Third-party brachytherapy source calibrations and physicist responsibilities: Report of the AAPM Low Energy Brachytherapy Source Calibration Working Group

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The AAPM Low Energy Brachytherapy Source Calibration Working Group was formed to investigate and recommend quality control and quality assurance procedures for brachytherapy sources prior to clinical use. Compiling and clarifying recommendations established by previous AAPM Task Groups 40, 56, and 64 were among the working group's charges, which also included the role of third-party handlers to perform loading and assay of sources. This document presents the findings of the working group on the responsibilities of the institutional medical physicist and a clarification of the existing AAPM recommendations in the assay of brachytherapy sources. Responsibility for the performance and attestation of source assays rests with the institutional medical physicist, who must use calibration equipment appropriate for each source type used at the institution. Such equipment and calibration procedures shall ensure secondary traceability to a national standard. For each multi-source implant, 10% of the sources or ten sources, whichever is greater, are to be assayed. Procedures for presterilized source packaging are outlined. The mean source strength of the assayed sources must agree with the manufacturer's stated strength to within 3%, or action must be taken to resolve the difference. Third party assays do not absolve the institutional physicist from the responsibility to perform the institutional measurement and attest to the strength of the implanted sources. The AAPM leaves it to the discretion of the institutional medical physicist whether the manufacturer's or institutional physicist's measured value should be used in performing dosimetry calculations.
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I. INTRODUCTION

Beginning in 1994 with the report of Task Group 40,[1] the American Association of Physicists in Medicine (AAPM) has issued a consistent set of recommendations regarding calibration of sources for brachytherapy implants. Regarding calibration of sources, TG-40 states:

> Ideally, every radioactive source that is to be implanted in a patient should be calibrated. In practice, however,

> limitations of time, personnel exposure, or other physical constraints may preclude this level of thoroughness. We recommend that all long half-life sources be calibrated. Traceability by statistical inference may be appropriate for short half-life sources, depending upon the number of ribbons or seeds in the designated strength groupings under consideration. If the grouping contains only a few seeds or ribbons, we recommend the calibration of all seeds. For groupings with a large number of loose seeds, we recommend that a random sample containing at least 10% of the seeds be calibrated; for a large number of seeds in ribbons, a minimum of 10% or two ribbons (whichever is larger) should be calibrated. For sources purchased in a sterile configuration, we recommend purchasing and calibrating a single (nonsterile) seed for each designated-strength grouping.

Brachytherapy sources are assigned a "calibration" by the manufacturer. It is not uncommon for an institution to accept the manufacturer's calibration. However, it is the responsibility of the institution to verify that this calibration is correct. The institution should compare the manufacturer's stated value with the institution's standard. If the two are within acceptable limits, either the manufacturer's or institution's value may be used. We recommend that if the institution's verification of source strength disagrees with the manufacturer's data by more than 3%, the source of the disagreement should be investigated. We further recommend that an unresolved disparity exceeding 5% should be reported to the manufacturer. It is always advisable to ask the manufacturer to review its calibration of the sources to help resolve these discrepancies.

A subsequent AAPM report from Task Group 56[2] reiterated the preceding paragraphs and inserted the following sentences into the second paragraph:

> Every institution practicing brachytherapy shall have a system for measuring source strength with secondary traceability for all source types used in its practice. Prior to using newly received sources for treatment, the vendor-supplied calibrations must be verified as per TG-40 recommendations.

Finally, the AAPM Task Group 64 report,[3] which dealt primarily with treatment planning and dosimetry of permanent prostate seed implants, did not explicitly repeat the TG-40 and TG-56 statements but simply recommended that:

> Radioactive seeds may be obtainable in loose seeds, ready-loaded cartridges, or absorbable suture. In whatever form the seeds are procured, the manufacturer's assay *must* be independently confirmed. As recommended by AAPM Task Group No. 56, a random sample of at least 10% of the seeds in the shipment *should* be checked.

