Quality Management

Outlines of TQM, QA, and QC

Total Quality Management (TQM)

- All-Embracing discipline to ensure the organization's output (product/service)

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Quality Management

Outlines of TQM, QA, and QC

Principle of Quality Management (ISO9000:2015)

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

These are the Principles for "All" Types of ISO Management System (Not limited 9000)

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Quality Management

Outlines of TQM, QA, and QC

Why Quality should be “Improved”…?

Isn’t it an excess of quality that exceeds current criteria…?

NO!

Higher quality raises the value of the product.

High quality analysis data can:

- Decrease the number of samples.
- Provide the new knowledge from the survey.

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Quality Management

Outlines of TQM, QA, and QC

Elements/Requirements of QMS

- Clarified Policy / Objectives
- Documented Protocol (Manual / Rule/ Procedure)
- Framework
- Evidence (Check and Record)
- Resource Management (Human/Material/Budget/Time/Information)
- etc.

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Outlines of TQM, QA, and QC

Elements/Requirements of QMS

Are Policy and Objective Clear?

Is Procedure Appropriate?

Are Rules and Procedure Fully Documented?

Are Resources Managed Appropriately?

Is Process Conducted Correctly? Is There Sufficient Evidence (Record)?

Is the Quality of Product (Data) Adequate? Are there Sufficient Check Procedures and Evidence (Record)?

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Quality Management

Outlines of TQM, QA, and QC

Significance of Quality Management

Quality management is not for "ISO standard accreditation".

Quality management provides:

- Clarification of data quality to make it comparable
- Maintaining of data quality
- Improvement in data quality

High quality provides additional value to product (data) .

SOP and Record: Process Clarity

Quality Assurance / Quality Control

Quality Assurance

- *"part of quality management focused on providing confidence that quality requirements will be fulfilled"*

Quality Control

- *"part of quality management focused on fulfilling quality requirements"*

Source: ISO (2015). Quality management systems – Fundamentals and vocabulary.

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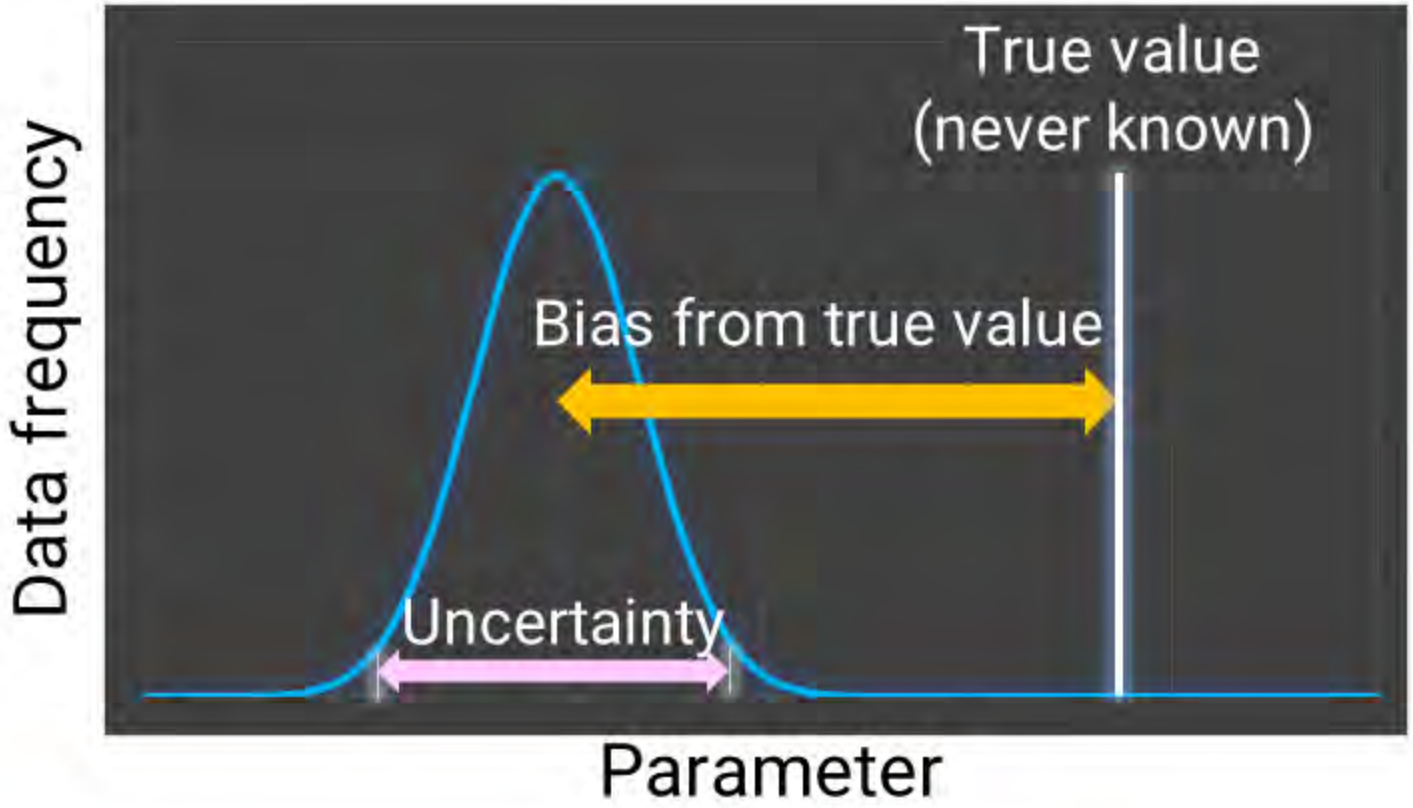
SOP and Record: Process Clarity

