Issues to be Discussed Regarding Application of Conformity Assessment Using Upper Confidence Level of Measurement to Radiological Safety Regulations

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Abstract. The Joint Committee for Guides in Metrology (JCGM) issued an internationally used document, JCGM106 (ISO/IEC Guide 98-4: 2012), providing standards or guidelines regarding conformity assessment considering the uncertainty of measurements. On the basis of JCGM106, the German Commission on Radiological Protection (SSK) adopted in September 2016 a recommendation regarding the conformity assessment in radiation measurement, requiring that the upper confidence level of the measurement must be below the regulatory level, taking relevant uncertainties into account. In this paper, whether such a strict requirement of uncertainty is necessary for radiological safety regulations is reviewed from various viewpoints, e.g., the conservativeness in the methodology used to derive radiological regulatory levels, the graded approach for acceptable uncertainty, and the difference between product control.

KEYWORDS: Uncertainty, Conformity assessment, Regulation, Clearance level, Dose limit

1 INTRODUCTION

The Joint Committee for Guides in Metrology (JCGM) is an organization that prepares the "Guide to the expression of uncertainty in measurement" (GUM) and the "International vocabulary of metrology – basic and general concepts and associated terms" (VIM). The JCGM consists of eight organizations including the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). JCGM106 (ISO/IEC Guide 98-4: 2012) [1] is an internationally used document providing standards or guidelines regarding conformity assessment considering the uncertainty of measurements. This document provides general guidance and procedures for assessing the conformity of an item (entity, object or system). On the basis of JCGM106, the German Commission on Radiological Protection (SSK) adopted a recommendation [2] regarding the conformity assessment in radiation measurement in September 2016, requiring that the upper confidence level of the measurement must be below the regulatory level, taking relevant uncertainties into account. This requirement of conformity assessment was also incorporated into a new Japanese standard of examination in compliance with the clearance level by the Nuclear Regulation Authority (NRA) in September 2019 [3]. Also, since 2018, the need for this requirement has also been discussed at an international level in the framework of the ongoing revision of the International Atomic Energy Agency (IAEA) Safety Guide RS-G-1.7 [4]. The first draft of the revised safety guide for clearance, DS500, entitled "Application of the Concept of Clearance", was uploaded in the IAEA website in April 2020 for the purpose of web consultation with IAEA member states and related international organizations. The above requirement was included in paragraph 4.72 in the DS500 draft. IAEA received many negative comments objecting to this requirement. As a result, the above requirement finally remained with some flexibility (e.g., the upper confidence level can be appropriately selected) in paragraph 4.74 in the second draft uploaded in the IAEA website in September 2020. However, in RASSC 49, WASSC 50, and TRANSSC 41 joint virtual meeting in November 2020, this second draft of DS500 was not immediately approved, because remaining issues including the above requirement were argued and not finally resolved within the meeting.

The above requirement on the uncertainty in clearance regulation raises serious concerns about its effects on various other radiological protection regulations. This is because if we need strict treatment for uncertainty even in the case of compliance with a trivial dose criterion for clearance, the same or a stricter treatment for conformity assessment might need to be applied to other radiological protection criteria for doses higher than 10 μSv year^{-1}, e.g., dose limits for workers, national regulatory levels for radon concentration, surface contamination criteria for daily radiation control using survey meters, ambient dose equivalent rates on an external surface and at two meter distance from the surface of transport packages, etc., derived discharge limits for liquid and gaseous materials, and on- and off-site measurements in

Fukushima. There is a possibility that this requirement might be shared worldwide in due course, leading to worldwide effects on radiological safety regulations among the IAEA member states.

In this paper, whether such a strict requirement of uncertainty is necessary for radiological safety regulations is reviewed from various viewpoints, e.g., the conservativeness in the methodology used to derive radiological regulatory levels, the graded approach for acceptable uncertainty, and the difference between product control and radiological protection.

