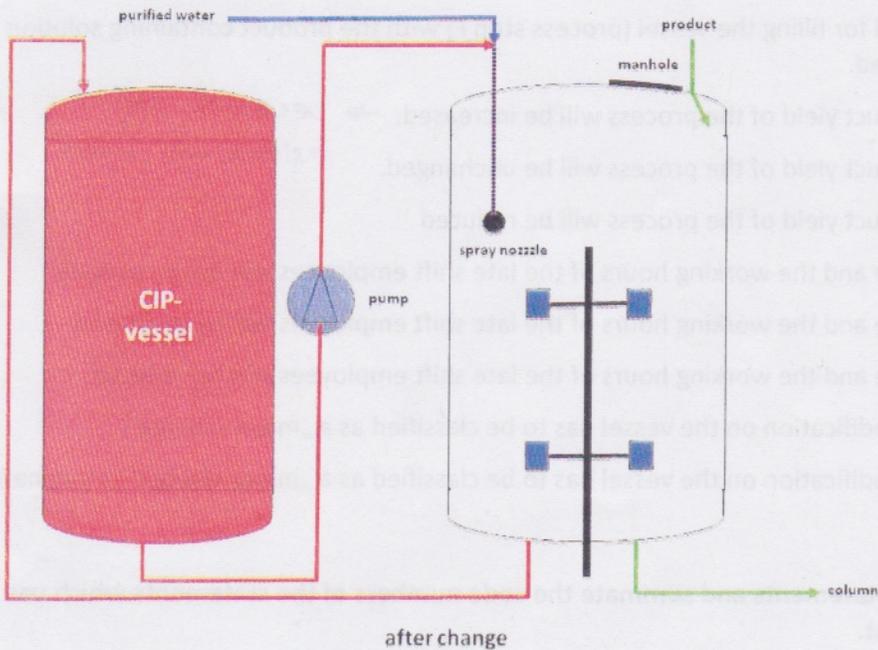
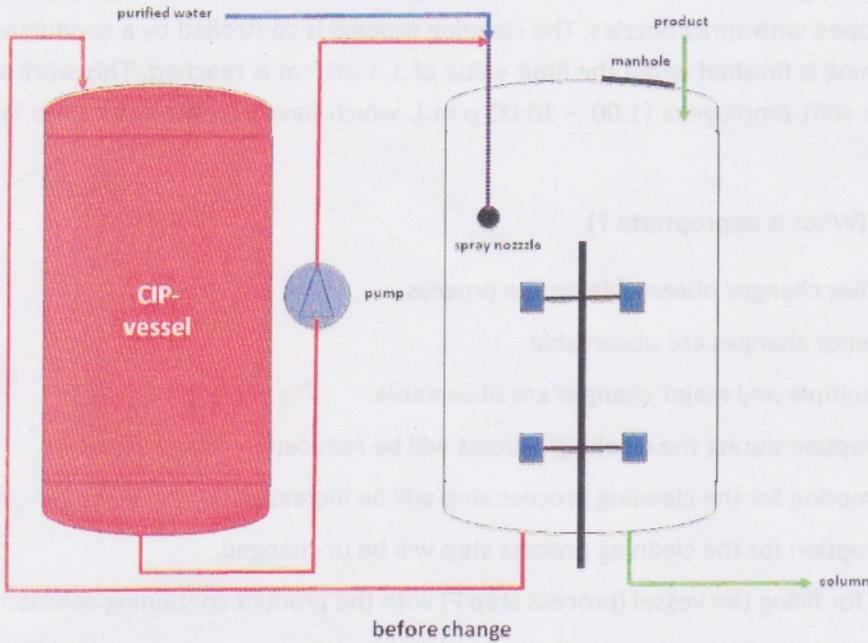


CASE STUDY

Participant:

On behalf of the department for operational safety the feed pipe of a 3000 L vessel which was installed beside the manhole was prolonged and curved aside as shown in the figures:



Reasons for the application: Service technicians has injured by the feed pipe their shoulders during climbing in and out the vessel for maintenance of the stirring device repeatedly.

Development of analytic tests is much faster than drugs (10-15a)

The vessel is used throughout a monoclonal antibody purification process once a week for sampling the protein containing solution after a downstream step (transfer from an other vessel after ultrafiltration = process step F). The product solution is pumped from there slowly to a chromatography column.

After draining the vessel the cleaning of the vessel is started with an automated cleaning-in-place-system (CIP-System) with high concentrated hot sodium hydroxide solution and highly purified water. The vessel is equipped with spray nozzles. The cleaning process is controlled by a conductivity- and pH-sensor. The cleaning is finished when the limit value of 1,3 mS/cm is reached. This work step is supervised by the late shift employees (1:00 – 10:00 p.m.), which have flexible work time labor conditions.

What may be the case ? (What is appropriate ?)

- 01 There are no further changes observable on the process.
- 22 On the process minor changes are observable.
- 33 On the process multiple and major changes are observable.
- 14 The water consumption during the cleaning process will be reduced.
- 25 The water consumption for the cleaning process step will be increased.
- 36 The water consumption for the cleaning process step will be unchanged.
- 27 The time needed for filling the vessel (process step F) with the product containing solution will be reduced.
- 38 The time needed for filling the vessel (process step F) with the product containing solution will be increased.
- 49 The time needed for filling the vessel (process step F) with the product containing solution will be unchanged.
- 20 The overall product yield of the process will be increased. → because of less foam on the insides of vessel
- 31 The overall product yield of the process will be unchanged.
- 42 The overall product yield of the process will be reduced
- 03 The process time and the working hours of the late shift employees will be unchanged.
- 14 The process time and the working hours of the late shift employees will be increased.
- 35 The process time and the working hours of the late shift employees will be reduced.
- 66 The technical modification on the vessel has to be classified as a „major change“.
- 77 The technical modification on the vessel has to be classified as a „minor change“ (marginal)

Assign the appropriate statements and summate the code numbers of the statements which you have selected as relevant.

Amount: 217

Much higher yield → more money, but authority gave high penalty because chromatography column wasn't ausgelegt für so viel Protein.

Lehre daraus:
Dr. U. Behrendt

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page 2 of 2

Personal darf nicht mal so kleine Änderungen ohne Permission durchführen