Theory 7, PDA-Training Course

Maintenance and fault correction

2022 PDA Europe
Freeze-Drying in Practice

Outline

CHAPTER I: Introduction to a preventive maintenance concept

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

CHAPTER II: Introduction to the most frequently occurring faults

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

CHAPTER III: Documents

- Overview
- AMC, Maintenance 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:
  European standard EN31051 explicitly names and defines basic measures and is structured in maintenance types.

  „Maintenance” is a combination of different administrative and technical measures

  - Inspection
  - Preventive and scheduled maintenance
  - Corrective maintenance
  - Improvement

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

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

Maintenance tasks

Inspection	preventive maintenance	Corrective maintenance	Predictive maintenance	Improvement
				
assessing the actual condition of a unit	activites to reduce wear stock	after wear, malfunction or breakdown	techniques that help forcasting maintenance	a process making something better

PM: Inspection and Preventive maintenance

- The primary goal of PM is to avoid consequences of failure of equipment.
- This can be done by preventing the failure before they actually occur or turn into major defects by the 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 occurring 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.

IMP: Improvement maintenance

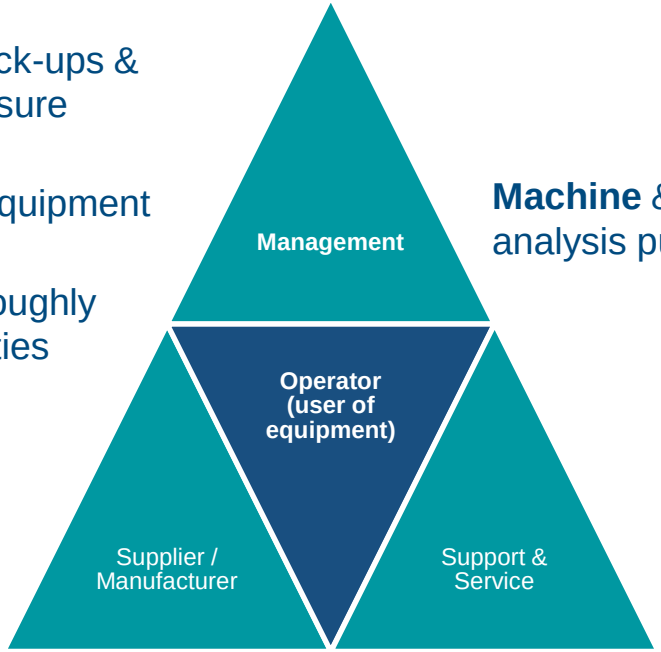
- Techniques undertaken to make an asset better or more capable to its duties
- Improvements can include
  - replacing components with more sustainable, rugged or accurate of its kind
  - Updates for software, firmware, operating system,..
  - Replacement of gases, liquids (i.e. refrigerants phase-down)
  - Retrofit, overhaul
- Positive: keep the system up to date with lates technology

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 thoroughly 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

