UK Health Security Agency

Radiation Metrology Group Technical Note
Decision rules and conformity assessments applicable to ISO/IEC 17025 accredited instrument calibrations

The Radiation Metrology Group calibrates radiation protection instruments in its ISO/IEC 17025 accredited laboratory. Calibration certificates are currently supplied with a 'Satisfactory' statement on them. This is considered a decision rule by UKAS under the ISO/IEC 17015 accreditation system. The 'Satisfactory' decision is for conformance with the requirement for adequate testing and examination of instruments used for monitoring workplaces under Regulation 20(3) of the Ionising Radiations Regulations 2017 (IRR17, HSE, 2019).

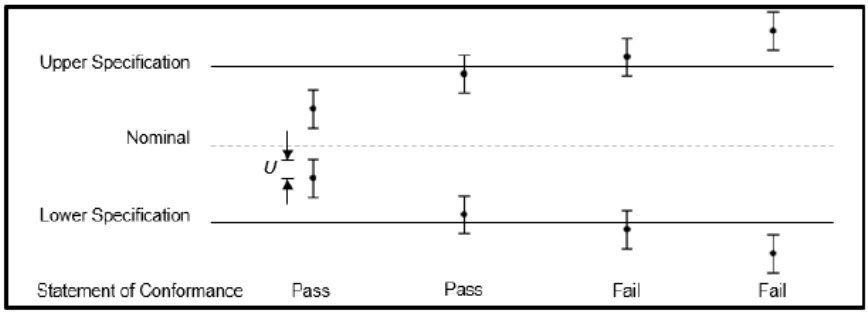
The laboratory uses the National Physical Laboratory Measurement Good Practice Guides (GPG) for the development of accredited calibration procedures; mainly GPG 14 (Marriott et al., 2021) and GPG 113 (Threadingham et al., 2022). The laboratory additionally uses a series of binary Simple Acceptance Rules, as defined by the International Laboratory Accreditation Cooperation body (ILAC, 2019), see Figure 1.

Figure 1. Excerpt including a graphical representation of a binary Simple Acceptance rule from (ILAC, 2019)

4.2.1 Binary Statement for Simple Acceptance Rule ($w = 0$)

Statements of conformity are reported as:

- Pass - the measured value is below the acceptance limit, $AL = TL$.
- Fail - the measured value is above the acceptance limit, $AL = TL$.



U = 95% expanded measurement uncertainty

The decision rules are for each of the following parts of the calibration and testing process performed in the accredited laboratory:

(i) Measurement uncertainty,
(ii) Response to high dose rates (ie overload),
(iii) Background indication,
(iv) Dose rate linearity,
(v) Energy dependence, and
(vi) Directional dependence (for test before first use only).

Details of each separate decision rule are described below.

1. Measurement uncertainty

Where a Simple Acceptance Rule for a tolerance value is used, UKAS require measurement uncertainty to also be considered (UKAS 2022). The laboratory considers measurement uncertainty first, prior to considering the other decision rules. There are three test conditions for measurement uncertainty. Table 1 provides the acceptable limits (that is a binary Simple Acceptance Rule) on measurement uncertainty at each stated reference dose rate. Only instruments meeting these conditions will be deemed to have satisfied this rule from whence the other supplementary rules are then considered. For calibrations that do not include the stated test reference rate, that condition is not considered further.

Let I = full scale deflection, ie maximum Indicated range of the instrument.
Let U = expanded measurement uncertainty.
Let k = coverage factor = 2, ie confidence level of approximately 95%.

Table 1. Tolerance values for expanded measurement uncertainty

Test Condition	Reference air kerma rate (K_a) or ambient dose equivalent rate ($H^*(10)$) (µGy h^{-1} or µSv h^{-1})	Expanded measurement uncertainty (U) conformance values (k = 2)
1	2.5	± 30%
2	For instruments with logarithmic scales: 0.05 I	± 20%
	For other instrument types (non-logarithmic scales): 0.1 I	± 20 µSv h^{-1}
3	0.1 < $I \leq$ 1.0	± 10%

SATISFACTORY:

Simple Acceptance Rule when

$U \leq$ conformance values stated in Table 1 for the given dose rate, OR

$U \leq$ the manufacturer's coefficient of variation for the stated dose rate.

FAIL: Otherwise.

2. Response to High Dose rates (ie Overload)

For instruments suitable for subjection to this test, the laboratory operates a two-part Simple Acceptance Rule;

(i) If the dose rate is > maximum range of the instrument, the instrument must display the correct overload indication for the instrument model type (as defined by the manufacturer), and;

(ii) the instrument must return to normal operation after that dose rate, that is response returns to within ±10% of the original response when re-exposed to the same pre-overload test (within the timeframe indicated by the manufacturer, typically ≤ 5 minutes from ceasing the over-load irradiation).

The criteria for this part of the test are therefore;
Let R_0 = pre-overload response, and R_1 = post-overload response.

SATISFACTORY:

Simple Acceptance Rule when

1. Correct overload indication in the accredited laboratory, as defined by the manufacturer, AND
2. $0.9\ R_0 \leq\ R_1 \leq 1.1\ R_0$.

