Quality Assurance in the Laboratory

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Why a Quality Assurance System?

- To carry out the tests and research activities in a demonstrable good and controlled way
- To obtain accurate results
  - *For the correct sample*

International Standard

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

ISO/IEC 17025 requirements

- Management requirements
- Technical requirements

ISO/IEC 17025
Management Requirements

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Organisation

- Responsibilities and authorities of employees
- Supervision of staff
- Protection of confidential information
- No internal or external inappropriate pressure

Document Control

- Review and approval of documents
- Use of actual, authorised documents
- Change of documents

Review of requests, tenders and contracts

- Ensure that
  - The requirements are adequately defined and understood
  - The laboratory has the capability and resources to meet the requirements
  - Appropriate tests are selected

Purchasing services and supplies

- Selection of suppliers
- Tests for incoming materials

Complaints and non conformances

- Registration
- Cause analysis
- Corrective and preventive actions
- Evaluation
- Continuous improvement

Control of records

- Original observations
- Readily achievable
- Changes in records

Internal audits and management review

- Internal audits
  - Audit plan – yearly all elements of the system
  - Corrective actions
  - Follow up
- Management review
  - Review of the quality management system to ensure continuing suitability and effectiveness

ISO/IEC 17025
Technical requirements

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Personnel

- Competence – relevant knowledge and experience
- Training and development
- Job descriptions

Test methods and method validation

- Appropriate methods (fit for purpose)
- Preferably international or national standards
- Validation of methods necessary for own developed methods and non-standard methods
- Estimation of uncertainty of measurement
- Control of data (calculations and data transfers)

Equipment

- Comply with specifications, relevant to the tests
- Operating instructions
- Identification
- Preventive maintenance
- Calibration

Handling samples

- Receipt
- Identification
- Handling
- Storage
- Disposal

Assuring the quality of test results

- Internal controls
  - reference materials,
  - replicate tests
- Retesting samples (unknown to the analyst)
- Proficiency testing or inter-laboratory comparison

Reporting the results

- Detailed specifications with respect to the content of the report

Accreditation

- Assessment of compliance to the quality system requirements by an independent organisation

Daily practice

- Initial validation
- QA in routine analysis

Initial validation

- Determine performance characteristics of the method
  - Linearity (solvent versus matrix)
    - Matrix spiked before extraction and matrix spiked just before final measurement
  - LOD, LOQ, Repeatability, Reproducibility, accuracy, recovery etc

- Analyze 20 blank samples
- Analyze on three different days six blanks spiked on 0,5; 1,0 and 1,5 MRL
- In total at least 74 samples have to be analyzed

Validation

PERFORMANCE PARAMETERS					
Omschrijving	*eenheid*	*werkgebied*	*niveau 1*	*niveau 2*	*niveau 3*
JUISTHEID					
Gehanteerd model voor bepaling juistheid [7]	* ~~met behulp van (gecertificeerd) ref. mat.~~ * ~~met behulp van ref. methode~~ * met behulp van spikes				
Het gehanteerde hoge resp. lage conc.niveau	ng/g	NVT	1	5	20
Niveau van de richtwaarde			NVT	NVT	NVT
Berekende juistheid	J		94	86	87
Berekende relatieve standaardafwijking van de juistheid	RSD_J		3,9	3,4	5,1
Berekende terugvinding	%		84	86	87
Berekende systematische afwijking	%		-5,9	-14	-13
PRECISIE					
Standaardafwijking herhaalbaarheid op geselecteerd niveau	s_r		0,037	0,15	0,89
Herhaalbaarheid (2.8* s_r)	r		0,10	0,91	2,5
Standaardafwijking binnen lab reproduceerbaarheid op geselecteerd niveau	s_{RL}		0.12	0.15	1.1
Binnen lab. reproduceerbaarheid	R_L		0.34	0.43	3.2
Geëxpandeerde meetonzekerheid (2* s_{RL})	U		0.24	0.30	2.3