The recommendations of these AAPM Task Groups have been adopted by some state and federal regulatory bodies[4] and by professional organizations such as the American College of Radiology (ACR),[5,6] and jointly by the American Brachytherapy Society (ABS), American College of Medical Physics (ACMP), and American College of Radiation Oncology (ACRO).[7] Where applicable to source calibrations, differences with manufacturers, and medical physicist actions, the recommendations made herein are meant to supersede those of TG-40, TG-56, and TG-64.

In the last decade, the number of low-energy photon-emitting (mean energy <50 keV) brachytherapy source manufacturers has grown dramatically, and there are now about 16 active manufacturers of encapsulated ^{125}I, ^{103}Pd, and ^{131}Cs sources for permanent and temporary brachytherapy. Some of these sources are of distinctly different design from one another, and the response of measurement equipment must be determined for each source model.

More recently, several third-party source handling and calibration services, some based in commercial radiopharmacies, have begun marketing "independent assays" of brachytherapy source strength. Such assays often are ancillary to a fee-based service of loading sources into sterile needle assemblies according to the user's treatment plan or the creation of custom, stranded sources in sterile packages. These third-party services act as an intermediary between the source manufacturer and the user, sometimes performing source strength assay for an order prior to assembling needles and strands and then shipping it to the end user.

While such services may help reduce the physics workload required in source preparation for brachytherapy implants, they also raise significant medical physics, patient safety, and legal issues. These issues may be summarized by the question of whether source strength verified by entities other than the final user's institution might substitute for source strength assay at the final user's institution. The answer to this question has ramifications not only to the practice of brachytherapy, but also to the professional responsibilities of the clinical medical physicist. The Low Energy Brachytherapy Source Calibration Working Group (LEBSC), Chaired by Wayne Butler, was constituted to address these issues.[8]

II. DISCUSSION

II.A. Appropriateness of third-party source handling and calibration services

Because of semiautomated processing in a well-shielded environment, third-party source handling and calibration services (henceforth referred to as third-party services) typically assay all the sources in a customer's order prior to preloading them as loose seeds and spacers into needles or assembling the sources into strands. These assays are more comprehensive than that required of the end user by AAPM task groups and contain information of obvious value. However, this does not guard against errors subsequent to the assay, such as vendor misaddressing of orders or mixing sources from inappropriate strength groupings.[9]

Although some processes at source manufacturers and radiopharmacies are under the purview of state or federal regulatory agencies, there is no explicit oversight of custom load-

ing and strength verification activities. Many vendors take pride in the competence and qualifications of their personnel and the timeliness of their equipment calibration, but there exists no requirement that the personnel be licensed or certified or that the dosimetry equipment have traceability to national standards through the services of an AAPM Accredited Dosimetry Calibration Laboratory (ADCL). Further, there is concern that a third-party service have appropriate independence from its parent organization when the parent organization is the manufacturer of the sources that the third-party service is assaying. The International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standard 17025 (ISO/IEC 17025) specifies the general requirements for the technical competence and administrative functioning of testing and calibration laboratories.[10] Decision of which brachytherapy source to purchase may in the future be based on companies being ISO/IEC/EN 17025 accredited.

When TG-40, TG-56, and TG-64 were written, third-party services did not exist. Although TG-64 simply states, "the manufacturer's assay must be independently confirmed," the independence distinguishes the end user from the manufacturer and should not be taken as an endorsement of outsourcing the responsibilities of the local physicist to a remote location. There is nothing in the TG-64 report that repudiates the TG-40 statement that "The institution should compare the manufacturer's stated value with the institution's standard" or the requirement of TG-56 that "Every institution practicing brachytherapy shall have a system for measuring source strength with secondary traceability for all source types used in its practice." The intent of TG-40, TG-56, and TG-64 was that an "independent" source strength assay would exclude manufacturer calibration and third-party services. The medical physicist responsible for patient care at the center where the patient is to be treated is responsible for performing the assay.

