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Small Sample Size Capability Index for Assessing Validity of Analytical Methods

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Context

- Use of capability index to decide about analytical methods validity
- E.g.:

$$Cpk = \min\left[\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right]$$

- Key issue:
  - works well with **high sample size**
  - **Validation** (very) **small** sample size
  - Validation model: **Random one-way ANOVA**

Objective

- ***Develop a small sample size capability index for a random one-way ANOVA model***

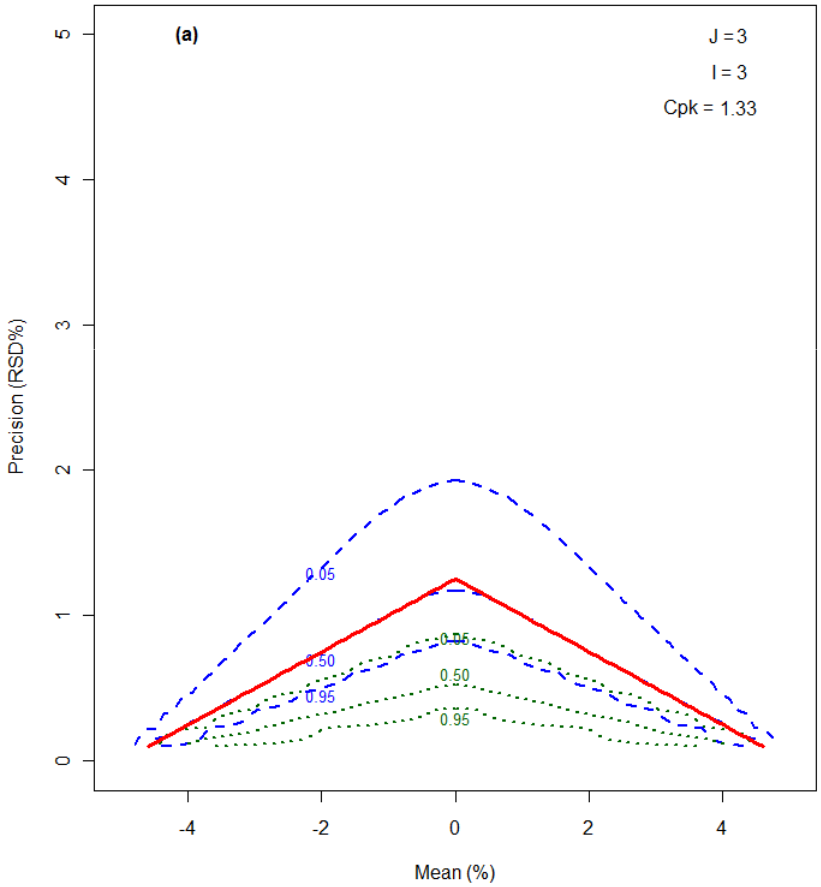
➔ Cpk-tol:

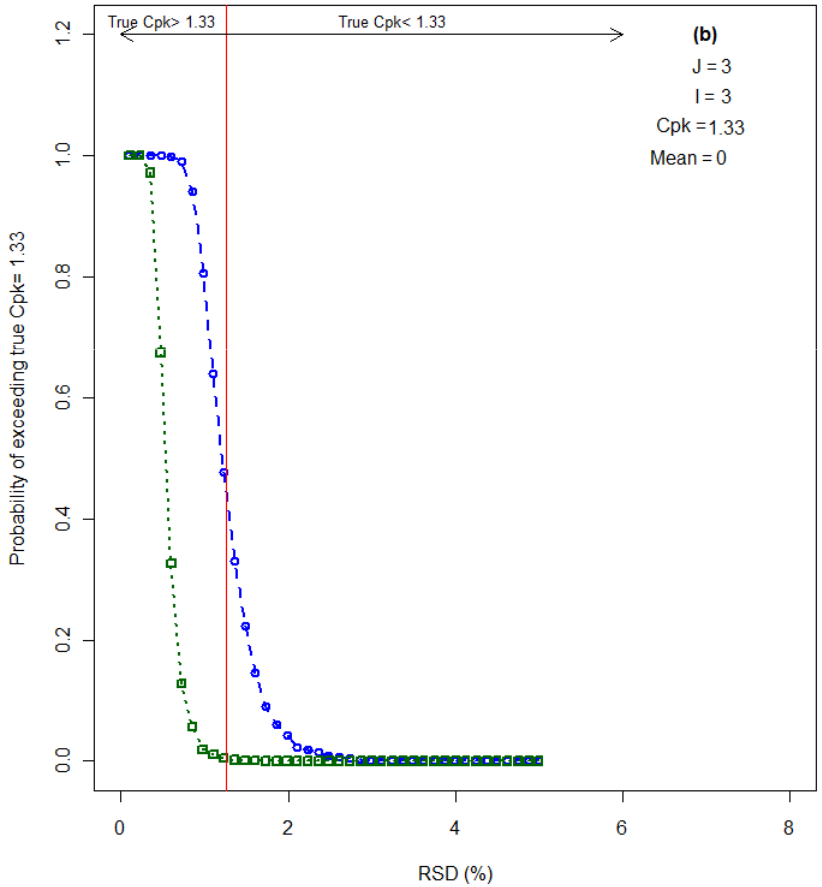
$$Cpk-tol = \min\left[\frac{USL-\hat{\mu}}{t_{(df,\frac{(1+\beta)}{2})}\sqrt{1+\frac{J\hat{R}+1}{JI\left(\hat{R}+1\right)}}\hat{\sigma}_{IP}}, \frac{\hat{\mu}-LSL}{t_{(df,\frac{(1+\beta)}{2})}\sqrt{1+\frac{J\hat{R}+1}{JI\left(\hat{R}+1\right)}}\hat{\sigma}_{IP}}\right]$$

$$\text{with} \quad df = \frac{\left(\hat{R}+1\right)^2}{\frac{\left(\hat{R}+\frac{1}{I}\right)^2}{J-1}+\frac{\left(1-\frac{1}{I}\right)}{JI}}, \hat{R} = \frac{\hat{\sigma}_B^2}{\hat{\sigma}_W^2}, \hat{\sigma}_{IP}^2 = \hat{\sigma}_B^2+\hat{\sigma}_W^2$$

J series and I repetitions

Simulations





Conclusions

- Using the common Cpk index: **50% risk of making the wrong decision**
- Cpk-tol index **controls well the costumer risk** (i.e. the risk to conclude the method is capable while it is not capable)
- **The producer risk** (i.e. the risk to conclude the method is not capable while it is truly capable) **is relatively high.**
- However this risk can be **reduced by increasing the sample size** of the method validation

Thanks for your attention

- Check our publications at:

http://orbi.ulg.ac.be/

- Contact:

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