

Preface

Validation of measurement methods has been used for a very long time in chemistry. It is mostly based on the examination of a measurement procedure for its characteristics such as precision, accuracy, selectivity, sensitivity, repeatability, reproducibility, detection limit, quantification limit and more.

When focussing on quality comparability and reliability in chemical measurement, the fields of interest to this Journal, one stumbles into various interpretations of the term *validation*. It is one more example of a term which is used sometimes very consistently, sometimes very loosely or indeed ambiguously. Since the term is very common in the chemical community, it is important that its meaning be clear. Turning to the 2nd edition of the International Vocabulary of Basic and General terms in Metrology (VIM) (1993), surprisingly we do not find a definition. Webster's Dictionary of the English language (1992) tells us that validation is 'making or being made valid'. Obviously *validation* has to do with *valid*. The same Webster indicates the meaning of the corresponding verb: to validate seems 'to make valid or binding, to confirm the validity of (Latin: *validare*)', where *valid* means: 'seen to be in agreement with the facts or to be logically sound'. We certainly can build on this to have a 'valid' discussion. Validation of a method clearly seems to mean making 'valid' the measurement results obtained by this method. The first definition 'seen to be in agreement with the facts', is rather difficult to apply. The second definition however, tells us that 'validation of a method is to make the method to be seen as logically sound'. It looks as if validation of a method is a process whereby it is tested and demonstrated by somebody or some authority to be logically sound. Such a validation should enable everybody to use it. That implies a list of methods 'validated' by competent authorities in the field concerned, which sounds possible and useful. Is that not what AOAC does?

Sometimes, the notion of validating a measurement result also shows up. Apparently it means to make a result 'valid', and even binding, i.e. confirming its 'validity'. Since *valid* means 'seen to be in agreement with the facts', that almost sounds as a synonym for 'accurate'. That makes sense and there seems to be no argument as to whether a method or a result can be validated (they can). An important question arises: does a validated method automatically give a validated measurement result, i.e. a quantity value¹ with asso-

ciated measurement uncertainty? The answer must be: no. There can never be a mechanism or recipe for producing *automatically* 'valid' results because one can never eliminate the skills, the role and the responsibility of the analyst.

ISO 9000:2000, item 3.8.5 defines *validation* as 'confirmation by examination and provision of objective evidence that the requirements for an intended use are fulfilled'. The revised edition of the VIM ('VIM3'), is likely to fine-tune this definition of the concept 'validation' to be 'confirmation through examination of a given item and provision of objective evidence that it fulfills the requirements for a stated intended use'.

Looking at simple practice, many people are looking for a formal decision that a given measurement method *automatically* gives them 'valid' i.e. reliable results. One wonders what this has to do with 'stated intended use'. Reliability clearly is a property of a measurement result. Checking whether that result fulfills the requirement for a stated intended use, seems to be a totally different matter. That requires the formulation of a requirement a priori, i.e. before the measurement is made, and derived from the need for a measurement result, not from the result itself.

This anthology contains 31 outstanding papers published in the Journal "Accreditation and Quality Assurance" since its inception, but mostly in the period 2000–2003, on the topic 'validation'. They reflect the latest understanding – or lack thereof –, of the concept and possibly some rationale(s) for the answer to the question why it is important to integrate the concept of 'validation' into the standard procedures of every measurement laboratory.

It is hoped that this anthology is of benefit to both the producers and the users of results of chemical measurements: the basic concepts and the basic thinking in measurement are the same for both.

Prof. Dr. P. De Bièvre

Editor-in-Chief

Accreditation and Quality Assurance

Kasterlee 2004-04-02

¹quantity (German: 'Messgrösse', French: 'grandeur de mesure', Dutch: 'meetgrootheid') is not used here in the meaning 'amount', but as the generic term for the quantities we measure: concentration, volume, mass, temperature, time, etc., as defined in the VIM.

Validation in Chemical Measurement

De Bièvre, P.; Günzler, H. (Eds.)

2005, X, 168 p., Hardcover

ISBN: 978-3-540-20788-7