Quality of Analysis Data

- Most important quality component of analysis data is

  "Error"
  - bias
  - uncertainty



Evaluation of error of the data and continuous efforts to reduce them are the basis of the QM of analysis.

Quality Assurance

Is Process Adequate?

- Clarified Standard Procedure (SOP)
- Evidence of Correct Operation (Record)
- Evidence of Schedule Control

Is Result Adequate?

- Results of QC test samples
- Evaluations of LOD, LOQ, uncertainty
- Results of Proficiency Tests (PT)

Standard Operation Procedure (SOP) (1/3)

Clarify the process of operation.

- People outside of the system to objectively confirm the operations being performed

Preventing changes in operation procedure and quality.

Easy education and training of operation staff.

Easy technology transfer to other laboratories.

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Standard Operation Procedure (SOP) (2/3)

SOP is the document referred to in operating in laboratory.

- Keep as simple as possible while providing necessary information for operations.
- Better to describe operational tips and warnings on the same page of the operation explanation or close to it.
- All elements that may affect data (e.g., amount of sample and reagent, reaction temperature and time) should be included.
- When such parameters are changed, they must be described in SOP and effective date is clarified.

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Standard Operation Procedure (SOP) (3/3)

- Better to use figures and photographs frequently.
- When revising the SOP, specify the effective date and remove the old version promptly.
- Develop SOP for management of samples (naming (ID assignment), classification, transportation and storage).
- Better to attach test data confirming the validity of the method to the SOP when preparing the procedure.

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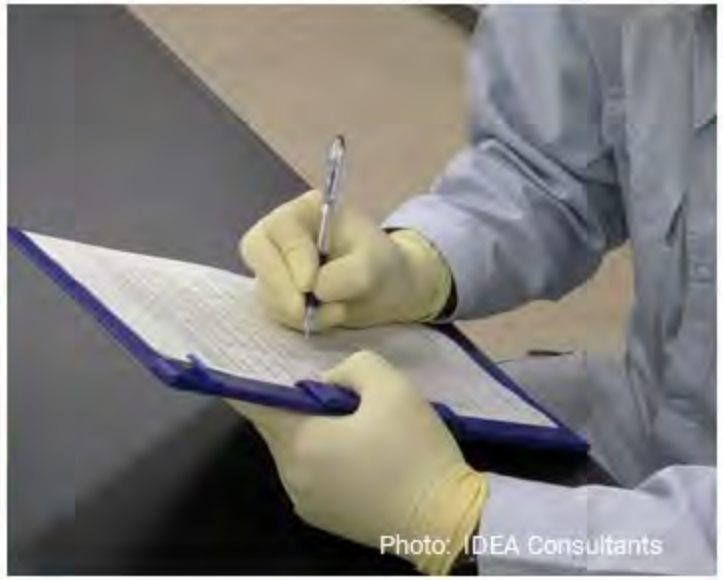
Record (1/2)

Prove the analytical operation performed according to SOP.

Facilitate to investigate the cause of anomality if it has analytical error or valid reasons.

Used as a reference when determining analytical conditions for special samples.



"memory is gone, but record remains"

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SOP and Record: Process Clarity

Record (2/2)

- Record as much as possible operational conditions including ones rarely change in each operation.
- Create a format for easy reference in the future (Record is the document to refer after).
- Assign a unique **ID** to each sample.
- Analysis date and time, laboratory room and operator should be recorded.
- A remark column to accommodate findings etc. at the time of analysis.

QA/QC Analysis of Samples: Result Validity

Operation Blank (1/2)

The operation blank should be minimised.

- Apparatus (glassware) must be thoroughly cleaned so that no mercury remains in the sample (memory effect).
  * Soaking in **acid** is effective for mercury analysis.
- Be careful not to mix droplets of a sample solution to other samples / standards / blanks during the analytical operation (cross contamination).

