THE ESTIMATION OF UNCERTAINTY OF RADIOACTIVITY MEASUREMENT ON GAMMA COUNTERS IN RADIOPHARMACY

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ABSTRACT

In this paper the estimation of uncertainty of measurement of radioactivity on gamma counter in Laboratory for radioisotopes is presented. The uncertainty components, which are important for these measurements, are identified and taken into account while estimating the uncertainty of measurement.

Key words: uncertainty of measurement, gamma counter, ISO/IEC 17025

1. Introduction

International Standard ISO/IEC 17025 [1] specifies the general requirements for the competence of testing and calibration laboratories that these laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. The compliance these requirements enables the acceptance of testing and calibration results between countries. One of the requirements of standard ISO/IEC 17025 is estimation of uncertainty of measurements.

Gamma counters are widely used instrument in radiopharmacy during research, development, production and quality control of radiopharmaceuticals. According to GMP (good manufacturing practice) and GLP (good laboratory practice) gamma counters have to be calibrated for every radionuclide used in this laboratory.

2. Concept of uncertainty of measurements

Measurement of certain physical quantity means presentation of some quantitative index of quality which enables the estimation of measurement reliability. Both error and accuracy of measurement are quoted like most usual indexes. Presentation of measurement error and accuracy means that true value is well estimated. True value is indeterminable because the measurement process is not perfect. [2]. Because of these reasons the concept of the uncertainty of measurement become dominant in metrology. The term “uncertainty of measurements” is defined as: “parameter, associated with the

results of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand“ [3]. The parameter may be a standard deviation or the half-width of interval having a stated level of confidence. Uncertainty of measurement consists of many components. There are two types of evaluation of uncertainty: A and B. Type A is a method of evaluation components based on statistical distribution of the results of series of measurement. These components can be characterized by experimental standard deviation. The other components, on which method B is applied, are evaluated from assumed probability distributions based on experience or other information. Imply that the result of the measurement is the best estimate of the value of the measurand and that all components of uncertainty contribute to the dispersion.

According to standard ISO/IEC 17025, testing laboratories have to have and have to apply procedures for estimating uncertainty of measurement. The laboratories should identify all the components of uncertainty, which are of importance and make a reasonable estimation, that imply knowledge of the performance of the method and the measurement scope. Test reports, where necessary for the interpretation of the test results, have to include a statement on the estimated uncertainty of measurement.

3. Results and discussion

In accordance to requirements of standard JUS ISO/IEC 17025, Laboratory for radioisotopes is accredited at YUAT (Yugoslav accreditation body) for the test of quality of radiopharmaceuticals for in vivo and in vitro use, 99Mo/99mTc generators, sealed radioactive sources and containers for storage and transport of radioactive materials.

In the Laboratory for Radioisotopes recognized and validated methods are applied. In these methods the presentation of the results is specified. For all tests-measurements properly functioning and calibrated measuring equipment is used. Environmental conditions and samples properties are always controlled. The tests are performed by highly qualified persons who are familiar with the sources of uncertainty of measurement. The methods which are applied for testing of radiopharmaceuticals like identification, radionuclide purity, radiochemical purity, specific radioactivity or others basically are related to measurement of activity of radionuclides.

Radioactivity measurement is performed by dose calibrator or gamma counter. Both apparatus are always, according to yearly calibration plans, calibrated by competent laboratories and for both of them the uncertainty of measurement is determined. Dose calibrator can be considered as referent standard. For gamma counter the control card and measurement range have to be prepared.

Control card of gamma counter CompuGama 1282-LKB has been prepared by radioactivity measurement of reference standard source - capsule iodine-129 batch No. 0952B, cat. No. 1270-102 activity 1445 Bq (equivalent to 1155,88 Bq iodine-125) during the time interval from January 2003 to January 2004 for many times by many operators.

The data about activity of standard in specification of standard capsule are presented in fig. 1. The activity measurement of the standards is based on a comparison with NBS Standard Reference Material No 4949. The estimated accuracy of the absolute activity is ± 3% including the linear sum of both systematic errors and the standard errors (at 99% confidence level) involved in the preparation procedures. On the basis of these results the mean value and standard deviation are calculated. The control card in the range $\overline{x} \pm 2\sigma$ for 95% level of confidence, i.e. $\overline{x} \pm 3\sigma$ for 99% level of confidence.