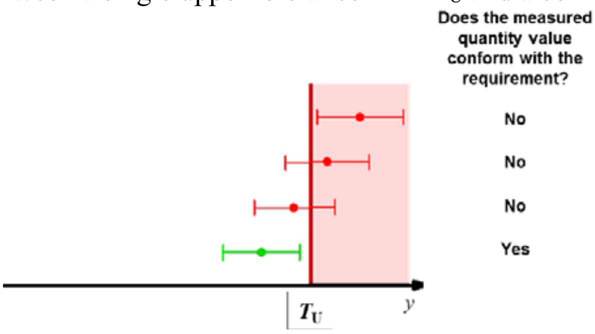
2 INTERNATIONAL STANDARDS AND RECOMMENDATIONS FOR UNCERTAINTY IN MEASUREMENTS

2.1 Standards in ISO and JCGM, and Recommendation in Germany

ISO11929 [5] is an international standard in 2019 entitled "Determination of the characteristic limits (decision threshold, detection limit, and limits of the coverage interval) for measurements of ionizing radiation". In ISO1129, there is no description about conformity assessment using the upper confidence level of the measurement and evaluation data. ISO11929 simply provides a scientific foundation for the concepts of the decision threshold, the detection limit for measurements, and the coverage interval (called the "confidence interval" in previous ISO11929 in 2010).

JCGM106 (ISO/IEC Guide 98-4: 2012) [1], entitled "Evaluation of measurement data - The role of measurement uncertainty in conformity assessment", is an internationally used document providing standards or guidelines regarding conformity assessment considering the uncertainty of measurements. This guide provides general guidance and procedures for assessing the conformity of an item (entity, object, or system) with specified requirements. Examples of quantity intended to be measured for assessing the conformity are given in the scope of this guide, e.g., a gauge block, a grocery scale, or a blood sample. On the basis of JCGM106, the SSK adopted in September 2016 a recommendation [2] regarding the conformity assessment in radiation measurement. An example of the conformity assessment in this guide is shown in Fig. 1.

Figure 1: Relationship between a single upper tolerance limit T_U and a conforming value y [2].



This figure shows that the upper confidence level of the measurement must be below the regulatory level, taking relevant uncertainties into account. In Germany, this requirement has been recommended to be applied to the conformity assessment in radiological safety regulation by the SSK.

2.2 Standards in IAEA and Recommendation in ICRP

Paragraphs 7.43 and 7.45 of General Safety Guide No. GSG-7 [6] provide important recommendations regarding the uncertainty in the measurement by personal dosimeters with reference to the relevant report in ICRU [7] and ICRP Publication 75 [8], respectively:

"*7.43. For single measurements of the operational quantities, the ICRU [58] recommends that:*

"in most cases, an overall uncertainty of one standard deviation of 30% should be acceptable. …The error of instruments may substantially exceed this limit at some radiation energies and for

certain angles of incidence, but conform to it when they occur in a radiation field with a broad energy spectrum and broad angular distribution.'"'

"*7.45. Thus, the recommendations of the ICRP in Ref. [56] indicate acceptable levels of uncertainty at two dose levels:*

(a) *In the region near the relevant dose limit, a factor of 1.5 in either direction is considered acceptable.*
(b) *In the region of the recording level, an acceptable uncertainty of ±100% is implied.*"

These recommendations indicate that the acceptable uncertainty for a dose of about 20 mSv $year^{-1}$ is up to 1.5 times the dose limit, and an uncertainty of up to twice the recording level is permissible for a dose of 1 (or 2) mSv $year^{-1}$, which shows a tendency that the upper limit of the acceptable uncertainty increases with decreasing dose criterion for conformity assessment.