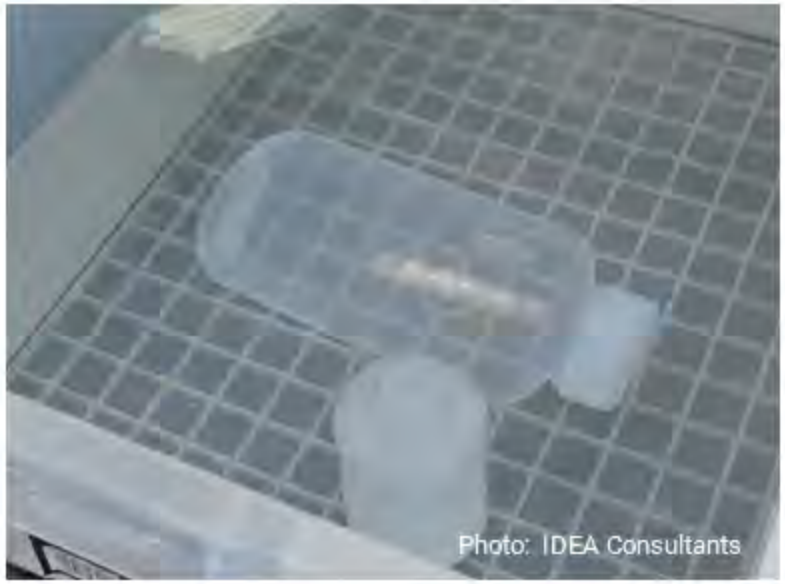
Photo: IDEA Consultants

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Operation Blank (2/2)

However,...

- If reagents (especially acid) contains mercury, it is not easy to eliminate.
- If most of the operation blank comes from the reagent, it affects all samples more or less the same degree.
  > If the deviation of operation blank is sufficiently smaller than the sample, blank amount can be subtracted from the sample.

(Average) operation blank amount and its deviation should be estimated prior to the sample analysis.

Duplicate Sample Analysis

Multiple analysis of the sample

- To confirm the reproducibility (precision) of the analysis, same sample analysis is conducted multiple times in the same manner.
- Sample with general properties should be selected for duplicate analysis.
- The concentration should not be too low (sufficiently higher than the limit of detection).

If the total amount of sample is insufficient to conduct analysis multiple times, duplicate can be performed with other sample (such as the reference material).

Reference Material (RM)

- To confirm the reproducibility of the analysis among the different day analysis, analysis of same sample (reference material) by each analysis batch (day) is recommended.
- Certified Reference Materials (CRMs) with the accredited certified value (concentration) are available.

Photo: IDEA Consultants

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QA/QC Analysis of Samples: Result Validity

Certified Reference Materials (CRMs)

"Certified Value: X.XX ± 0.YY µg/g"

- The Certified value is a value that is usually obtained through joint experiments by multiple institutions, with guaranteed traceability and estimated uncertainty.
- "± 0.YY " is the uncertainty of the certified value, not the criteria for analysis.
- Certified value is determined by the result of many analyses. Thus, the result of the CRM analysis sometimes exceeds this range.

The criteria of the CRM analysis should include the uncertainty analysis in laboratory.

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Limit of Detection, Limit of Quantification (1/2)

If Limit of Detection (LOD) is not sufficiently low, the analysis data may not be useful for the objective of the survey (most data are "n.d.").

- LOD and Limit of Quantification (LOQ) should be confirmed prior to the survey to confirm whether the analysis result can satisfy the objective of the survey.
- When the condition of the analysis is changed (e.g., replace or major repair of the instrument), LOD and LOQ should be re-evaluated.

Limit of Detection, Limit of Quantification (2/2)

LOD/LOQ should be estimated from two perspectives:

Sensitivity

- The measurement signal should be certainly detected from background (noise).
  >Many case Signal/Noise (S/N) ratio > 3

Quantitativeness

Sufficiently higher than

- Deviation of operation blank value
- Deviation of the analysis result of very low concentration (close to expected LOD) of sample

There are some ways to estimate LOD/LOQ.
For example:

- Calculated from the standard deviation (e.g., LOD=3s, LOQ=10s).
- Calculated from the "t value" of the analysis result (risk rate=5 % or 1 %) .

(Usually, 5-7 times or more of repeated analysis)

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Criteria for QA/QC Samples

How should the criteria be determined?

- QA / QC sample criteria should consider the objective and situation of the survey / analysis.
- Criteria for operation blank should be determined by the required LOD, and the determination of the criteria for duplicate analysis should consider the acceptable uncertainty.
- Reference material criteria also consider acceptable bias and uncertainty of the laboratory analysis.

QA / QC criteria written in manuals is determined based on the quality expected if the analytical procedure is performed correctly.

Quality of Data: Bias and Uncertainty

Comparable Data in the Minamata Convention

- Minamata Convention, Article 22 Paragraph 2

  "To facilitate the evaluation, the Conference of the Parties shall, at its first meeting, initiate the establishment of arrangements for providing itself with comparable monitoring data on the presence and movement of mercury and mercury compounds in the environment as well as trends in levels of mercury and mercury compounds observed in biotic media and vulnerable populations"

- What is "Comparable Data" ?

