Accreditation of Flexible Scopes

3rd February 2016

Food, Health and the Role of National Reference Laboratories Conference
INAB

Irish National Accreditation Board for Ireland, under Regulation 765/2008, since 1985

Part of the Health and Safety Authority, since 2014

Signatory to international recognition agreements for accreditation of testing laboratories
INAB Scope of Activity

- **ISO 17025 testing labs** – 102
  - **8 labs accredited for flexible scope**
    - ISO 17025 calibration labs – 19
    - ISO 15189 medical testing labs – 67
    - ISO 17021 management systems certification bodies – 5
    - ISO 17065 product certification bodies – 9
    - ISO 17020 inspection bodies – 8
    - ISO Guide 34 RMP – 1
    - GLP – 2; EMAS - 3
Scope of Accreditation

• Accreditation is the 3rd party independent confirmation of competence

• Description of Competence
  • Visible, accurate, unambiguous
  • Scope of accreditation
  • Fixed vs. Flexible scope

• Specific conformity assessment activity (testing) for which accreditation is sought/has been granted
Requirements on an AB

- ISO 17011 - standard for AB
  - Tests or type of test performed
  - Materials or products tested
  - Methods used, where appropriate

- EA-2/15(M) - requirements for FS
- ILAC (G)18 - requirements for scopes
- [EA-4/17 (M) - scopes for medical testing labs]
Fixed Scope

- Historical method of describing scope of accredited activities
- Accurate
- Additional activity – evaluation of competence
- Is it restrictive?
<table>
<thead>
<tr>
<th>INAB Classification number (P9)</th>
<th>Type of test/properties measured</th>
<th>Standard specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials/products tested</td>
<td>Range of measurement</td>
<td>Equipment/techniques used</td>
</tr>
<tr>
<td>811 .01</td>
<td>Aerobic colony count</td>
<td>Documented in-house methods based on BS/ISO Methods, unless otherwise indicated</td>
</tr>
</tbody>
</table>
Flexible Scope

Move from listing specific activities to......

Defining competence to apply knowledge, skills and experience

Move focus from what is accredited to what lab is capable & competent to do
INAB & Flexible Scopes

- Accrediting flexible scopes since 2007
- Restricted to Chemical testing labs only
- Based on Regulator and client feedback
  - New regulations
  - Opportunity to improve response to extensions to scope
INAB & Flexible Scopes (PS11)

- Process of revision to extend policy
  - To all ISO 17025 testing laboratories
  - To all ISO 15189 medical testing laboratories
- Consultation workshops
- Assessor consultations
- Review by Management and INAB Board
- Pilot assessments
- EA-2/15(M) mandatory requirements
Key points of the policy

- Combination of fixed and flexible
- Key personnel, responsibilities
- Key processes
  - Contract review
  - Verification
  - Management system
- Lab responsibility - AB
Key points of the policy

- List of activities under FS, publicly available
- Requirement for proficiency testing
- Responsibility – consequences
- Permissions & restrictions
Flexible Scope - Permitted

- Change in matrix or sample type
- Change in sample prep, dilution concentration
- Change of kits, reagents
- Change in equipment / upgrade provided same underlying methodology is used
- New test /examination providing the same underlying methodology is in use
### Examples and explanations

<table>
<thead>
<tr>
<th>INAB Classification Number (P9)</th>
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<th>Equipment/Technique</th>
<th>SOP/Standard Reference</th>
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<td>811. Microbiological tests on foods</td>
<td>.01 Bacillus cereus</td>
<td>Dairy Products</td>
<td>Colony count technique</td>
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<td></td>
<td>Add on</td>
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<td>.02 Bacillus cereus</td>
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<td>.03 Bacillus cereus</td>
<td>Meat and Meat Products, game and poultry</td>
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Flexible Scope - Restricted

- Change in underlying methodology (extraction, analysis, detection)
- Change in major classification / scientific discipline
- Use of equipment / kits outside of manufacturers’ specifications
- Change from manual to automated even if underlying methodology is the same
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<td>870. Waters</td>
<td>Coliforms and E.coli</td>
<td>Bacteriological condition of potable waters</td>
<td>Membrane Filtration</td>
<td>Microbiology of Drinking Water 2009, Part 4A, SOP 001</td>
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<td>811. Microbiological Tests on Foods</td>
<td>Coliforms and E.coli</td>
<td>Dairy Products</td>
<td>Enumeration by pour plate method</td>
<td>SOP 123 based on ISO 4831:2006</td>
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<td>.01 Determination of Sodium</td>
<td>Dairy Products</td>
<td>3 mg/kg - 80%</td>
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<td>In house developed atomic absorption method, SOP 101</td>
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Verification vs. Validation

- Validation
  - Confirmation, that
  - Requirements for specific intended use, through
  - Objective evidence
  - INAB policy – PS15 (chemical labs)

- Verification
  - Confirmation, that
  - Specified requirements have been fulfilled, through
  - Objective evidence
  - INAB policy – PS24 (all labs)
Making Flexible Scope Work

- Labs to ensure as many (all) key techniques accredited
- Embed into QMS
- Clear responsibilities
- Review use
- Responsibility for authorising test as accredited
- Publicly available (on request) list
- Additional assessment time needed
- Continue to use traditional route for extension of scope
Benefits of Flexible Scope

- Laboratories & ABs
  - Reflects competence
  - Less restrictive
  - Responsive

- End Users
  - Regulators & customers
  - Promotes use of accreditation
Thank you for your attention
Documents available at
  www.inab.ie
  www.european-accreditation.org
  www.ilac.org