The uncertainty components, which are important for these measurements, are identified and taken into account while estimating the uncertainty of measurement. Sources contributing to the uncertainty include: the reference standard used (uncertainty of measurement ± 3% - calibration certificate), γ counter (combined uncertainty of measurement ± 14.5% - calibration certificate), applied method (validated), environmental conditions (different temperature during year) and different operators.

In this manner, expanded uncertainty ± 4.24% for level of confidence 95% is determinate. Expanded uncertainty is "quantity defining an interval about the results of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand" [3]. Expanded uncertainty is calculated multiplication of the combined standard uncertainty with coverage factor which is typically in the range 2 to 3 depending on level of confidence. All our measurements of radioactivity are in the range $\overline{x} \pm 2\sigma$, thus could be think reasonable.

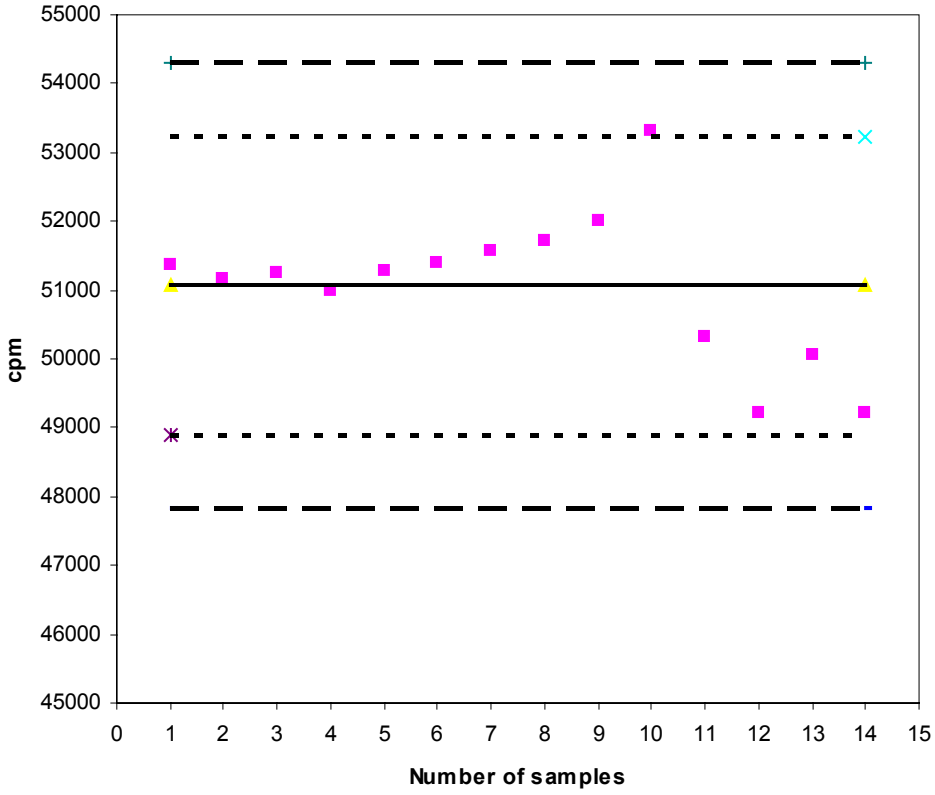

Fig.1 Control card of gamma counter CompuGama 1282-LKB
(—— $\overline{x}$,- - - - $\overline{x} \pm 2\sigma$, -- -- -- $\overline{x} \pm 3\sigma$)

4. Conclusion

According to requirements of standard ISO/IEC 17025, the estimation of uncertainty of measurement is the obligation for calibration and testing laboratories. The testing laboratory could identify all the

components of uncertainty and make reasonable estimation. Only the results of measurement calculated and shown in this manner, could reasonable.

5. References

[1] ISO/IEC 17025 : 1999

[2] N.D.Tjapkin, M.I.Trtanj, APPLICATION OF THE CONCEPT OF UNCERATINITY OF MEASUREMENT IN TESTING LABORATORIES IN ACCORDANCE WITH THE STANDARD JUS ISO/IEC 17025, Vinca Institute of Nuclear Sciences Bulletin, Supplement 3, 2003.

[3] Guide to the Expression of Uncertainty in Measurement 1993, BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML