

# Measurement uncertainty and conformity assessment in analytical measurement – Considerations for the university curriculum

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1

## Introduction

- Many analyses are carried out to check compliance with a specification or regulation
- Necessary to take into account the measurement uncertainty when assessing compliance
  
- What do we need to know?
- What do we need to **understand**?

2

## Basic use of limits



Why is this here?

Upper control limit

### • Function

- Safety regulation
- Environmental regulation
- Manufacturing control
- Product specification

### • Origin

- Risk assessment
- Epidemiology
- Toxicology
- Economics ...



3

## Basic use of limits



Upper control limit

Need additional information to deal with case (iii)



(i)  
Result above limit



(ii)  
Result above limit



(iii)  
Result at limit



(iv)  
Result below limit

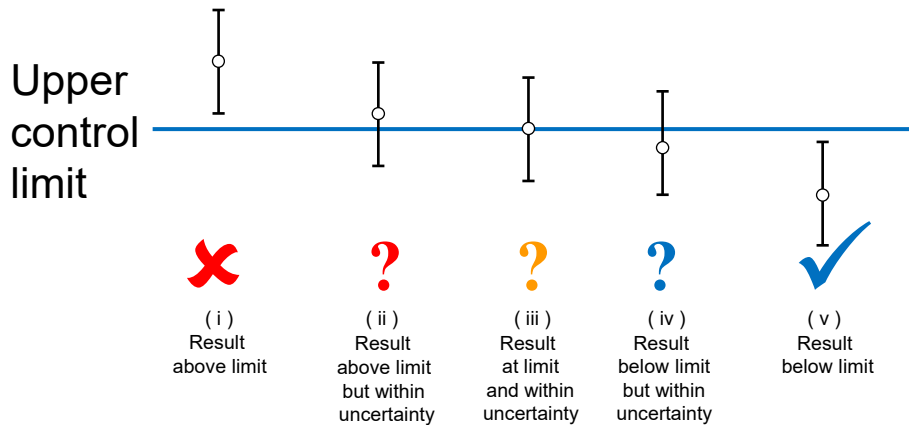


(v)  
Result below limit



4

## Basic guidance



Need additional information to deal with cases (ii) - (iv)



5

Consistent decisions need rules



6

## ISO/IEC 17025:2017



- Decision rule:  
“rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement”
- §7.1.3: “When the customer requests a statement of conformity...the decision rule shall be clearly defined.”



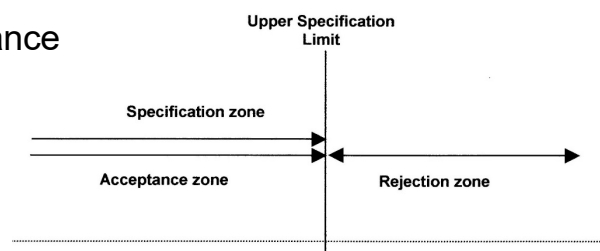
7

## Example of a decision rule



- A result equal to or above the upper limit implies non-compliance  
– result below the limit implies compliance

“Simple acceptance”



- IF uncertainty is below a specified value  
– e.g. uncertainty is small compared with the limit
- THEN the risk of making a wrong decision is acceptable



8

## Concepts so far



- **Limits**

- Function (regulation, control...)
- Setting (how limits are decided)

- **Interpretation**

- Comparison
- “Borderline” cases
- Measurement uncertainty
- Expanded uncertainty
- The idea of “decision rules”
  - Including action on borderline cases



