

JCTLM Working Group 1 Team, Quality System and Procedures Writing

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JCTLM WG1 - PURPOSE SLIDE #1

The purpose of JCTLM Working Group 1 (WG1) is to implement the JCTLM Framework for the international recognition of reference measurement procedures and reference materials of a higher metrological order.

The JCTLM Framework facilitates the implementation of traceability to higher order materials and reference measurement procedures as required by the European IVDD. Nominated reference procedures and reference methods are reviewed by WG1 for compliance with the standards, ISO 15193 and ISO 15194.

JCTLM WG1 - PURPOSE SLIDE #2



It is the policy of WG1 to make this evaluation by an openly distributed, transparent process that can be and is known to all interested parties.

The procedures provided in this Quality System document are those by which the evaluations are made.

OBJECTIVES:

Develop a Quality System Manual that ensures transparency of the process by which reference materials and reference measurement procedures have been and are selected for listing

Provide guidance to providers of reference materials, developers of reference measurement procedures and users of these materials and procedures for:

Submitting materials for review

Understanding the process by which review and acceptance for listing occurs

PROCEDURES AVAILABLE

JCTLM WG1-P-00 *Quality Policy and Definitions*

Contents

Purpose

Acronyms

BIPM – International Bureau of Weights and Measures

...

*JCTLM – Joint Committee for Traceability in Laboratory
Medicine*

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Definitions

Related Documents

Directive 98/79/EC In vitro diagnostic medical devices

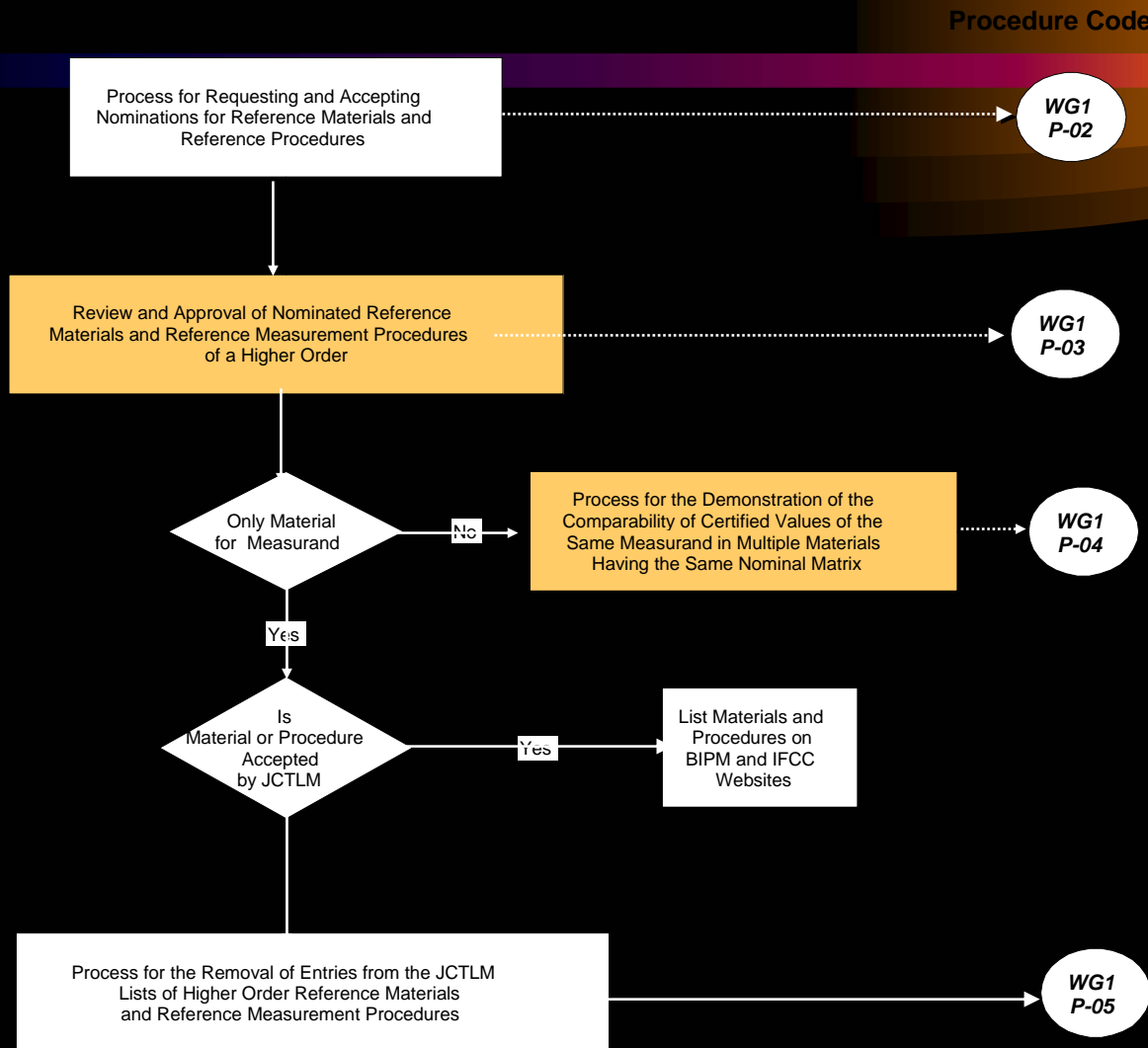
ISO 15193 - ... Reference Measurement Procedures