II.B. Calibration of loose sources

There is no change in the TG-40 and TG-56 recommended threshold of a 3% difference between the mean of a batch as measured by the using institution and the strength certificate of the manufacturer as leading to an investigation into the disagreement. A difference of 5% between the measured mean source strength and manufacturer values should be discussed with the manufacturer.

A detailed analysis of the statistics of source assay by Yue *et al.*[11] indicates that the number of sources from a typical permanent seed prostate implant order that must be assayed to assure that the measured sample mean differs from the population mean by less than the 3% tolerance threshold is dependent on the measured deviation of the source strengths. For example, they calculated that for a sample strength deviation of 5%, 14 sources must be assayed to determine that the sample mean is within 3% of the population mean with 95% certainty. Although Yue *et al.* concluded that the number of sources to be assayed is dependent only on the tolerance threshold and the strength deviation and not on the size of the source population, there is little information regarding strength deviation and the shape of source strength distributions as a function of radionuclide and manufacturer. Accordingly, the AAPM does not advocate adopting this approach at this time. The AAPM recommends continued adherence to the TG-40 and TG-56 numbers of $\geqslant$10% of the sources in an order. For smaller orders, $\geqslant$10 sources should be assayed, and for orders of $<$10 sources, all sources should be assayed. If more than one strength grouping is present in an order, $\geqslant$10% or ten sources, whichever is larger, of each strength grouping should be assayed and all the sources in strength groups with $<$ ten sources.

TG-40 and TG-56 set the tolerance limit for individual source measurements at 5%. This threshold remains valid for orders of $<$ ten sources. However, manufacturers of low-energy photon-emitting sources for permanent brachytherapy implants employ a variety of source binning strategies for storage and customer order assembly. For example, ^{125}I sources are often assigned to bins that are nominally 8% wide (e.g., $\pm$4% tolerance) because that radionuclide decays about 8% per week. Measurement uncertainty in assigning sources to the appropriate bin is expected to make the actual bin width somewhat greater. There are only a few clinical measurements of seed strength distributions,[12–14] but the evidence is consistent with a 5% value for two standard deviations at the 95% confidence level. However, if the sample mean is allowed to differ from the manufacturer's value by 3% (largely due to combined calibration-coefficient uncertainties between the manufacturer's and user's instruments), individual sources will exceed the 5% threshold more than 5% of the time. Combining in quadrature the $\pm$5% spread in seed strengths with the 3% mean tolerance results in a 6% individual seed strength tolerance when ordering relatively large numbers of low-energy photon-emitting brachytherapy sources.

II.C. Calibration of sources in sterile needles, cartridges, or strands

The TG-40 and TG-56 reports recommended the purchase and calibration of a single loose source from each strength grouping when the remaining sources intended for implantation were in sterile strands or assemblies. This criterion, notably weaker than the 10% recommendation for loose, nonsterile sources, arose because there was no established method for assaying accurately sources in sterile assemblies, and sources not implanted into the patients might not be reimbursed. The latter concern has abated in recent years as reimbursement has moved away from a per implant charge to billing for individual sources. The American Society for Therapeutic Radiation and Oncology (ASTRO) advises, "It is appropriate to bill for all the sources ordered for an individual patient, even if some are wasted and not implanted in the patient."[15] Although private insurers often balk at paying for generic quality assurance, a strong case can be made for patient specific source strength verification for which additional sources should be purchased for the purpose of source assay that may also be required for patient contingencies.

Currently, there are CPT billing codes that include the work done in performing source strength verification, e.g., 77331, special dosimetry, or 77370, medical physics consultation, but those codes may apply only when the work is done locally. Source calibrations performed by the manufacturer or other services are not usually billed separately and are included in the cost of the sources. Regardless of the financial circumstances, the AAPM recommends (through this report) that the institutional medical physicist perform the source strength measurement to satisfy the need for independent assay.