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Daily practice

- QA in routine analysis

Daily practice

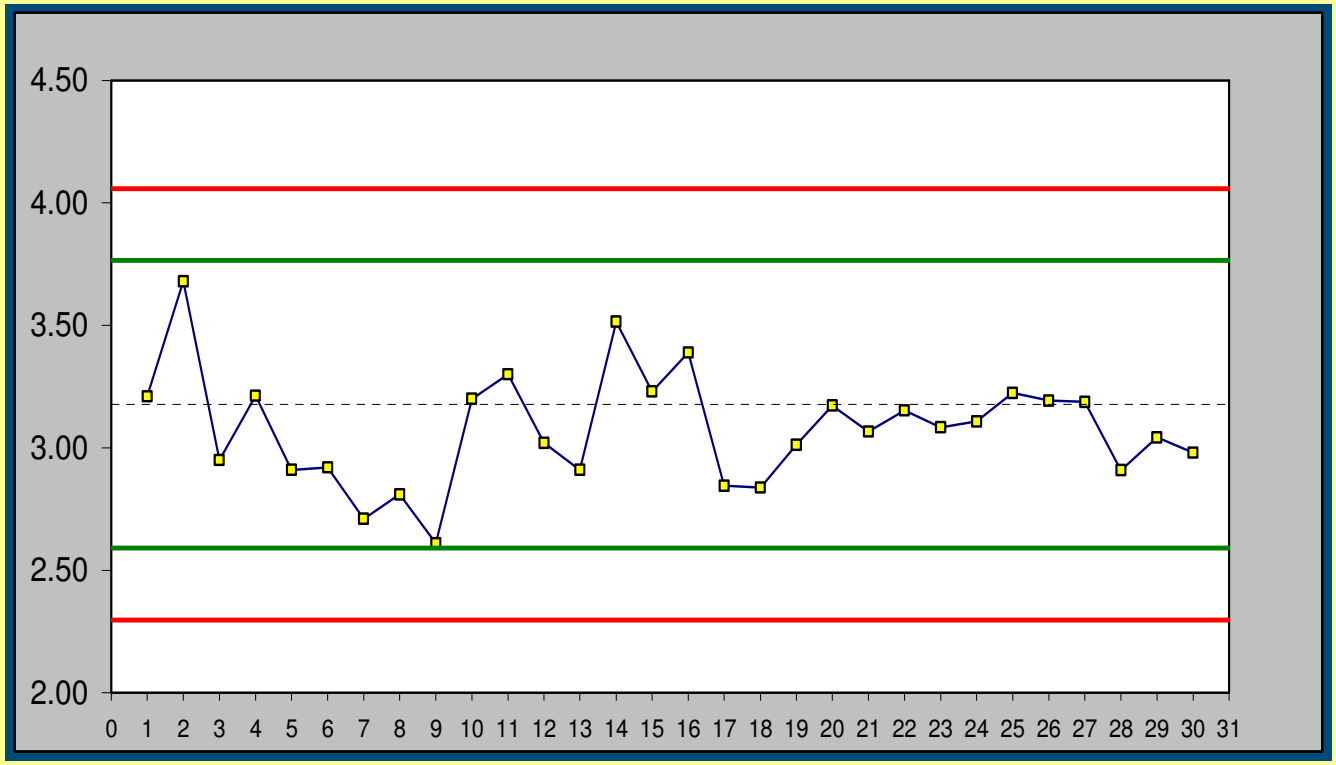
- QA in routine analysis
  - Each series of samples which have to be analyses should consists of
  - Standard curve
  - Solvent blank
  - Procedure blank
  - CRM 1 or spiked sample
  - CRM 2 or previously analyzed (positive) sample
- Participate in PT

Controlekaart v1.2

naam kaart:	Dioxines in 3019, lower bound, kaart 2
code contr.mat.:	3019
richtwaarde contr.mat.:	3.18
datum start kaart:	11-2005
methode:	RSVA0565

waarnemingen

	init	datum	waarde	attentie	outlier
1		30-11-05	3.21		
2		21-11-05	3.68		
3		6-12-05	2.95		
4		15-12-05	3.21		
5		11-1-06	2.91		
6		23-1-06	2.92		
7		26-1-06	2.71		
8		25-1-06	2.81		
9		27-1-06	2.61		
10		24-1-06	3.20		
11		13-1-06	3.30		
12		28-1-06	3.02		
13		30-1-06	2.91		
14	C.O.	19-01-06	3.52		
15	C.O.	02-02-06	3.23		
16	C.O.	2-02-06 b	3.39		
17	C.O.	02-02-06c	2.85		
18	C.O.	03-02-06 I	2.84		
19	C.O.	4-02-06 1	3.01		
20	C.O.	4-02-06 2	3.17		
21	C.O.	06-02-06	3.07		
22	C.O.	6-02-06 1	3.15		
23	C.O.	6-02-06 2	3.08		
24	C.O.	9-02-06 II	3.11		
25	C.O.	07-02-06 I	3.22		
26	C.O.	7-02-06 II	3.19		
27	C.O.	9-02-06 II	3.19		
28	C.O.	02-02-06	2.91		
29	C.O.	17-02-06	3.04		
30	C.O.	03-02-06	2.98		



UCL	4.06	LCL	2.30	deze kaart	
UWL	3.76	LWL	2.59	gemiddelde	3.08
				aantal	30
richtwaarde	3.18	sd	0.29	sd	0.23

aantal significante decimalen		>
bovengrens		>
ondergrens		

O = Outlier > in berekening opgenomen X = Outlier > niet in berekening opgenomen

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Questions?

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