“Measurement [metrological] traceability” is defined by the International vocabulary of metrology as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.”[^1] Three aspects must be particularly noted: The need for documentation (generally in terms of available reports), calibrations (measurements against physical standards), and measurement uncertainty (considering all possible sources of uncertainty in the measurement, both statistical and otherwise). Without any one of these aspects, traceability cannot be achieved. And, while measurement traceability cannot guarantee a particular outcome, without it, system calibrations are uncertain and results can often be unreliable (“Is the tumor really smaller, or have conditions changed since the last imaging?”). Even beyond supporting confidence in results for the practitioner and for the patient, measurement traceability is often needed to fulfill regulatory requirements and provides a foundation to support the national and international market place. The International Laboratory Accreditation Cooperation (ILAC) has recognized a coherent policy on measurement traceability as crucial for confidence in calibration, testing and inspection by accredited laboratories and others covered by the ILAC arrangement.[^2]

Like the National Institute of Standards and Technology (NIST), National Metrology Institutions (NMIs; including designated institutions) around the world provide the crucial, fundamental metrological infrastructure that supports measurement traceability for a variety of applications, including medical physics. NMIs are generally nonregulatory, enabling them to facilitate the development of traceability from research through development to implementation. Through participation in international measurement comparisons with each other, NMIs, along with the International Bureau of Weights and Measures, make possible world-wide uniformity of measurements and their traceability. International comparisons of National standards are a major means of assuring the quality of an NMI’s measurement capabilities and of satisfying consistency of reference standards among NMIs (and with the International System of Units, or SI) within stated uncertainties (which are derived from the measurement uncertainties of all the participants). The consideration of uncertainties is absolutely essential for the determination of confidence in a measurement and, without it, measurement traceability is impossible. The Guide to the Expression of Uncertainty in Measurement, or the GUM, is used by factories, laboratories and NMIs to demonstrate quality control, develop and maintain physical reference standards and materials, and calibrate those standards and associated instrumentation as a major component in achieving traceability to National standards.[^3]

While the influence of training and experience (“traceability for personnel”) and patient preparation (“traceability of protocols”) on procedure results are crucial components to reliable outcomes through traceability, measurement traceability is most obviously applicable to the instrumentation [the detector, the X-ray unit, the computed tomography (CT) scanner, the radiopharmaceutical, etc.] aspect of applied medical physics. In medical imaging (diagnostic), radiotherapy (beam and brachytherapy), and nuclear medicine applications, measurement traceability has become an integral part of the medical physicist’s toolbox.

### Applications

In the United States, the Food and Drug Administration (FDA) regulates radiation-emitting products, including as related to the Mammography Quality Standards Act (MQSA) of 1992.[^4] Toward meeting the requirements of the MQSA, mammography equipment and facilities undergo periodic survey and evaluation. Recent changes in technologies (e.g., W anode with Ag or Rh filter) have led to the need to perform noninvasive kVp and dose measurements using air-kerma measuring instruments calibrated to a NIST-traceable standard at least biennially (once every two years).[^5] As the NMI for the US, the NIST maintains the measurement standards for X rays and gamma rays, and calibrates the measurement instrumentation, including for mammographic X rays.[^6]

With the expanding use of radiation-based imaging techniques such as positron emission tomography (PET), CT, and multimodality methods (such as PET/CT) as tools not only for medical diagnosis but also to follow the therapeutic process and to inform pharmaceutical developers of effects early during trials, NMIs have begun to

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[^1]: International Vocabulary of Metrology (VIM), 2nd ed., BIPM, IFI, ISO, IUPAC, IUPAP, OIML, 2012.
[^2]: International Laboratory Accreditation Cooperation (ILAC).
[^3]: Guide to the Expression of Uncertainty in Measurement (GUM).
[^4]: Mammography Quality Standards Act (MQSA).
[^5]: National Institute of Standards and Technology (NIST).
[^6]: International Bureau of Weights and Measures (BIPM).
develop the tools that will eventually enable measurement traceability for medical images. At the NIST, for example, a clinical PET/CT unit is being used to develop phantoms for instrument calibration and for image quality, as well as for developing methodologies to more directly link primary measurement standards to clinically applied standards as a critical step for measurement traceability.\(^{[7,9]}\)

