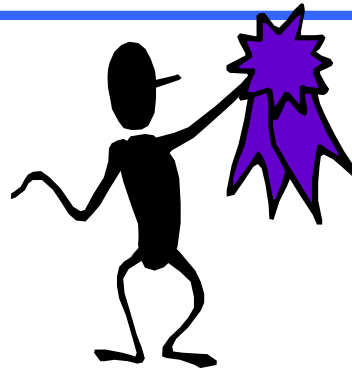



“ISO17025:2005 and accreditation under “open scope” NT-18 and NT-19. Required changes in Quality Management System

Imma Alsina
Quality Assurance Manager
Laboratori Agroalimentari – DARP

Ljubljana, April 18th 2006



 Generalitat de Catalunya
Departament d'Agricultura,
Ramaderia i Pesca

OPEN SCOPE ACCREDITATION INTRODUCTION

- Testing and calibration laboratories: Accreditation by test category “Open scope” NT-18 Rev. 1 June 2004
- New terms
- The experience of the Laboratori Agroalimentari:
 - **Changes in Management requirements**

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ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

- "Its concrete objective is to establish the rules so that the laboratory can assume the responsibility of the management from its scope of accreditation and to use concrete, validated and suitable test methods, with no need for a previous evaluation on the part of Accreditation body of this method." NT-18 Rev.1
- Advantages of Open scope?
- Management of accreditation scope by the Laboratory.
- It's possible to give accredited results within a test category without an assessment of a accreditation body.

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

- What requirements for technical note NT-18?
- The Laboratory will have to develop and to validate test procedures when the client asks for a test by category not included in the opened list of tests.

GREATER TECHNICAL DEMAND

- The Laboratory will have to implement a management system that guarantees that all the requirements of the technical Note are fulfilled

GREATER MANAGEMENT DEMAND

ACCREDITATION BY TEST CATEGORY

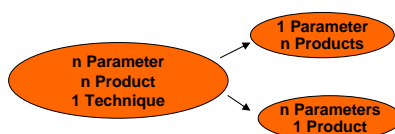
NT-18 Rev. 1 Junio 2004

- NEW TERMS:
- TEST CATEGORY: set of tests made by a common technique or test to determine a parameter or family of parameters in a product or family of products.

TEST



TEST CATEGORY



ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

- NEWS TERMS:
- TEST CATEGORY:
- When the laboratory solicits an accreditation by a category of test is declaring its technical competence to develop procedures and to do all the specific tests included in the category.

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

1. EXAMPLES

- Test procedure
- Group of products/Products
- Family of parameters/Parameters
- Range

PROCEDIMIENTO DE ENSAYO	FAMILIA DE PRODUCTOS/ MATRIZ	FAMILIA DE PARÁMETROS/ ANALITOS	RANGO
030016Rev.6	Orina Agua	Cimaterol Clenbuterol Clenpropeterol Mabuterol Salbutamol Terbutalina	>2 µg/L >2 µg/L >2 µg/L >2 µg/L >2 µg/L >2 µg/L
030036Rev.5	Orina Agua	Cimaterol Clenbuterol Clenpropeterol Mabuterol Salbutamol Terbutalina	2-100 µg/L 2-100 µg/L 2-100 µg/L 2-100 µg/L 2-100 µg/L 2-100 µg/L
030018Rev.5	Piensos Materias para Alimentación Animal	Cimaterol Clenbuterol Mabuterol Salbutamol Terbutalina	>20 µg/Kg >20 µg/Kg >20 µg/Kg >20 µg/Kg >20 µg/Kg
030040Rev.5	Piensos Materias para Alimentación Animal	Cimaterol Clenbuterol Mabuterol Salbutamol Terbutalina	20-100 µg/Kg 20-100 µg/Kg 20-100 µg/Kg 20-100 µg/Kg 20-100 µg/Kg

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

- NEW TERMS:
- OPEN SCOPE LIST: Document controlled by the Laboratory where the tests are included for which the Laboratory is accredited within a category (LEBA or LPE).

Within a category, only the tests included in the open list are accredited.


ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

1. OPEN SCOPE LIST. Contents :

- Title
- Number of revision and date of approval.
- Reference to the code and revision of the Attached Technician of ENAC.
- Family(s) of products
- Family(s) of parameters
- Test Procedure applicable to the category
- Intervals of measurement or limits of quantification according to application

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Responsible
for revision

Responsible
for approval

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

- 2. Management of requests and contracts:
 1. Analysis Request Reception
 2. Decision about method development / validation / term and price
 3. Inform customer about "incidence form":
 - Customer reject: End of process
 4. Customer acceptance

Head of Department /
Head of Laboratory

New management of request for category test

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ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

2. DEVELOPMENT / VALIDATION OF METHODS

- 1. Analytical method development
- 2. SOP elaboration or modification
- 3. Validation of analytical procedure
- 4. Validation Final Report:
 - Approved
 - Rejected

Head of Department /
QUA Manger

Head of Department /
QUA Manger

Head of Department /
Head of Laboratory

Head of Department /
QUA Manger /
Head of Laboratory

New management for validation studies

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

3. MODIFICATION, REVISION and APPROVAL OF THE OPEN SCOPE LIST:

1. Validation Final Report Accepted
2. New revision of LEBA
3. Inform about new LEBA
4. Accredited analytical result issued

QUA Manger

Head of Department /
Head of Laboratory

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

■ 4. NON-CONFORMING WORKS and CORRECTIVE ACTIONS:

1. Validation Final Report rejected
2. Non Conforming Work
3. Corrective Action
4. Inform customer

QAU Manager /
Head of Laboratory

Validation Final Report Rejected: NON CONFORMING WORK

QUA Manger

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

- #### ■ 4. NON-CONFORMING WORKS and CORRECTIVE ACTIONS:
- A Register of Non-Conforming Work produced by a "Report of unfavorable validation of a test by category not included in the opened list of test under accreditation." Corrective Actions will always be undertaken. These include:

- To inform the client
- To modify the procedures or methods
- To redefine, if it applies, the category of test, and consequently to modify the opened list of tests by category

ACCREDITATION BY TEST CATEGORY

NT-18 Rev. 1 Junio 2004

CHANGES IN MANAGEMENT REQUIREMENTS

- SUMMARY OF CHANGES:
 1. New quality policy
 2. Creation of the opened Lists of tests. Format, management, revision and approval.
 3. Certification of qualifications. New responsibilities in key activities.
 4. Management of requests
 5. Development of methods
 6. Validation of methods
 7. Non-Conforming Works and Corrective actions
 8. Management reviews
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