JCTLM WG1 Quality System Procedures Team -

Craig M. Jackson – Hemosaga Diagnostics

David L. Duewer – NIST
Kathleen Sharpless – NIST (New member)
Robert Wielgosz – BIPM
Richard Miller – Dade Behring

JCTLM WG1 Quality System Procedures Team

Work Product – A set of Quality System procedures that accurately describe the process by which Working Group 1 reviews and recommends CRMs and RMM/Ps to be listed on the JCTLM list of materials and procedures of higher metrological order.

The procedures are intended to make WG1 review activities transparent to the laboratory medicine community while being minimally burdensome on the volunteers who serve on the WG1 review teams and at the same time ensure that all review teams perform the reviews consistently and fairly.

JCTLM WG1 Review Teams

Work Product - Recommendations

Recommendations of reference materials and reference measurement methods are made to the Executive that after review are deemed compliant with the requirements of the ISO standards.

Approved recommendations are posted by the Secretariat as lists of higher-order CRMs and RMM/Ps which are available as searchable databases that are openly accessible on the JCTLM web pages on the JCTLM pages of the BIPM website.

http://www.bipm.org/jctlm/

JCTLM Lists of Reference Materials and Methods -

List I

Certified reference materials and reference measurement methods for well-defined chemical entities or internationally recognized reference method-defined measurands.

Reference materials and measurement methods included in this category are those that provide values that are traceable to the SI units. Examples are: electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, vitamins, non-electrolyte metals and some proteins.

Source – Preamble to JCTLM Quality System

JCTLM Lists of Reference Materials and Methods, Cont'd -

List II.

Reference materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol,

Examples include: reference materials for blood typing, coagulation factors, microbial serology, nucleic acids, and some proteins and purified substances.

List II also contains a group of purified substances which due to the absence of reference measurement procedures should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognized standardized value transfer protocols to commutable samples are applied.

Source – Preamble to JCTLM Quality System

JCTLM WG1 Quality System Procedures

Procedure Categories:

Definitions and Roadmap to the Quality System Documents

Receiving, Reviewing and Recommending Nominated Reference Materials and Reference Measurement Methods

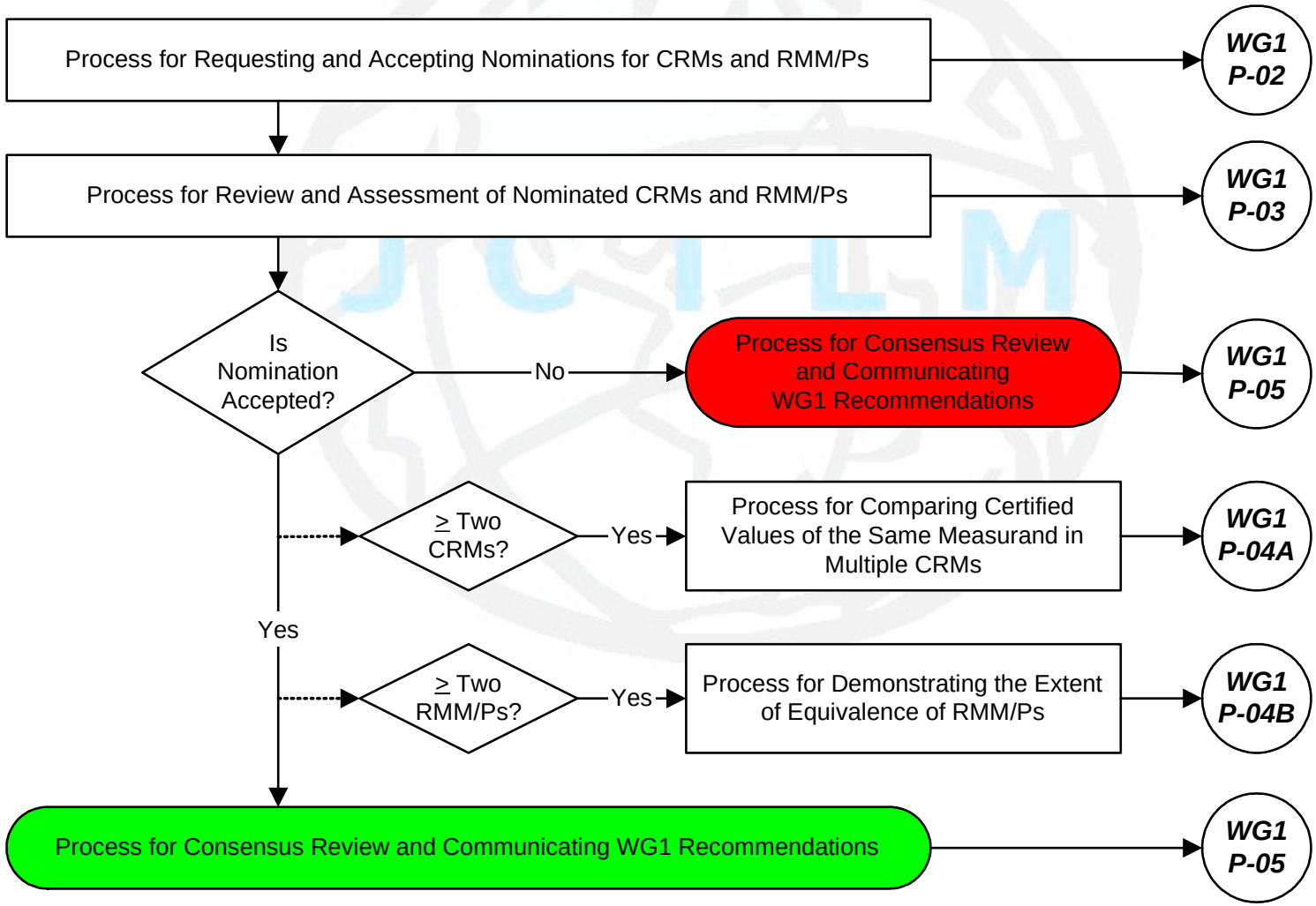
Comparing Materials and Measurement Methods to Assure the Equivalence of Measurement Results