ISO 15194 - ... Description of Reference Materials

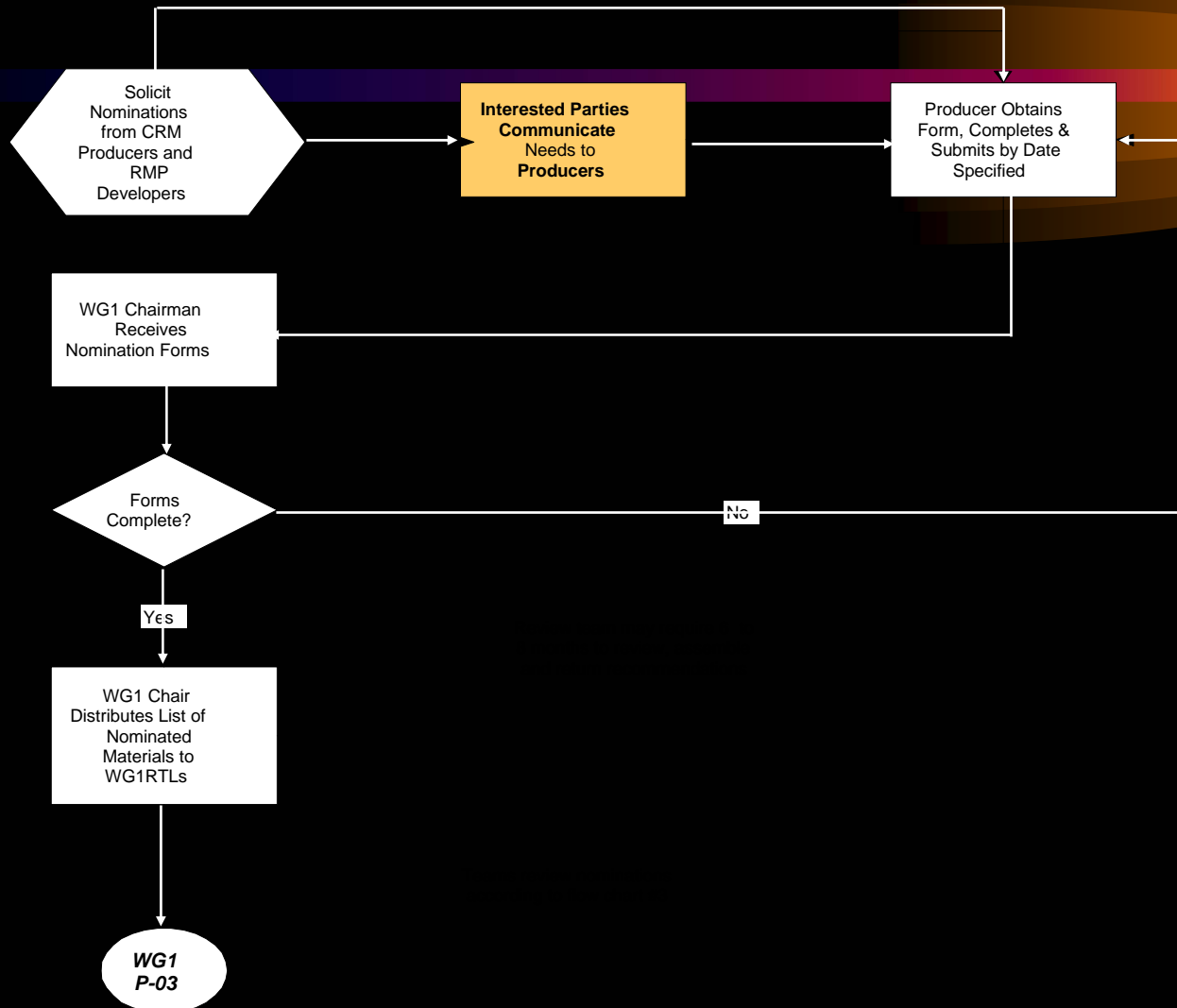
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Revision History