Source: Minamata Convention (2013). Text of the Minamata Convention on Mercury for adoption by the Conference of Plenipotentiaries.

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Data to be Compared

By its nature, data is always compared with something.

- ❑Temporal: past and future
- ❑Spatial: Geographical, hydraulic, meteorological
- ❑Several Index: standards, health risk

The data is often compared with **other data obtained by many institutions**.
(Especially, for the purpose of the research of global environment.)

Comparability of data is very important.

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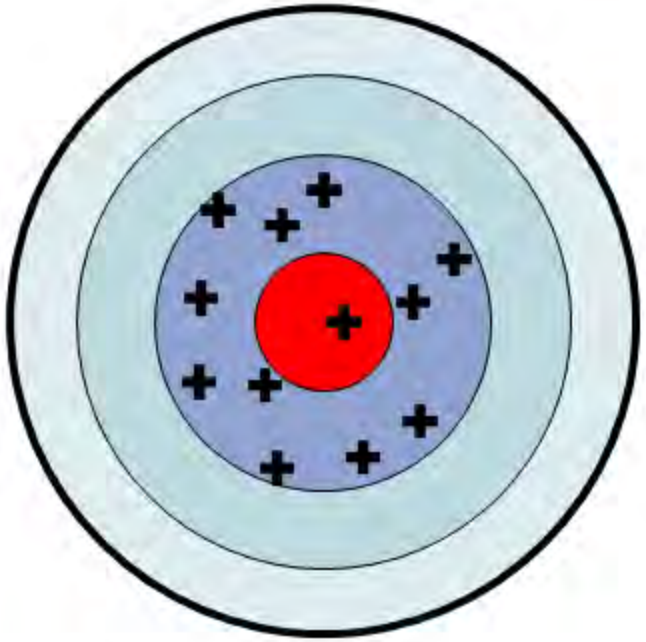
Comparable Data

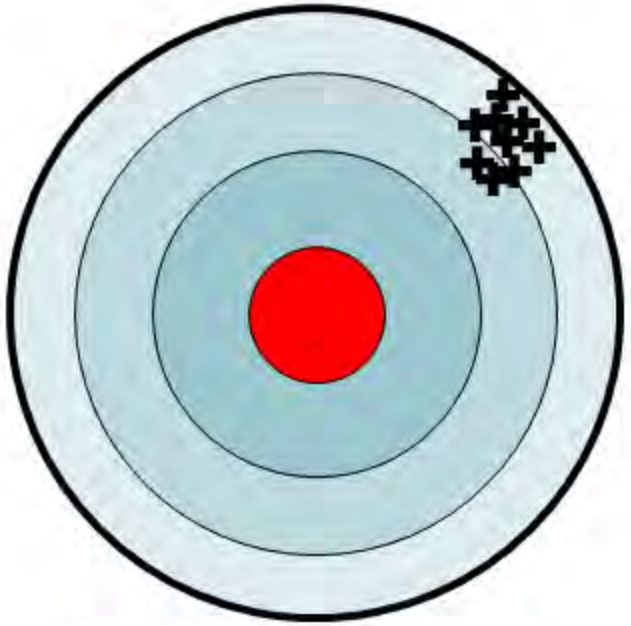
- What is “Comparable Data” ?
  It is not defined in the Convention text.

- Objectivity, Reproducibility, Robustness
  For Example:
  - The process is obvious.
  - The method has been verified.
  - An external audit verification has been performed.
  - The uncertainty and bias have been verified.

