Newsletter

The Official Newsletter of the Texas Society for Histotechnology

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HISTO*TEXas

Volunteers are needed for the Austin NSH Symposium/Convention.

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In This Issue

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www.txsh.org

40th Annual NSH Symposium/ Convention August 22-27, 2014 Austin, Texas

NSH Website

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Education: The Role of the Texas Society For Histotechnology

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TSH Education Chairperson

The Texas Society for Histotechnology (TSH) is committed to the continued growth and development of the histotechnology profession. In order to maintain a high level of competency within the profession, the society puts forth every effort to provide high quality continuing medical education (CME) programs for its members. Technicians/technologists are able to develop their knowledge and skills through workshops and/or symposiums offered by TSH Conventions year after year at conventions and regional meetings.

In addition to addressing the CME needs of histotechnologists, the society must also play a role in the growth and development of students throughout the state of Texas. With the explosion of new scientific knowledge and technological advances, and as techniques and equipment become more and more complex, CME is of the utmost importance. To foster the skills necessary to help prepare students for careers in histotechnology, and to instill in them the desire for lifelong learning while still a student, TSH sponsors several student activities:

- Through its scholarship awards program, the society supports and encourages students to achieve the highest level of academic and clinical training through traditional histotechnology programs. TSH awards each program in Texas $500.00 each year. In addition, various scholarships sponsored by TSH and Vendors are available to assist students who apply.

- The TSH/Newcomer Supply Company co-sponsored Student Slide Contest provides competition, and requires students to use critical thinking skills in order to troubleshoot the special stains requested. This year students participating were from Programs in Histotechnology at the University of Texas Health Science Center in San Antonio, Houston Community College (HCC) in Houston, and Tarelton State University in Fort Worth, Texas. Out of eight students who participated, five students received awards: First Place - $100.00, Second Place - $75.00, Third Place - $50.00 and two Honorable Mentions - $25.00.

- The TSH sponsored Poster Presentation allows students to use research methodologies as well as communication skills in order to prepare and present a poster. This year all students participating were from the Program in Histotechnology at HCC. Out of 12 students who participated, 5 students received awards: First Place - $75.00, Second Place - $50.00 and three Honorable Mentions - $25.00.

Students from all of the programs in Texas are encouraged to participate in these activities. These activities are intended to provide students with positive learning experiences and to aid them in their development as they prepare to take their places in the lab. Every student cannot win a cash prize but each student receives a certificate of participation and the opportunity to further develop their knowledge and skills.

Instrument, Method and Control Material Validation

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Introduction

Regulatory requirements and standardization drive the need for documented instrument, method and control material validations. The Quality Circle, part of the Total Quality Management (TQM) system, consists of four parts which includes a Quality Management Plan, Quality Control, Quality Assurance and Quality Improvement. Validation is a component of the Quality Assurance section of the Quality Circle. The reality, in a 2010 study in the Archives of Pathology & Laboratory Medicine[1] it was stated that rework in a large, academic anatomic pathology laboratory could cost as much as $540.00 per day and the cost for Hematoxylin and Eosin stained slides could rise to $18.00 per slide and advanced stains such as Immunohistochemistry (IHC) could cost as much as $50.00 per slide. Standardizing histology laboratory practices, such as instrument, method and control material validations will drive down work flow defects; reducing patient anxiety and laboratory stress.

Acquisition of Instrumentation

According to CLSI-31A Vol. 29 No.11-*A Laboratory Instrument Implementation Verification and Maintenance, Approved Guideline*, a successful validation implementation begins before the actual acquisition of the instrument. It is recommended that the laboratory consider the skill levels of the laboratory personnel and in-house or outsourced service engineers, the laboratory conditions, the remoteness of the laboratory for service and delivery. The laboratory should assess all electrical, water, and safety requirements for both maintenance and operation when placing the instrument into the laboratory. Ensure that the laboratory checks all applicable federal, state and local regulatory requirements prior to beginning any validation.