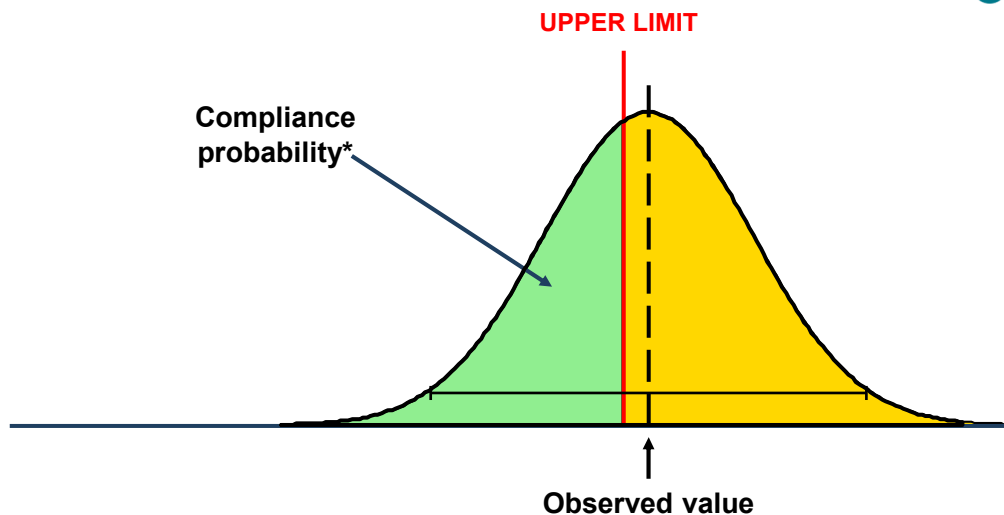
9



## Probability

10

## Probability of compliance



\* Strictly, for an observed value, this should be interpreted as a posterior probability



11

## Concepts so far

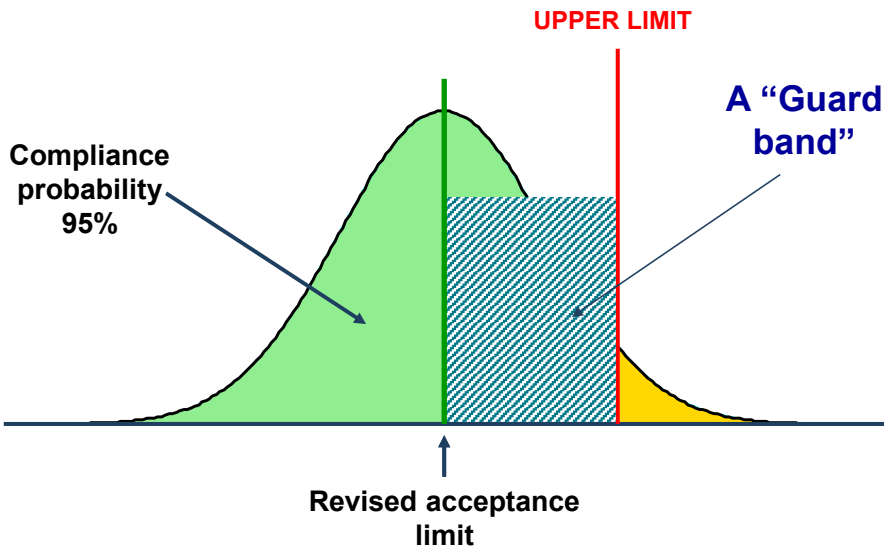


- **Limits**
  - Function (regulation, control...)
  - Setting (how limits are decided)
- **Interpretation**
  - Comparison
  - “Borderline” cases
  - Measurement uncertainty
  - Expanded uncertainty
  - The idea of “decision rules”
- **Probability distributions**
- **Uncertainty as a distribution**
- **Probability of compliance**



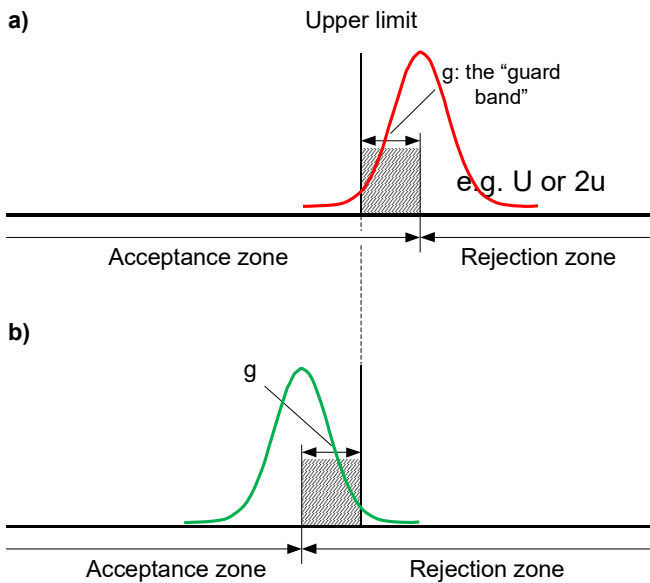
12

## Improving probability of compliance



13

## Decision rules & guard bands



"Relaxed acceptance"  
(test for *non-conformity*)