Appealing Listing Decisions

Making Changes to the Quality System Procedures

Review Team Membership and Review Team Management

JCTLM WG1 Quality System (Roadmap and Definitions) -



JCTLM WG1 Quality System

Requesting & Accepting Nominations P-02

Solicitation – Website and announcements in relevant publications

Nomination Forms – Download forms and instructions from JCTLM website

Forms Submitted to JCTLM Secretariat – Secretariat reviews for completeness and requests further information if the form is incomplete. One resubmission is permitted in a solicitation/review cycle after making corrections.

Nominations transferred to WG1 Chairs for distribution to the Review Teams

JCTLM WG1 Review Process

The Standards Used

Review of Nominated Certified Reference Materials (CRMs)

ISO 15194 - ***In vitro*** **diagnostic systems — Measurement of quantities in samples of biological origin — Description of reference materials**

Review of Nominated Certified Reference Methods/Procedures (RMM/Ps)

ISO 15193 - ***In vitro*** **diagnostic systems — Measurement of quantities in samples of biological origin — Requirements and layout of reference measurement procedures**

JCTLM WG1 Quality System –

Review and Assessment Procedures P-03

Review Criteria – Checklists are used to ensure consistent reviewing among measurand-related review teams

Procedure – explicitly defined in the Quality System documents

Form- Based – to ensure completeness of information and consistency of application of the review criteria. Technical judgment is used to evaluate the adequacy of the information provided on a nomination form.

Transparent – Listing decisions and the basis for not listing are provided to the nominators of CRMs and RMM/Ps

JCTLM WG1 Review Process

Procedures - Based On

Checklists – “distillations” from the appropriate ISO Standard

Review Team - Consensus process – discussion of the checklist-based results of team member’s reviews

WG1 Review – Discussion and consensus at a general WG1 meeting

Review Report – Summary of the Review Team recommendations are presented to the Executive for approval/disapproval

Review Report – Provided to the nominator of the CRM or RMM/P

JCTLM WG1 Quality System

Comparisons - Equivalence

Risk of Discordant Performance of Nominated CRMs or RMM/Ps that nominally meet the ISO Standard criteria

Comparison studies of CRMs and RMM/Ps listed in the JCTLM Lists (Database) – Extent-of-Equivalence Evaluation

