Human Errors and Quality of Chemical Analytical Results

by Ilya Kuselman

An International Workshop on Human Errors and Quality of Chemical Analytical Results was held 13 January 2015, in Kfar Maccabiah, Israel, as a milestone of IUPAC project 2014-027-1-500. An earlier workshop on human error was held in Israel in 2013 to discuss experiences classifying and modeling human error accumulated in aviation, medicine and other fields, which could be helpful in analytical chemistry, as well [1]. The idea of the current workshop arose from the quality management system approach. Applied for routine chemical analytical (testing) laboratories, this approach provides continual improvement of a laboratory quality system. One of the improvement targets is the prevention of human error. However, human activity is never free from error: they are the root cause of the majority of incidents and accidents. In analytical chemistry, human error may lead to atypical test results of questionable reliability [2]. There are, for example, test results that fall outside the established specifications in the pharmaceutical industry, or that do not comply with regulatory, legislative or specification limits in other industries and fields, such as environmental and food analysis. When an atypical test result is identified, it is important to determine the root cause of the event and to avoid recurrence of such results. Where no limits have yet been established (e.g., for an environmental object or a new material), human error may lead to an incorrect evaluation of the tested property. Thus, a study of human error is necessary in any field of analytical chemistry. A laboratory demonstrating competence in analytical chemistry and conformity assessment should also be able to develop relevant, human error-related corrective and preventive actions [3].

The workshop was organized by the Israel Analytical Chemistry Society (IACS) with the participation of the Israel Laboratory Accreditation Authority (ISRAC), in cooperation with the International Union of Pure and Applied Chemistry (IUPAC), Cooperation on International Traceability in Analytical Chemistry (CITAC), and A Focus for Analytical Chemistry in Europe (Eurachem). The event was sponsored by Sigma-Aldrich Corporation and arranged by Bioforum Ltd.

Opening remarks were given by Dr. Ilya Kuselman, Modiin, Israel, Chair of the Workshop Organizing Committee, and Prof. Wolfhard Wegscheider, the University of Leoben, Austria, Chair of Eurachem. Prof. Wegscheider then delivered the keynote lecture “The measurement cycle: principles of quality of analytical results and decisions which can be made on their base”. The lecture described a logically structured approach consisting of a closer examination of the customers’ needs by mapping them onto the performance characteristics of the anticipated analytical procedure. This approach may be regarded as a “measurement cycle” if it is followed up to the actual usage of measurement results in the decision process of the customer. More reliable decisions are reached by reducing the size of the guard band around a specification limit where no decisions can realistically be made, i.e. reducing the measurement uncertainty. An optimization of the analytical procedure may be necessary, even resorting to an alternative measurement principle based on the quality-by-design methodology.

Another keynote lecture “Metrology and quality of test results: documents of the Joint Committee for Guides in Metrology (JCGM)” was delivered by Dr. Walter Bich, Istituto Nazionale di Ricerca Metrologica (IN-RIM), Italy. Dr. Bich discussed the publications of JCGM, in particular the guides for measurement uncertainty evaluation. The scope of the new revision of the guide to the expression of uncertainty in measurement (JCGM 100) and a separate collection of examples (JCGM 110) attracted the attention of the workshop participants. It was important to hear that methods for the evaluation of measurement uncertainty will be agreed upon and adopted world-wide. This implies that the methods will be universal, in the sense that they can be useful in any application, including analytical chemistry.

Dr. Raphael Bar, BR Consulting, Israel, provoked a discussion by his lecture “Should the pharmaceutical laboratory report test results with uncertainty?” Dr. Bar said that the current regulatory requirement in a pharmaceutical laboratory is only the validation of analytical methods. Yet, a typical certificate of analysis of a drug substance or product shows no uncertainty of the test results. The new USP-suggested approach for validating analytical methods will discuss measurement uncertainty evaluation in the validation process.

Dr. Kuselman’s lecture reported on the progress of IUPAC projects 2012-021-1-500 and 2014-027-1-500, as well as quantification of human error in an analytical laboratory based on expert judgments. Examples were provided using earlier published sets of expert judgments on human error in pH measurement of groundwater [3], multi-residue analysis of pesticides in fruits and vegetables [4], and elemental analysis of geological samples by inductively coupled plasma mass spectrometry [5]. Evaluation of the residual risk of human error remaining after the error reduction by the laboratory quality system and the risk influence on the quality of the analytical
results and associated measurement uncertainty were discussed [6].