"Stringent acceptance"  
(test for *conformity*)



14

# Decision rules can control probabilities of false decisions



15

## Concepts so far



- **Limits**
  - Function (regulation, control...)
  - Setting (how limits are decided)
- **Interpretation**
  - Comparison
  - “Borderline” cases
  - Measurement uncertainty
  - Expanded uncertainty
  - The idea of “decision rules”
- **Probability distributions**
- **Uncertainty as a distribution**
- **Guard bands**
  - and effect on false acceptance
- **Probability of compliance**



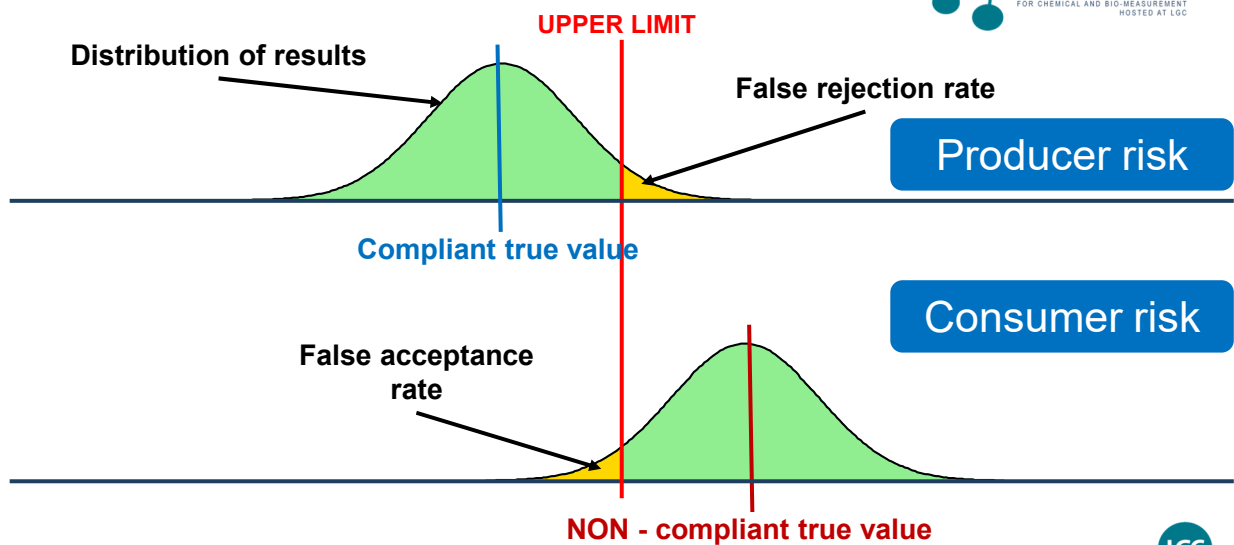
16



# False acceptance and rejection rates – Consumer and producer risk

17

## Producer and consumer risk



18

## Concepts so far

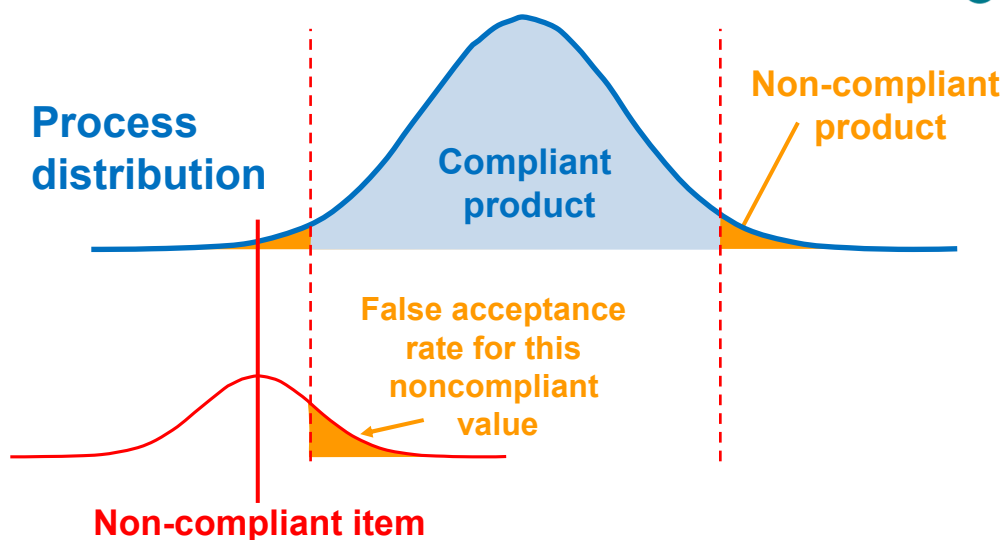


- **Limits**
  - Function (regulation, control...)
  - Setting (how limits are decided)
- **Interpretation**
  - Comparison