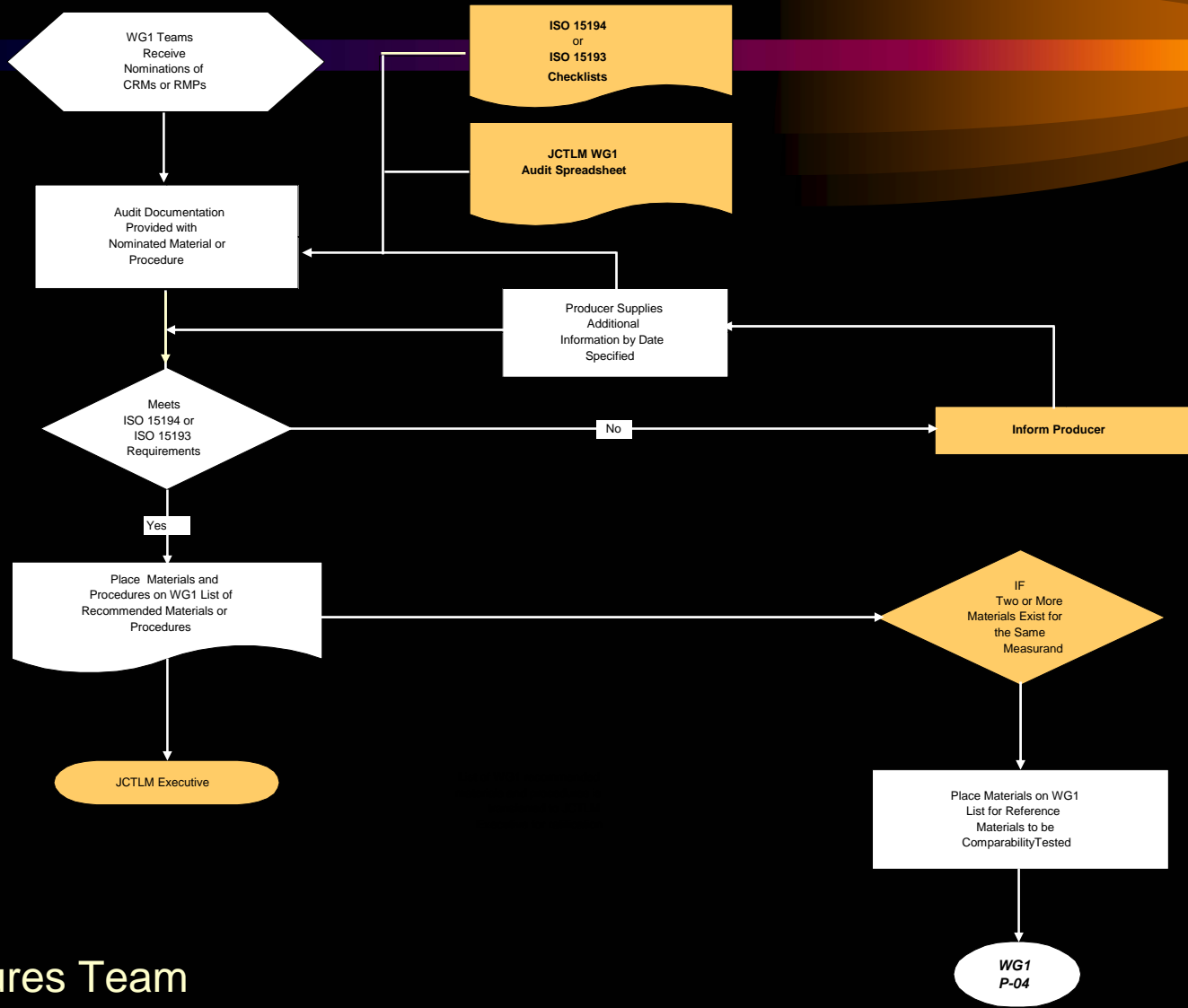
JCTLM WG1-P-01 Outline of JCTLM Procedures for Evaluating Certified Reference Materials and Reference Measurement Procedures to be Listed as being of Higher Metrological Order



