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# RM/CRMs in ISO/IEC 17025 Quality Systems – RMP Quality Systems and Traceability

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# Smolder Test



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# NIST SRM 1196

**2 Cartons  
(400 cigarettes)  
\$248**



FEB 25 2004

DEPARTMENT OF COMMERCE

BUREAU OF STANDARDS  
CERTIFICATE OF ANALYSES

OF

STANDARD SAMPLE NO. 107  
NICKEL-CHROMIUM-MOLYBDENUM CAST IRON

	<u>Percent</u>
Carbon (total).....	2.57
Carbon (graphitic).....	1.86
Manganese.....	.706
Phosphorus.....	.197
Sulfur (gravimetric).....	.090
Sulfur* (evolution with HCl, sp.gr. 1.18).....	.082
Silicon.....	2.34
Copper.....	.074
Nickel.....	.807
Chromium.....	455
Vanadium.....	.015
Molybdenum.....	.687
Titanium.....	.037
Arsenic.....	.01

\*Sample covered with graphite and annealed  
20 minutes at 685° C.

LYMAN J. BRIGGS,  
Director

Washington, D. C.

May 10, 1933.



PJLA



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# PJLA in Brief

- Formed in 1999
- Member/Signatory of the ILAC MRA for Testing, Calibration
- Member/Signatory of the APLAC MRA for Testing, Calibration, RMP
- Office in Troy, MI

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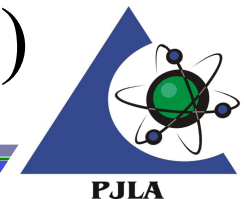
# Suggested Topics to Cover

- Requirements – ISO Guide 34 and related documents, APLAC TC 008
- Judgments by AB – AB Responsibilities
- RMs/CRMs in ISO/IEC 17025 Quality Systems
- Method Selection and Validation in ISO/IEC 17025
- RMP Quality Systems and RMs/CRMs

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# Mutual Recognitions

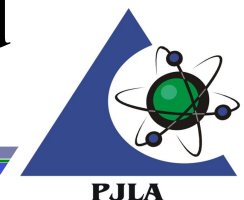
- There currently is no International Laboratory Accreditation Cooperation's – ILAC - RMP recognition
- There is an Asia Pacific Laboratory Accreditation Cooperation – APLAC - Mutual Recognition Agreement for Reference Material Producers (RMPs)
- In the USA there are 3 signatories to the APLAC MRA for RMP (9 total in APLAC)



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# ISO Guide 34 and Related Documents

- ISO Guide 34 “General Requirement for the competence of reference material producers
- ISO Guide 30 “Terms and definitions used in connection with reference materials”
- ISO Guide 30/Amd 1 “Terms and definitions used in connection with reference materials ... Revision of definitions for reference material and certified reference material”
- ISO Guide 31 “Reference materials – contents of certificates and labels”
- ISO Guide 35 “Reference materials – general and statistical principles for certification”





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# APLAC TC 008

- Purpose – to ensure a more uniform approach
  - to assessment of reference material producers
  - and resulting scopes of accreditation
  - Since the document contains both requirements and guidance ...”shall” designates requirements
- Authorship – APLAC Technical Committee

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# APLAC TC 008

- Stresses – no additional accreditation requirements – ISO Guide 34 and ISO/IEC 17025 in combination. TC 008 is an “application document” for the accreditation criteria.
  - Includes some requirements for assessment procedures, scopes of accreditation, criteria arising from the APLAC MRA
  - Guidance maintained in the document – “General” guidelines and principles – too specific may be too rigid and hamper judgment, undermine assessment of competence
  - Not intended to give specific guidelines

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# APLAC TC 008

- Accredited to ISO Guide 34 and ISO/IEC 17025 in combination
  - With ISO Guide 34 – Guides 30, 31 and 35
  - VIM
- Gap analyses/cross references in the document
  - Annex 1: ISO Guide 34 and ISO/IEC 17025:2005
  - Annex 2: ISO/IEC 17025:2005 and ISO Guide 34
  - Annex 3: Application of ISO/IEC 17025 to RMP tasks

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# APLAC TC 008

- The RMP shall be the body subject to accreditation – can be a “producer” or “facility” but not just a “laboratory” – includes activities in the Table in Section 2.5
- Accreditation criteria are ISO Guide 34 and ISO/IEC 17025 in combination. RMP to meet all requirements in both relevant to its activities.
- ISO Guide 34 is applicable to all activities of the RMP including testing, calibration and measurement. Relevance of the requirements in both documents should be assessed in context of the activities performed.