Accuracy and Precision

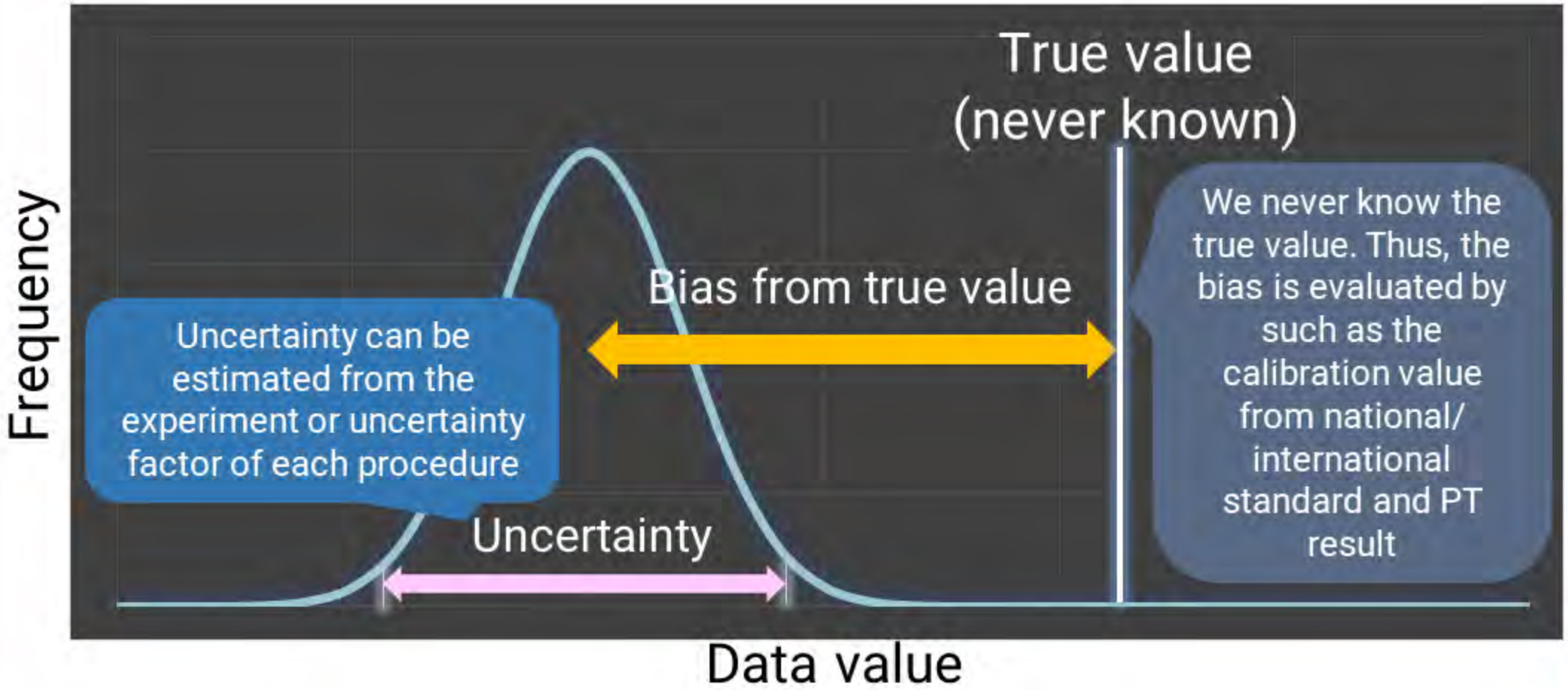


- Good Accuracy
- Bad Precision



- Bad Accuracy
- Good Precision

Bias (Accuracy) and Uncertainty (Precision)



Bias of Data

Traceability

- *Metrological Traceability (traceability): "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty"*

Source: JCGM (2012). International vocabulary of metrology – Basic and general concepts and associated terms.

Traceability is guaranteed
=Bias of the data from the national / international standard is correctly estimated.

"True value" is unknown-
However, data related to national / international standard (SI) can be compared and estimated their bias each other through the standard.

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Bias of Data

Intercalibration, Proficiency Testing

- Intercalibration / Proficiency testing (PT):
  - Multiple laboratories conduct measurement (analysis) for the same parameter in the same sample.
  - The result of each laboratory can be compared to the data of other laboratories, their average and accredited value, thus the bias from the other laboratories (or standard laboratories) can be evaluated.

Uncertainty

Uncertainty

- *"Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used"*

Source: JCGM (2012). International vocabulary of metrology – Basic and general concepts and associated terms.

