, causes, correction

Root cause analysis is going back to the 60th, were *Kaoru Ishikawa* invented a diagram
Root cause analysis is intended to reveal relationships
Each potential cause is tracked back to reveal the root cause (The 3Ss , 5Ms)



Database collecting and sort data

The more complex a functional unit, the more components involved

Collect and transfer all data (facts) into Database and investigate

Draw major categories; i.e. Management, Process, Skills, Material, Environment

Categorize and brainstorm causes

Start questioning (Why) to determine deeper causes and identify root causes

Introduction to the most frequently occuring faults

General terms:

- Failure database: gathering failures and incidents to determine critical points (week point analysis) to prevent „frequently occuring faults“
  - Using methods such as 5D or 8D reports (D = disciplines)
  - Asking the following to reveal the trigger
    1. Effect: What happened ?
    2. Action: Emmediate resonse required by/with ?
    3. Measure: How to solve it ?
    4. RCA: Why did it happen ?
    5. Virtue: How to avoid in future ?

- Just identifying and replacing i.e a defective component is not the solution – RCA (root cause analysis) starts at this point with questioning.

Pictures taken from incidents

Effect: vacuum leak observed during Sublimation-phase.
Cause: destroyed/burned diaphragm of steam inlet valve

- Why is the membrane destroyed?
- Why not replaced/uncovered?
- Why was the membrane beyond its useful service life?
- Why not capable to resist steam temperature?

- No manufacturers batch issue
- No missing maintenance as it was replaced a week before
- Not installed in a wrong manner

Root cause:

- Steam gernerator runs at wrong offset
- Steam temperature to high (pressure) and exceeding the spec limit.
- Operators trained according to utility specification

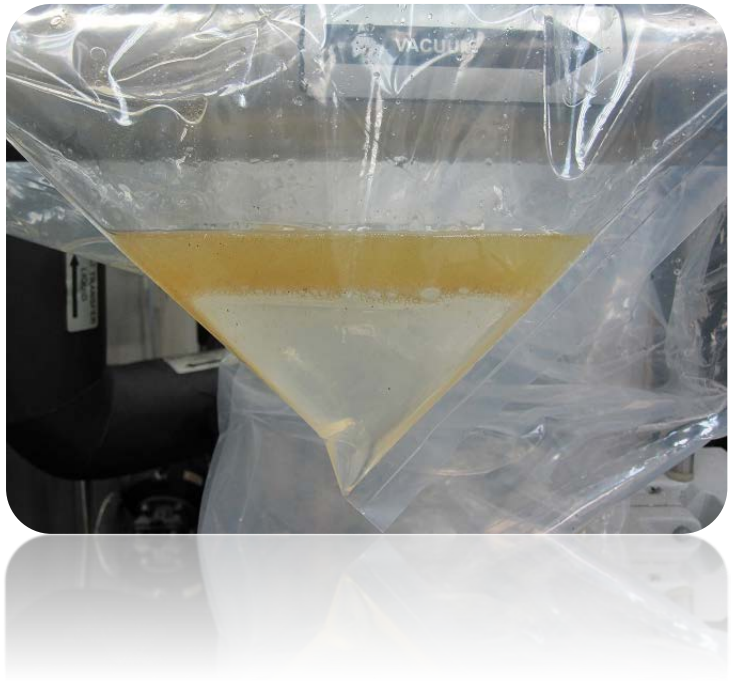
Pictures taken from incidents

Effect: Vacuum performance out of spec.
Cause: Vacuum pump oil mixed with condensate (water).

- Why is the oil was contaminated?
- Why vapor was not captured by ice condenser?
- Why the oil was not replaced?
- Why not adapted the recipe?