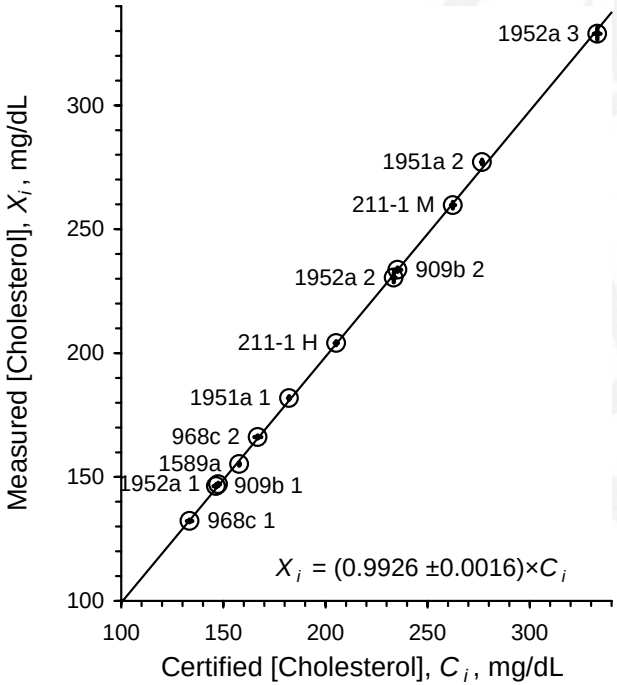
Only two measurands evaluated to date

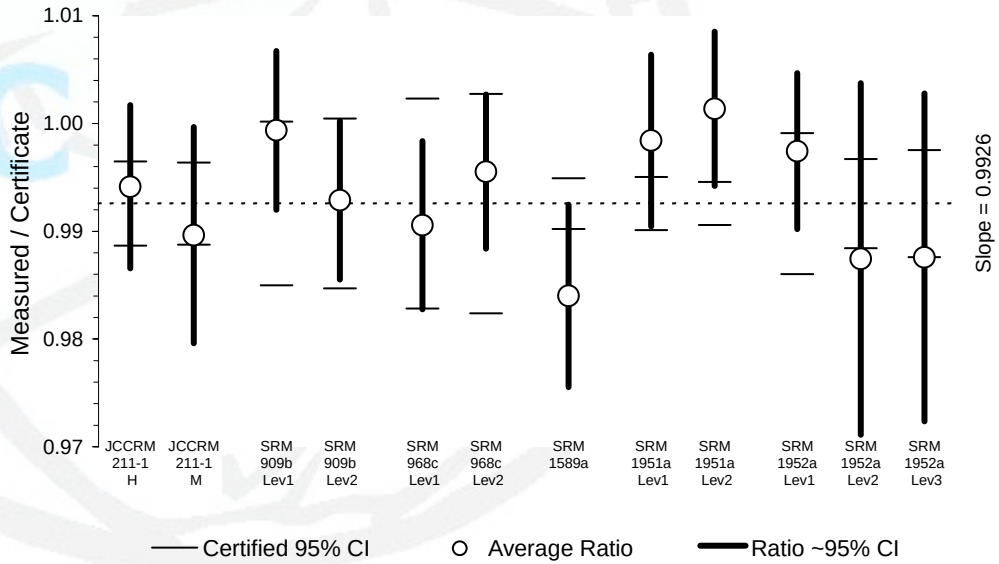
Potassium and Cholesterol

Future comparisons – may be provided by inter-laboratory comparison studies carried out under the direction of JCTLM WG2

