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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Accurate Fluorescence Measurements Consortium

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice; request for information.

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, is establishing the Accurate Fluorescence Measurements Consortium and invites organizations to participate in this Consortium. The Consortium will develop tools for improving the accuracy of quantitative fluorescence measurements including reference materials, reference data and reference methods for relative spectral correction of spectra, lifetimes and quantum yields and for assessing the associated uncertainties and utilities. Participation in this Consortium is open to all eligible organizations, as described below.

DATES: NIST will accept responses for participation in this Consortium on an ongoing basis. The Consortium's activities will commence on [INSERT 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] ("Commencement Date"). Acceptance of participants into the Consortium after the Commencement Date will depend on eligibility and the availability of NIST resources.

ADDRESSES: Information in response to this notice and request for additional information about the Consortium can be directed via mail to the NIST Consortium Manager, Dr. Paul DeRose, Biosystems and Biomaterials Division of NIST's Material Measurement Laboratory, 100 Bureau Drive, Gaithersburg, Maryland 20899-8312, or via electronic mail to lili.wang@nist.gov.

FOR FURTHER INFORMATION CONTACT: For further information about partnership opportunities or about the terms and conditions of NIST's Cooperative Research and Development Agreement (CRADA), please contact Jeffrey DiVietro, CRADA and License Officer, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to jeffrey.divietro@nist.gov, or by telephone at (301) 975-8779.

SUPPLEMENTARY INFORMATION: Quantitative fluorescence measurements are used for instrument qualification and method validation in the pharmaceutical and chemical industries. It is also increasingly being used for detection of antibodies in clinical diagnostics and biomedical research. The measurements made on different instrument platforms at different times and locations cannot be compared accurately, which makes diagnostic decisions unreliable and slows down advances in these areas. In response to this limitation, NIST, secondary standards manufacturers and other stakeholders have developed methodologies to implement quantitation fluorescence measurements.

NIST produced SRMs 2940 through 2944 in the past nine years as relative intensity correction standards for fluorescence spectroscopy. These standards are needed by fluorescence instrument manufacturers and regulated communities that use quantitative fluorescence detection. For instance, the pharmaceutical and biotechnology communities use SRMs 2940 through 2944 to calibrate and verify the performance of their fluorescence instruments, which is required to achieve accurate results in secondary screening of drugs and in quantitative analysis of bioassays. Many other communities that use fluorescence detection need similar standards, but cannot afford the price of these SRMs or require different sample formats.

Few secondary standards of this type have been produced by industry because most companies do not have the fluorescence measurement capabilities and expertise to make high accuracy measurements. This Consortium is intended to give secondary standard manufacturers, as well as other stakeholders in the fluorescence measurement community, access to highly accurate fluorescence measurement capabilities available at NIST. In return, these manufacturers provide NIST information about new materials, future material needs, and new customer bases. These manufacturers know the needs of different communities and have developed new materials to meet these needs. Many of the fluorescent materials to be measured have not been used as standards and the suitability of these materials as standards is of great interest to NIST. NIST's understanding of the fluorescent characteristics of such materials through collaborative research and information exchange may lead to new NIST standards in this and other related areas. It is also important for NIST to know about additional standards needed in

emerging technologies. Collaborators will supply NIST with this knowledge and work with NIST to design and characterize the best standards for such emerging technologies. Through this process, collaborators will assist NIST to develop better reference materials.

Participation Process:

Eligibility will be determined by NIST using the information provided by an organization in response to this notice based on the information requested below.

An organization responding to this notice should provide the following information to NIST's Consortium Manager:

(1) Type of Reference Materials: Format of the sample (e.g., standard cuvette, microwell plate, microscope slide); and Quantitative Target for Improved Accuracy (e.g., relative spectral correction of emission, fluorescence lifetime, fluorescence quantum yield).

(2) Types of Applications: Fluorescence measurements are used for detection in many areas, but how will the proposed reference materials address the quantitative needs of high impact communities requiring better accuracy and reproducibility?

(3) Experience in production and characterization of reference materials for quantitative fluorescence.

A responding organization should not include any business proprietary information in its response to this request for information. NIST will not treat any information provided in response to this request as proprietary information.

NIST will notify each organization of its eligibility. In order to participate in this Consortium, each eligible organization must sign a Cooperative Research and Development Agreement (CRADA) for this Consortium. All participants to this Consortium will be bound by the same terms and conditions.

Authority:
15 U.S.C. 3710a

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