- No program/recipe change as validated cycle
- Not replaced as not uncovered

Root cause:
- Recipe created lots of vapor
- Ice condenser capacity reached
- Operators do not change oil frequently



Pictures taken from incidents

Effect: overload of Vacuum Pump motor.
Cause: Blocked Vacuum Pump exhaust filter

Root cause:

- No maintenance happened
- Operators not aware (trained)

Pictures taken from incidents

Effect: Refrigeration System fails due to excess pressure
Cause: Algae causes insulation layer in watercondenser

Root cause:

- No maintenance happened
- No agent added to chiller (i.e. glycol)

Pictures taken from incidents

Effect: Vacuum leakages
Cause: Porous o-rings

Root cause:

- „No maintenance“ philosophy by management

Pictures taken from incidents

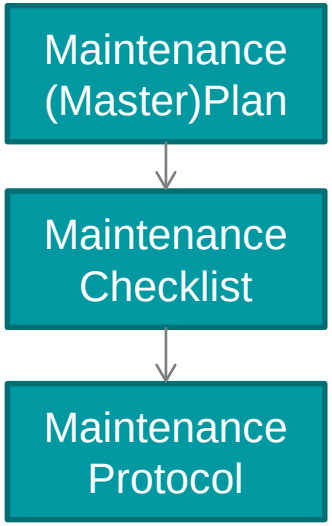
Effect: Leaking silicon oil though ss-hose
Cause: pinhole at stainless steal hose

Root cause:

- No 10 year maintenance happened
- Friction between hoses, routing to be optimized

Documents

Document order and content



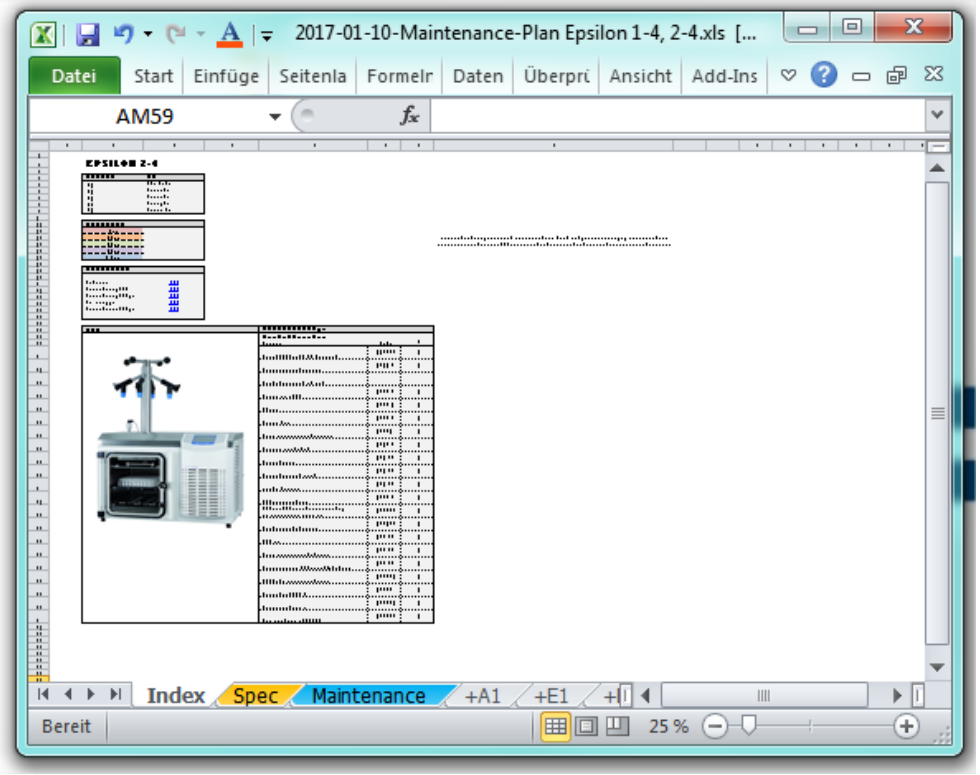
Includes all necessary information: What, how, specs, spares, maintenance, OEM manuals, P&ID and electrical drawings …
Maintenance Plan also considers issues from our „Failure Report database“

Overview of recommend tasks and interval shown in the user manual and provided to customers

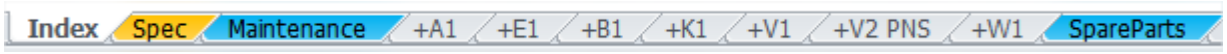
Maintenance protocol describes all point of checklist in protocol manner.

