What I will talk about

- How to interpret EQA results
  - Key factors/challenges
- How to handle an EQA error
  - History
- The flowchart
Aims of EQA

• To identify poor performance, detect analytical errors, and make corrective actions
  • To monitor the analytical quality
  • To document the analytical quality

• Evaluation of each individual laboratory
• Evaluation of the methods
How to interpret the EQA result?

**Key factors**

1. Control material
2. Target value assignment
3. Number of replicates
4. Between lot variation
Control material

- Commutable
- Stable
- Homogeneous
- Clinical relevant concentrations
Assignment of target value

- Commutable sample
  - Reference method/Value transfer
  - (Overall mean/median)
  - Method specific target value

- Commutablebility unknown
  - Method specific target value
Number of replicates

- One – most common
  - Assessment of total error
- Two or more
  - Assessment of bias and imprecision
Between lot variation

- Will influence participant assessment
- Lot variation in non-commutable EQA samples may NOT reflect native samples

EQA organizer should register lot numbers and comment on lot variation in feedback reports

EQA-based troubleshooting

WHY?
ISO 15189: 2012; 5.6.3

- An accredited laboratory shall:
  - participate in EQA programs
  - monitor and document the results
  - implement corrective actions when predetermined performance criteria are not fulfilled

Little aid in the process of finding the sources of errors when they appear
The History

- Group works at NKKs annual meeting in 2008 and 2009
- Further processed by NKKs Expert group
- Resulted in a flowchart with additional comments (2010)
Evaluation in 2012-2013

- Participants in Labquality’s 2-level Clinical Chemistry scheme (2050) were asked to use the flowchart to assess and state the cause of the error for 180 deviating EQA results (56%)
  - Most errors were the laboratories responsibility (81%), 15% EQA provider, 4% a mix
  - About 60% used the flowchart regularly
  - Comprehensive and a bit complicated, but very useful in training/educational situations
  - Change the order and start with transcription errors (most common)
Revised version in 2016

FLOWCHART 2.0
Ideal EQA sample

- Commutable
- Reference value with small uncertainty

Not fulfilled: Errors NOT related to the quality of the laboratory may arise generating cost without benefit!
An EQA-error is defined by the following relation:

\[ \lvert R - AV \rvert \leq L \]

- \( R \) = Laboratory result
- \( AV \) = Assigned value
- \( L \) = Acceptable limits
Flowchart 2.0

Order of the flowchart

- Transcription error
- Pre-survey issues
- Sample receipt/handling
- Test Performance
- Data Handling EQA Provider
- Report and interpretation
Flowchart 2.0

Structure of the flowchart

Observation
What is the potential error?

Responsibility
Who is responsible for the error?

Comment
Short comment on action to undertake

Note
A more detailed description of actions
Examples

<table>
<thead>
<tr>
<th>Observation</th>
<th>Responsibility</th>
<th>Comment</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error in reporting test results to EQA organisation</td>
<td>Participant</td>
<td>Review process of result reporting</td>
<td>2</td>
</tr>
<tr>
<td>Problem with sample stability</td>
<td>EQAP</td>
<td>Insufficient sample stability may affect your performance assessment. Claim for explanation</td>
<td>11</td>
</tr>
<tr>
<td>Deviation in accordance with previous EQA results</td>
<td>Participant → EQAP → Manufacturer</td>
<td>Review whether the deviation is caused by an internal or external source.</td>
<td>26</td>
</tr>
</tbody>
</table>
Errors related to the EQA provider

**Pre-survey issues**
- Poor EQA sample (non-commutable, unstable, inhomogeneous)
- Errors in labelling, packaging or distribution of EQA samples
- Errors in instruction letter

**Data Handling EQA Provider**
- Inappropriate statistical procedure
- Error in assignment of target value
- Error in presentation of results
- Between lot variation

Should be commented on in the report or comment letter!!
Incitement!!

- In order to improve their schemes, the EQA provider should create a checklist based on this flowchart as a tool to make ongoing EQA schemes more useful for the participant.
Future plans

- The flowchart should become available in the public domain - e.g. EQALM’s website
  - “Dynamic” document - continuously being improved and revised according to comments from the users