Suggest improvements, updates, …

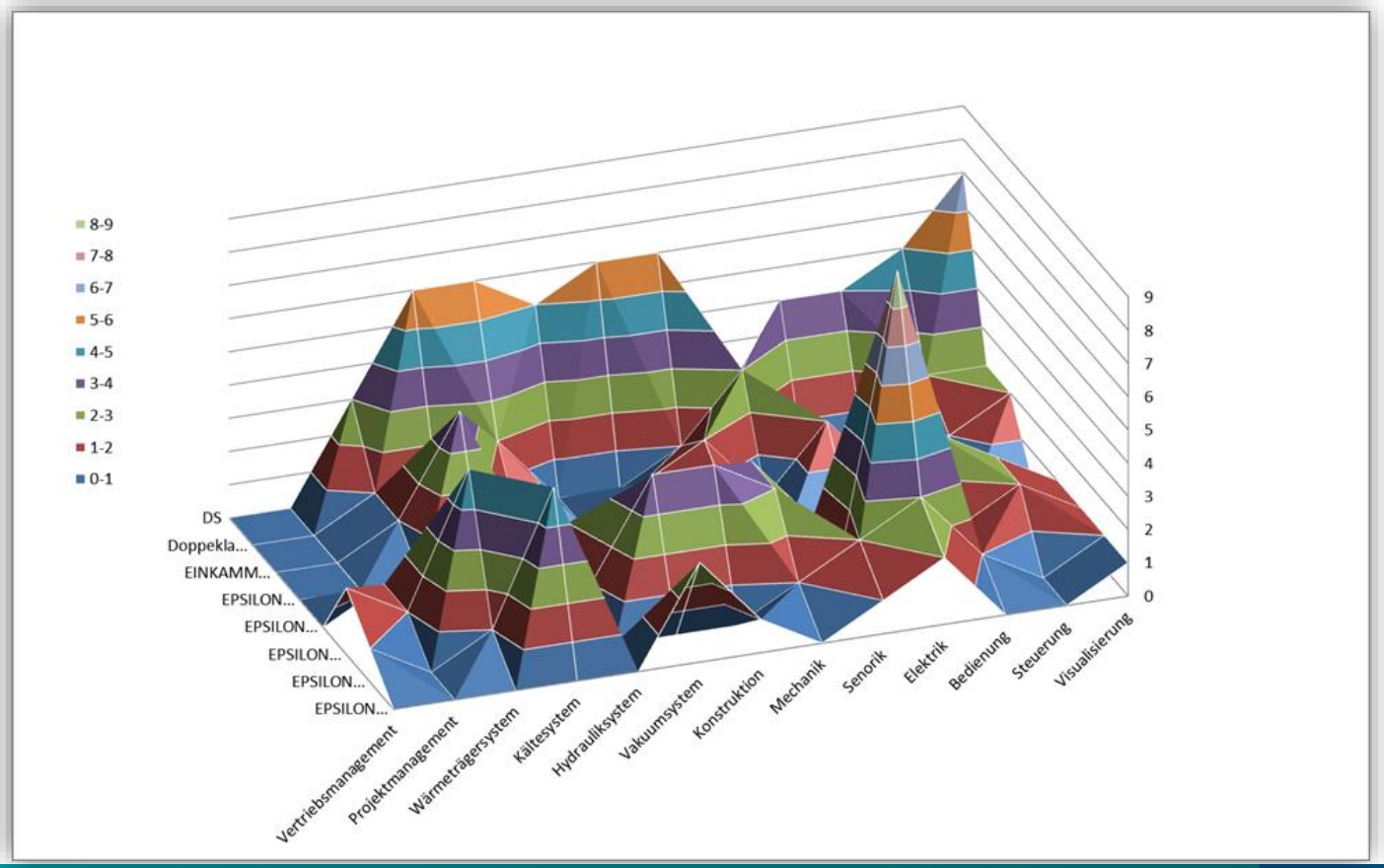
Maintenance conclusion

- An 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