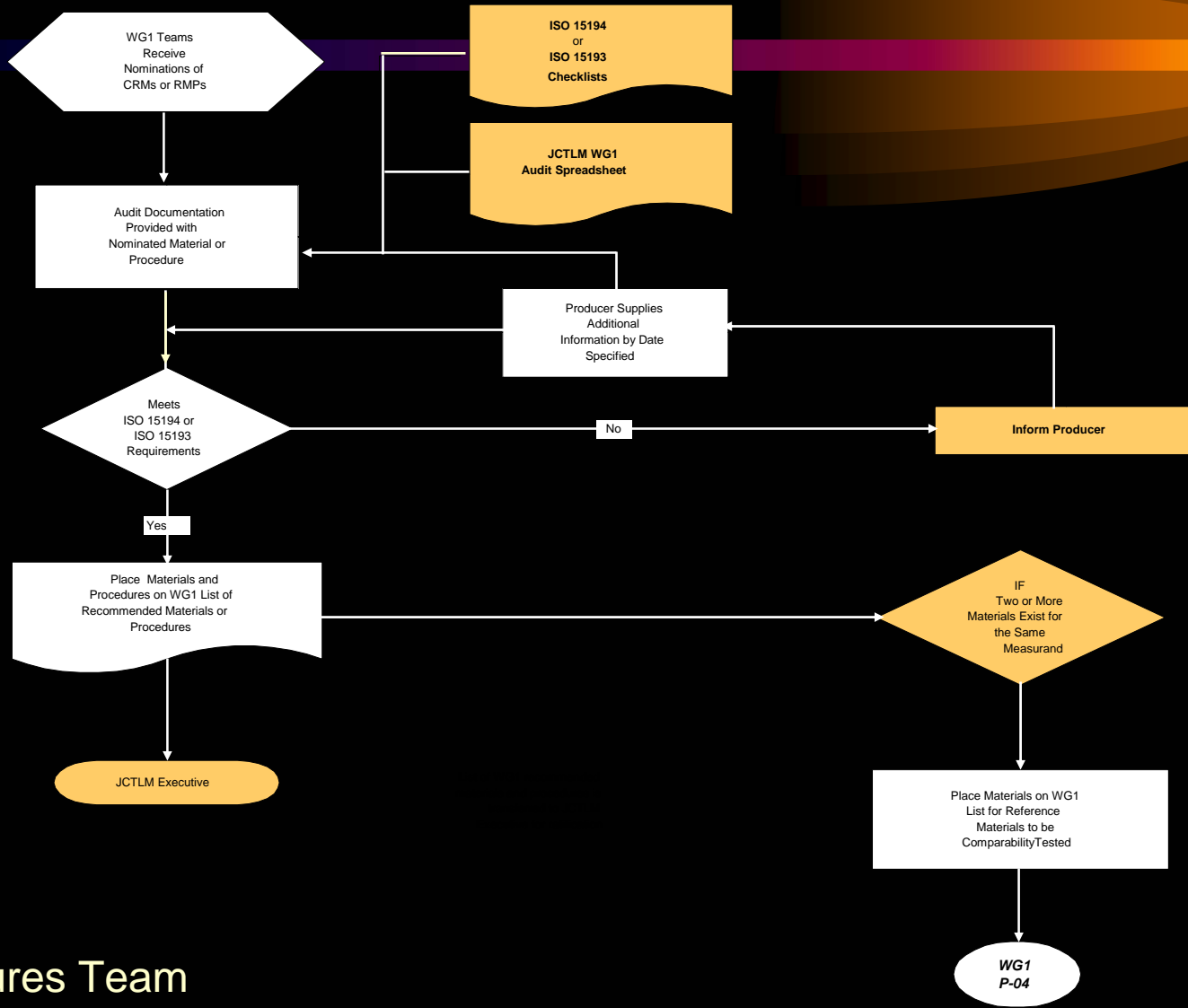
JCTLM WG1-P-02 Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Procedures