The other example for acceptable uncertainty can be found in a probabilistic approach that was adopted in IAEA Safety Report No. 67 [9]. In the case of clearance judgment, there may be an issue on how to treat the uncertainty in the measurement and the nuclide vector. The nuclide vector is the ratio of difficult-to-measure nuclides such as beta and alpha emitters (e.g., Sr-90 and Pu-239) to easy-to-measure nuclides such as gamma emitters (e.g., Co-60 and Cs-137) used in clearance judgment. The uncertainty of the nuclide vector is usually significantly larger than that of the measured value because the uncertainty in the measurement is restricted while satisfying the concept of the detection limit. If the ratio of difficult-to-measure nuclides to easy-to-measure nuclides is high, e.g., in the case of a nuclear power plant with nuclear fuels damaged by an incident, this issue would be very serious.

To resolve this issue, a probabilistic approach was established in a nongovernmental standard of the Atomic Energy Society of Japan (AESJ) entitled "Monitoring for Compliance with Clearance Level" in 2005 [10] and incorporated into IAEA Safety Report No. 67 in 2012 [9]. This approach provides a method of judging whether the uncertainty of the nuclide vector is too large by using a Monte Carlo calculation tool provided for free use and can be downloaded from the website of the Standards Committee of the AESJ. If the uncertainty in the measurement and the nuclide vector is too large, clearance applicants are required to set a safety factor for clearance judgement, which means a reduction in the clearance level for the easy-to-measure nuclides. If it is not too large, clearance applicants do not have to consider the uncertainty further in the clearance judgement. This approach gives us the acceptable uncertainty for clearance to be up to ten times the dose criterion of 10 μSv $year^{-1}$. This acceptable uncertainty is consistent with the tendency given in the recommendations in General Safety Guide GSG-7 and ICRP Publication 75.

This probabilistic approach is also supported by ICRP Publication 104 [11]. This publication provides a definition of the scope of radiological protection control measures through regulations. In paragraph 95, we can find important information regarding uncertainty in the measurement and the nuclide vector:

"*In the case of a mixture of nuclides, it is generally only practical to measure easily measurable gamma emitters. To estimate the other alpha or beta emitters, most applicants of clearance use a previously assessed nuclide spectrum (namely, a nuclide vector) to ensure that the sum of the values obtained by dividing radioactivity concentrations by clearance levels is lower than 1 (IAEA, 2004b). The Commission recognises that there may be uncertainty (or variation) in the radionuclide composition of a material. In such a case, there are some concerns that the public could be exposed to a dose above the dose criterion for exemption without further consideration (10 μSv/year), although this has quite a low probability of occurring. However, in the derivation of exemption levels in the BSS (IAEA, 1996) and in the safety guide on the application of the concepts of exclusion, exemption, and clearance (IAEA, 2004b), which were agreed internationally, two dose criteria were used; 0.01 mSv/year for realistic scenarios and 1 mSv/year for low-probability scenarios. This indicates that the exemption levels agreed under the aegis of intergovernmental organisations allow the possibility of doses greater than 10 μSv/year in the case of low-probability situations. In this regard, the Commission considers that, in cases of uncertainty (or variation) in the radionuclide composition of* *a material, there is not usually a need to make clearance levels stricter. However, if the uncertainties in nuclide composition are very large, or if the presence of alpha- and beta-emitting nuclides cannot be adequately inferred through gamma measurements, the regulatory body may establish specific criteria for clearance, or may demand assessments involving radionuclide analysis in addition to, or in place of, gamma measurements.*" (ICRP, 2007b).

As seen in the above paragraph in Publication 104, ICRP considers that there is usually no need to make the activity concentration level to be used for clearance judgment lower and stricter, taking the uncertainties for nuclide vector into consideration. This permission can also be justified in a procedure in which the clearance levels were selected as rounded values, e.g., 0.1, 1, 10, and 100 Bq g^{-1}, from calculation results of the activity concentration that is equivalent to the dose criterion of 10 μSv $year^{-1}$ for each scenario [4]. ICRP also recommends the establishment of specific criteria for clearance if the uncertainty in the nuclide vector is too large. One of the specific criteria would be based on the probabilistic approach given in the AESJ standard and IAEA Safety Report No. 67.