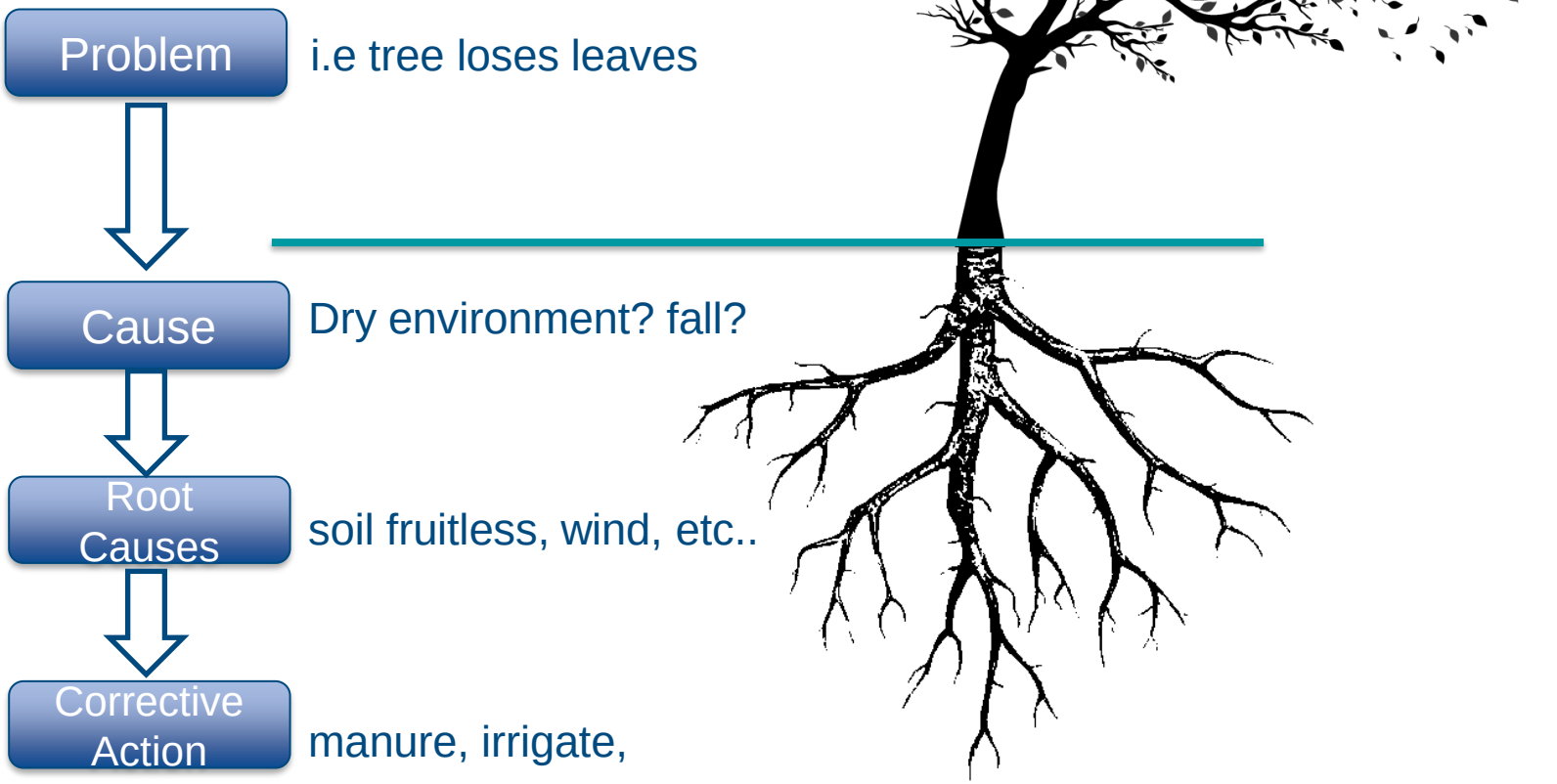
Failure and fault report

- 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)