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# APLAC TC 008- Subcontractors

- RMPs may choose or require subcontractors to perform various tasks in the production of the (C)RMs.
- However, APLAC MRA Council resolved that an accredited RMP is an organization that:
  - Plans projects and manages them
  - Assigns/decides on property values
  - Determines associated uncertainties
  - Authorizes property values and issues certificates
- Accredited RMPs shall be competent to perform these activities and cannot outsource them to subcontractors or other parties.
- The RMP assumes responsibility to ensuring subcontracted tasks are performed in a competent manner and requirements for subcontractors in ISO Guide 34 and ISO/IEC 17025 are met.
- The RMP shall retain information that details roles and relationships of subcontractors and other related parties.
- Reference to Table in Section 2.5 – reproduced on next slide. This is guidance and is not to be considered exhaustive of all arrangements.

Stages/ Tasks of (C)RM production	Relevant ISO Documents	Responsible organisations							
		Type 1	Type 2	Type 3	Type 4	Type 5	Type 6	Type 7	Type 8
<i>Production planning</i>	ISO Guide 34 + ISO/IEC 17025	R	R	R	R	R	R	R	R
# Material preparation**	ISO Guide 34 + ISO/IEC 17025	R	S	S	S	S	R	S	R
# Homogeneity/ Stability testing	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	S*	R
# Characterization of Property Values	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	R	S*
<i>Assignment of and decision on Property Values</i>	ISO Guide 34 + ISO/IEC 17025	R	R	R	R	R	R	R	R
<i>Authorization of property values and issue of certificate</i>	ISO Guide 34	R	R	R	R	R	R	R	R
# Handling and storage (including post certification testing)	ISO Guide 34 + ISO/IEC 17025	R	R	S	R	S	S	S	R
Distribution & post distribution service	ISO Guide 34	R	R	S	R	S	R	S	R

**Tasks denoted by *italics* shall be performed by the RMP**

R = Tasks performed by the RMP

S = Task performed by subcontractor

# If performed by a subcontractor, the RMP shall ensure the technical competence of that subcontractor

\* Any conclusions in regards to these tasks shall be made by the RMP.

\*\* Testing, calibration and measurement activities involved in material production and preparation should comply with the relevant parts of ISO/IEC 17025.



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# AB Responsibilities

- Based on modes of operation and the activities of the RMP AB determines the the “most applicable” combination of accreditation criteria (see table).
- AB investigates technical standards that would be applicable (e.g.. ISO 6141 – requirements for gas mixture certificates & ISO 6142 – gravimetric preparation of gas mixtures).
- Note: a RMP may operate in different modes a different times for different (C)RMs

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# AB Responsibilities

- The AB shall obtain from the RMP how it is organized and how it meets the relevant criteria of ISO Guide 34 and ISO/IEC 17025.
- This shall include (not limited to):
  - Type or categories of RMs produced
  - Technical standards used for production
  - Tasks/activities performed by the RMP for specific RMs

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# AB Responsibilities

- If the RMP uses subcontractor(s) the following is required:
  - Name and address of subcontractor
  - Scope of tasks/activities performed
  - Type of testing, calibration and measurement activities (if any)
  - Evidence of technical capability (e.g. ISO 9001 certification, ISO/IEC 17025 accreditation for testing, calibration and measurement (required))
- Plans to accredit testing/calibration/measurement activities to ISO/IEC 17025 - if RMP does them.



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# AB Responsibilities

- Applicability of ISO Guide 34 and ISO/IEC 17025 requirements to be done on a case by case basis. AB should perform an analysis of the RMP operation using TC 008 as a reference.
- Assessment of the RMP's compliance to ISO/IEC 17025 to testing/calibration/measurement should be given special attention
  - Even if the RMP has all testing/calibration/measurement done by other parties – key activities in ISO/IEC 17025 would still be performed
  - All requirements of ISO/IEC 17025 may be applicable to testing/calibration/measurement activities – not just the performance of these activities (review of requests, selection of methods, validation etc.).
  - The requirements of ISO/IEC 17025 are not applicable to the RMP other than testing/calibration/measurements

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# AB Responsibilities

- (cont'd from previous slide)
  - There should not be inconsistent requirements - only more specific requirements given in ISO/IEC 17025 for testing/calibration/measurement. Refer to Annex 3.
  - All requirements (ISO Guide 34 and ISO/IEC 17025) need to be considered for each of the RMP tasks.
- If the RMP or the specified subcontractor is accredited to ISO/IEC 17025 by an APLAC and/or ILAC MRA signatory – this accreditation can be considered satisfactory for the testing or calibration competency for the relevant parts of ISO/IEC 17025.

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# AB Responsibilities

- If the RMP is not accredited to ISO/IEC 17025 but performs the testing/calibration/measurement determination activities – the AB shall include an assessment of the the RMPs testing/calibration/measurement activities against relevant parts of ISO/IEC 17025.
- If the RMP has subcontractor(s) that perform testing/calibration/measurement activities the AB shall assess how the RMP determines their competency if they are not accredited to ISO/IEC 17025.



