

JCTLM Review Teams – Terms of Reference

Nominations of certified reference materials and reference measurement methods/procedures to be considered for listing as higher-order in the JCTLM database require review against the requirements specified in the current versions of the applicable ISO standards. JCTLM Working Group Review Team members provide the technical expertise necessary to review nominations and make recommendations to the Database Working Group (DBWG) for certified reference materials, reference measurement methods/procedures and reference measurement services. The review teams make recommendations to the DBWG Chairs of the nominations that are qualified to be designated as being of a higher metrological order as required by the European In Vitro Diagnostic Directive (EC IVDD), (98/79/EC, Annex I (A)(3) 2nd paragraph). Recommendations to the DBWG Chairs are placed before the entire WG membership at an annual JCTLM meeting for recommendation to the Executive Committee of JCTLM for final approval. Approved nominations are listed by the JCTLM Secretariat in the JCTLM database hosted at the BIPM and thus become available to all who wish to identify and use this database of approved materials, procedures and services. This JCTLM three-tier review and recommendation process has been designed to ensure comprehensive, fair and impartial review of all nominations.

Review of nominations is guided by explicit procedures that comprise the JCTLM Quality System, and DBWG procedures are applied for review of reference materials and reference methods, and measurement services. The ISO standards applicable to review are: ISO 15194 2nd Ed (2009), ISO 15193 2nd Ed (2009) for materials and procedures, ISO 15195, ISO 17025, ISO 17511 for measurement services and ISO 18153 for procedure defined measurands, e.g. some enzymes.

It is the policy of JCTLM to solicit applications and nominations for membership to review teams by a transparent process that is available publicly to all interested parties as described in the JCTLM Quality System Procedure, DBWG-P-06. Review team members are volunteers who disclose their qualifications, credentials and employers to ensure that potential conflicts of interest, if arising, have been addressed prior to the reviewer's participation in reviewing any particular nominations for which a perceived conflict might exist.

JCTLM Review Teams – Technical Expertise-based Groups

Review teams within the JCTLM are based on the expertise required to review categories of materials, methods and services. The credentials of all individuals nominated to serve are reviewed by the WG Chairs and ultimately must be approved by the JCTLM Executive Committee. Overlapping technical expertise is present on most review teams. To take advantage of all expertise, input is solicited from all Review Team members during the common review of nominations at the annual JCTLM meeting. As new measurands are nominated new review teams are created to provide the technical expertise needed.

Review Teams and Descriptions of the Materials, Procedure and Services that Each Reviews

All DBWG review teams use forms from the DBWG Quality System procedure: DBWG-P-02A-F01.xls and DBWG-P-02A-F02.xls for materials and methods/procedures, respectively and DBWG-P-02B-F01.xls for services. Review and completion of these forms, which are concordant with the current ISO standards is guided by the instructional document, DBWG-P02A-I-01, and DBWG-P-02B. The current membership of each review team and blank forms used by DBWG are available for review at <http://www.bipm.org/en/committees/jc/jctlm/>.

Blood Cell Counting and Typing - Reviews nominations of certified reference materials that are intended for use in cell counting in bodily fluids, red blood serology, tissue typing and antibody quantification, and reference methods/procedures for cell counting in bodily fluids. One particular focus area is the products and applications listed in Annex II Lists A and B of the *In Vitro* Medical Devices Directive 98/79/EC (IVDD).

Coagulation Factors – Reviews nominations for reference materials described by their functional activity and as reference materials for coagulation factor antigen quantification including plasma protein inhibitors of the blood coagulation system. It also reviews reference thromboplastins when submitted for listing in the JCTLM database.

Drugs - Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of drugs of therapeutic drugs and drugs of abuse. Included within the drugs are neat substances of defined purity and materials that contain drugs in a biological matrix.

Electrolytes and Blood Gases – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of electrolytes and/or blood gases in biological fluids.

Enzymes – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in the measurement of catalytic activity of enzymes for which procedure-defined reference measurement procedures are available.

Infectious diseases – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in tests to demonstrate the presence of pathogens related to infectious disease or measure the immunological response of the human body to these pathogens.

Metabolites and Substrates – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of naturally occurring organic and organometallic compounds found in bodily fluids that are markers for the diagnosis and treatment of diseases.

Non-electrolyte Metals – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of these metals and/or compounds containing these metals in bodily fluids or other matrices.

Non-peptide Hormones – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of these substances in either purified form or in bodily fluids or tissues.

Nucleic Acids – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of oligo and polynucleotides employed for identification and/or quantification of nucleic acid derived substances in biological materials, or where the intended use depends on a nucleic acid based method. Specific information regarding review of nucleic acid sequence based RMs can be obtained at <http://www.bipm.org/en/committees/jc/jctlm/>, under “[Criteria to assess the quality of nominated nucleic acid reference materials with stated nominal properties](#)”.

Proteins – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of proteins of clinical relevance (excluding enzymes certified for activity). Measurement may include identification (a nominal property).

Vitamins and Micronutrients – Reviews nominations of certified reference materials and reference methods/procedures that are intended for use in measurement of vitamins and/or other micronutrients in biological fluids.

Quality System – Maintains the quality system procedures originally drafted by the Quality System team and approved by the JCTLM Executive to define and describe the processes by which the JCTLM DBWG solicits, reviews and recommends nominated materials, methods/procedures and services for listing as higher-order in the JCTLM database. It also maintains the procedures for appointment to JCTLM DBWG review teams and management of the JCTLM database.