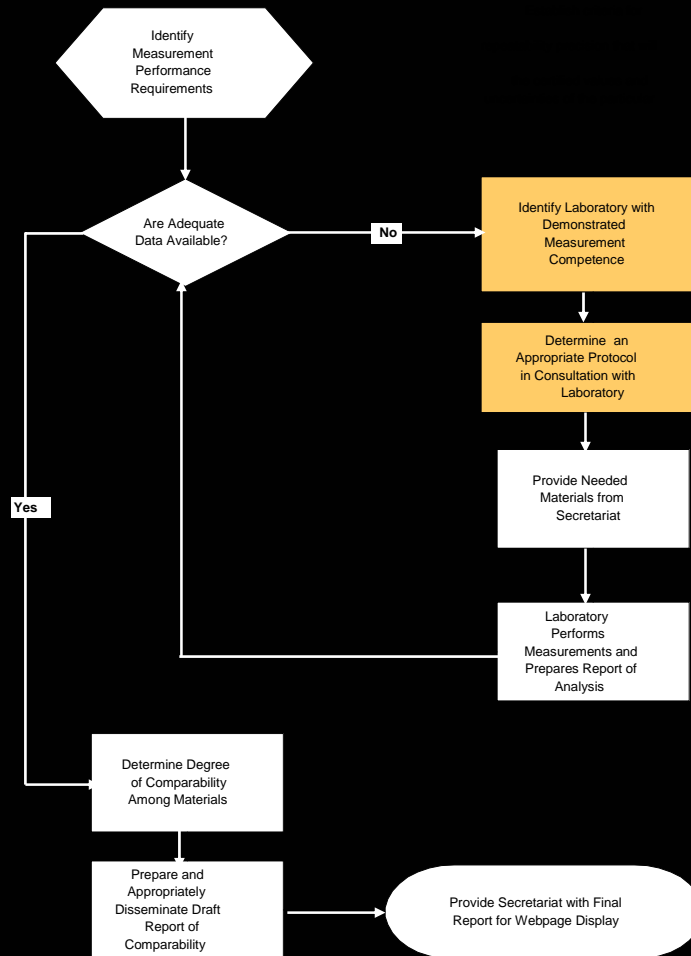
JCTLM WG1-P-03 Review and Approval of Nominated Certified Reference Materials and Reference Measurement Procedures



JCTLM WG1-P-03 Review and Approval of Nominated Certified Reference Materials and Reference Measurement Procedures



JCTLM WG1-P-04 *Process for the Demonstration of the Comparability of Certified Values of the Same Measurand in Multiple Materials Having the Same Nominal Matrix*



JCTLM WG1-P-04 Process for the Demonstration of the Comparability of Certified Values of the Same Measurand in Multiple Materials Having the Same Nominal Matrix