To be able to provide the measurement standards that allow for traceability, the NIST and NMIs in other countries develop and maintain the primary standards for the relevant quantities. A “primary standard” in ionizing radiation generally depends on absolute measurement of the quantity, and not on other standards; it is traceable to the SI. In radiation dosimetry as applied in radiation therapy, for example, the primary standard for radiation dose (air kerma) is maintained through realization of the gray (Gy), the derived SI unit (in J/kg) of absorbed dose. At the NIST, active research programs in radiation-induced air-ionization measurements and water calorimetry lead to the development of the primary standards that support determination of dose distribution in tissue and provide the reference dosimetry for a variety of radiotherapy approaches. The NIST Wide-Angle Free-Air Chamber is used in providing brachytherapy source manufacturers with measurement traceability of the conventional radioactive “seeds” used to treat prostate cancer, while on-going research (directly realizing air-kerma rate) is leading to the standards needed for traceability of technologies using low-energy (<50 keV) X-ray sources in electronic brachytherapy applications.\(^{[10]}\)

The radiopharmacy is a vital contributor in medical physics for both diagnostic (e.g., PET, cardioimaging, cholescintigraphy, etc.) and therapeutic (e.g., brachytherapy, targeted alpha therapy) applications, and depends heavily on measurement traceability. Accurate and reproducible measurements of radioactivity in nuclear medicine procedures, directly tied to subsequent radiation dose, are required for reliable diagnoses and safe and efficacious therapy. To obtain such measurements, a full understanding and analysis of potential interferences in the measurement must be taken into account. In radioisotope production, the presence of “impurities,” contaminating radionuclides (either coproduced or inherent in the sample) is almost always present. Therefore, not only is the measurement traceability of the radionuclide of interest to be demonstrated, but also, often, of that of the principal impurities. For example, \(^{32}\)P often contains a nearly indistinguishable \(^{31}\)P impurity, which is also radioactive and can give a falsely high reading (leading to a lower-than-prescribed dosage) on many “dose calibrators”-clinical instruments used to measure radioactivity before application to the patient. To achieve measurement traceability for the (desired) \(^{32}\)P, the amount of \(^{31}\)P must be known (within a defined uncertainty). Fortunately, in this example, the two radionuclides have very different half-lives and the amount of \(^{33}\)P can be determined retroactively, which is indicative of the expected impurity levels from the specific production process. Comparisons of such samples among NMIs over time can track any changes in this expectation through measurements of the \(^{33}\)P content in \(^{32}\)P samples.

Recently, a study undertaken by the NIST in collaboration with academia and clinical centers in the US demonstrated the problems that can arise in the absence of measurement traceability.\(^{[11]}\) With the development of the US National standard for \(^{68}\)Ge (a relatively long-lived radionuclide used to calibrate PET instrumentation), it became possible for the first time to evaluate the response of clinical dose calibrators using a radioactive source traceable to the National measurement standard. Mock-syringes containing traceable \(^{68}\)Ge were measured at three clinics (nearly 40 dose calibrators) at the manufacturer-recommended settings for \(^{18}\)F (measurements between results for \(^{68}\)Ge and \(^{18}\)F were within 2%). The results showed that, using the manufacturer predetermined settings for \(^{18}\)F (the usual radionuclide for PET imaging in these clinics), the reported dose calibrator measurements were consistently too high (on the order of 5%-6%), overestimating the true activity of \(^{18}\)F at this setting and affecting the accuracy of clinical PET images, illustrating a source of calibration error of PET scanners. Using a source that is directly traceable to the National standard would allow controlled adjustment of the dose calibrator setting to overcome the errors.

