

Scope of Activity for JCTLM Review Teams

Blood Cell Counting Review Team Scope of Activity

Our review team focuses on reviewing Reference Methods, Procedures and Materials submitted for cell counting in body fluids and recommending those that meet the 'higher order' criteria on the basis of the ISO/CEN standards to the JCTLM board for their inclusions in the JCTLM database.

Lili Wang, Blood Cell Counting Review Team Leader

Blood Groupings Review Team Scope of Activity

The 'Blood Groupings' review team is responsible for reviewing candidate reference materials of 'higher order' in the areas of red cell serology, tissue typing and antibody quantitation, in particular those that are relevant to the products and applications referred to in Annex II Lists A and B of the *In Vitro* Medical Devices Directive 98/79/EC (IVDD). The review team has, so far, reviewed 3 nominations in this analyte category, received during Cycle II.

Susan Thorpe, Blood Groupings Review Team Leader

Coagulation Factors Review Team Scope of Activity

The Coagulation Factors review team deals with measurement claims for functional activity and antigenic level of coagulation factors and inhibitors.

Elaine Gray, Coagulation Factors Review Team Leader

Drugs Review Team Scope of Activity

The Drugs Review Team is evaluating submissions of both drugs of abuse and therapeutic drugs to be used for calibration of higher order measurement procedures. These may be neat substances of well defined purity next to materials containing the drug in certified concentration in biological matrix.

André Henrion, Drugs Review Team Leader

Metabolites and Substrates Review Team Scope of Activity

The Metabolites and Substrates review team is charged with reviewing reference measurement procedures, reference materials, and reference laboratory services for naturally-occurring organic and organometallic compounds, found in bodily fluids, that are markers for the diagnosis and treatment of diseases. These compounds have well-defined structures and measurement of their concentrations can be traceable to the mole. Examples include cholesterol, glucose, creatinine, and uric acid, among others. Examples of substances not covered by this review team, but covered by other review teams include hormones, enzymes, drugs, vitamins, and large biomolecules.

Michael Welch, Metabolites and Substrates Review Team Leader

Microbial Serology Review Team Scope of Activity

Selection of Reference Materials and Reference Measurement Procedures used for the standardisation of the serological tests performed to demonstrate:

- the presence of antigens related to infectious diseases in the human body, or
- the response of the human body (antibodies) to these infectious agents to establish its contact with the immune system.

Claude Giroud, Microbial Serology Review Team Leader

Non-electrolyte Metals Review Team Scope of Activity

The non-electrolyte metals review team is consisted of a group of experts in metrology of non-electrolyte metals. The activities of the team include reviewing the nominations against the relevant international standards and forwarding results of the review to JCTLM working group chairs for the purpose of inclusion or exclusion in the JCTLM database. The nominations within the scope of activities of the team are non-electrolyte metals (e.g., Hg, As, and Se) and non-electrolyte metals in various conformations (e.g., methylmercury, arsenobetaine, and selenomethionine).

Lee Yu, Non-electrolyte Metals Review Team Leader

Non-peptide Hormones Review Team Scope of Activity

The non-peptide hormone review team will evaluate reference material, reference measurement procedures (methods) and reference measurement services related to compounds with hormonal function, excluding peptides or proteins, either in purified form or in human body fluids and tissue. The reference materials, reference measurement procedures (methods) and reference measurement services will be evaluated for their compliance with the relevant international standards (ISO 15193 and ISO 15194) and the latter for their compliance with the JCTLM quality manual.

Heinz Schimmel, Non-peptide Hormones Review Team Leader

Nucleic Acids Review Team Scope of Activity

The Nucleic Acids review team will evaluate JCTLM nominated reference materials, reference measurement procedures (methods) and reference measurement services related to nucleic acid based materials and measurement methods. The scope therefore is guided both by the nature of the nominated material, the value assignment method and the intended use. For example: i) synthetic oligonucleotide / plasmid / genomic NA based RMs would be included ii) viral particles in serum RMs would be included IF the intended use is viral load monitoring by PCR.

Helen Parkes, Nucleic Acids Review Team Leader

Proteins Review Team Scope of Activity

The protein review team for JCTLM Working Group 1 (WG1) reviews nominations of certified reference materials (CRMs) and reference measurement procedures (RMPs) for clinically-relevant proteins (excluding enzymes certified for activity). The nominated CRMs reviewed by the protein review team include both primary and secondary materials. The CRMs and RMPs reviewed are most commonly for the amount-of-substance concentration of the protein analyte. Also within the scope of activities of the protein review team is the review of CRM and RMP nominations in which a nominal property (such as identification or sequence) of a clinically-relevant protein analyte is certified.

For JCTLM Working Group 2 (WG2), the protein review team reviews nominations of reference laboratories that offer measurement services for clinically-relevant proteins (excluding enzymes).

David Bunk, Proteins Review Team Leader

Vitamins and Micronutrients Review Team Scope of Activity

The scope of the Vitamin Review Team's activities for recommending reference measurement procedures and reference materials for inclusion in the JCTLM database covers vitamins and other micronutrients in biological fluids. (Note that because it is a metabolite, two reference measurement procedures for 5-methyltetrahydrofolic acid were reviewed by the Metabolites and Substrates Review Team before the Vitamin Review Team was established.)

Katherine Sharpless, Vitamins and Micronutrients Review Team Leader

Working Group 1 – Quality System Development Team Scope of Activity

The Quality System Development Team of Working Group 1 (WG1) develops and maintains the JCTLM Quality System Procedures that guide the processes by which this WG1 operates. The quality system includes procedures governing nominations for certified reference materials and higher order reference methods/procedures; review of nominations for compliance with the applicable ISO standards for approval for listing in the JCTLM database; comparison of different approved materials and methods; and reporting the findings from the reviews communicated to the JCTLM. Procedures for nominating individuals to serve on WG1 review teams and for resolution of concerns regarding review team recommendations are also provided to guide the activities of WG1.

Craig M Jackson, WG1 Quality System Team Leader

**Electrolytes and Blood Gases Review Team
Enzymes Review Team**