Monte Carlo simulation of expert behaviour in quantification of human error was the subject of the lecture by Dr. Francesca Pennecchi, INRIM, Italy. Any expert is a human being whose judgments are influenced by intra-personal conflicts and other factors. Therefore, an evaluation of the robustness of the error quantification scores to the doubts of an expert is required. To that aim, a Monte Carlo simulation of expert judgments on human error was used for determining the distributions of the error quantification scores. An expert judgment, represented by a choice on the scale (0, 1, 3, 9), is a discrete quantity characterized by a probability mass function (pmf). Appropriate pmfs were considered in order to model confident, reasonably doubting, or irresolute expert behavior, respectively. An R code was developed for the random generation of expert judgments as discrete values and the propagation of the considered pmfs according to the Monte Carlo approach [5].

After these lectures Dr. Michela Sega, INRIM, Italy, moderated the round-table discussion “Can human error be taken into account as a component of measurement uncertainty?” First, she proposed that the participants ask questions to the lecturers. The question posed to Dr. Bich was “how can one explain the difference between Type A and Type B evaluations of measurement uncertainty, as well as the benefit of this classification?” The problem is that Type A evaluation is defined as the method of evaluation by statistical analysis. However, Type B evaluation is also based on rectangular, triangular or another distribution of observations, in spite of the definition in JCGM 100 and JCGM 200 as evaluation by means other than statistical analysis. Dr. Bich explained the historical reasons for that problem, and noted that such a classification of methods for uncertainty evaluation will not be used in the new JCGM 100 issue under development. Dr. Kuselman briefly presented the position of the task group of the IUPAC projects on the possibility of taking human error into account as a component of measurement uncertainty. While gross errors are easily identifiable and corresponding results can be separated from the data set, small human errors are in principle not distinguishable from other components of measurement uncertainty. Therefore, an uncertainty budget is not complete when consequences of possible human error are not evaluated as a contribution to the budget. Quantifying residual risks of human error allows such evaluations to be made.

The second half of the workshop day began with the lecture by Dr. Kuselman “Knowledge is Power (Francis Bacon 1597): comparability concept and global metrology system”. The lecture was dedicated to knowledge-based mistakes, which are more frequent than other kinds of human error and have significant severity in different scenarios. On the other hand, these mistakes are
the simplest to prevent. The lecturer directed the attention of the participants to the global metrology system and publications in this system containing knowledge important for chemical analytical laboratories. There are guidelines, recommendations and documents of the International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML), the International Organization for Standardization (ISO), the International Laboratory Accreditation Cooperation (ILAC), the National Conference of Standard Laboratories – International (NCSLI), IUPAC, CITAC, Eurachem and others.

Ms. Erica Pinco, ISRAC, Israel, reported on the improvement of error management in accredited medical laboratories in the country. The identification and control of nonconformities of test results are a part of the quality management system, based on ISO 15189. Those results that are not in line with specifications may indicate a medical condition, when in fact they result from human error. When the management identifies that the irregularities of the results are due to human error, a set of activities including corrective actions should be taken in order to reduce the error probability.

Dr. Shula Levin, Waters (TC) Ltd, Israel, impressed the workshop participants with the lecture “Distinguishing between human error and instrumental malfunction in HPLC”. HPLC instrumentation and software have advanced significantly in recent years and have become technologically sophisticated. Therefore, the task of distinguishing between human error and system malfunction has become more and more challenging, and requires collaboration between service engineers and analytical chemists. Dr. Levin presented examples of investigations during which there were real instrument malfunction vs. human error; recommendations for minimal details of the HPLC method which must be specified in a standard operation procedure; and some useful Chromatographic Data Systems’ modules and reference chemical kits, which can reduce human error.

“Can human error be reduced in a pharmaceutical laboratory?” asked Dr. Orna Dreazen of Nextar Chempharma Solutions Ltd, Israel, in her lecture. Human error, said Dr. Dreazen, is the main source of unnecessary activities in a laboratory, wasting energy and resources. In the worst case, human error may cause an adverse effect and the recall of pharmaceutical products. GMP, GLP and ISO 13485 contain requirements designed to reduce human error. The lecturer analyzed examples from a pharmaceutical laboratory and discussed corrective and preventive actions for error reduction.

Finally, a round-table discussion “Is a laboratory quality assurance system effective against human errors?” moderated by Prof. Emil Bashkansky, ORT Braude College, Israel, again allowed participants to receive answers to their questions to the lecturers. Dr. Kuselman presented the scores for evaluation of the quality system effectiveness developed by the task group of the IUPAC projects. Prof. Bashkansky reported about his matrix approach to human error problems in engineering. The opinions on the effectiveness of a laboratory quality system against human error were diverse, but the majority of the participants agreed with the optimistic position of the IUPAC project task group.

It was a very fruitful, interesting, and pleasurable meeting. Some participants expressed their wish to continue the traditional biannual workshop, and supported further development of the topic of human error and quality in an analytical chemical laboratory.

The next two days, 14-15 January, the workshop lecturers and participants took part in the Isranalytica 2015 Conference and Exhibition. A summary of these events is available at http://bioforumconf.com/isranalytica15.

References

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www.iupac.org/project/2014-027-1-500