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

PS32

1) Purpose

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

- **Renovation -** where there is no change in address
- **Refurbishment -** where there is no change in address
- **Expansion** – where there is no change in address
- **Relocation**
  - when there is a change in address (to new building/ new site)
  - when there is no change in address
- **Movement of equipment**
  - Movement of equipment involved in accredited testing to a new address (new building/new site)
  - Movement of equipment involved in accredited testing to a new position/location within the same building where there is no change in address
- **Purchase of new equipment**

Note: Equipment intended to be mobile (e.g. equipment secured on carts/wheels, pipettes, hand-held equipment etc.) is excluded from this policy.

Note: Equipment such as glassware, balances, pipettes, manual sieves etc is excluded from this policy.

2) Statement

2.1) Laboratory renovation/refurbishment/ expansions (the address does not change)

2.1.1) In the event of a laboratory refurbishment/renovation/expansion (including the expansion of the existing laboratory where the address does not change), the CAB shall

- Notify INAB and submit an **AF-1-F (Organisation Change Information Form)**
- Submit a risk assessment detailing the planned change(s) and all potential impacts of the change(s) before implementation of the change(s). The risk assessment shall be submitted to the relevant INAB assessment manager for review prior to the

implementation of the changes**.** Further information may be requested by the assessment manager.

Note: The risk assessment submission should include context on the details of the renovation/refurbishment/expansion. (i.e. refurbished office space, portacabin, upgrade to an existing laboratory etc)

2.1.2) Depending on the extent of the planned change(s), the outcome of the risk assessment and the potential impact on testing/calibration results, the CAB should consider **voluntary suspension of accredited testing/calibration**.

2.1.3) The changes regarding the renovation/refurbishment/expansion may need to be reviewed and assessed by a technical assessor/technical expert either via assessment by correspondence, remote assessment, or via an on-site assessment. The on-site assessment will comprise of a technical assessor/technical expert and/or a lead assessor

2.1.4) Where laboratory refurbishment/renovation/expansion involves the purchase of new equipment or movement of existing equipment, the laboratory shall refer to section 3.0 of this policy statement

3) Laboratory relocations

3.1.1) **Relocation** - where there **is a change** in address (to new building/ new site).

- Notify INAB and submit an **AF-1-F (Organisation Change Information Form)**

The relocation of a site, already under a CAB's existing accreditation, to a new address or the addition of new sites/building requires an onsite assessment visit by INAB. The CAB must submit an **extension to scope** application at least six months in advance of the planned move. The onsite assessment will include review of the site suitability in accordance with the relevant standard. A completed internal audit is also a requirement for new sites/relocations. The CAB should consider voluntary suspension of accreditation until such time as the move is complete.

Note: Where a CAB is relocating multiple pieces of the same equipment to a new address; the laboratory can relocate some of the equipment to the new site (new address). INAB can then perform an on-site additional assessment visit via extension to scope. Providing that NCs are cleared and the decision is successful, the CAB can move the remainder of equipment to the new location/site thereafter and document it in accordance with PS24. This will then be reviewed at the next annual surveillance visit. 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.

3.1.2) **Relocation –** where there is **no change** in address (same building)

- Notify INAB and submit an **AF-1-F (Organisation Change Information Form)**
- Submit a **risk assessment** detailing the planned change(s) and all potential impacts of the change(s) before implementation of the change(s). The risk assessment shall be submitted to the relevant INAB assessment manager for review prior to the implementation of the changes

Depending on the significance and extent of the relocation/repositioning of existing equipment within the same building and the outcome of the risk assessment review by INAB, INAB will decide either to;

a) review the execution and implementation of the move at the next scheduled surveillance visit,

b) carry out an additional on-site assessment

c) recommend the CAB to consider voluntarily suspension of its accreditation until such time as the move has been completed (R1).

In all cases, once the move has been completed, INAB will review either on site at the additional visit or at the next surveillance visit, evidence of calibration, validation and verification of all the equipment that was moved in accordance with INAB PS24.

Move of equipment involved in accredited testing

3.1.3) Movement **of existing equipment** where there is no change in address (same building/site)

Before the movement of any equipment, the CAB shall;

- **Notify INAB and submit an** AF-1-F (Organisation Change Information Form)
- Submit a **risk assessment** detailing the planned change(s) and all potential impacts of the change(s) before implementation of the change(s). The risk assessment shall be submitted to the relevant INAB assessment manager for review prior to the implementation of the changes

Submission of the above (AF-1-F and a risk assessment) 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.

Depending on the significance and extent of existing equipment being moved within the same building and the outcome of the risk assessment review by INAB, INAB will decide either to;

a) review the execution and implementation of the move at the next scheduled surveillance visit,

b) carry out an additional on-site assessment

c). recommend the CAB to consider voluntarily suspension of its accreditation until such time as the move has been completed (R1)In all cases, once the move has been completed, INAB will review either on site at the additional visit or at the surveillance visit, evidence of calibration, validation and verification of the equipment (INAB PS24).

3.1.4) Movement **of existing equipment** where there is a change in address (new building /site)

See section 3.1.1. The relocation of equipment to a new address or a new building/site will require an onsite assessment visit by INAB. The CAB must submit an **extension to scope** application at least six months in advance of the planned move. The CAB should consider voluntary suspension of accreditation until such time as the move is complete.

4) Purchase of New equipment

4.1.1) 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).

4.1.2) 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.

4.1.3) 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.

4.1.4) 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.

4.1.5) 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.

6) Timelines

6.1) 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.

7) Fees

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

Abbreviations

PS24: Minimum verification requirements for ISO/IEC 17025 & ISO 15189 testing laboratories

CAB: Conformity Assessment Body.

PS11: INAB Flexible scope policy

AF-1-F: Organisation Change Information Form

R1: INAB Regulations

9) Status and Implementation

This policy is mandatory and applicable from date of issue.

10) Contact

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

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