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# AB Responsibilities

- The AB should pay particular attention to these activities covered by ISO/IEC 17025 whether done by the RMP or subcontractor
  - Selection of test or calibration methods (ISO Guide 34 5.10, 5.14, 5.15) and analytical development and validation. Robust assessment of traceability and measurement uncertainty
  - Measurement uncertainty estimations for testing/calibration/measurement processes – will affect final assigned values

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# AB Responsibilities

- (cont'd from previous slide)
  - If traceability to the SI cannot be established, certified reference materials should be used when possible.  
Uncertainties of the CRMs shall be suitable for the RMs being produced.
  - Proficiency testing – used to monitor competence of testing and calibration processes.
    - If RMP performs testing/calibration/measurement – RMP to participate in PT as required by ILAC P9
    - When an accredited laboratory is a subcontractor – PT is also required as per ILAC P9
    - Non-accredited subcontractor shall also demonstrate competence by PT or other equivalent means
    - If PT is unavailable – measurement audits, check samples, etc.

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# Annexes

- Annex 1: Gap Analysis Between ISO Guide 34 and ISO/IEC 17025
- Annex 2: Cross-Reference between ISO/IEC 17025:2005 and ISO Guide 34:2009
- Annex 3: Application of ISO/IEC17025 to RMP Tasks

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# RMs/CRMs in ISO/IEC 17025

- Part of the documentation of validation of non-standard or modified standard methods- (Sections 5.4.4.2 Note f), 5.4.5.2 Note 2)
- Document as needed as sources of variation – (Section 5.4.6.2 Note 1)
- Incorporation the overall program for measurement traceability – (Section 5.6.1 Note)
- When traceability in terms of SI units – traceability can be traced to CRMs from competent suppliers – giving reliable physical or chemical characterization – (Section 5.6.2.1.2)

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# RMs/CRMs in ISO/IEC 17025

- Used as part of the program of quality control and measurement assurance – (Section 5.9.1 a)) – CRMs and as secondary RMs for QC

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## Method Selection and Validation in ISO/IEC 17025

- ISO Guide 34 (Section 5.4.2)
  - Labs to use test and/or calibration methods that:
    - Meet customer needs
    - Appropriate for tests and/or calibrations undertaken
    - Methods published in international, regional or national standards *shall* be preferably used
  - When customers do not specify – lab selects:
    - Published methods (above), scientific texts or journals
    - Manufacturer specified methods
    - Laboratory developed methods – if appropriate & *validated*



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# Method Selection and Validation in ISO/IEC 17025

- ISO Guide 34 (Section 5.4.2)
- Standard methods:
  - Laboratory shall confirm it can operate standard methods
  - Repeat confirmation if standard method “changes”
- Regardless of method
  - Customer must be informed of method chosen

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# RMP Quality Systems and RMs/CRMs

- Measurement Methods – ISO Guide 34
  - RMP *shall* meet requirements of ISO/IEC 17025 for tests, calibration and measurements – including (Section 5.9.1)
    - Preparation
    - Sampling
    - Handling, preservation, storage, packaging, transport to subcontractors
    - Estimation of uncertainty
    - Analysis of measurement data

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# RMP Quality Systems and RMs/CRMs

- Measurement Methods – ISO Guide 34 (Section 5.9.2)
  - In-house developed methods *shall* be validated and authorized before use
  - Such methods *shall*:
    - Be thoroughly investigated
    - Clearly and exactly describe necessary conditions and procedures for which property values are:
    - Valid at level of accuracy related to intended use of the RM.
    - Records of validation kept
    - Validation to meet ISO/IEC 17025

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# RMP Quality Systems and RMs/CRMs

- Measurement Equipment – ISO Guide 34 (Section 5.10)
  - Shall meet requirements of ISO/IEC 17025
- Data Evaluation – ISO Guide 34 (Section 5.11)
  - RMP shall ensure calculations & data transfers are subject to appropriate checks
  - Computer or computer controlled systems subject to requirements of ISO/IEC 17025

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# RMP Quality Systems and RMs/CRMs

- Metrological Traceability – ISO Guide 34 (Section 5.12)
  - RMP *shall* provide evidence on measurement traceability of measurement results to a stated reference
  - Traceability through “unbroken chain” or correlation of the results to evaluation of:
    - Measurement process OR
    - Certified Reference Materials (CRMs) (higher in hierarchy)

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# RMP Quality Systems and RMs/CRMs

