ASCP BOC ASCP BOARD OF CERTIFICATION®

The Value of Medical Laboratory Science Education and ASCP BOC Certification for Medical Laboratory Professionals

The American Society for Clinical Pathology Board of Certification (ASCP BOC) is seeking proposals to design and conduct research that examines the efficacy of certification and medical laboratory science education for testing personnel who work in clinical laboratories. The research will culminate in a publication in a relevant journal. Your institution is invited to submit a proposal for funding in response to this Request for Proposal (RFP).

1. Background Information

The ASCP BOC is an independent, non-profit certification agency governed by representatives from sponsoring societies including the American Society for Clinical Pathology (ASCP), the American Society for Clinical Laboratory Science and the Association of Genetic Technologists along with eight participating laboratory organizations. While maintaining a corporate relationship with ASCP for fiscal and operational purposes, the Board of Certification has autonomy in all governance and credentialing-related activities. Initiated in 1928 as the ASCP Board of Registry (BOR), the BOC was formed by the merger of the ASCP BOR and the National Credentialing Agency (NCA). The mission of the ASCP BOC is to provide excellence in certification of laboratory professionals on behalf of patients worldwide. To date the BOC has certified over 560,000 individuals and continues to set a high standard for quality and continuing competency. The ASCP BOC certifies those individuals who meet academic and clinical prerequisites and who achieve acceptable performance levels on examinations. The ASCP BOC is the only certifying body for laboratory professionals in the United States accredited by the American National Standards Institute and has one of the largest accredited certification programs (23 certifications) in the country. ASCP BOC credentials are recognized for licensure in all US licensure states. ASCP BOC is the sole provider of licensure exams in the state of New York.

The designation used for the professional certification of those with a bachelor's degree and training in medical laboratory science has evolved over the years and has included the terms Medical Technologist (MT), Clinical Laboratory Scientist (CLS), and Medical Laboratory Scientist (MLS). Currently, the designation for those who have achieved certification is Medical Laboratory Scientist and this terminology will be used herein. Degrees earned by candidates for the certification exam may be in medical laboratory science or basic science such as biology or chemistry. Most individuals who become certified as an MLS have completed a training program in medical laboratory science either as part of the bachelor's degree or through a post-baccalaureate certificate program. Individuals with bachelor's degrees may also qualify for the MLS certification examination if coursework and experience requirements are met. Testing personnel may receive medical laboratory science education in a Medical Laboratory Technician (MLT) training program, leading to an associate's degree. The designation for those with education and training, an associate's degree and certification is MLT. With the exception of states that require testing personnel in the clinical laboratory to be licensed, neither certification nor licensure are required under the federal Clinical Laboratory Improvement Amendments (CLIA) passed by Congress in 1988. Individuals with a bachelor's or associate's degree meeting CLIA requirements may legally function as personnel who test human samples in hospitals, public health settings, and in reference laboratories.

Data from the Bureau of Labor Statistics (BLS) estimates that there were 331,700 MLS and MLT (combined) in 2018. Furthermore, the BLS has projected an 11% increase in job growth between 2018 and 2028[1]. This demand may be due to multiple factors including a greater demand for laboratory services and advances in technology that increase the numbers of diagnostic tests available. The job outlook may also be coupled to an aging workforce wherein laboratories are

experiencing a greater numbers of retirees. In support of these observations and projections, the 2018 ASCP Vacancy Survey reported employee vacancy rates between 5.68% and 11.48%, depending on laboratory department [2]. Unfortunately, only 3,932 MLS and 2,886 MLT students graduated from NAACLS-accredited training programs in 2016[3]. Similarly, 3,952 individuals were certified as MLS and 2,653 as MLT in 2018[4]. The number of appropriately trained and certified individuals has not kept pace with demand, leading laboratories to hire individuals with bachelor's degrees in biological and chemical sciences, but no specific medical laboratory training and no certification. While meeting CLIA requirements for employment, such individuals may not be as qualified or prepared as the certified MLS and MLT, putting patients at risk for receiving an erroneous laboratory result.