  - “Borderline” cases
  - Measurement uncertainty
  - Expanded uncertainty
  - The idea of “decision rules”
- **Probability distributions**
- **Uncertainty as a distribution**
- **Guard bands**
- **Probability of compliance**
- **Producer & consumer risk**



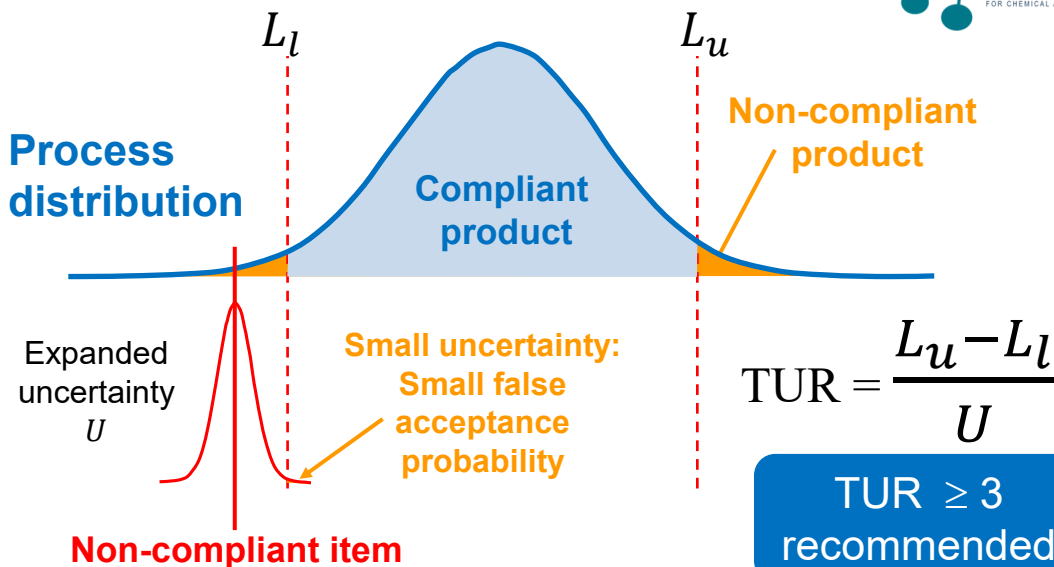
19

## Reducing risk – Test/Uncertainty ratio



20

## Reducing risk – Test/Uncertainty ratio



21

## Concepts so far



- **Limits**
  - Function (regulation, control...)
  - Setting (how limits are decided)
- **Interpretation**
  - Comparison
  - “Borderline” cases
  - Measurement uncertainty
  - Expanded uncertainty
  - The idea of “decision rules”
- **Probability distributions**
- **Uncertainty as a distribution**
- **(Conditional) Probability of compliance**
- **Guard bands**
- **Producer & consumer risk**
- **The process distribution**
- **Test uncertainty ratio (TUR)**

