A70 Validation, Verification, and Performance Checks of Anthropological Equipment and Software: The Importance of Quality Assurance in Forensic Anthropology Laboratories

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After attending this presentation, attendees will have a better understanding of the recent efforts undertaken at the Harris County Institute of Forensic Sciences (HCIFS) to address the pertinent issue of establishing a validation program and Standard Operating Procedures (SOPs) for anthropological equipment and software, specifically the MicroScribe® 3D digitizer and the 3Skull and FORDISC® software programs used to collect and analyze osteometric data.

This presentation will impact the forensic science community by providing best practices to mitigate potential issues of method and measurement error. The present research will illustrate the significance of validating anthropological equipment in every laboratory as a quality assurance measure, notwithstanding its general acceptance within the forensic anthropological community.

Establishing a quality assurance program and achieving laboratory accreditation has become paramount for forensic anthropology. It is through these processes that the field of forensic anthropology can demonstrate the level of surety associated with anthropological analyses. In August 2015, the HCIFS's Forensic Anthropology Division (FAD) became the first forensic anthropology laboratory to be accredited under the American National Standards Institute-American Society of Quality (ANSI-ASQ) National Accreditation Board's (ANAB's) International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17020 inspection body program. One challenge posed during the accreditation process was answering the question, "Do validation, verification, and performance checks of anthropological methods and activities follow a written procedure?"

Equipment and software programs, including the digitizer, mandibulometer, 3Skull, and FORDISC®, were in use prior to accreditation. Their use and data were assumed to be reliable since members of the forensic anthropology community deem them acceptable and references for their functionality are available in peer-reviewed literature; however, no internal validations were performed when the equipment and software were received. Plans were made to collaborate with the HCIFS's Quality Management Division (QMD) to properly validate the equipment and software in order to meet accreditation standards. All accredited laboratories, per ANAB's Guidance on Uncertainty for Testing Laboratories, must review significant factors that may contribute to the error or variability in measurements. Thus, accreditation standards require in-house validations for analytical equipment to demonstrate the level of surety associated with analyses.

To perform the internal validation of the digitizer, a reference standard was created by selecting an anatomical skull and pre-marking the osteometric landmarks. The elements were measured using calipers and standard collection protocols. Then, the analysts collected the landmarks following the newly-written digitizer SOP, checked that the coordinates were accurately captured in the 3Skull software, and compared the output to the caliper-derived measurements. In the course of establishing this procedure, measurement uncertainty calculations for 35 Interlandmark Distances (IDLs) and one angle were performed using Root Sum Squared (RSS) and following the National Institute of Standards and Technology (NIST) procedure for measurement uncertainty.

For the in-house FORDISC® validation, cranial and postcranial metric data were collected from four known, donated specimens typical of the Black and White groups within the Forensic Databank. These data were processed through FORDISC®, retaining a log of the osteometric measurements used and analytical iterations. The IDLs were then provided to the FAD analysts, who entered them into FORDISC® without viewing the previous results. Validation was considered successful when the FAD FORDISC® classification results were reasonably similar to the previous results when comparable analytical iterations were employed. While the FAD's equipment and software validation SOP is specific to the MicroScribe, 3Skull, and FORDISC®, forensic anthropologists will be able to identify the important elements that should be included in any anthropology software program validation (i.e., 3D-ID, (hu)MANid, Macromorphoscopics) or software update.

Formalizing a process for internal validation to the point where instructions can be documented in SOPs may seem unnecessary to practitioners, especially if anthropologists believe they are already employing validated methods/equipment; however, in-house verification is warranted to guarantee the appropriateness of their use for fulfilling the service needs of the laboratory. The goal is to advance analyses toward uniformity and higher quality. While this may be challenging for laboratories with only one forensic anthropologist, or offices without a QMD, validation, verification, and performance checks for *your* equipment in *your* laboratory is vital in this era of forensic science critique. Therefore, one of the primary deliverables for this project is the availability of the HCIFS's equipment and software validation plans and SOPs, which can be used as a template to meet the needs of any forensic anthropology laboratory.

Validation, Quality Assurance, Accreditation