Maintenance Plan

Maintenance (Master)Plan



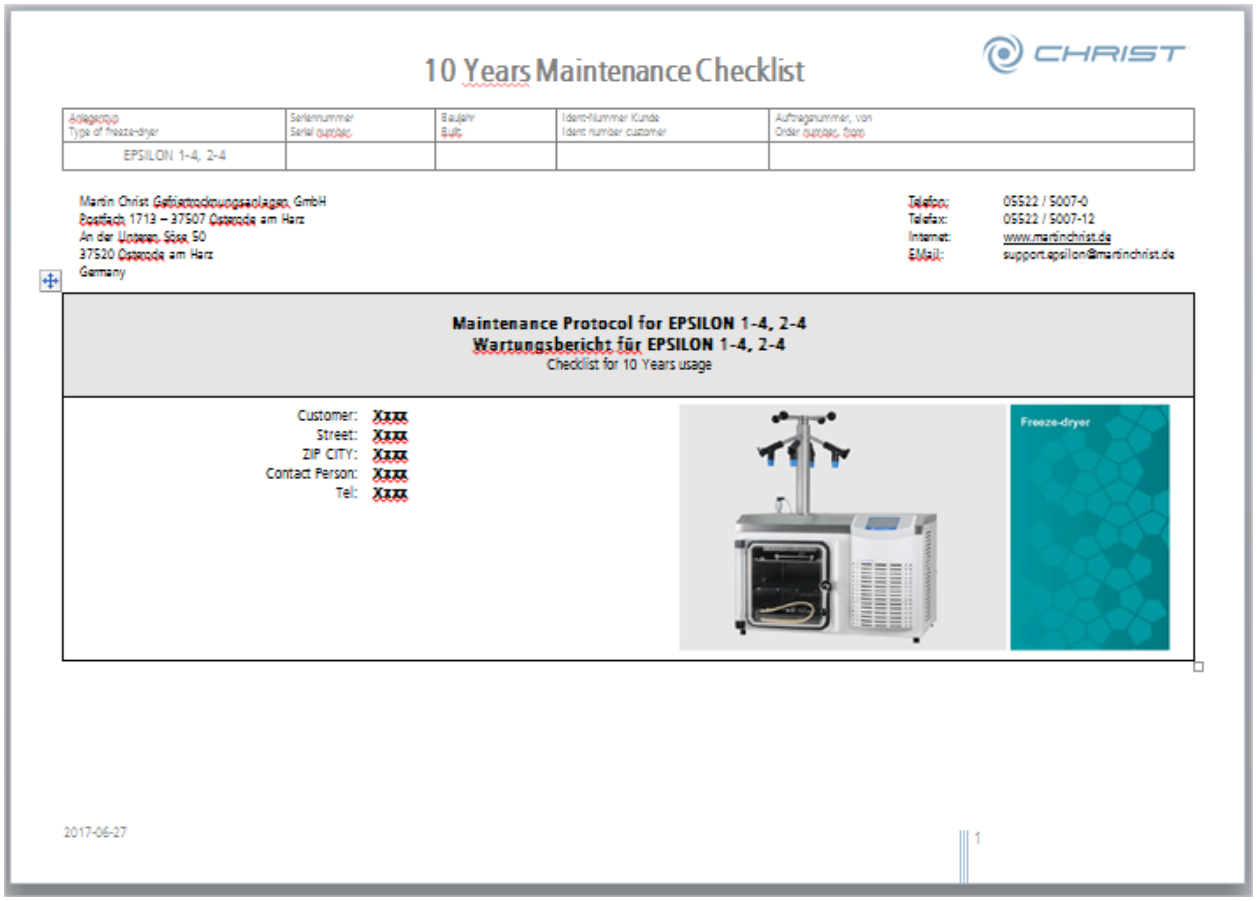
- Structure according to electrical drawings E-Plan



Maintenance Checklist

Maintenance Checklist

- Checklist with overview



10 Years Maintenance Checklist

Anlagentyp Type of freeze-dryer	Seriennummer Serial number	Baujahr Built	Ident-Nummer Kunde Ident number customer	Auftragsnummer, von Order number, from
EPSILON 1-4, 2-4				

