DIMENSIONS NBS

The magazine of the
National Bureau of Standards
U.S. Department of Commerce
Volume 61/Number 12

December 1977

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ON LINE WITH INDUSTRY

RADIOPHARMACEUTICALS

by David Chaffee

The term radiopharmaceutical may not be as familiar to people as the words polio vaccine or mercurochrome, but that may well change in the coming years. Radiopharmaceuticals are now a $100 million a year industry and they play an important role in the way modern medicine is developing.

A radiopharmaceutical is simply a radioactive substance given to a patient to aid in the diagnosis or treatment of disease. Two examples of radionuclides used in radiopharmaceuticals are technetium-99m (used for a number of imaging studies, including brain, lung, thyroid, bone, kidney and liver) and iodine-131 (used for a number of purposes, including the diagnosis and treatment of thyroid-related disease, localization of brain tumors, and liver studies.)

Recognizing the industry's responsibility for safe and conscientious handling of these products, The Atomic Industrial Forum (AIF) sought the cooperation of the National Bureau of Standards in developing a plan to provide the unbiased measurement technology necessary for quality assurance. This plan was implemented in late 1974 by establishment of an AIF-sponsored Research Associate Program* at the Bureau, with Dr. Ronald Colle serving as the first Research Associate.

Through this cooperative program, AIF and NBS work together to provide maximum confidence in the accuracy of the critical radioactivity measurements involved. As stated in the Memorandum of Agreement between the two groups, "The objectives of this program are to provide Standard Reference Materials and develop techniques for their application to radioactivity measurement assurance in the radiopharmaceutical industry." The present Research Associate, Daniel Golas, replaced Dr. Colle in November of 1976. He is one of some 90 Research Associates who work at NBS in a given year.

"This is the first research program in the world, so far as I know, dealing with the measurement of radiopharmaceuticals in this cooperative way," says Peter de Bruyn, NBS Industrial Liaison Officer. He stresses the importance of measurement accuracy because of the serious problems that can arise if too great or too small an amount of radioactive material is given to a patient.

Golas, aided by NBS scientists and facilities, measures the radioactivity concentration of solution samples. Once accurately characterized, this solution becomes a Standard Reference Material (SRM), duplicates of which then become available. They are sent as blind samples to the AIF participants (and as known samples to any one else wishing to purchase them). The AIF companies then make measurements on the SRM using their own equipment. Agreement between these measurements and the certified radioactivity concentration of the SRM is evidence of the effectiveness of the company's own measurement procedure. If there are discrepancies, corrective actions are taken.

The results of NBS findings and those of the participating companies are normally within five percent of one another, according to Lucy Cavallo, a chemist in the NBS Radioactivity Section, who spends part of her time helping Golas. Occasionally, however, larger variations exist. If there is a substantial difference, it may be necessary for AIF and NBS officials to get together to identify the reason for the difference.

The radionuclides used in SRM's are the ones used in radiopharmaceuticals. Some of the more popular materials, such as iodine-131, molybdenum-99, and xenon-133, are included in SRM distributions every year.

"The trend in industry has been to go to radioactive materials with shorter and shorter half-lives," says Golas. For example, iodine-123, with a 13-hour half life, is finding increasing use in the diagnosis and treatment of various illnesses. This contrasts with the eight-day half life of iodine-131 and 60-day half life of iodine -125 which were used more extensively in the past.

Golas and Cavallo point out that the calibrations NBS makes are based on the requests they get from the radiopharmaceutical manufacturers, evidence of the good working relationship that exists between the two groups. "The Research Associate Program is a clear example of industry and the government working together for the common good," says Calvin Brantley, Chairman of AIF's Committee on Radioisotopes Production and Distribution, and a representative of the New England Nuclear Corporation. This, coupled with strong statements of support from NBS officials, tends to be a good omen for the program's future.

"NBS is in an admirable position to do this work because we have both the personnel and facilities. There is no other independent third body that has both the facilities and the objectivity to do this, and that's why our role is so important," says Wilfrid Mann, NBS Supervisor of the program and Chief of the Radioactivity Section. As radiopharmaceuticals take on an ever-increasing role in modern medicine, the Research Associate Program assumes even greater importance. And, as Mann says only half-jokingly, the program looks as though it will "continue forever."

Chaffee is a DIMENSIONS staff writer.

*The Research Associate Program has brought researchers from all areas of industry to NBS labs for over 50 years to work on projects of mutual interest—for mutual benefit. For information, contact P. R. de Bruyn, Industrial Liaison Officer, Room A402, Administration Building, National Bureau of Standards, Washington, D.C. 20234. Phone: (301) 921-3591.