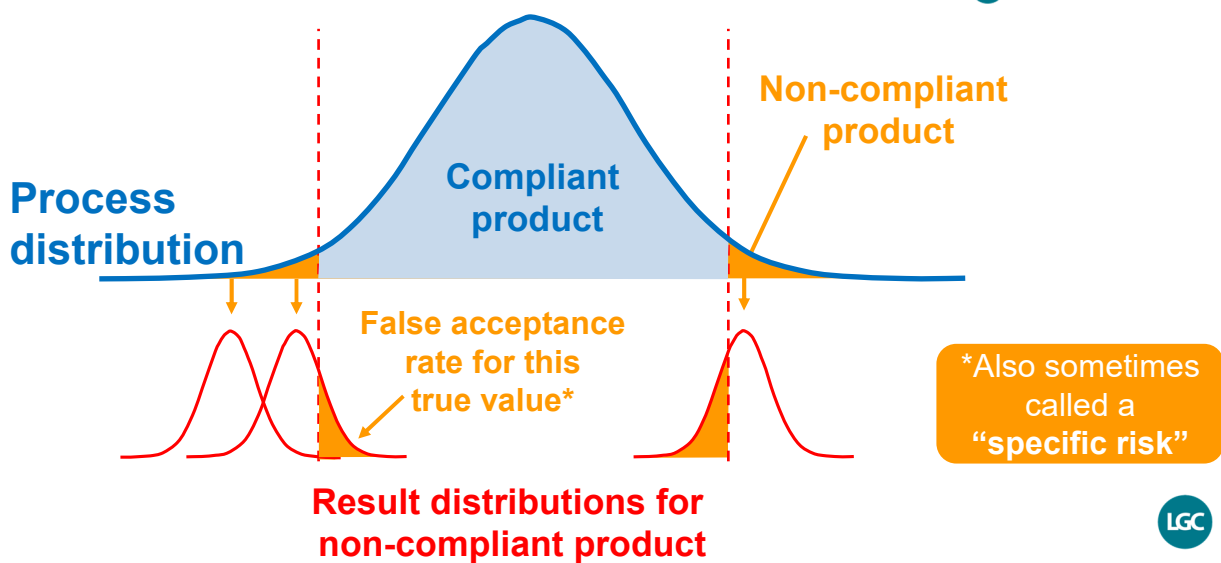


22

# Calculating Consumer and Producer risk

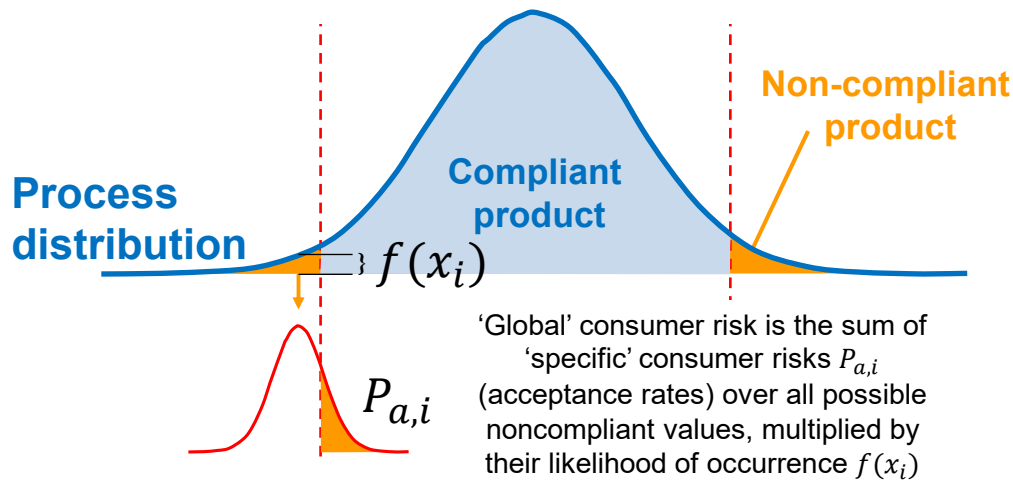
23

## Principle of risk calculation - consumer risk



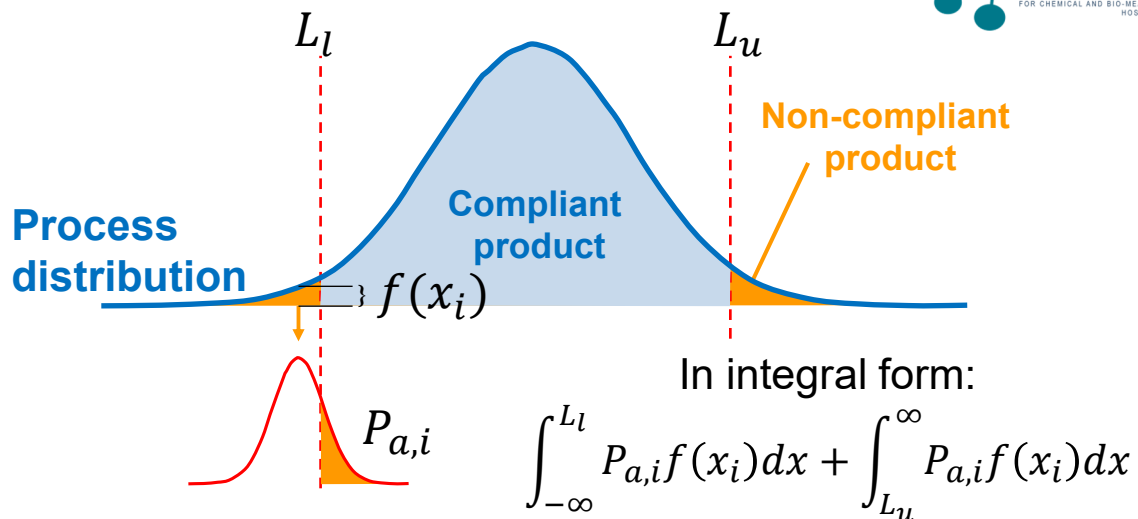
24

## Principle of risk calculation - consumer risk



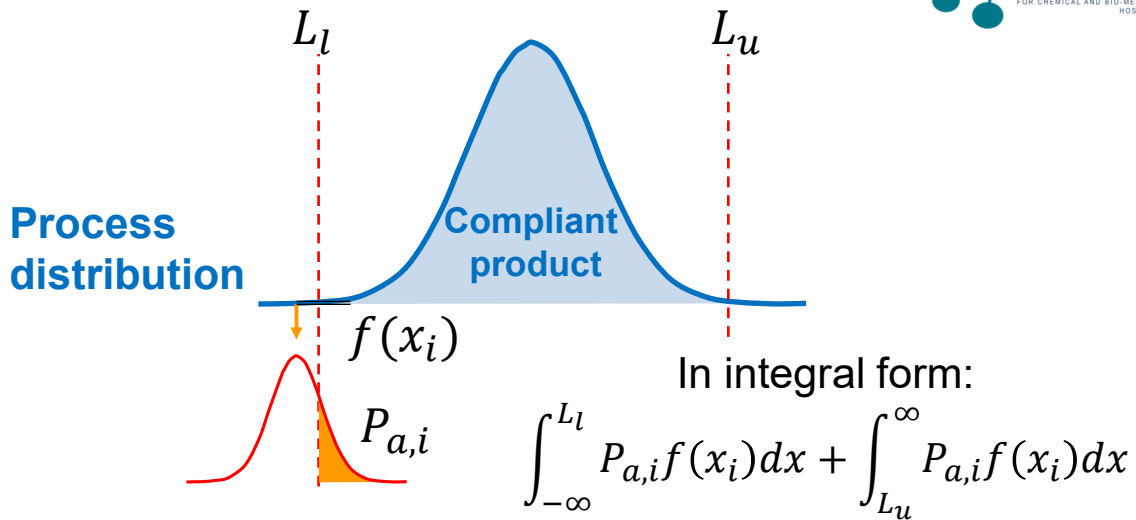
25

## Principle of risk calculation - consumer risk



26

## Consumer risk for a good process



27

**A narrow process  
distribution delivers  
smaller risks of false  
acceptance**



28

## Concepts so far



- **Limits**
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- **Interpretation**
  - Comparison
  - “Borderline” cases
  - Measurement uncertainty
  - Expanded uncertainty
  - The idea of “decision rules”
- **Probability distributions**
- **Uncertainty as a distribution**
- **Guard bands**
- **Probability of compliance**
- **Producer & consumer risk**
- **Specific risk**
- **The process distribution**
- **Test uncertainty ratio (TUR)**
- **Integration to obtain ‘global’ risks**



29

## Additional technical problems

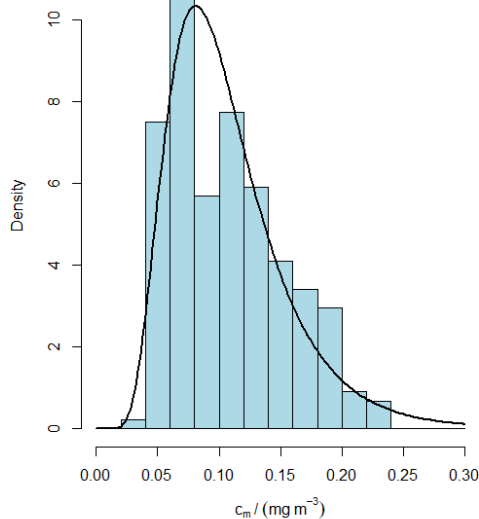


- **Multiple observations in compliance assessment**