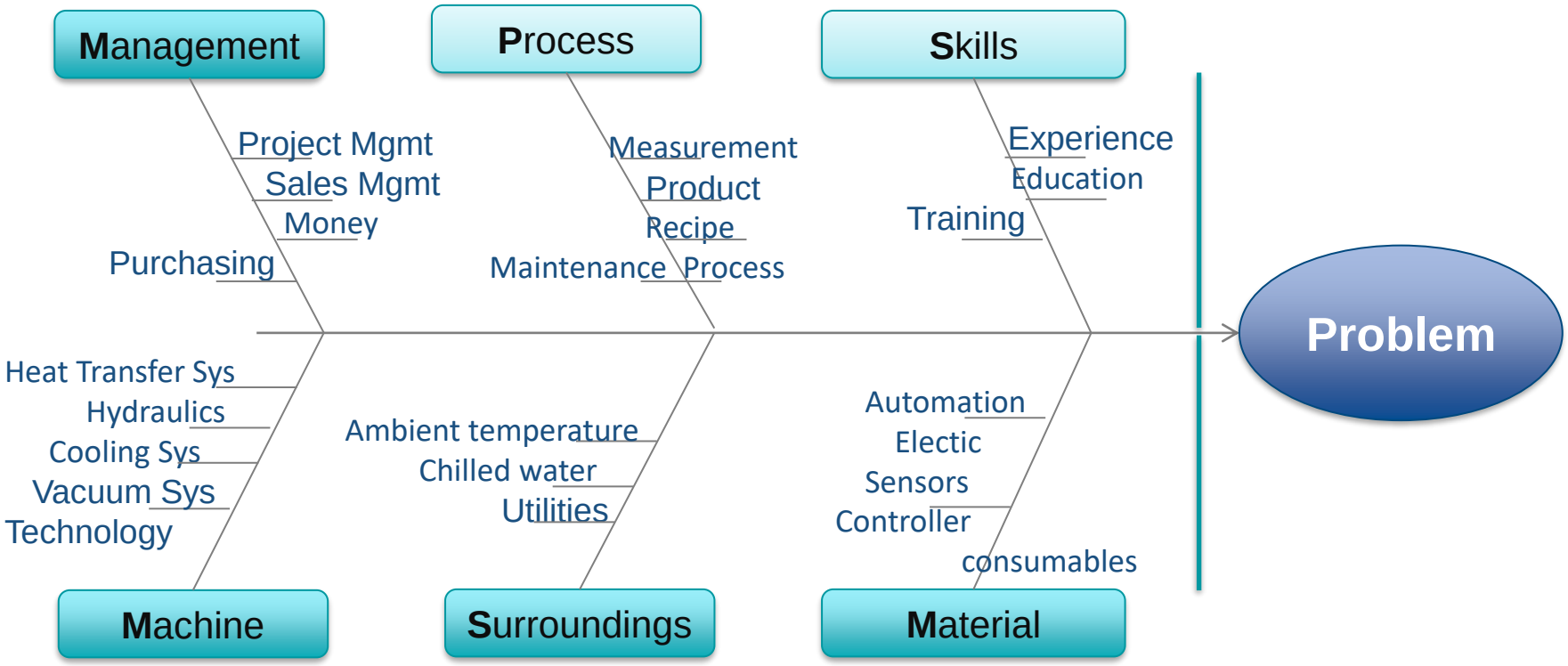
Diagnosis, causes, correction

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 occurring faults“
  - Using methods such as 5D or 8D reports (D = disciplines, automotive)
  - Asking the following to reveal the trigger
    1. Effect: What happened ?
    2. Action: Immediate response 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.

- Similar approach is 6σ - DMAIC (Define - Measure - Analyse - Improve – Control)