Martin Christ Gefriertrocknungsanlagen GmbH
Postfach 1713 – 37507 Osterode am Harz
An der Unteren Söse 50
37520 Osterode am Harz
Germany

Telefon: 05522 / 5007-0
Telefax: 05522 / 5007-12
Internet: www.martinchrist.de
EMail: support.epsilon@martinchrist.de

Maintenance Protocol for EPSILON 1-4, 2-4
Wartungsbericht für EPSILON 1-4, 2-4
Checklist for 10 Years usage

Customer: Xxxx
Street: Xxxx
ZIP CITY: Xxxx
Contact Person: Xxxx
Tel: Xxxx

Freeze-dryer

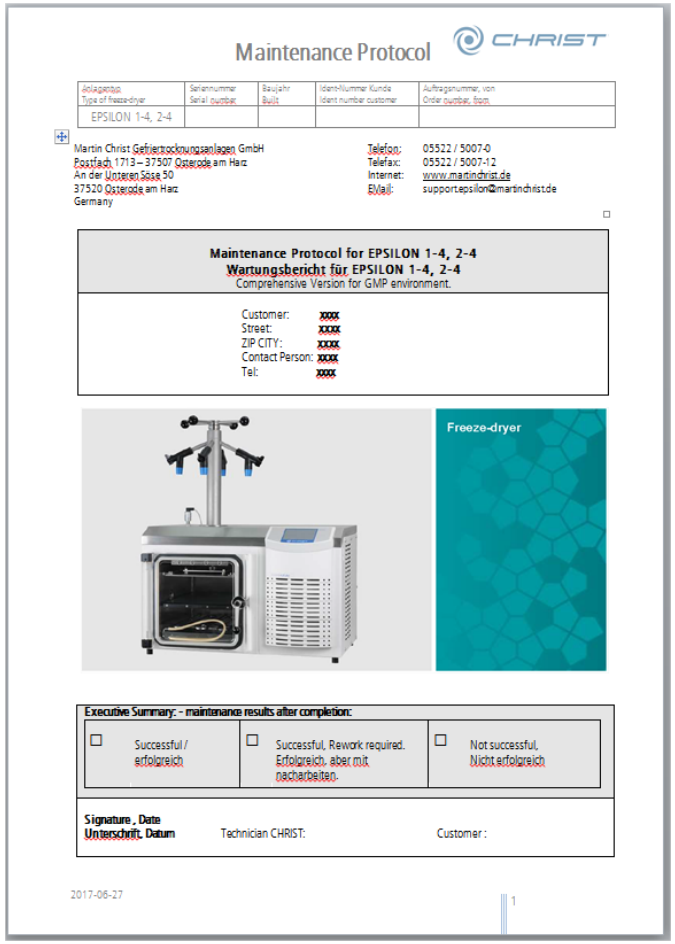
2017-06-27

1

Maintenance Protocol

Maintenance Checklist

- Maintenance plan to prove actions taken



Maintenance Protocol

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Martin Christ Gefriertrocknungsanlagen GmbH
Postfach 1713 – 37507 Osterode am Harz
An der Unteren Söse 50
37520 Osterode am Harz
Germany

Telefon: 05522 / 5007-0
Telefax: 05522 / 5007-12
Internet: www.martinchrist.de
EMail: support.epsilon@martinchrist.de

Maintenance Protocol for EPSILON 1-4, 2-4
Wartungsbericht für EPSILON 1-4, 2-4
Comprehensive Version for GMP environment.

Customer: xxxx
Street: xxxx
ZIP CITY: xxxx
Contact Person: xxxx
Tel: xxxx

Freeze-dryer

Executive Summary: - maintenance results after completion:

☐ Successful / erfolgreich	☐ Successful, Rework required. Erfolgreich, aber mit nacharbeiten.	☐ Not successful, Nicht erfolgreich

Signature , Date
Unterschrift, Datum Technician CHRIST: Customer :

2017-06-27

Contact

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