3 DISCUSSION

It should be carefully reviewed whether the strict requirement using the upper confidence level is justified for compliance with radiological safety regulations, taking into consideration all discussions from various viewpoints given in the following sections, e.g., the conservativeness in the methodology used to derive radiological regulatory levels, the graded approach for acceptable uncertainty, and the difference between product control and radiological protection. Through all the discussions below, the author recommends that there is no need to apply a methodology of conformity assessment provided by international standards, e.g., JCGM 106, to radiological safety regulations. The author also considers that this recommendation should be carefully and continuously reviewed by the international radiological protection community.

3.1 Conservativeness in the methodology used to derive radiological regulatory levels

Dose limits for workers and the public are one of the principles in the current radiological protection system. Some radiological regulatory levels, e.g., surface contamination criteria for daily radiation control using survey meters, derived discharge limits for liquid and gaseous radioactive materials, and so on, are derived on the basis of dose limits assuming that parameters for dose assessment are sufficiently conservative. Clearance levels are also fundamental regulatory levels below which regulatory control may be removed from a source of radiation within a notified or authorized practice. Although a number of conservative assumptions can be seen in all the regulatory levels when they are established, two examples of hidden conservativeness in the derivation of dose limits and in the use of clearance levels are described here below.

3.1.1 Conservativeness in derivation of dose limits and assessment of internal dose

When ICRP determined the dose limits for both workers and members of the public, age- and sex-specific additional death probability rates of a hypothetical population were calculated assuming an annual exposure of 10 to 50 mSv for workers with a working time of 47 years (age 18 to 65 years) and an annual exposure of 1 to 5 mSv for the public for the entire lifetime (age 0 to 100 years), as provided in Appendix C "Basis for judging the significance of the effects of radiation" of ICRP Publication 60 [12]. In this publication, the dose limits for workers were determined as effective doses of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and 50 mSv in any single year. The dose limits were obtained by comparing the age- and sex-specific additional death probability rates of workers with an annual occupational fatality probability of 10^{-3}. The dose limit for members of the public was derived as an effective dose of 1 mSv per year by comparing the age- and sex-specific additional death probability rates of the public with an annual fatality probability of 10^{-4}, which is one-tenth of that for workers, and by considering the magnitude of natural background radiation level. It was also allowed as an option for the dose limit for the public that in special circumstances, a higher effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv year^{-1}. These dose limits are still valid in the latest ICRP 2007 main recommendation [13].

From the above scientific basis on which the dose limits were established, a hidden conservative assumption can be seen in the calculation of additional death probability rates, that is, the annual exposure at the dose limit is assumed to continue every year in each exposure period for both workers and the public. However, in actual situations of occupational and public exposure, it is unlikely that one continues to be exposed at levels close to the dose limit for the entire exposure period.

When the exposure is of internal type, committed dose is used for the estimation of effective dose. For compliance with the dose limit, ICRP recommends that the committed effective dose is always assigned to the year when the intake occurred, although the intakes of long-lived radionuclides lead to continuing doses over many subsequent years. For this reason, the use of committed dose introduces hidden conservativeness into calculations of doses from annual intakes [14]. This hidden conservativeness for radiation workers was quantitatively estimated for some representative radionuclides [15]. From this estimation, it was found that the conservativeness range was 1.1 to 1.6 for Sr-90, 1.0 to 1.5 for Cs-137, and 1.6 to 2.2 for Pu-239, depending on the route of intake (ingestion or inhalation), material and absorption type.