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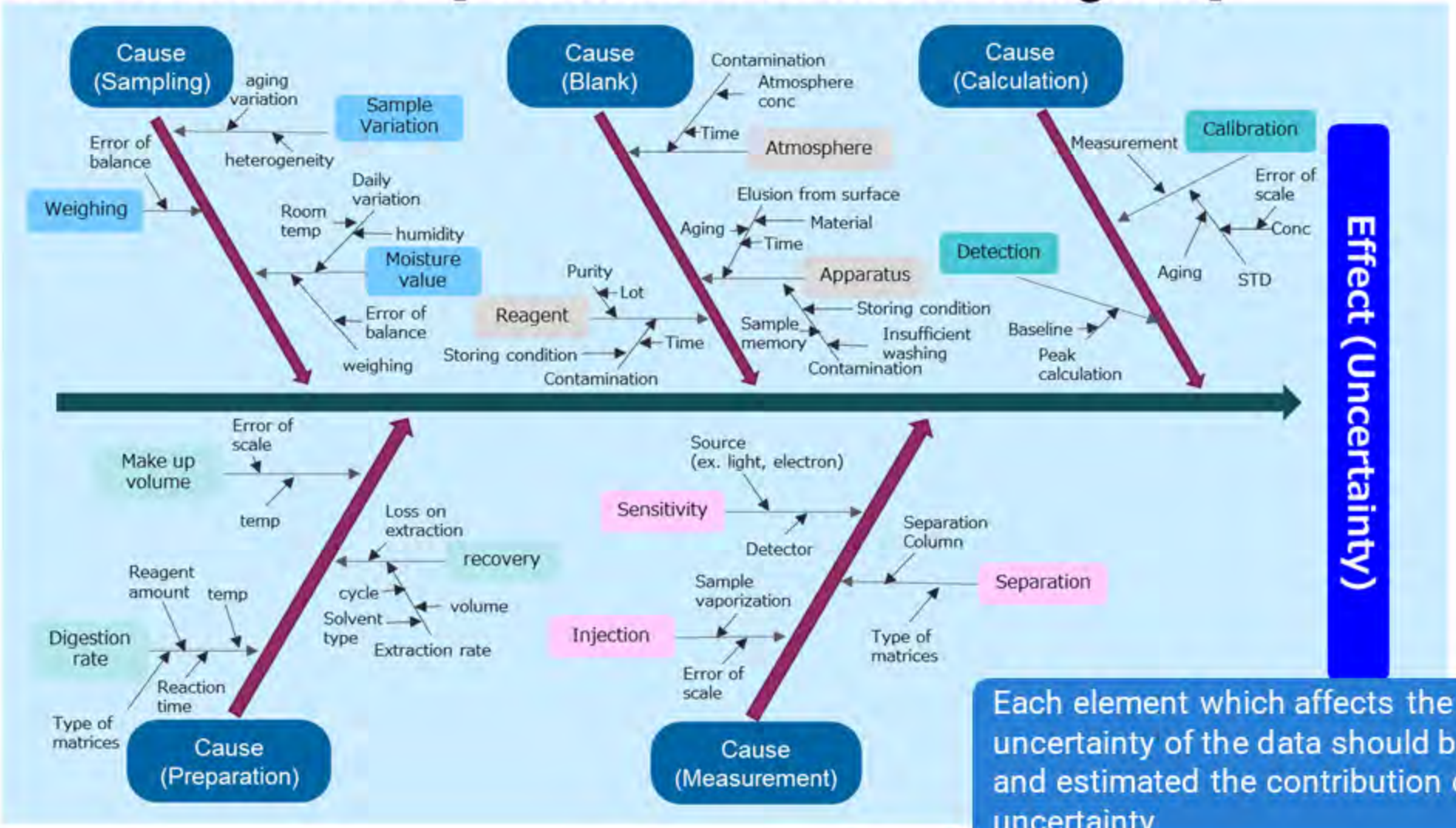
Estimation of the Uncertainty

Fishbone Chart [A Cause-and-Effect Diagram]



Each element which affects the uncertainty of the data should be extracted, and estimated the contribution of uncertainty

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Uncertainty

Uncertainty

- In the *"Guide to the expression of uncertainty in measurement (GUM)"* two approaches for the evaluation of a component of uncertainty is described.

Type A

- *"evaluation of a component of measurement uncertainty by a statistical analysis of measured quantity values obtained under defined measurement conditions."*

Type B

- *"evaluation of a component of measurement uncertainty determined by means other than a Type A evaluation of measurement uncertainty"*

Source: JCGM (2008). Guide to the expression of uncertainty in measurement.

Type A Evaluation

- Actual Measurements are conducted multiple times.(n=5 or more) (For example, to evaluate the uncertainty of adding of standard, take standard (by the pipet or syringe) multiple times, and measure their masses.

- Uncertainty = SD of analysis (Experimental Standard Deviation)
- If mean value of multiple times measurement is used for analysis, uncertainty is SD of report (mean) value: $S(\bar{x})$

$$S(\bar{x}) = \frac{s(x)}{\sqrt{n}}$$

Type B Evaluation

- Evaluation by other than Type A approach

  For example:

  - Calibration report / certification
  - Manufacturer's specification
  - Guaranteed value
  - reference data taken from handbooks (e.g.: physical properties such as thermal expansion coefficient)
  - Data from manuals, textbooks

In many case, such reference data are not described the actual uncertainty.
If actual uncertainty is unknown, the uncertainty should be evaluated to estimate the probability distribution.

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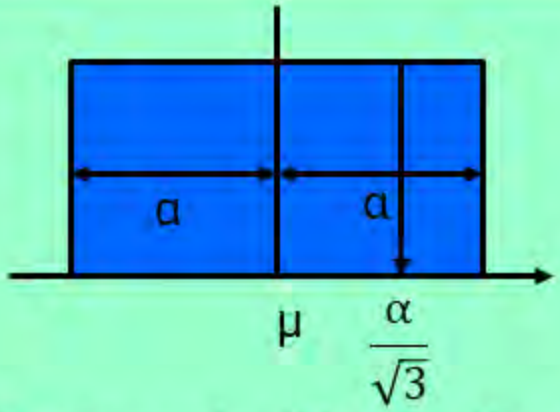
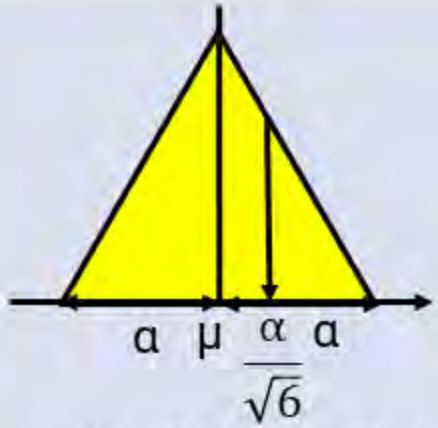
Probability Distribution

- Uncertainty and guaranteed value (ex. pipet, volumetric flask)
  - Guaranteed value :α (-α≦μ≦α)
  - Probability Distribution..?



Rectangular Distribution
(Uniform Distribution)
Uncertainty = $\frac{\alpha}{\sqrt{3}}$



Triangular Distribution
Uncertainty = $\frac{\alpha}{\sqrt{6}}$

- If the probability distribution is assumed to be normal distribution, the triangular distribution can be used for calculation.
- If the probability distribution is within the guaranteed value range, the rectangular distribution can be used for calculation.

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Uncertainty

Synthesis of Uncertainty

- **Synthetic Standard Uncertainty:**
  - Uncertainty of each factor: u_a, u_b, u_c …
  - Synthetic Standard Uncertainty (u_{syn})

Actually, if the uncertainty is 10 times less than the most uncertainty element, their contribution is very small (mostly negligible).

$$u_{syn} = \sqrt{(u_a)^2 + (u_b)^2 + (u_c)^2 \ldots}$$

  - (All the relevant available information of analysis should be considered:
    But all information need "not" to be calculated precisely)

- **Expanded Uncertainty (U):**
  - $U = k \times u_{syn}$ (k: coverage factor, Usually k = 2)

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Uncertainty

How much uncertainty is sufficient?

- Answer: depend on the objective of the survey or experiment
  - Comparison with specific value (ex. standards)
  - Analysis of trends (spatial and temporal)
  - Significant difference of sample cases

- If the expected differences are small, the uncertainty must be smaller
- If the differences are expected to be relatively larger, larger uncertainty might be sufficient

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Analysis precision (uncertainty) and significant difference

- When analysing data statistically, the uncertainty of the analysis result is a very important information.
  - When judging a significant difference between groups, the uncertainty of analysis is one of the elements that regulates the limit of judgment of significant difference.
  - When using survey data for an environmental model, uncertainty directly affects the precision of the model.

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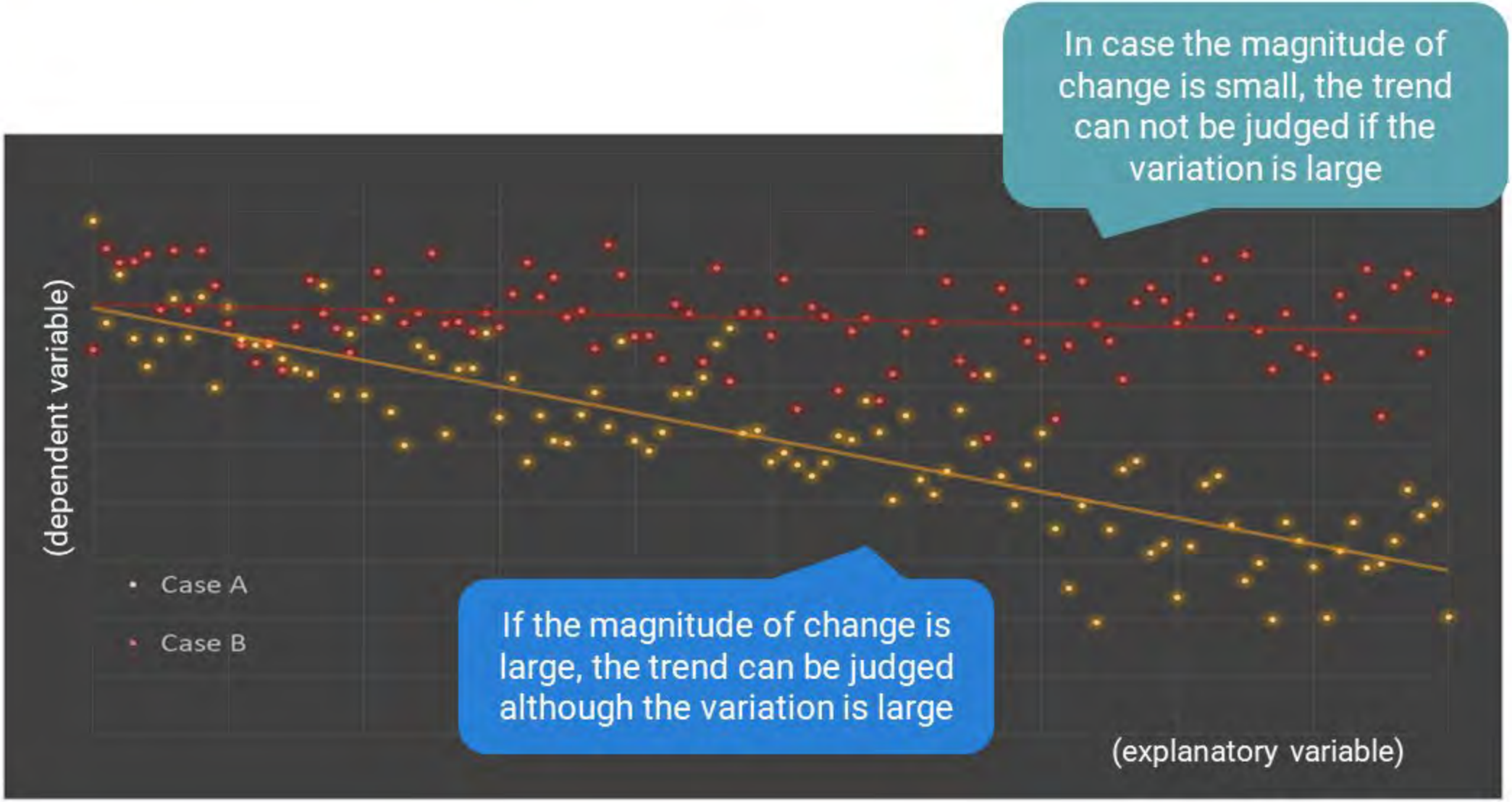
Uncertainty

