



# Effects of ISO Guide 34 for Reference Material Production

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# LECO

- LECO Corporation was accredited by A2LA for ISO Guide 34:2009 in April of 2013.
  - The scope of accreditation included inorganic “metal” reference materials
  - The expansion of this scope into organic reference materials is currently pending approval with A2LA
- The LECO Technical Services Laboratory was accredited by A2LA to ISO/IEC 17025:2005 in May of 2012.
  - The scope of accreditation was also inorganic and is currently pending expansion approval into organics.

# Why?

- Why did LECO decide to pursue these accreditations?
  - The LECO Technical Services Laboratory (TSL) was interested in obtaining accreditation to ISO/IEC 17025:2005 for quite some time to add credibility to the laboratory results.
    - This was the first step in the process
  - Before LECO TSL was accredited, A2LA issued a memorandum that stated all ISO/IEC 17025:2005 accredited labs through A2LA must obtain, where possible, reference materials from and ISO Guide 34 accredited manufacturer or NMI.
  - After reviewing ISO Guide 34, LECO decided to pursue the accreditation despite resistance from the analytical community to conform to ISO Guide 34.
    - It was viewed as an opportunity to better our products and to be able to meet the demand of our customers

# Transition

- After the LECO TSL was accredited, we made a goal to get accredited to ISO Guide 34 in one year.
- During this period, LECO consistently received calls and emails from our customers regarding ISO Guide 34 materials.
  - Typically the customer was being audited and did not have a Guide 34 standard and was getting a deficiency
  - LECO informed our customers of our intention of getting accredited.
  - The deficiency was from A2LA's traceability policy. A waiver can be filed and approved for this issue, but must be done before the assessment every year to not get a deficiency.
  - LECO informed our customers of the waiver.
    - Most customers had never heard of the waiver and were happy to hear there was a temporary fix.

# Transition

- As LECO was working on documentation for the ISO Guide 34 accreditation, we discovered areas where we could improve on our process.
- We started to have committee meetings regarding the production of reference materials
  - Discussed material sourcing
  - Production problems/requirements
  - Documentation
- Updated statistical procedures were written in an official document rather than old manuals.
- Organized the production process through internal auditing
  - Flow charts
  - Storage conditions/monitoring
  - Inspection procedures

# Effects of the Accreditation Process

- Negative Effects
  - This was not a planned move
  - Had to make the changes under pressure from customer requirements and a tight time frame
  - Cost and time
  - The creation of extra documentation
  - We estimate only about 30% of our customer base requires this; cost is passed on to the other 70%

# Effects of the Accreditation Process

- Positive
  - Continuous improvement of our products
  - Improves credibility of LECO Reference Materials
  - Made us improve the format and content of our certificates
  - Allows us to meet customer/industry demand
  - Made us monitor and participate in more proficiency testing
  - Made us improve our inter-company communication for the testing and production of reference materials
  - Made us streamline and update our manufacturing process (e.g. going paperless to PDF forms and records)



## Guide 34 Accreditation and CRM's

# CRM's

- LECO has been producing reference materials for over 30 years
- Current ISO Guide 34 documentation can be interpreted that we are making reference materials or certified reference materials
  - This is due to how it is worded in the standard.
- LECO originally was going to only do CRM's by interlaboratory study.
- After our most recent assessment, one assessor claimed that the word "Primary" in "A single (primary) method in a single laboratory" can be taken as optional because it is in parenthesis. (Reference 5.15 ISO Guide 34)
  - LECO had procedures for making RM's from a single lab using reference methods not CRM's.
  - From this we received a deficiency because of an interpretation of the current standard and the draft ISO Guide 35. The assessor claims we are making "Secondary" CRM's and labelling them as RM's and we did not have a procedure for making "Secondary CRM's".
    - Secondary CRM comes from the draft ISO Guide 35 expected to be released next year which states that CRM's can be made in a single lab and when compared to a primary CRM (NIST or other NMI) are a classified as a secondary CRM or you can use a secondary CRM to characterize a tertiary CRM.



## For More Information

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