Policy on laboratory refurbishments/renovations/relocations, the movement of laboratory equipment and new laboratory equipment (ISO 17025 & ISO 15189)

PS32

1) Purpose

1.1) This statement sets out the Irish National Accreditation Board (INAB) policy on communication with INAB by laboratories carrying out accredited testing/calibration. The purpose of this policy statement is to ensure mutual understanding between INAB and the laboratory on when INAB must be notified of significant changes that can affect accredited activities;

- Renovation
- Refurbishment
- Expansion – where there is no change in address
- Relocation
- Purchase of new equipment – Note that this excludes the purchase of glassware, balances, pipettes, manual sieves etc.
- Movement of existing equipment – This relates to types of equipment such as GC-MS, LC-MS, PCR systems, clinical chemistry/ immunochemistry analysers, ICP-MS, HPLC, automated purification/extraction systems, ion chromatography etc. Note that this list is not exhaustive and clarification can be sought from INAB if in doubt of whether this section of the policy applies. Equipment intended to be mobile (e.g. equipment secured on carts/wheels, pipettes, hand-held equipment etc.) is excluded from this policy.

2) Statement

2.1) Laboratory refurbishments/renovations/expansions

2.1.1) In the event of laboratory refurbishment/renovation/expansion (including the expansion of the existing laboratory where the address does not change), the CAB shall complete a risk assessment considering all potential impacts of the changes before the implementation of those changes.

2.1.2) The risk assessment shall be submitted to the relevant INAB assessment manager for review prior to the implementation of the changes.

2.1.3) Depending on the extent of the planned change(s), the risk assessment and summary of changes may need to be reviewed by a technical assessor/technical expert. This will be completed by document review.

2.1.4) Depending on the extent of the planned change(s) and the potential to impact testing/calibration results identified as a result of the risk assessment, the CAB should consider the voluntary suspension of accredited testing/calibration.

2.1.5) Depending on the extent of the change(s) in the laboratory and the outcome of the INAB review of the risk assessment, an on-site visit may be required. The on-site visit will comprise of a technical assessor/technical expert and/or a lead assessor. At a minimum, and depending on the significance of the planned changes, a document review by a technical assessor/technical expert will be required.

2.1.6) Where laboratory refurbishment/renovation/expansion involves the purchase of new equipment or movement of existing equipment, the laboratory shall refer to section 2.2 and 2.3 of this policy statement.

2.2) Laboratory relocations

2.2.1) The relocation of an existing accredited site to a new address or the addition of new sites require an onsite visit by INAB. The CAB must submit an ETS application at least six months in advance of the planned move. The onsite assessment will include a review of the below points where applicable and also a review of the site suitability in accordance with the relevant standard. A completed internal audit is also a requirement for new sites/relocations.

2.2.2) The laboratory can voluntarily suspend their scope until the move is completed and INAB have assessed the move.

2.2.3) Where the laboratory have multiple pieces of the same equipment, the laboratory can move a small number of the equipment to the new site. INAB will assess this move and providing that any NCs are cleared and the decision is successful, the laboratory can move the remainder of equipment to the new location/site and document it in accordance with PS24. This will then be reviewed at the next annual surveillance. The INAB policy document on multi-site CABs, PS19, will also apply if this approach is used. This includes but is not limited to reports and certificates documenting the location from where the conformity assessment activity is performed

2.2.4) Where the laboratory has purchased new pieces of equipment for the new location/site which is the same make/manufacturer and model of an existing piece of equipment used for accredited testing/calibration, the CAB shall carry out a risk assessment to identify any potential risks with the proposed move. Depending on the outcome of the INAB review of the risk assessment, an on-site visit may be required. The on-site visit will comprise of a technical assessor/technical expert and/or a lead assessor. If an on-site visit is not required, the laboratory shall document their conformance with INAB PS24. This will be reviewed by INAB during the next on-site assessment. The CAB can report results as accredited following satisfactory validation/verification, provided the CAB is accredited for the specific test.

2.2.5) Where the laboratory has purchased new pieces of equipment for the new location/site which is an upgraded model, different make/manufacturer or model than other pieces of equipment used in accredited testing/calibration or a different underlying measurement technique to other pieces of equipment used in accredited testing/calibration, an onsite assessment will be required.

2.3) Movement of existing equipment involved in accredited testing/calibration

2.3.1) Before the movement of any equipment, as outlined in section 1 of this policy, the CAB shall carry out a risk assessment to identify any potential risks associated with the move of that equipment. This is irrespective of the equipment being covered by flexible scope (INAB PS11). Equipment intended to be mobile (e.g. equipment secured on carts/wheels, pipettes, hand-held equipment etc.) is excluded from this section of the policy.

2.3.2) The risk assessment shall be submitted to the relevant INAB assessment manager for review prior to the move of equipment. The risk assessment may need to be reviewed by a technical assessor/technical expert. This will be processed by document review.

2.3.3) Depending on the significance of equipment being moved and the outcome of the risk assessment review by INAB, a minimum of a document review will be required to assess the move of the equipment. An on-site assessment by a technical assessor/technical expert may be required. The CAB shall provide evidence of calibration, validation and verification of the equipment once moved to its new position in the laboratory (INAB PS24).

2.3.4) The CAB may need to consider voluntary suspension of accreditation.

2.4) New laboratory equipment

2.4.1) The laboratory shall inform INAB prior to the use of any new laboratory equipment, as outlined in section 1 of this policy, which is involved in accredited testing/calibration. For laboratories accredited under flexible scope, this is not required provided that there is no change to the underlying measurement/detection technique of the new equipment (INAB PS11) and provided that the laboratory is accredited to add new equipment under their flexible scope (Note 4).

2.4.2) Where the laboratory has purchased a piece of analytical equipment with a different underlying measurement technique to other pieces of equipment used in accredited testing/calibration, the laboratory shall apply for extension to scope. This will involve an on-site assessment by a lead assessor and technical assessor/technical expert. The laboratory shall document conformance with INAB PS24. The CAB shall not report results as accredited until assessed by INAB and a positive decision is made by the INAB manager.

2.4.3) Where the laboratory has purchased a piece of analytical equipment with the same underlying measurement technique, but with a different make/manufacturer and model than other pieces of equipment used in accredited testing/calibration, the laboratory shall apply for extension to scope. This may involve either an on-site assessment or an extension to scope by correspondence. The laboratory shall document conformance with INAB PS24. The CAB shall not report results as accredited until assessed by INAB and a positive decision is made by the INAB manager. Sub-clause 2.3.3 does not apply if accredited under flexible scope (INAB PS11) with Note 4.

2.4.4) Where the laboratory has upgraded the model of equipment (same make/manufacturer and underlying measurement technique) used in accredited testing/calibration, the laboratory shall apply for extension to scope. Depending on the significance of updates between models, this may be able to be facilitated by correspondence. The laboratory shall document conformance with INAB PS24. The CAB shall not report results as accredited until assessed by INAB and a positive decision is made by the INAB manager. Sub-clause 2.3.4 does not apply if accredited under flexible scope (INAB PS11) with Note 4.

2.4.5) Where the laboratory has purchased a piece of equipment which is the same make/manufacturer and model of an existing piece of equipment used for accredited testing/calibration, the laboratory shall document their conformance with INAB PS24. This will be reviewed by INAB during the next on-site assessment. The CAB can report results as accredited following satisfactory validation/verification, provided the CAB is accredited for the specific test.

3) Timelines

3.1) The laboratory shall adhere to R1 INAB regulations with regards to applications for extensions to scope. For document reviews/on-site assessments which do not fall under extension to scope, the laboratory shall allow 3-6 months for the scheduling and assessment of changes.

4) Fees

4.1) The INAB fee schedule sets out the fees for off-site and on-site assessments.

5) Status and Implementation

This policy is mandatory and applicable from date of issue.

6) Contact

For further information about this statement please contact your INAB assessment manager at **The Irish National Accreditation Board.**

Phone: 01 6147182
E-mail: inab@inab.ie
Website: www.inab.ie