Source manufacturers who also sell stranded source products do not guarantee that loose sources supplied with an order of stranded sources will all come from the same batch because of logistics within the factory. This is unlike the specialty stranding services and preloaded needle vendors who claim to prepare their assemblies from the package of loose sources sent to them by the manufacturer. In this latter case, sources ordered but not incorporated into the sterile product are forwarded in a shielded vial along with the sterile product to the user. Whether the sterile product comes from the manufacturer or a third-party service, techniques and hardware now exist for sterile strands, line sources, cartridges, or source trains extracted in sterile sleeves from needles to be calibrated using the ADCL-measured single-source calibration coefficient for the well chamber.[16] Similar source assay techniques had been published,[17,18] and acknowledged in the TG-64 report of 1999, but were of limited use because of noncommercial source holders and pronounced source positioning effects. These source holders are now commercially available, and source positioning effects have been addressed.

One disadvantage to the assay of sterile assemblies remains—sterile considerations at most institutions require that the electrometer, well chamber, and sterile inserts be deployed in or near the operating room relatively close to the time of implant. Sterile assemblies are typically assayed by batch techniques, and two techniques (use of an imaging plate or a reentrant well ionization chamber) can assess source strength while preserving sterilization. With an imaging plate, a 0.999 correlation coefficient (R^2) of linear response to source strength for 15 seeds in a cartridge as well as for overall source strength has been observed by Furutani *et al.*[19] Due to capability for direct traceability of source strength to NIST, the AAPM at this time supports the reentrant well ionization chamber technique for assaying sterile source assemblies and considers imaging plate assaying as investigational. Brame *et al.* performed a probabilistic evaluation of Mick® cartridge source strength assays using a reentrant well ionization chamber.[20] They concluded that the only schemes likely to detect out-of-calibration seeds and still result in time savings was one in which every cartridge in an order is measured. In this scheme, the time penalty for a cartridge well chamber reading out of the acceptance range is to open the cartridge and assay the sources individually. Applying such a procedure to assay individual sources in a sterile strand if the whole strand measurement is out of specification would defeat the purpose of the strand even if an out-of-calibration source were to be identified. An outlier source may be held in reserve as a contingent extra or it may be implanted as planned, particularly if it is packaged as part of a sterile or stranded source train. The compromise between replacing a strand of sources with loose sources lies in the sensitivity of the treatment plan to an out-of-calibration source versus the approximately 1% probability of loose-source loss to treatment, primarily in the periprostatic region.[21–23] The consequences of source outliers or source loss due to migration may be modeled by the medical physicist, but the tolerance for such loss should be understood and agreed upon by the implant team.

III. RECOMMENDATIONS

It is the AAPM's position that a qualified medical physicist is responsible for the dosimetric accuracy of brachy-

TABLE I. Quantities of brachytherapy sources to be assayed by the end-user physicist.

Source form	Number to be assayed[a]
All loose sources, nonsterile	⩾10% of total or 10 seeds, whichever is larger.
Nonsterile cartridges	⩾10% of total via whole cartridge assay or via single sources.
Mixture of nonsterile loose sources and sterile assemblies	Loose sources amounting to ⩾10% of the total order or ten seeds, whichever is larger.
Sterile source assemblies	⩾10% of assemblies via sterile well chamber inserts or quantitative image analysis. Alternatively, order and assay nonsterile loose seeds equal to 5% of the total or five seeds, whichever is fewer.
Strands	⩾10% of total or two strands, whichever is larger, using single-seed calibration coefficient (see Ref. 15). Alternatively, order and assay nonstranded loose seeds equal to 5% of the total or five seeds, whichever is fewer.

[a]Each source-strength grouping in an order should be sampled. If the number of sources in a strength group is <10, the entire group should be assayed.