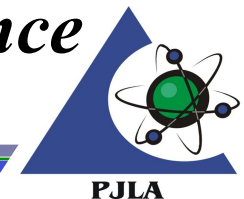
- Metrological Traceability – ISO Guide 34 (Section 5.12)
  - Concept applies to homogeneity, stability & assignment of values for characterization
  - Definition of “reference material” – “sufficiently homogeneous and stable with respect to one or more specified properties” – *requires a clear definition of these properties*
  - Metrological traceability of measurement results *shall be ensured* to make statements on degree of homogeneity and stability



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# RMP Quality Systems and RMs/CRMs

- Metrological Traceability – ISO Guide 34 – Different requirements for *relative* and *absolute* measurements (5.12.3)
  - For results compared to each other – homogeneity and some stability studies (repeatability, isochronous) it shall be ensured that (5.12.3.1):
    - The measurand is the same as the value assigned
    - The calibration for measurement is valid in the range of the measurement results
    - Measurement process sufficiently precise to make meaningful statements of variation
  - ***Then – no traceability to higher order reference is required***



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# RMP Quality Systems and RMs/CRMs

- Metrological Traceability – ISO Guide 34 –Different requirements for *relative* and *absolute* measurements (5.12.3)
  - For results *compared to each other* – homogeneity and some stability studies (repeatability, isochronous) it shall be ensured that (5.12.3.1) (cont'd) :
    - ISO Guide 34 allows for homogeneity only on a subset of assigned values – evidence *shall be provided* the measurand quantified correlates with measurand of the assigned value
    - Note 1- in principle no “trueness “ of measurement is required for this type of study
    - Note 2 – these requirements are met with selectivity, range and precision of the method is known

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# RMP Quality Systems and RMs/CRMs

- Metrological Traceability – ISO Guide 34 –Different requirements for *relative* and *absolute* measurements (5.12.3)
  - For studies in which absolute values are compared (characterization studies, stability under reproducibility conditions – it *shall be ensured* (5.12.3.2):
    - The measurand is the same as the value assigned
    - The calibration for measurement is valid in the range of the measurement results
    - The measurement procedure has an appropriate limit of quantification
    - Measurement process sufficiently precise to make meaningful statements of variation (cont'd)

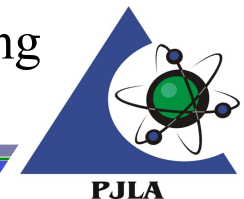


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# RMP Quality Systems and RMs/CRMs

- Metrological Traceability – ISO Guide 34 –Different requirements for *relative* and *absolute* measurements (5.12.3)
  - For studies in which *absolute* values are compared (characterization studies, stability under reproducibility conditions – it *shall be ensured* (5.12.3.2):
    - The measurement procedure is calibrated the same reference as the assigned value
    - All other relevant inputs have been calibrated
    - Note 2 – these requirements are met with appropriate selectivity, limit of quantitation, working range, precision, and trueness of the method is established
  - The RMP *shall provide evidence* the measurement results used to for value assignment are traceable to the same reference as the assigned value (also see Note for combining results from different methods/labs)



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# RMP Quality Systems and RMs/CRMs

- Assessment of homogeneity *is always required* to establish that the degree of homogeneity with respect to the property(ies) of interest is fit for purpose (5.13.1)
- Assessment of stability *is always required* to establish that the degree of stability of the reference material is fit for purpose (5.14.1)
- Stability can only be determine is homogeneity is sufficient, determined first
- Both require *all* testing, calibration, measurement, and sampling are performed in compliance with ISO/IEC 17025 and the studies are designed and performed per ISO Guide 35

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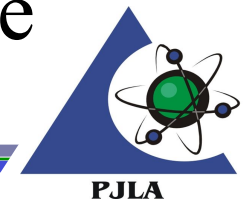
# RMP Quality Systems and RMs/CRMs

- For *CRMs* the RMP *shall use* and document valid procedures to *characterize* the material (5.15)
  - Characterization to comply with ISO Guide 35
  - Testing, calibration, and related activities per ISO/IEC 17025
- Results from proficiency testing can only be used if the competence of the laboratories has been checked and the measurements comply with ISO/IEC 17025

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# RMP Quality Systems and RMs/CRMs

- Several ways to characterize a RM
  - One single lab, one single/primary method
  - Two or more methods, one or more laboratories
  - One or more methods, a network of competent laboratories
  - Method specific, operationally defined property values by a network of laboratories
- Depending of the type of material, intended use, competence of the labs, and the methods, one approach or another may be appropriate



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# RMP Quality Systems and RMs/CRMs

- Assessment of uncertainties is important in establishing property values of a reference material (5.16.2)
- Uncertainty assessment *shall* follow the GUM
- A statement of uncertainty is *mandatory* for *certified values*
- For non-certified values (eg “indicative”, “informative” values) a statement of uncertainty is “highly recommended”



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# Questions?