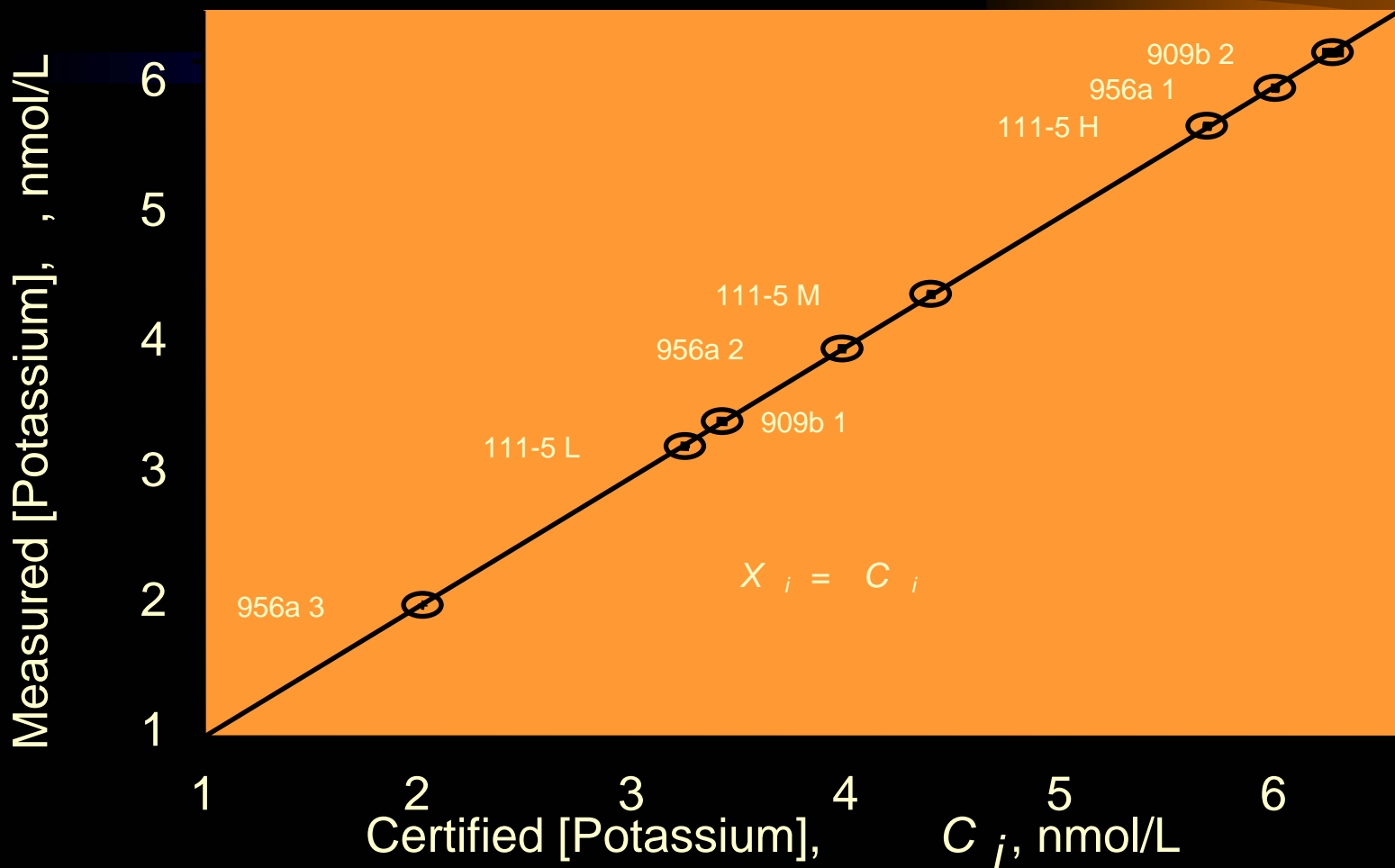
