

NRMAP/NIST Program

Radiopharmaceutical Industry Program

Origin

Since the early 1970's the Nuclear Energy Institute (NEI, originally the Atomic Industrial Forum) and the National Institute of Standards and Technology (formerly the National Bureau of Standards) have cooperated in a measurements assurance program in the field of nuclear medicine. Currently operated by NRMAP, Inc., participation in the program allows sponsors an independent verification, traceable to NIST, of their capability to make accurate radioactivity measurements, as described in NRC Regulatory Guide 4.15, in order to demonstrate compliance with NRC and FDA regulations.

Benefits of Sponsorship

The NRMAP/NIST Radiopharmaceutical Industry Program offers ***greater measurement certainty and confidence*** for participants, who have regular, direct access to proven national standards developed through stringent testing.

The program enables participants to achieve ***reduced production costs*** because it reduces costly measurement conflicts between suppliers and customers.

Sponsors receive ***timely evaluations of their measurement procedures*** monthly so that they can promptly determine if their measurement procedures or instruments have gone awry. If the measurements are satisfactory, they receive reassurance and confidence that they are performing good measurements and providing accurately dispensed products.

The program provides ***customized testing priorities*** sponsors can choose the radionuclides for testing that they have scheduled for production.

The program provides ***standards relevant to participants' businesses*** the activity levels in the standards are close to the actual activity levels that they routinely measure.

Participants receive ***third-party verification for product claims.***

Services of the Program

Distribution of radioactivity Standard Reference Materials (usually a high level [10^7 Bq to 10^{10} Bq] and low level [10^6 Bq to 10^8 Bq] pair of sources), for quantification, to sponsoring participating companies nine times per year.

Analysis and interpretation of the sponsor's quantification of the distributed radioactivity standards to identify any discrepancies in the measurements.

Three "open" months per year when the sponsors have the opportunity to send in sources of their choice for calibration. Sponsors use these months to:

Submit radionuclides that they sell but are not on the schedule for NIST production during the current year.

Submit samples to resolve measurement conflicts between suppliers or customers.

Document measurement capabilities on newly calibrated radionuclides when submitting New Drug Application (NDAs) to the U.S. Food and Drug Administration (FDA).

Assistance to sponsoring participants in eliminating difficulties and correcting errors in their measurement techniques.

NIST traceability certificates provided without charge to sponsors.

Sources Distributed

A typical schedule of Standard Reference Materials (SRMs) for a year:

Month	Radionuclide	High Level	Low Level
January	^{131}I	750 MBq (20 mCi)	25 MBq (700 μCi)
February	^{99}Mo	3 GBq (80 mCi)	75 MBq (2 mCi)
March	OPEN	n/a	n/a
April	^{67}Ga	375 MBq (10 mCi)	20 MBq (500 μCi)
May	$^{99\text{m}}\text{Tc}$	7.5 GBq (200 mCi)	n/a
June	^{201}Tl	225 MBq (6 mCi)	35 MBq (900 μCi)
July	OPEN	n/a	n/a
August	^{111}In	375 MBq (10 mCi)	20 MBq (500 μCi)
September	^{133}Xe	7.5 GBq (200 mCi)	750 MBq (20 mCi)
October	^{90}Y	75 MBq (2 mCi)	19 MBq (500 μCi)
November	OPEN	n/a	n/a
December	^{125}I	750 MBq (20 mCi)	6 MBq (150 μCi)

Steering Committee

A Steering Committee with a representative from each sponsor reviews the program at least annually and determines the programs technical content. A chairman chosen from one of the participating companies heads the Steering Committee.

Sponsoring Fee

The current sponsoring fee is \$18,000 per year. For this \$18,000 the sponsors receive three open month calibrations at no charge. Additionally, each sponsor may purchase as many high- and low-level SRMs as desired at \$869.00 for each high level, and \$806.00 for each low level, substantially lower than the NIST price.

Technical Program Information

For additional information on the technical program, please call Daniel Golas, the program's Senior Project Manager, at NIST (301) 975-5540.

To Become a Sponsor

For information on becoming a sponsor of the NRM/ NIST Radioactivity Measurements Assurance Program, please contact Nancy Brown, NRM/ NIST Executive Director, at: nancygbrown@sbcglobal.net

Radiopharmaceutical Industry Program

Current Sponsors

Algeta ASA (Oslo, Norway)

Capintec, Incorporated

Best Medical International

Cardinal Health Nuclear Manufacturing Services

Covidien, Inc.

GE Healthcare (South Plainfield, NJ and Arlington Heights, IL)

International Isotopes Idaho, Inc.

Jubilant Draximage, Inc. (Kirkland, QC)

Lantheus Medical Imaging, Inc.

McMaster Nuclear Reactor

MDS Nordion (Kanata, ON and Vancouver, BC)

Perkin Elmer Life and Analytical Sciences

University of Missouri Research Reactor

NRMAP/NIST Program Web Site

Radiopharmaceutical Industry Program

The NRMAP/NIST Program Web site, hosted by NEI, <http://nistph.nei.org>, enables sponsors to do all of their radioactive sample measurement reporting online and obtain anonymous comparative information involving other sponsors' results as soon as it is available. In addition, sponsors can contact other sponsors through email links provided by the site. The Web site saves time, eliminates paperwork, and is a readily available information resource.

Benefits

Using the NRMAP/NIST Program Web site, program sponsors can:

Enter their radioactive sample measurement results online immediately after they are obtained at the plant, saving time and avoiding reporting delays.

Enter measurement results from multiple radiological detectors.

Enter the measured value *as well as* answer questions about impurities.

Enter results for the current month's radioactive sample, as well as for the previous month, if you are late.

Once a participant submits his results and has access to the NIST value, the results cannot be changed.

View other sponsor's results anonymously through tabular summation reports.

Obtain official NRMAP/NIST Program measurement value immediately after reporting results.

Obtain contact information for other sponsors of the program and contact them immediately through the email links provided.

Modify their contact information online.

Request technical measurement support.