TABLE II. Actions to be taken by the physicist at the end-using institution based on the sample size assayed and the relative difference, ΔS_K, found between the manufacturer's source strength certificate and the assay by the physicist at the using institution.[a]

Sample size for assay of sources by end-user medical physicist	ΔS_K	Action by end-user medical physicist
Individual source as part of an order of $\geqslant$10 sources[b]	$\Delta S_K \leqslant 6\%$	Nothing further.
	$\Delta S_K > 6\%$	Consult with the radiation oncologist regarding use of the outlier source: Dependent on the radionuclide, intended target, source packaging, and the availability of extra sources.
$\geqslant$10% but <100% of order, or batch measurements of individual sterile strands, cartridges or preloaded needles	$\Delta S_K \leqslant 3\%$	Nothing further.
	$5\% \geqslant \Delta S_K > 3\%$	Investigate source of discrepancy or increase the sample size.
	$\Delta S_K > 5\%$	Consult with manufacturer to resolve differences or increase the sample size. For assays performed in the operating room, consult with the radiation oncologist regarding whether to use the measured source strength or to average with the manufacturer's value.
100% of order, or batch measurements of each and every individual sterile strand, cartridge or preloaded needle	$\Delta S_K \leqslant 3\%$	Nothing further.
	$5\% \geqslant \Delta S_K > 3\%$	Investigate source of discrepancy.
	$\Delta S_K > 5\%$	Consult with manufacturer to resolve differences. For assays performed in the operating room, consult with the radiation oncologist regarding the consequences of proceeding with the implant using the measured source strength.

[a]Assay results obtained at sites other than the end-user institution should not replace the source strength value on the manufacturer's certificate. The source strength value to be used in planning may be either that stated on the manufacturer's certificate or the value determined by institutional medical physicist when the difference is $\geqslant$5%.
[b]For orders consisting of < ten sources, the action threshold is $\Delta S_K > 5\%$ for individual sources.

therapy treatment plans, including source strengths. The qualified medical physicist shall be employed by or be under contract with the institution where the brachytherapy implants and assays are performed. Source assay duties may be assigned to individuals under direct supervision of the medical physicist who is in the department and available for immediate consultation and guidance when the assay procedures are being performed. As stated in TG-56, every institution practicing brachytherapy shall have a system for measuring source strength with secondary traceability for all source types used in its practice. Because of the availability of well chambers and inserts capable of measuring sterile source assemblies and the widespread acceptance of reimbursement for patient-specific quality assurance of extra, unused sources, users should either perform batch measurements of the sterile assemblies or order up to 5% or 5 extra loose sources, whichever is less. These quantity recommendations differ from those of TG-56, and are summarized in Table I. When possible, the physicist is encouraged to assay samples randomly from the cartridge.

Third-party services provide independent source strength verification and information of value to the institutional medical physicist, but those assays do not remove the responsibility of the institutional medical physicist to perform the verifications required by TG-56. The mean assay value from the third-party service should not replace the manufacturer's certificate without confirming measurements by the institutional medical physicist. Table II details the actions to be taken by the institutional medical physicist based on the sample size and the assay results. The mean source strength value to be used in treatment planning may be either that stated on the manufacturer's certificate or the value determined by the institutional medical physicist when the two values agree to within 5%. Individual source outliers may be discarded or retained at the discretion of the institutional medical physicist and radiation oncologist, who should agree on how to proceed. The range of source strengths in a given order is manufacturer and radionuclide dependent; therefore, the 5% action threshold for a single source may or may not be a serious deviation from the expected distribution.

IV. CONCLUSION

The AAPM has considered the issues raised by the growing use of third-party services and of sources cast into sterile assemblies such as sterile strands or preloaded needles. The responsibilities of the brachytherapy physicist are essentially unchanged from the recommendations of TG-40, TG-56, and TG-64 with the exception of increasing the sample size for orders consisting of sterile source assemblies.

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