JCTLM WG1 Quality System

Comparisons – CRMs for Cholesterol

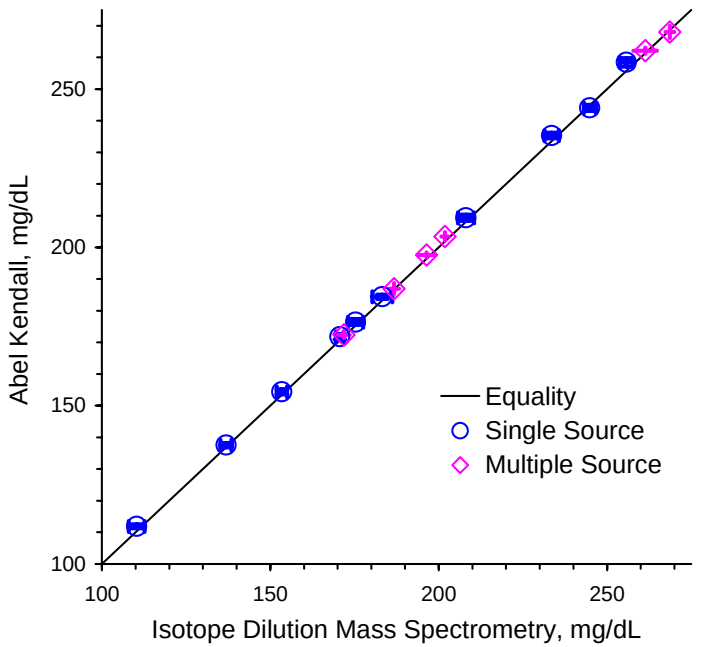


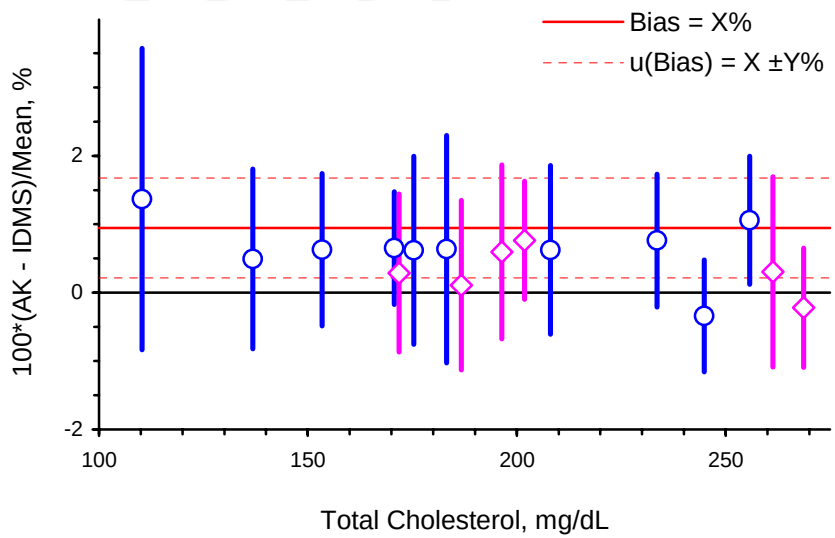


Measurements performed at NIST – data and descriptions are available in WG1-P-04a

JCTLM WG1 Quality System

Comparisons - Total Cholesterol in Liquid Frozen Serum
IDMS and Abell-Kendall Methods





Measurements performed at NIST and CDC – data and descriptions will be in WG1-P-04b

JCTLM Quality System (WG1 Management) -

Process for Nomination and Approval of WG1 Review Team Leaders/Members

WG1-P-06

Process for Making Changes in WG1 Quality System Procedures

WG1-P-07

Process for Creating, Restructuring and Retiring Review Teams

WG1-P-08 (*Not discussed further*)

Process for Appealing Decisions of the JCTLM Executive

WG1-P-09

JCTLM Quality System (WG1 – Membership) -

Requirements –

- Technical Expertise – Measurand Related
- Knowledge of ISO Standards
- Willingness to
  - Perform Reviews of CRMs and RMM/Ps
  - Meet Review Deadlines
  - Comply with Quality System Procedures
  - Employ Consensus-Based Decision Making
  - Disclose Conflicts of Interest

Desired Attributes –

- Wide Geographic Representation
- Broad Stakeholder Representation

JCTLM Quality System (WG1 – Changing the Quality System) -

Submission of a change request form initiates a review of each proposal by the Procedures Team by asking a series of questions:

Is the proposed change consistent with JCTLM mission and concordant with the normative standards?

Does the change clarify or improve the WG1 process or procedure?

IF YES

The change is submitted to the WG1 members for comment, possible revisions and placed before the WG1 for their consent to make the change.

IF NO

The individual proposing the change is informed of the action and the basis for the decision.

JCTLM WG1 Quality System

Appealing Decisions of Executive

IF the Executive disagrees with a recommendation, WG1 via the appropriate review team has an opportunity to review the stated based for the disagreement, review the basis for the initial recommendation and if disagreement remains, the review team presents a brief, written statement describing the basis for the disagreement.

After discussion and consensus within the entire WG1, the recommendation can be resubmitted to the Executive.

JCTLM Measurand-Based Review Teams (WG1) -

Coagulation Factors	Elaine Gray, NIBSC, United Kingdom
Drugs	Andre Henrion, PTB, Germany
Electrolytes	Richard Miller, Dade Behring, United States
Enzymes	Mauro Panteghini, University of Milan, Italy
Metabolites/Substrates	Michael Welch, NIST, United States
Nucleic Acids	Helen Parkes, LGC, United Kingdom
Non-Peptide Hormones	Heinz Schimmel, IRMM, European Union
Proteins	David Sogin, Abbott Laboratories, United States
Blood Group Substances	Susan Thorpe, NIBSC, United Kingdom
Viral Markers	Morag Ferguson, NIBSC, United Kingdom
Vitamins	Katherine Sharpless, NIST, United States
Non-electrolyte Metals	Lee Yu, NIST, United States
Blood Gases	Merged with Electrolytes, November 3, 2005
Quality System	Craig M Jackson, HDC, United States

JCTLM WG1 Quality System

Appealing Decisions of Executive

Flowchart from P-09