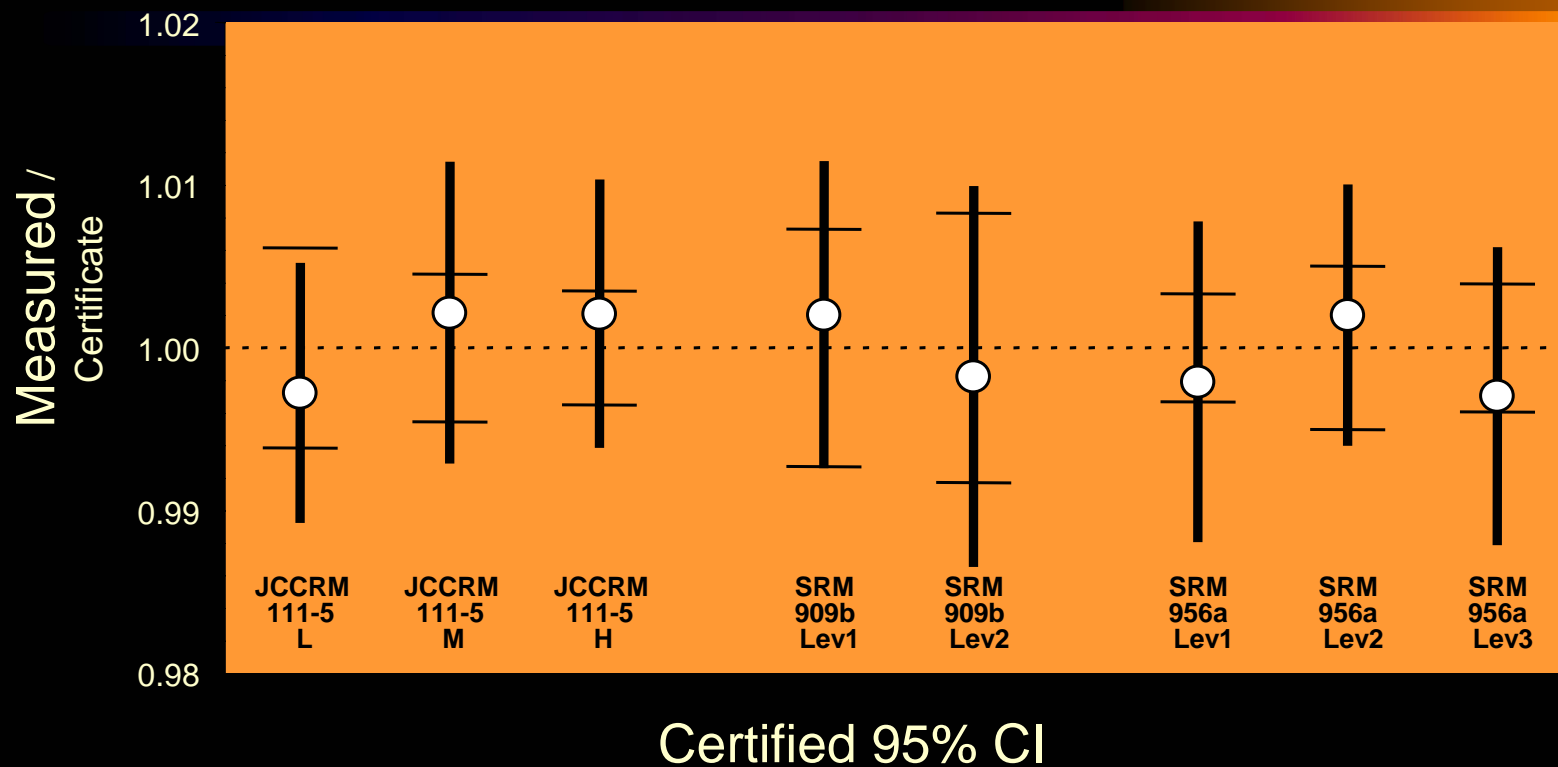