As many of the radionuclides used in nuclear medicine have relatively (\(^{99m}\)Tc), very \((^{18}\)F) or extremely \((^{15}\)C; \(^{18}\)O; \(^{82}\)Rb) short half-lives, traceability of time becomes an important factor. Especially for the extremely short half-life radioisotopes, an uncertainty of even a few seconds can lead to a final uncertainty on the delivered dose of up to 10% or more. Measurement traceability in nuclear medicine depends on not only the measurement of the radioactivity and of time, but also of such fundamental inputs such as atomic and nuclear data; measurement traceability of these vital components are an on-going field of study for radiation and radioactivity metrologists.\(^{[12]}\) Finally, measurement traceability for computer-based image analysis (e.g., computational dose distribution selection, algorithms for defining regions of interest), display conditions (e.g., screen contrast, color balance, ambient lighting for readers), and even data storage (e.g., fidelity and security of bits and bytes) are all fundamental to assuring quality in medical physics.

The Future

Although, at the present time, there are relatively few National standards (such as for mammography, brachytherapy) upon which the whole of medical physics can rely for measurement traceability, the field is expanding.
Efforts in positioning NMI attention strategically to address stakeholder needs [such as the International Committee for Weights and Measures’ Consultative Committee on Ionizing Radiation (CCRI), (http://www.bipm.org/utils/common/pdf/CCRI22.pdf) and of the Committee on Ionizing Radiation Measurements and Standards, CIRMS (www.cirms.org)] have increased in recent years. With the collaborations that continue to develop between NMIs and stakeholders such as clinics, user groups (the Radiological Society of North America, the Society of Nuclear Medicine, and the American Association of Physicists in Medicine in the Americas as examples), international organizations (such as the International Organization of Medical Physics, IOMP, http://www.iomp.org/) and others, measurement traceability will lead to confidence in the key results needed for drug and device development and marketing, therapy planning and efficacy, disease screening, patient safety, and industry support for now and into the future.

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References

1. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), 3rd ed. JCGM 200:2012 (JCGM 200:2008 with minor corrections). Available from: http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf (or via the BIPM homepage at www.bipm.org), 2012 [Last accessed on 2013 Dec 17].
2. ILAC Policy on the Traceability of Measurement Results. Available from: https://www.ilac.org/documents/ILAC_P10_01_2013.pdf, 2013 [Last accessed on 2013 Dec 17].
3. Evaluation of measurement data — Guide to the expression of uncertainty in measurement (GUM), JCGM 100:2008 (GUM 1995 with minor corrections). Available from: http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf, 2008 [Last accessed on 2013 Dec 17].
4. U.S. National Archives and Records Administration. Code of Federal Regulations. Title 21. Quality Standards. 2011. Available from: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol8/pdf/CFR-2011-title21-vol8-sec900-12.pdf [Last accessed on 2013 Dec 17].
5. Available from: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ [Last accessed on 2013 Dec 17].
6. Lamperti PJ, O’Brien M. Calibration of X-ray and gamma-ray measuring instruments. NIST Special Publication 250-58 NIST Measurement Services. 2001. Available from: http://www.nist.gov/calibrations/upload/sp250-58.pdf [Last accessed on 2013 Dec 17].
7. Karam LR. Radiation-based quantitative bioimaging at the national institute of standards and technology. J Med Phys 2009;34:117-21. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2807674/ [Last accessed on 2013 Dec 17].
8. Available from: http://www.nist.gov/pml/div682/grp04/pet-scanner.cfm [Last accessed on 2013 Dec 17].
9. Available from: http://www.nist.gov/pml/div682/grp04/pet-scanner.cfm [Last accessed on 2013 Dec 17].
10. Available from: http://www.nist.gov/pml/div682/grp04/pet-imaging.cfm [Last accessed on 2013 Dec 17].
11. Zimmerman BE, Kinahan P, Galbraith W, Allberg K, Mawlawi O. Multicenter comparison of dose calibrator accuracy for PET imaging using a standardized source. J Nucl Med 2009;50:472.
12. Zimmerman BE, Judge S. Traceability in nuclear medicine. Metrologia 2007;44:S127-32.

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