Standard Operating Procedures (SOP) for Preparing Academy of Diagnostics & Laboratory Medicine Documents

This SOP outlines the process of developing clinical documents under the Academy. While the procedure below refers to Guidance Documents specifically, the major milestones will remain the same across all document types. Differentiation from the process outlined below for other document types can be found in Appendix A.

PROCEDURES:

1. **Selection of topics for guidance documents**
   Oversight of guidance documents is under the direction of the Academy's Content Development Committee (Academy CDC) and approved by the Academy Council (Council). On an annual basis, the Council will review potential topics and prospective authors for guidance document preparation. Potential topics are identified by the Academy CDC, members of the Council or can be proposed by any member of the Association for Diagnostics and Laboratory Medicine (ADLM). If a topic is deemed significant enough to warrant a guidance document, the Academy CDC and Council will identify a prospective author(s) and invite them to chair the guidance document and submit a proposal. Proposals should contain the following components:

   - Title
   - History, statement of need, motivation, and significance of topic
   - Potential Author list (optional at this stage)
   - List of questions to be answered (optional at this stage)

   All proposals will be evaluated and reviewed by the Academy CDC. If the topic is determined to be of relevance and importance as a guidance document, the proposal is then submitted to Council for further review and approval. The review process by both the Academy CDC and Council may include constructive comments for improving the proposal and a recommendation to invite, resubmit or reject. Based on the review, a decision is made by the Council and communicated back to the proposers/authors.

   Criteria for proposal evaluations include but are not limited to:
   1) relevance and importance of the proposed topic as a guidance document;
   2) experience and expertise of the proposed author(s) (if applicable)
   3) existence of a similar guidelines or guidance document

2. **Writing Group selection**
   Document chairs may select their writing group with approval of the Academy Council. The purpose of Academy clinical guidance documents is to inform the laboratory medicine community of current best practices to improve the practice of laboratory medicine, healthcare and patient outcomes. Writing groups should consist of typically 4-6 authors who have expertise and experience in the topic, ideally representing multiple institutions and/or organizations. Inclusion of a clinician in the writing group is strongly encouraged if applicable to the topic. . Expertise from authors engaged in academic medicine (hospitals, health system, reference laboratories), non-academic medicine (community hospital, reference laboratories, private practice, industry) and public health are all welcome. Authors in all stages of their career (early, mid, experienced) with relevant expertise can

be considered to serve on writing groups. Authors are not required to be Academy fellows, though it is preferred.

When submitting a writing group to the Council for approval, document chairs should submit a (a) complete author list (b) CVs and (c) Conflict of Interest (COI) disclosure forms for all authors. The COI disclosure forms are provided by the Academy staff. The Academy CDC will initially review all CVs and COI forms and then send recommendations to the Council. COI should be considered by the Academy CDC and mitigation will be addressed before a recommendation is made to Council. Industry connections or corporate sponsorship of previous work are not conflicts for document authorship as long as the potential conflict is declared within the document and bias is not apparent within the document. Council will review and may approve the writing group at this stage or request additional information. The results of the review are communicated back to the writing group chair(s).

3. Role of the Content Development Committee

The Academy CDC was formed to oversee the development of Academy documents. The Academy CDC maintains and prioritizes a list of future document topics to recommend to the Academy Council and will routinely review published guidance documents and Laboratory Medicine Practice Guidelines to determine if they remain relevant or require update. The Academy CDC also assists council in identifying chairs for document committees. The Academy CDC also serves as a resource for each writing group, with a committee liaison assigned to each document. Academy CDC members communicate with document chairs to ensure all steps of the SOP are completed, and that documents are completed in a timely manner. The Academy CDC reviews all materials related to documents and recommends actions to Council.

4. Review process for guidance documents

If a proposal is accepted or a topic is selected to warrant a guidance document, a guidance document will be invited. An invitation to author a proposed guidance document and invitation for submitting the full manuscript should not be interpreted as acceptance of the full guidance document manuscript. Each completed guidance document will undergo a separate peer review process handled by the Council, Academy CDC and if needed additional designee(s). A period for public review and comment will occur for all guidance documents. The comments received during the public comment period must be addressed before the document is approved by the Council. The acceptance/rejection decision will be made based on criteria defined by the Council. A more detailed description of the review process is found in Appendix C.

5. Instructions for Authors

The recommendation for the length and preparation of the document is as follows:

- Approximately 20-25 published pages, including table, figures and references.
- Up to 10,000 words, excluding, tables, figure and references.
- Up to 7 tables and figures (total).
- The document should be submitted in Calibri font, 11-point font size, double spaced with line numbers.
- Guidance documents should include a statement that it is expert opinion.
- Conflicts of interest should be included in all guidance documents.
- The suggested format is an Abstract at the beginning with section headers that match the approved focus questions.

- Each section should conclude with key summary points or recommendations for each focus question.
- Collaborations should be determined prior to writing the manuscript.
- Recommended parameters are flexible based on topic and publication requirements of the Journal the paper is submitted to. The Academy has an agreement with the Journal of Applied Laboratory Medicine (JALM) for publication without further peer review. Publication in any other journal must be discussed and approved by the Council prior to document development and may be subject to additional review.

Outline/Focus Questions

The document writing committee will submit an outline of the document in the form of focus questions. Where applicable, a description of all phases of the laboratory testing process should be included. Focus questions should provide adequate coverage of the topic while still conforming to the document length recommendations above. The Academy CDC and Council may request revisions to the proposed outline/questions, e.g. if the resulting document might be too lengthy, or if key aspects of the proposal topic are inadequately addressed.

6. **Suggested timeline for preparation of Academy documents**: ~12-15 months
   Begins after topics and document chairs have been identified. All timeframes are suggested and flexible based on circumstances.
   a. Guidance document chair proposes their committee. Proposed committee is reviewed by the Council – 2 weeks.
   b. Committee members are invited to join the project – 1 month (for invitations and responses).
   c. Committee formulates an outline in the form of focus questions and submits questions for review by the Academy CDC and Council – 1 month.
   d. Academy CDC and Council reviews the proposed questions – 2 weeks.
   e. The committee formulates answers to the questions and creates a "guidance document draft" – 4-6 months.
   f. Guidance document draft is reviewed by the Academy CDC and Council and– 2-4 weeks.
   g. Committee responds to the comments from the Council. – 2-4 weeks.
   h. Document is publicly posted for comments – 1 month.
   i. Academy CDC reviews comments to ensure rigorous peer review – 2 weeks.
      - Additional peer or journal review may be required – 2-3 weeks if needed.
   j. Committee responds to comments – 2-4 weeks.
   k. Document is sent to Council for approval – 2 weeks.
   l. Document is sent to ADLM Board of Directors (BOD) for approval – 2 weeks.
   m. Final draft of guidance document is "published."
   n. Authors are invited to submit to journal by Academy staff (JALM, unless an alternate journal has been previously agreed upon)

7. **Distribution**
   Guidance documents will be made available for distribution on the Academy web site and will be promoted through regular channels. Guidance documents are normally submitted for publication in

JALM. Exceptions may be considered when collaborating with other organizations and must be approved by council prior to so.

Appendices:

A. Academy Document Types
B. Academy Guidance Document Process Flow Chart
C. Academy Internal Review Process
D. Academy Internal Collaboration Process
E. Academy External Collaboration Process