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

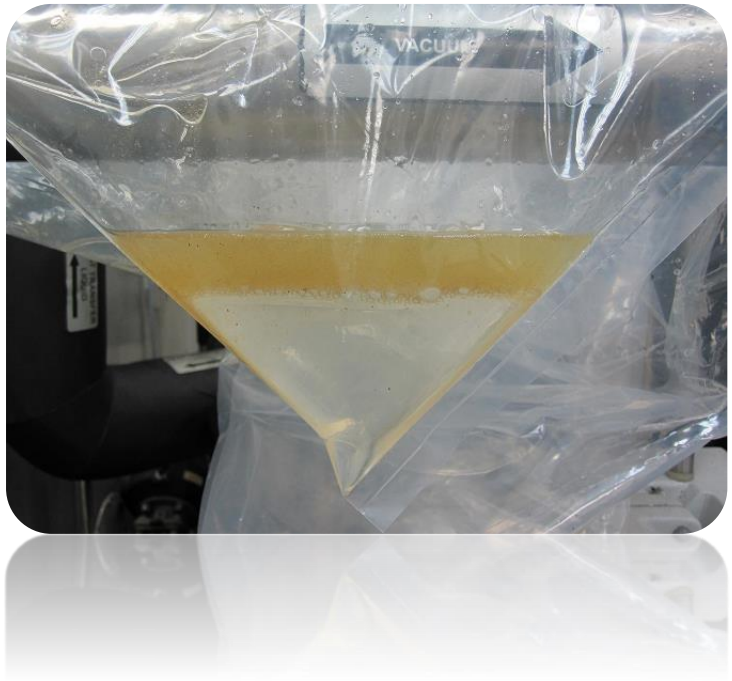
Pictures taken from incidents

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

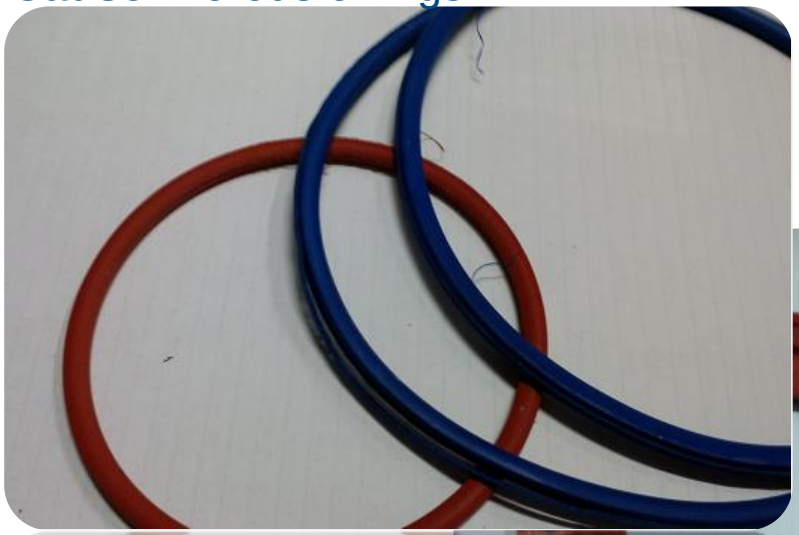
Effect: Refrigeration System fails due to excess pressure
Cause: Algae causes insulation layer in watercondenser

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

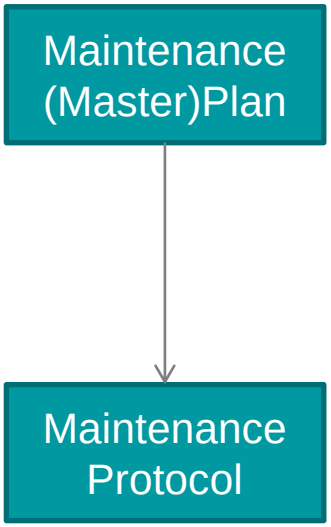
Effect: Leaking silicon oil though ss-hose
Cause: pinhole at stainless steal hose

Root cause:

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

Documents

Document order and content

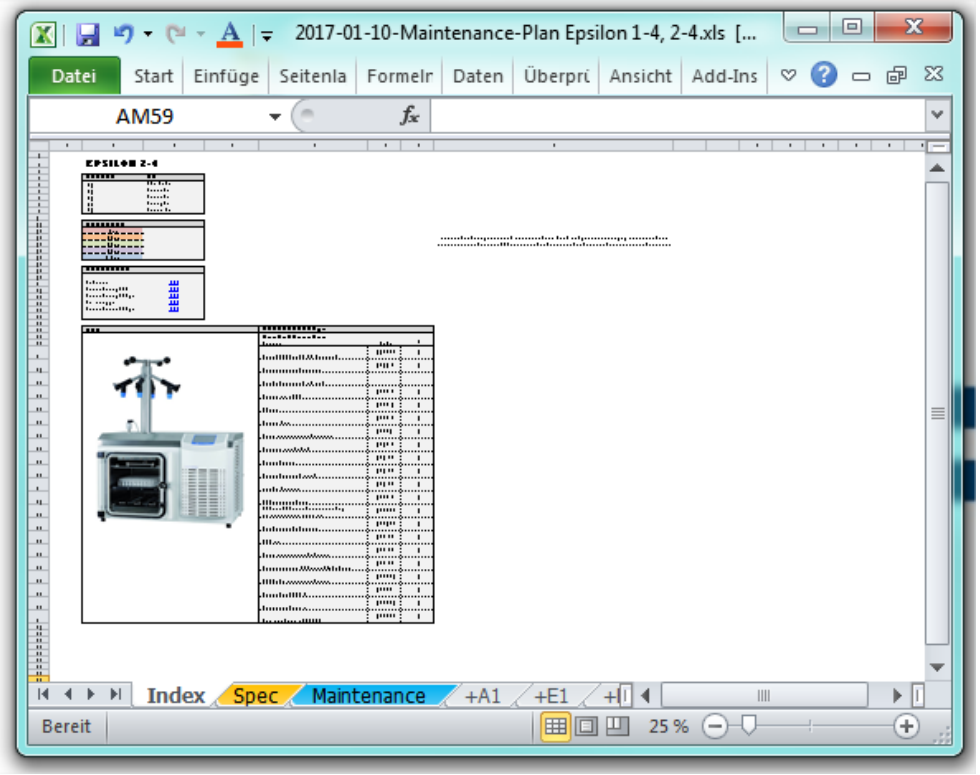


Includes all necessary information: What, how, specs, spares, maintenance, OEM manuals, P&ID and electrical drawings …
Maintenance Plan also considers issues from our „Failure Report database“

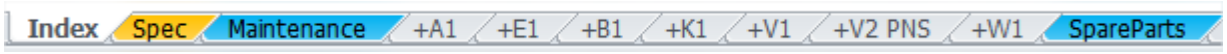
Maintenance protocol describes all relevant points in a protocol manner.

Maintenance Plan

Maintenance (Master)Plan



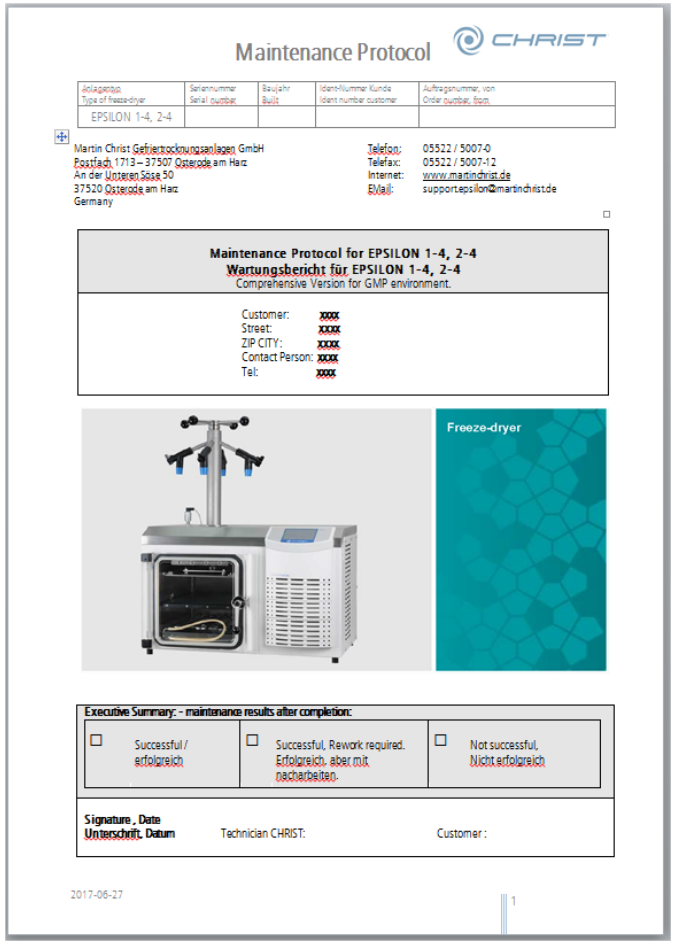
- Structure according to electrical drawings E-Plan



Maintenance Protocol

Maintenance Checklist

- Maintenance plan to prove actions taken



Maintenance Protocol

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
Comprehensive Version for GMP environment.

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

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 :

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Questions?

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