

# Nordtest QC Handbook

*Once upon a time there were a lot of Trolls in the Nordic countries ... They were sometimes pestering us so we have a saying something like*  
**The Troll is up to mischief** meaning there are some odd things going on which we do not understand like a control value in the red area in the QC diagram.



# The new version of the TROLLBOOK

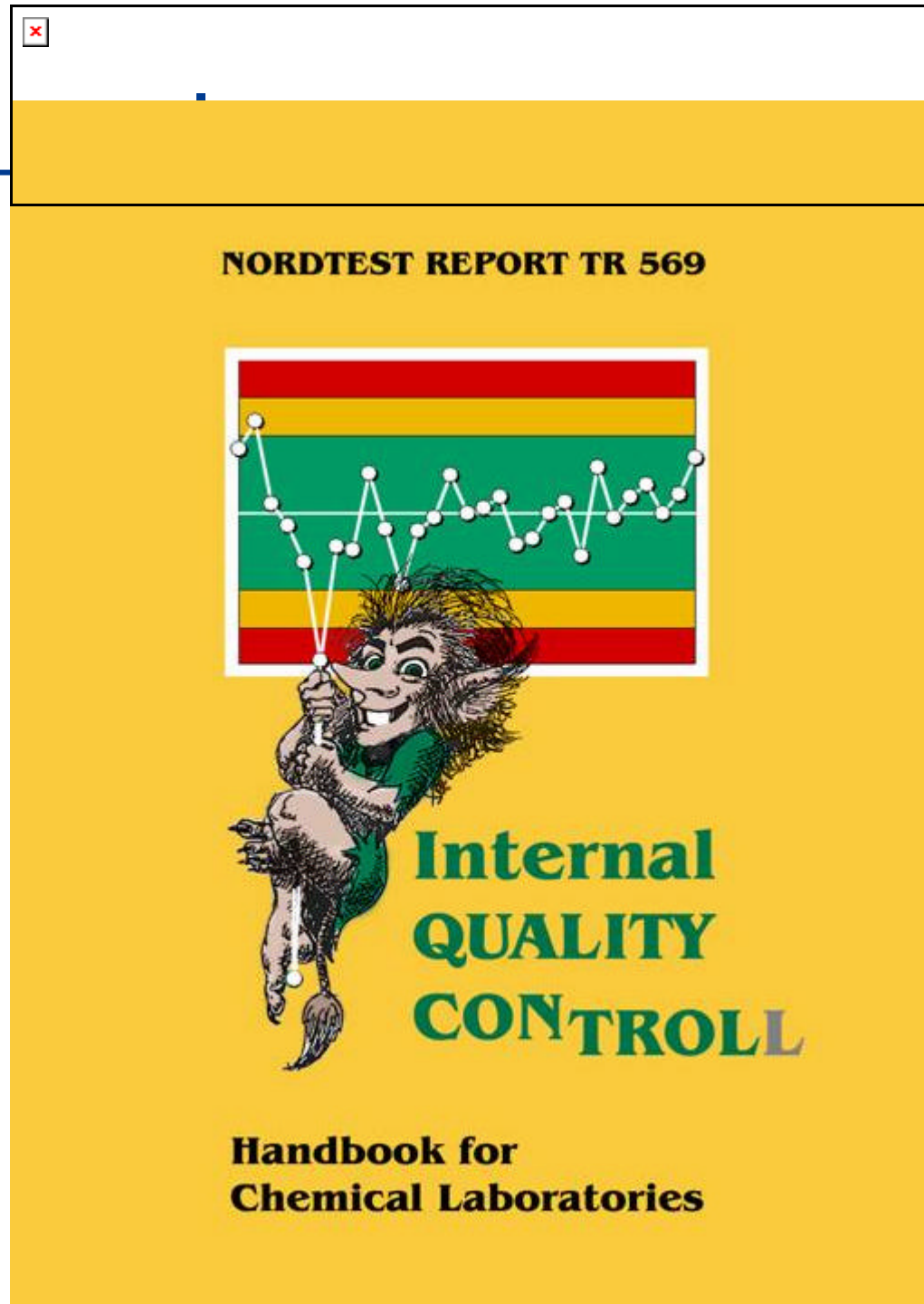
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## For whom

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The aim of the Troll book is to give good and practical guidance for internal quality control.