Responsibilities of Personnel

In order to ensure smooth implementation, it is crucial that all essential personnel be aware of their responsibilities (see table 1.1) *Laboratory Instrument Implementation, Verification, and Maintenance: Approved Guideline CLSI* GP31-A, Vol. 29 No.11

Laboratory Director Duties & Responsibilities	Technician Duties & Responsibilities	Manufacturer Duties & Responsibilities
• Implementing instrument verification and maintenance program including PM, periodic inspections, function checks • Monitoring results • Outlining remedial actions taken in response to detected defects • Ensure that program meets all regulatory requirements	• Assist in development of instrument verification and maintenance program • Oversee its implementation • Understand responsibilities and functions • Ensure maintenance is carried out in timely manner • Detect deficiencies or problems and correct as within their ability to do so • Maintain accurate documentation of maintenance activities and deficiencies • Keep supervisor and director apprised of activities	• Clear statement of instrument performance & maintenance specifications • Provide adequate training to laboratory personnel • Provide basic installation and operation manual outlining steps of instrument validation & maintenance programs • Provide support service • List functions user may perform and repairs that should only be made by a specially trained person or factory authorized personnel • List equipment required to monitor the function of instrument & any other equipment or tools for maintenance & repair

Table 1.1

Function Checks

In addition to preventative and corrective maintenance of testing equipment and instruments, the laboratory must develop specific guidelines for function checks (operational verification). Some instruments may only require a function test (e.g., tissue floatation water bath or slide drying oven) and not require an official instrument validation process be performed, and some instruments may require both function checks and instrument validation (e.g. tissue processors and slide stainers). All function checks must be documented.

The Clinical Laboratory Improvement Act of 1988 (CLIA'88) requires that equipment, instruments or test systems developed internally or those without manufacturer's guidelines for function checks must define a function check protocol to ensure accurate and reliable test results and reporting that must be conducted before testing patient samples.

The steps to developing a function check should include verifying the intended function of the piece of equipment. Establish the parameters for function checks per manufacturer's recommendations and consider the requirements for proper functioning of the instrument (e.g. temperature, humidity), mechanical checks and recommended frequency. Establish and document the initial baseline as well as any subsequent periodic function checks. Upon completion of the function checks ensure that the supervisor and Laboratory Director or designee approvals are obtained.

Instrument Validation

The laboratory must demonstrate that an instrument performs comparably to the manufacturer's established performance characteristics for accuracy, precision and reportable range of test results. Instrument validations must be performed any time a new instrument is installed, added, relocated and when a demo/loaner instrument is placed in the laboratory. All validations must be performed prior to testing patient samples.

To perform an instrument validation, the laboratory must establish the test sample size and test conditions. The laboratory may use previously tested samples if available. Compare the previously tested sample's results to results obtained with new instrument validation. Document results and corrective actions if necessary. Repeat testing on a series of consecutive days or runs to establish reproducibility, when the testing is completed obtain Laboratory Director or designee approval. This process may be repeated on relocated instruments, demo/loaner instruments as well as instrument to instrument validations.

Method Validation

A method validation is required when a new test or method modification is introduced into the laboratory. The laboratory must demonstrate that a new method or modification performs comparably to or better than the old method of testing. An example may include when a new staining and or tissue processing platform is introduced into the laboratory. To perform a method validation, write a method validation protocol, select the number of specimens from previously tested samples. Perform testing using the new method, document the results and compare to the previously tested results, document any failure and repeat if necessary. Obtain the Laboratory Director or designee approval and signature.

Control Material Validation

All control material obtained from commercial vendors or in house samples must be validated prior to being put into use with patient samples. It is always best to use control material that is processed and cut per the laboratory protocols when possible. When using commercially purchased control material the laboratory must stain a slide with the in-house protocol to validate that the stain shows the appropriate staining. The laboratory should stain the first and last slide in a series to ensure that the area of interest is still present. Document the validation and obtain the Laboratory Director's or designee's approval and signature. Organized storage of control material blocks is a must. Never pull control blocks that have not been validated for use. Keep all control material validations for 2 years.

Conclusion

In summation, it is critically important that the laboratory develop a process control plan for all key processes and that instrument, method and control validation is an integral part of the continuous quality improvement known as the Quality Circle.

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives" William A. Foster.

References

[1] Pathology Economic Model Tool: A Novel Approach to Workflow and Budget Cost Analysis in an Anatomic Pathology Laboratory

David Muirhead, Patricia Aoun, Michael Powell, Flemming Juncker, and Jens Mollerup Archives of Pathology & Laboratory Medicine 2010 134:8, 1164-1169

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