  - Replicate measurements on sampled items
  - Repeated results for borderline or failed product
  - Decision can be on an average, all results, or a proportion, within acceptable limits
- **Multivariate conformity assessment**
  - Products are subject to multiple requirements
  - Measurements may be correlated
- **Non-normality**
  - Of process or uncertainty distributions



30

## Non-normal processes



- **Example\*: Total suspended particulate matter in air near a quarry**

- 220 observations
- Line shows lognormal distribution

\* F. Pennecchi<sup>1</sup>, F. Rolle<sup>1</sup>, and A. Allard<sup>2</sup>

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Metrologica, Italy

2 Laboratoire National de Métrologie  
et d'Essais, Paris, France

EURAMET Project EMUE, Example A.1.2.3



31

## Concepts for conformity assessment with uncertainty



- **Limits**

- Function (regulation, control...)
- Setting (how limits are decided)

- **Interpretation**

- Comparison
- “Borderline” cases
- Measurement uncertainty
- Expanded uncertainty as an interval
- The idea of “decision rules”
- Using replicate or repeated results

*Basic*

- **Probability distributions**

- **Uncertainty as a distribution**
- **Guard bands**
- **Test uncertainty ratio (TUR)**
- **The process distribution**

*Useful*

- **Probability of compliance**

- **Producer & consumer risk**
- **Specific risk**
- **Integration for ‘global’ risks**
- **Non-normality**
- **Multivariate conformity**

*Advanced*



32



## Summary



- Conformity assessment with measurement uncertainty can be a complex topic
- A basic understanding of limits, decision rules and measurement uncertainty (as an interval) is essential
- A comprehensive understanding is likely to require extended statistical training or qualifications



33

## Further reading



- **Use of uncertainty information in compliance assessment (Eurachem/CITAC Guide)**  
– [www.eurachem.org](http://www.eurachem.org)
- **ILAC G8: Guidelines on Decision Rules and Statements of Conformity**  
– [ilac.org/publications-and-resources/ilac-guidance-series/](http://ilac.org/publications-and-resources/ilac-guidance-series/)
- **JCGM 106:2012 Evaluation of measurement data – The role of measurement uncertainty in conformity assessment**  
– <https://www.bipm.org/en/publications/guides/gum.html>



34