It is written for **you** – working with routine determinations in the analytical laboratory

### Major issues

- Use method performance or customer requirements to set the control limits
- Stresses long-term evaluation – one year
- Introduces new rules for in control and out-of control situations

# Setting the control limits – different approaches



Here two approaches are described

1. The now classical approach – setting the control limits (2 and 3 s) based on method performance where  
s = within-lab reproducibility
2. An alternative if the intended use and the analytical requirements are crystal clear – setting the control limits on the requirement for within-lab reproducibility

# Long term evaluation if possible



**Based on at least a year or > 60 data you get...**

## Fixed control limits

With 60 data a change of > 30 %  
in  $s$  is significant (95 %) (F-test)

## Fixed central line

With 60 data a change in the position of central line  
of more than 0,35  $s$  is significant (95 %) – t-test

**Conclusion! 60 data is OK but if you have  
more use more!**

# Daily interpretation



The method is in control if



the control value is within the warning limits



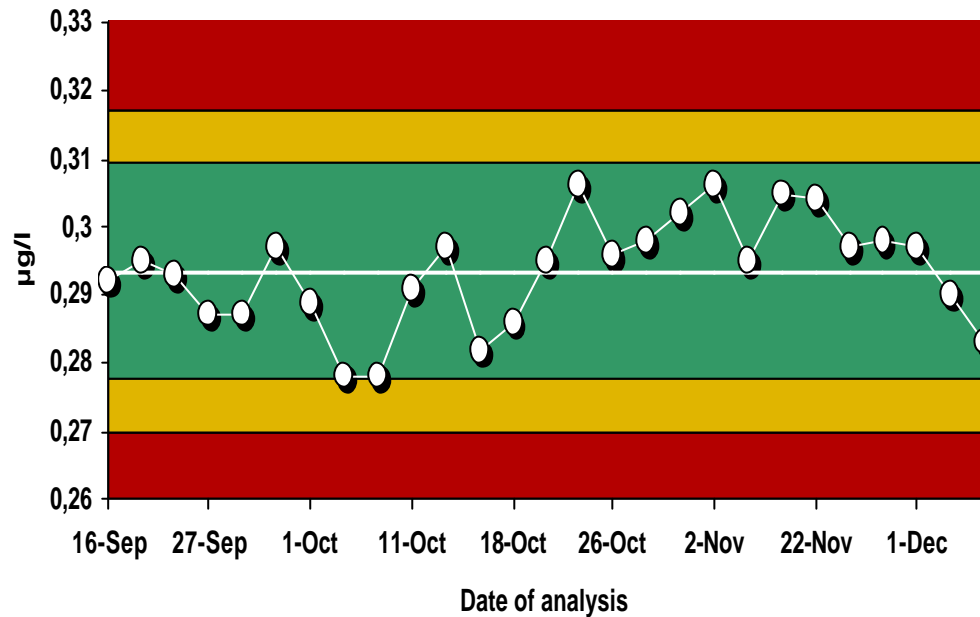
the control value is between warning and action limit and the two previous control values were within warning limits

*In this case the analyst can report the analytical results*

# Example of 11 point on the same side



X-Chart: Pb



**We allow slight, temporary deviations from the normal distribution as long as all data are within the control limits.**

# Conclusions – The Trollbook stresses

- **Setting reliable control limits**
- **Setting reliable central line**
- **When result can be reported – New rules of in and out-of control situations**
- **Customer requirements - Target control limits**

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English version

[www.nordicinnovation.net](http://www.nordicinnovation.net)

