Environmental Scan of Nonelectrolyte Metals Clinical Standardization Efforts

The nonelectrolyte metals review team (NEM) received no request for review of nomination in 2016. The team received two applications for review team membership: Dr. Enea Pagliano of NRC Canada, an LC-MS expert in anions and small molecules, and Dr. Rainer Stosch of PTB, an expert of Raman spectroscopy in small molecules of clinical concern.

Regarding new reference materials (RM), LGC and NIST are developing blood RMs for clinical diagnostic measurement of metals of implantable devices including Co, Cr, Mn, Mo, Ni. These RMs will be used for monitoring implant stability and for research in total joint replacement. The RM in development at NIST is SRM 1401 Trace Metals in Frozen Human Blood. LGC has been contacted regarding the name of the RM in development and a name is forthcoming. National Institute of Health Office of Dietary Supplement (NIH-ODS) held an Iron Initiative Workshop in September 2016 where a need of RM for total iron in blood was mentioned, and the point was affirmed by Dr. Graham Jones at the JCTLM meeting. The development of total iron in blood RM does not appear to be a technical challenge.

The emerging new measurands within the scope of NEM are biomarkers and exposomes of anions and small molecules containing metal element. These are not traditional elemental measurands NEM team review. Currently two anions, perchlorate and nitrate in urine matrix, are listed in the JCTLM database for RMs. Exposomes and biomarkers of clinical significance that are not yet listed in the database include thiocyanate and azide, for example.

There are a few nominations but there is no new listing in JCTLM DB for reference measurement procedures (RMP) since ISO 15193:2009 takes effect. Meeting the commutability requirement is a major challenge for nominations submitted for review. A potential path to resolve the review and listing obstacle is to encourage reference measurement service (RMS) providers to submit procedures that have been used for many clinical tests for consideration as higher order RMPs.

The NEM team has a strong representation from major RM producers, and consequently a good flow of nominations of RMs each year until 2013. The lull of nomination in recent years may be attributed to that the available RMs in the JCTLM DB largely meet the needs of the industry. There is no higher order RMS for nonelectrolyte metals listed in the JCTLM DB. Dr. Kathleen Caldwell (klc7@cdc.gov) at CDC is recommended as the contact for measurement services for her leadership and the critical role CDC plays in the US healthcare system. Dr. Kessler Anja (a.kessler@dgkl-rfb.de) is recommended for her responsible at the DGKL and for IFCC RELA work.