

## **JCTLM Working Group 1 – Operations Documents**

### **Review Documents**

1. JCTLM WG1-P-02-F-01      Reference Material Nomination Form, Microsoft Excel Spreadsheet
2. JCTLM WG1-P-02-F-02      Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet
3. CRM Review Checklist - ISO 15194, WG1-P-03-F-01 (Available only to JCTLM Review Team Members – The same checklist is Table 1 in ISO 15194:2009(E))
4. RMM/P Review Checklist - ISO 15193, WG1-P-03-F-02 (Available only to JCTLM Review Team Members – The same checklist is Table 1 in ISO 15193:2009(E))
5. Reference Material or Method/Procedure Review Report WG1-P-03-F-03

### **Help File for Nominators and Reviewers**

6. JCTLM WG1-P-02-I-01      Instructions for completing Excel files for the nomination of Reference Materials and Reference Measurement Methods/Procedures for the JCTLM Database

### **Reference Documents – Standards by which Nominations are Reviewed**

- ISO 15193 ..... In vitro diagnostic medical devices -- Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures. ISO, Geneva, Switzerland (2009). Website: <http://www.iso.org>
- ISO 15194 ..... In vitro diagnostic medical devices -- Measurement of quantities in samples of biological origin -- Requirements for certified reference materials and the content of supporting documentation. ISO, Geneva, Switzerland (2009)
- ISO 15195 ..... Laboratory medicine – Requirements for reference measurement laboratories. ISO, Geneva, Switzerland (2003)
- ISO 17511 ..... In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials. ISO, Geneva, Switzerland (2003)
- ISO 18153 ..... In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials. ISO, Geneva, Switzerland (2003)

**DOCUMENTS EMPLOYED DURING THE REVIEW AND APPROVAL OF  
CERTIFIED REFERENCE MATERIALS (CRMs)  
AND  
REFERENCE MEASUREMENT METHODS/PROCEDURES (RMM/Ps)**