FAIL: Otherwise.

For instruments that may be damaged by subjection to this test, this test is not performed and no criteria from this test is considered for assessing the conformance of that instrument model with IRR17.

3. Background Indication

The observed background indication should be comparable to that stated in reference data, taking local background conditions into account. The manufacturer may have a minimum measurement range for the model below which, the instrument may display a different reading indicating a below minimum dose rate, or it may display an indication that may fluctuate with a larger spread of values than for the instrument's specified measurement range.

These tests are performed in the accredited laboratory, where the background is well characterised and known to be approximately $H^*(10)$ = 2.5 µSv per day, that is < 0.2 µSv h^{-1}. Responses should be typical for the particular instrument model, ie within ±50%. Instruments measuring dose rate are expected to accurately indicate the laboratory's background air kerma or ambient dose equivalent rate within the limits stated by the manufacturer.

Let I_{bg} = instrument's indication to background radiation in the accredited laboratory.
Let I_{tbg} = manufacturer's stated typical indication to background radiation for the particular instrument model.

SATISFACTORY:

Simple Acceptance Rule when

For non-numeric indications: correct background indication as defined by the manufacturer, ELSE

For numeric indications:

a. $0.5\ I_{tbg}\ \leq I_{bg} \leq 2.0\ I_{tbg}$, OR

b. $I_{bg} \leq$ 0.5 µGy h^{-1} or ≤ 0.5 µSv h^{-1} (as relevant for the instrument model).

FAIL: Otherwise.

4. Dose rate linearity

This test is performed using a minimum of three different ^{137}Cs reference dose rates.
The laboratory operates a multi-part condition;

(i) responses typical for the particular instrument model, ie within ±30% of manufacturer's type-test data or specification datasheet, AND

(ii) responses (for each reference dose rate) within ±30% of the mean of all linearity responses, OR

(iii) responses consistent year to year or getting worse (when there have been no adjustments or repairs to the instrument in the meantime). Response may be gradually getting worse or may be a sudden change from previously consistent responses.

Let R_t = manufacturer's type test or reference data for the instrument model.
Let R_m = mean response to ^{137}Cs from all the linearity dose rates tested in this examination.
Let R = instrument's response in the accredited laboratory, that is ((instrument indication of dose rate - background dose rate) / reference dose rate), for each specified ^{137}Cs reference dose rate.
Let R_c = current year's response (at specified reference dose rate).
Let R_{prev} = previous year's response or average from several years (at same specified reference dose rate).

SATISFACTORY:

Simple Acceptance Rule when

1. $0.7\ R_t \le R_m \le 1.3\ R_t$, AND

2a. $0.7\ R_m \le R \le 1.3\ R_m$, OR

2b. $0.8\ R_{prev} \le R_c \le 1.2\ R_{prev}$.

FAIL: Otherwise.

5. Energy Dependence

This test is performed in the accredited laboratory using ^{241}Am and ^{137}Cs. The ratio of the ^{241}Am response to ^{137}Cs is within ±30% of reference ratio data (manufacturer's instrument model type test data or specification datasheet).

Let R_{Am} = instrument's response to ^{241}Am, that is ((instrument indication of dose rate - background dose rate) / reference dose rate), for specified ^{241}Am reference dose rate.
Let R_m = mean response to ^{137}Cs from linearity test.
Let A_t = ratio of ^{241}Am to ^{137}Cs response from manufacturer's data for the instrument model.

SATISFACTORY:

Simple Acceptance when $0.7\ A_t \le (R_{Am} / R_m) \le 1.3\ A_t$

FAIL: Otherwise.

6. Directional Dependence

This test is performed as part of an overall test before first use or after a major instrument repair, such as replacement of the detector. In the accredited laboratory, it is performed using ^{241}Am with the instrument at a specified angle from normal irradiation (and may be performed in 2 geometrical planes if response in one plane is significantly different to the other plane).

Let R_Ω = instrument's response to ^{241}Am at a specified angle (Ω,°), that is ((instrument indication of dose rate - background dose rate) / reference dose rate), for specified ^{241}Am and specified angle dose rate, °.
Let $R_{t,\Omega}$= reference data (manufacturer's stated model type test response at specified angle).

SATISFACTORY:

Simple Acceptance when $0.7\ R_{t,\Omega} \le R_\Omega \le 1.3\ R_{t,\Omega}$ (for specified angle, Ω)

FAIL: Otherwise.

Summary of UKHSA Decision Rules

The accredited laboratory decision rules involve additional supplemental criteria to that given in the GPG. The supplemental criteria are in the format of binary Simple Acceptance Rules, occasionally in the format of a series of simple conditional cases. No guard band is considered for these rules (that is w = 0) however measurement uncertainty is assessed as the first rule.

The certificate results are assessed to meet the requirements of a suitable test under the Ionising Radiations Regulations, 2017 (HSE, 2018) for a test before first use or periodic test. The certificate is assigned as overall 'Satisfactory' when all the separate decision rules have met their separate 'Satisfactory' criteria.

Prepared by: Fero Ibrahimi, Technical Manager and Tim Daniels, Quality Manager

References

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