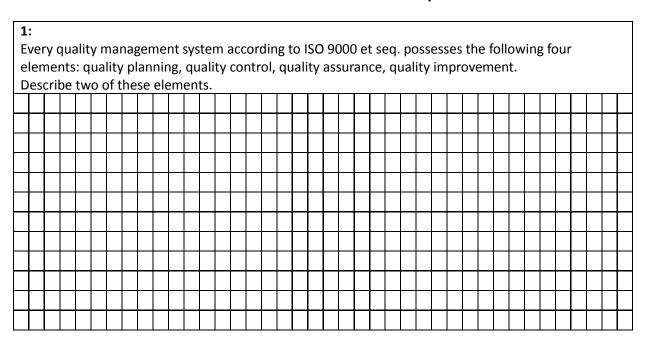
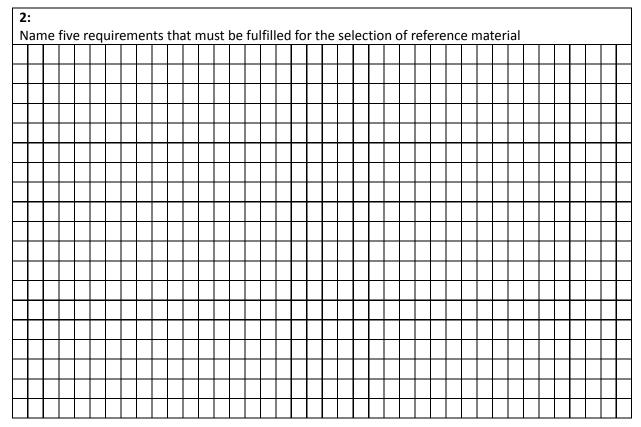
Technische Universität München Analytical Research Group PD Dr. Thomas Letzel; PD Dr. Johanna Graßmann Exam Questions – Part 2 – Unbound task Elective Subject Quality Management

Questions from the "PAL Prüfungsbuch" Quality Management All tasks are to be scored with 10 to 0 points









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One demand made on a set of quality rules is the creation of standard work instructions. Name **three** examples each for

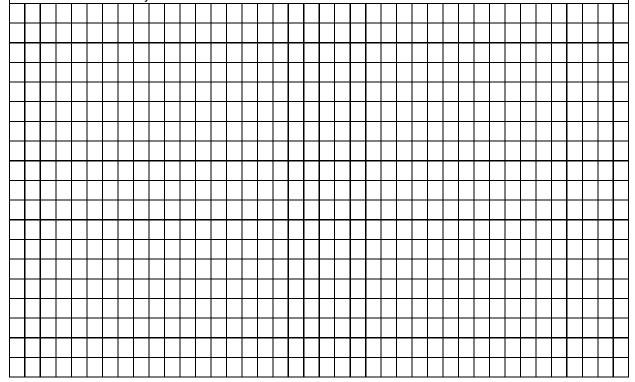
- formalities
- content of work instructions

Formalities	Content of a work instruction

4:

One demand within the framework of accreditation procedures in accordance with ISO 17025 is the participation in round robin tests.

- 1. Explain the term "round robin test"
- 2. Name two objectives of round robin tests







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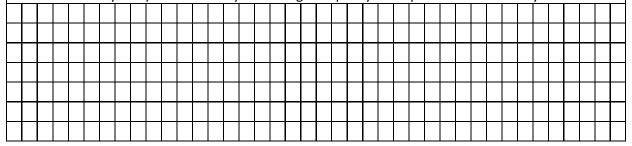
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5:

Within the control of its production procedure a company requires the hourly determination of the density of a product with an accuracy of at least 1.0 percent.

Laboratory A tests hourly and guarantees an accuracy of 1.0 percent. Laboratory B tests every 45 minutes and guarantees an accuracy of 0.6 percent. Laboratory B is 3% more expensive than laboratory A.

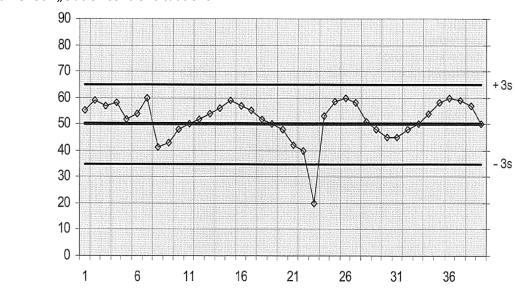
Which laboratory complies most likely with the given quality concept? Give reasons for your answer.

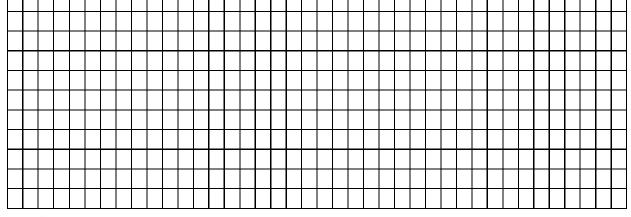


6:

The following illustration shows registration marks in a control chart.

Name four "Out-of-control-situations"









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7:
A sample matrix that is free of active substances is spiked with an active ingredient. The active ingredient has a certified purity of 98.0%. Three samples with different amounts of spiked active ingredient have been prepared. The analysis gave the following results:

Added amount of active ingredient with w(active ingredient) = 98,0%

100 mg

99.8 mg

Added amount of active ingredient with w(active ingredient) = 98,0%	Found amount of active ingredient
100 mg	99,8 mg
200 mg	192,4 mg
300 mg	278,5 mg

- 1. Calculate the recovery rate RR (in %) for each case
- 2. Specify how the found deviation of the above stated process is called

1)	Added amount of active ingredient with w(active ingredient) = 98,0%												Found amount of active ingredient													RF	ł							
		100 mg												99,8 mg																				
		200 mg											192,4 mg																					
	300 mg													278,5 mg																				
2)																																		
																																		n





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8

For the calibration of a process the fall time (in s) of a ball in the Höppler viscometer was measured ten times. From the measured values given below the following values are to be calculated:

- Arithmetic average x
- Median M
- Span width R
- Standard deviation s
- Variation coefficient VC (relative standard deviation RSD)

Measured values:

85.6	86.3
84.7	85.2
83.5	86.0
84.8	84.9
85.1	84.1