3.1.2 Conservativeness in use of clearance level

The derivation of clearance levels includes a number of conservative assumptions that were deliberately taken to encompass a large variety of exposure situations that could arise as a consequence of clearance from all types of material [16]. It is also significant that there is hidden conservativeness in the application of the summation rule when clearance levels are used, the summation of C/CL (ΣC/CL) is lower than (or equal to) one, where the activity concentration and clearance level of radionuclide *i* are C_i and CL_i, respectively. The clearance level for every nuclide has been derived and conservatively determined on the basis of the most critical exposure pathways. For example, if the easy-to-measure radionuclides are gamma emitters, their clearance levels are derived mainly on the basis of external exposure scenarios [16]. On the other hand, in the case that the difficult-to-measure radionuclides are beta or alpha emitters, their clearance levels are derived mainly on the basis of internal exposure scenarios [16]. Therefore, the summation rule to determine whether ΣC/CL for both easy-to-measure and difficult-to-measure radionuclides is lower than (or equal to) one requires us to consider rare cases (low-probability situations) in which the most serious scenarios with different nuclides occur simultaneously. This indicates that ΣC/CL is not strictly required to be lower than (or equal to) one, merely to strictly maintain the dose of 10 μSv year^{-1} for individuals.

3.2 Graded approach for acceptable uncertainty

Regarding a graded approach, IAEA GSR Part 3 [17] Requirement 6 states that

> "*The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.*
>
> *3.6. The application of the requirements of these Standards shall be in accordance with the graded approach and shall also conform to any requirements specified by the regulatory body.*" (IAEA, 2014).

In addition, in a chapter of definitions in GSR Part 3, the graded approach is defined as

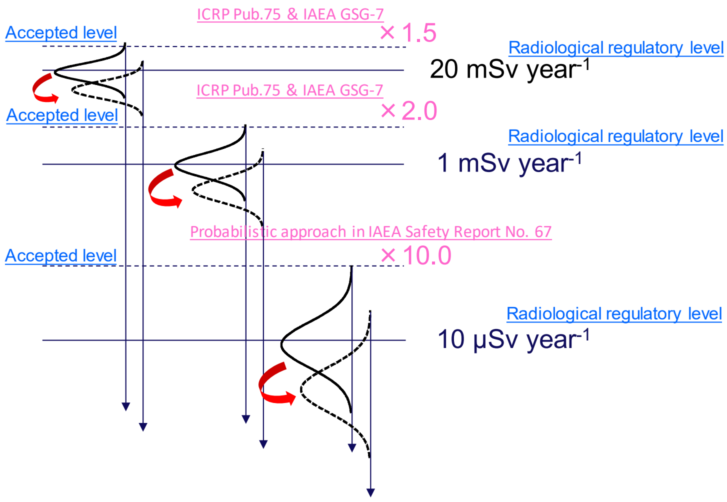
> "*For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.*" (IAEA, 2014)

The above-mentioned requirements can be simply summarized for radiological safety regulation as follows:

> "*The requirements for radiological regulation shall be applied using a method in which the stringency of the control measures is commensurate with the level of risk associated with radiological regulatory levels.*"

As shown in section 2.2, there is a tendency that the upper limit of the acceptable uncertainty increases with decreasing dose criterion for conformity assessment. This is a graded approach for acceptable uncertainty of measurement in compliance with radiological regulation. This graded approach can be comprehensively illustrated in Fig. 2. In this figure, the three probabilistic distributions shown in solid curves that have different upper limits according to the radiological regulatory levels indicate the graded approach. The distributions shown in dashed curves show an upper limit for uncertainty recommended by the SSK in Germany [2]. In the case of a radiological regulatory level of 10 μSv $year^{-1}$, the SSK's recommendation for uncertainty is about 10 times stricter than the probabilistic approach in IAEA Safety Report No. 67 [9].

Figure 2: Graded approach for acceptable uncertainty (solid curves) [6, 8, 9] and SSK's approach (dashed curves) in compliance with radiological regulatory levels [2].



In the derivation of clearance levels for artificial radionuclides, two dose criteria (10 μSv $year^{-1}$ for realistic scenarios and 1 mSv $year^{-1}$ for low-probability scenarios) were used in accordance with international agreements [4]. This approach indicates that clearance levels have been determined while permitting the possibility of a dose exceeding 10 μSv $year^{-1}$ in the case of low-probability situations. This permission can also be found in a procedure in which the clearance levels were selected as rounded values (e.g., 0.1, 1, 10, and 100 Bq g^{-1}) from calculation results of the activity concentration that is equivalent to the dose criterion for each scenario [4]. These approach and procedure may be also a form of graded approach. The stringencies between the derivation of clearance levels and the conformity assessment for clearance levels should be well balanced.