Figure 1a: Scattergram Display of the Comparability of Potassium in Human Serum CRMs

JCTLM WG1-P-04 Process for the Demonstration of the Comparability of Certified Values of the Same Measurand in Multiple Materials Having the Same Nominal Matrix

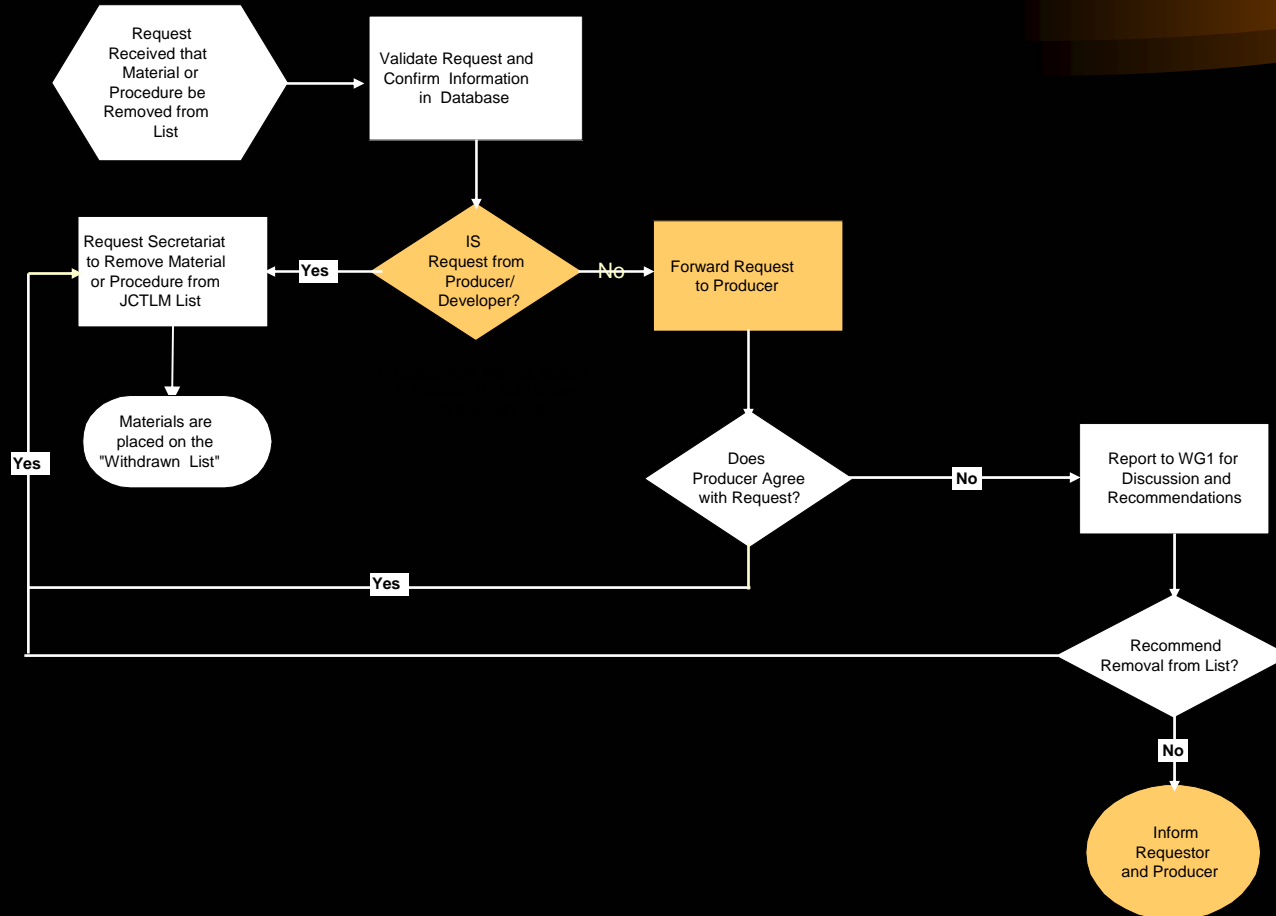


Average Ratio

Ratio ~95% CI

Figure 1b: Ratio Display of the Comparability of Potassium in Human Serum CRMs

JCTLM WG1-P-05 Process for THE removal of entries from the JCTLM Lists of available Higher Order Reference Materials and Reference Measurement Procedures





Welcome to the process of improving the comparability and “accuracy” of IVDs.

Please DO NOT hesitate to tell us where the procedures might be made clearer, simpler and more useful.

The WG1 Procedures Team