Effect of uncertainty -Trends-



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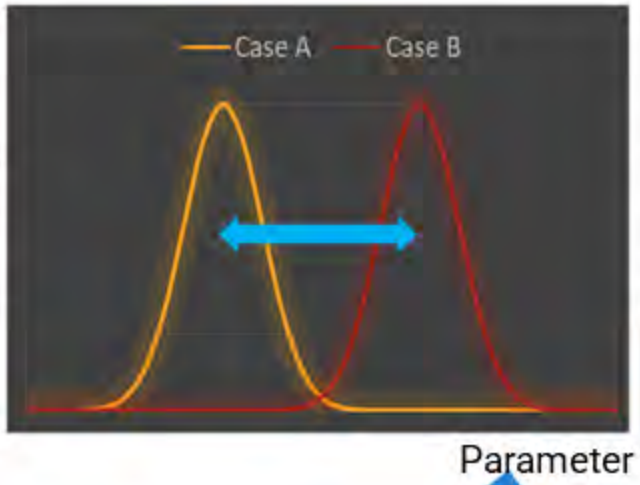
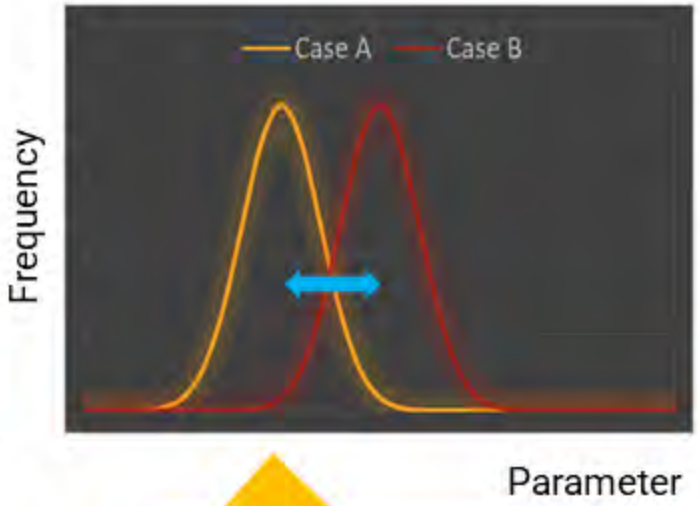
Uncertainty

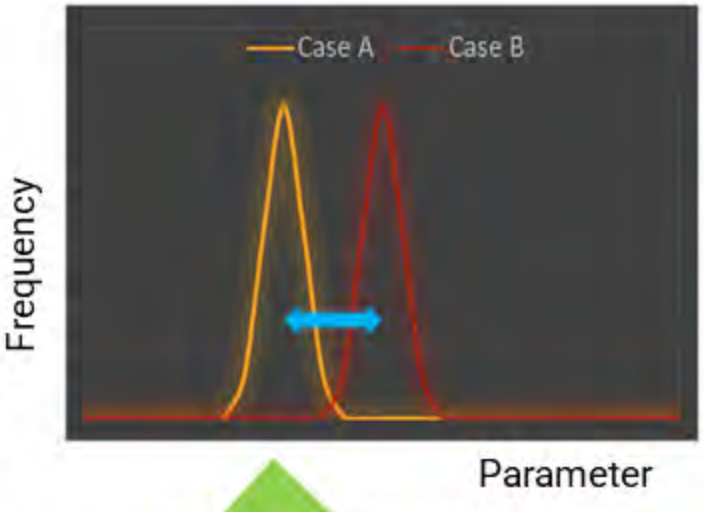
Effect of uncertainty -significant difference-



If difference is large, the significant difference can be judged although the variation is large



In case of small difference, the significant difference can not be judged if the variation is large



If variation is small, the significant difference can be judged if the difference is small

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Uncertainty