3.3 Difference between product control and radiological protection

In the scope of JCGM 106, examples of quantity intended to be measured for assessing the conformity are given, e.g., a gauge block, a grocery scale, or a blood sample. The scope of this guide seems to be mainly applied to product control with a very severe requirement for accuracy, for example, in their size or mass control. On the other hand, radiological protection criteria were mainly established by using a concept of effective dose. The concept of effective dose is itself an aggregated concept including reasonable assumptions and many simplifications and uncertainties, built for the purpose of radiological protection and applicable for a standardized individual, regardless of gender and age. The effective dose is a quantity that cannot be directly measured; it is assessed or calculated. In radiological protection, this concept presents many advantages and can be seen as a rough indicator of the risk but does not require too much precision.

The radiological protection regulatory system has two borders: the level at which we enter or leave the system, e.g., exemption or clearance, set because of the ubiquity of radioactivity and representing a trivial risk, and the level above which the risk is considered unacceptable, e.g., the dose limit in planned exposure situations. Furthermore, the dose limit is not a borderline between safe and dangerous but only a convention expressing the fact that, in the context of a planned exposure situation, doses above the limit mean that the exposure situation is not well managed. For the other types of exposure situation, e.g., emergency and existing, there is no clear borderline above which the risk is considered unacceptable. In these situations, it is recommended to apply the optimisation principle, i.e., to maintain or reduce the impact to be as low as reasonably achievable (ALARA) taking into account economic and societal factors. The global aim of the regulatory system is to avoid deterministic effects and to reduce the likelihood of stochastic effects. The reference levels used in emergency and existing exposure situations are levels above which we do not recommend to go or stay, and exceeding these levels does not constitute a failure. The effective dose criterion for clearance or exemption is a typical borderless case, because it is not a single value of 10 μSv year^{-1} but is defined as a flexible value on the order of 10 μSv year^{-1}. In addition, note that many conservative assumptions are included in the derivation of such radiological protection criteria.

When considering the meaning of conformity, we can easily find a significant difference between product control and radiological protection criteria. In the field of product control, there is no concept of the order of the dose criterion and radiation effects probabilistically occurring by gradation as a result of stochastic effects. Moreover, there is no similar rule such as a graded approach in the radiological protection system, as mentioned in the previous section.

It should also be noted that in the field of radiological protection, the uncertainty in the measurements is always appropriately restricted, as long as measurement conditions satisfy a detection limit defined in ISO11929 [5]. If the measurement method complies with a detection limit of a required measurement, it can be ensured that the uncertainty in the measurement is restricted to within about 30% [9].

4 CONCLUSION

With reference to JCGM 106, SSK adopted in September 2016 a recommendation regarding the conformity assessment in radiation measurement, requiring that the upper confidence level of the measurement must be below the regulatory level, taking relevant uncertainties into account. As a result of discussions from various viewpoints, e.g., the methodology used to derive radiological regulatory levels, the graded approach for acceptable uncertainty, and the difference between product control and radiological protection, it has been recommended that there is no need to apply a methodology of conformity assessment provided by international standards, e.g., JCGM 106, to radiological safety regulations.

Whether the strict requirement using the upper confidence level is justified for compliance with radiological safety regulation should be carefully and continuously reviewed by the international radiological protection community. In the review process, radiological protection experts including regulators, professionals, and operators should be aware of the essential meaning of the radiological protection criteria by considering the background scientific basis on which they were established. Moreover, consideration should also be given to the extensive national resources that must be supplied by both private and governmental organizations with nuclear reactors and facilities handling radioactive isotopes or accelerators, including hospitals and universities, when strict regulations with excessive conservativeness are imposed.

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