2. Project Background and Goals

Previous studies conducted prior to the year 2000 have demonstrated a positive correlation between the proportion of ASCP-certified and medical laboratory science educated staff in a laboratory and the accuracy score on external Proficiency Tests (PT) [5,6,7,8]. A Proficiency Testing Program is an external quality control program which provides simulated patient samples to laboratories to assess and compare their performance against a reference standard and other participating laboratories. Using PT data from physician's office laboratories (POL) in California, Hurst, *et al*. showed that laboratories that did not employ licensed CLS were 2.4 times more likely to produce unsuccessful results on PT challenges[5]. A similar study was conducted among clinical laboratories in Illinois utilizing PT administered by the College of American Pathologists. Laboratories employing only ASCP-certified MTs produced significantly more accurate results than laboratories that employed only noncertified MTs[6]. There was also a significant correlation between accuracy on PT and the proportion of certified MTs[6]. In 2009 Delost demonstrated that those performing PT tests who did not have a medical laboratory science degree were more likely to produce an unacceptable PT result compared to participants with academic training in clinical laboratory sciences[7]. In addition, testing personnel with less than 2 years of experience were significantly more likely to produce unacceptable PT results compared to those with more than 20 years of experience[7]. These studies confirmed the value of both certification and specific medical laboratory science education in achieving accuracy of testing of PT samples.

The ASCP BOC seeks proposals for research that might similarly determine the value of ASCP certification and MLS/MLT education. Studies may address any number of areas that denote the quality of work performed by laboratory personnel as related to certification and education. Study outcomes might include, but are not limited to performance on PT, errors in test performance, adherence to standard operating procedures, errors in test results, or deficiencies on inspections. Related areas for study may address the impact of certification and MLS/MLT education on readiness to work in the clinical laboratory or other workforce issues. Outcomes for study may include, but are not limited to measures such as length or cost of training of new laboratory employees, preparedness for promotion, and employee retention.

3. Proposal Logistics

a. Proposal Submission Date and Directions

Proposals should be submitted to the project office no later than March 2, 2020. All investigators intending to submit a response are requested to submit a letter of intent along with any questions they may have by January 31, 2020. Proposals will be considered valid for a minimum of 90 days after the closing date, during which time proposals will be reviewed. A bidder may withdraw a submitted proposal prior to the closing date. Submissions will be confirmed by reply email. Late proposals will not be evaluated. All costs incurred in preparation of a proposal shall be the sole responsibility of the institution submitting the proposal.

b. Place of Submission of Proposals

This RFP will be posted on the ASCP BOC website: https://www.ascp.org/bocrfp.
Proposals must be submitted electronically in pdf format to bocrfp@ascp.org:

Project Manager:

Jennifer Young, CT(ASCP)^{CM} at:
The American Society for Clinical Pathology Board of Certification (ASCP BOC)
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For questions: E-mail Jennifer Young, CT(ASCP)^{CM} at Jennifer.Young@ascp.org

c. Important Dates:

- Posting of RFP: December 2, 2019
- Letter of intent and any questions: January 31, 2020
- Closing date for submission of proposals: March 2, 2020
- Selection of Proposals: May 31, 2020 Recipients of an award will receive both electronic and written notice from the ASCP BOC by the selection date. Unsuccessful bidders will be notified by electronic and written notice after May 31, 2020.
- Contract acceptance: July 1, 2020. The successful bidder(s) has one month to sign, date and return the contract to the ASCP BOC. If the awardee chooses not to sign the terms of the contract by the acceptance deadline, the BOC may pass the award to another bidder.

Submission and Review Timeline:

Posting of RFP	December 2, 2019
Submission of Letter of Intent and Inquiries	January 31, 2020
Closing date for submission of proposals	March 2, 2020
Notice of receipt of Award	May 31, 2020
Contract acceptance	July 1, 2020

4. Elements of Proposal

A proposal must be submitted in the English language and, at a minimum, include the following elements as detailed in the ASCP BOC RFP - Directions for Proposal Submission:

- Description of the institution/organization that includes a general overview, names and credentials of creative team, number of full-time employees.
- Description of the submitter's strengths and distinguishing skills or capabilities as they might relate to the mission of the ASCP BOC.
- A list of previously funded successful projects that may be similar to the one proposed for ASCP BOC including names and contact information of appropriate references.
- A detailed description of the study set and research design, including any necessary review by institutional review boards (IRB).
- Financial proposal in U.S. dollars, including itemized budget.
- Project staffing information and curriculum vitae of individuals who will implement this project that highlight individuals' experience in research design and related work.
- Potential barriers to successful completion of the project.
- Authorized signature

5. Evaluation Criteria

Prior to review of proposals for selection, each proposal will be evaluated for completeness, the presence of major computational errors in the budget, institutional approvals, and signatures. The evaluation panel will be made up of members of the ASCP BOC Board of Governors and Research and Development Team. The award(s) will be given to a well-designed study intended to demonstrate the impact of MLS/MLT education and/or certification on specific outcome measures such as those described in section 2 above. The successful submission will utilize an innovative study design, well-defined objectives and outcome measures, and collection of discrete, quantitative data. Multi-center studies are encouraged. Applications from groups with a demonstrated history of successful research in health care or laboratory practice are highly desired. The weighting of the components of the proposal will be as follows:

Experience and capacity of submitters	30%
Technical component	50%
Financial component	20%

By issuance of the RFP, the ASCP BOC is not obligated to award a contract. The ASCP BOC maintains the right to accept any or all or reject any, all or part of the proposal. The ASCP BOC expects that there may be additional or clarifying questions after the proposal is submitted. The submitter should be prepared to answer follow-up questions.

6. Timeline for completion of the project and publication

Unless otherwise agreed upon in terms of the contract, the ASCP BOC expects the research to be conducted within a 12-month time frame. A progress summary will be expected 6 months after the award is received, approximately January 2021. A final progress summary report is due at the completion of the project, approximately June 30, 2021. A fully edited final report is required within three months of project completion, approximately October 1, 2021. The ASCP BOC reserves the right to review all manuscripts and provide comments prior to submission for publication in a peer-reviewed journal. Manuscript submission to a relevant journal is expected about 6 months after project completion.

Anticipated Study Timeline

Report	Approximate Due Date
Interim Progress Summary	6 months after receipt of Award
Final Progress Summary	End of Study/Project Completion
Final Report	3 months after project completion
Submission of Manuscript	6 months after project completion

7. Awards

Depending on the complexity of the proposal, the ASCP BOC may award a successful bidder or bidders with up to $100,000 in total grant funding to complete the research, subject to contract terms and conditions. Several proposals utilizing more modest budgets may be awarded. Smaller awards may be advantageous to submissions from individuals with less research experience in health care and laboratory administration. The ASCP BOC reserves the right to award funding to the project(s) of its choice and reject any proposals it does not wish to award. The ASCP BOC may fund multiple projects with similar design, project aims or goals. The ASCP BOC is not obligated to discuss with a bidder the reason their proposal was not accepted but will share the rating score for each rated component.

See attached directions for proposal submission for budget criteria.

8. Intellectual Property

At this time, ASCP BOC does not contemplate owning the Work Product developed by an institution who receives an award in connection with this RFP, but will request a license to use the Work Product without restriction, including but not limited to in editorials or other publications relating to ASCP BOC's business and mission.

9. Bibliography

1. Bureau of Labor Statistics Occupational Outlook Handbook. https://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm#tab-6. Accessed March 5, 2019.

2. Garcia, E, I Kundu, M. Kelly, R Soles. 2019. The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States. Am J Clin Pathol. 152:155-168.

3. The American Society for Clinical Laboratory Science. Addressing the Clinical Laboratory Workforce Shortage. Position Paper. (ASCLS) 2018.

4. https://s3.amazonaws.com/ascpcdn/static/BOC/Newsletter/2019/BOC_Newsletter_Feb.pdf

5. Hurst, J, K Nickel, LH Hilborne. 1998. Are physicians' office laboratory results of comparable quality to those produced in other laboratory settings? JAMA 279:468-471.

6. Lunz, ME, BM Castleberry, K James, J Stahl. 1987. The impact of the quality of laboratory staff on the accuracy of laboratory results. JAMA. 258:361-363.

7. Delost, MD, WG Miller, GA Change, WJ Korzun, TS Nadder. 2009. Influence of credentials of clinical laboratory professionals on proficiency testing performance. Am J CLin Pathol. 132:550-554.

8. Lunz ME, BM Castleberry, K James. 1992. Laboratory staff qualifications and accuracy of proficiency test results. A national study. Arch Pathol Lab Med 116:820-924.