Manual for Clinical Competence and Training Statement Writing Committees

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Purpose and Scope of CCS Writer's Guide

The ACC/AHA/ACP Task Force on Clinical Competence and Training Statements (CCS) will oversee the creation of this manual to assist writing committees in the development of clinical competence and training statements. The manual documents the procedures and methodology to be used for development of these statements.

The CCS understands the challenges in applying a uniform methodology to competence statements that represent diverse diseases, conditions, diagnostics, and interventions. Writing group members should familiarize themselves thoroughly with the manual, as these policies and standards provide the framework for document creation. However, if warranted the CCS may allow exceptions to the written policies. The CCS will review these policies periodically to ensure they are consistent with ACC clinical document policies and procedures.

Parent (Oversight) Committee: Task Force on Clinical Competence and Training Statements

Writing Committee: Specific ad hoc committee selected by the parent Task Force to develop clinical competence and training statements about specific topics (e.g., Echocardiography)

This Task Force shall serve as a central coordinating committee for the development of all ACC/AHA/ACP Clinical Competence and Training Statements that are to be published in the *Journal of American College of Cardiology* and *Circulation*. Clinical competence and training documents are developed to make recommendations for attaining and maintaining the cognitive and technical skills necessary for the competent performance of a specific cardiovascular service, procedure or technology. These documents are evidence-based, and where evidence is not available, expert opinion is utilized to formulate recommendations. These recommendations are intended to assist those who must judge the competence and training of cardiovascular health care providers entering practice for the first time and/or those who are in practice and undergo periodic review of their practice expertise.

The Task Force will act as an oversight committee and constitute writing groups that will act as subcommittees and operate within the established Task Force budget. The Task Force shall: 1) select topics for clinical competence and training statements through proposals submitted by individual members, ACCF committees and leadership; 2) define and maintain a rigorous methodological approach to document development; 3) coordinate the peer review and approval process; 4) coordinate document publication in *JACC* and on the ACCF web site; and 5) perform a periodic review of all ACC/AHA/ACP Task Force on Clinical Competence documents in order to ensure that the documents are current, planned for revision, or sunsetted, as appropriate.

Selection of Topics

A "Call for Topics" is distributed to ACC leadership and all committees on an annual basis. The list of submitted topics is reviewed by the CCS Task Force for consideration as future topics. The Task Force considers whether any other ACCF documents exist that addresses the suggested

topic areas, prioritizes the topic suggestions, and then determines its next topic. The Task Force is limited to two documents in development at any one time.

Selection/Role of Writing Committee Chair

Once a topic has been chosen, the writing committee chair is selected by the parent task force. For CCS, the chair must have expertise in the topic area. Duties include applying CCS methodology to the writing effort, building writing committee consensus, managing timely completion of the document, including writing committee member adherence to deadlines, enforcing the writing committee member relationships with industry policy and reviewing page proofs for publication. Chair suggestions are welcomed by the submitting physician, ACCF Committee, or organization.

Selection/Role of Writing Committee Members

The writing committee is composed of a balance of clinician users and content experts on the topic being addressed. The ACCF Committee Chair, pertinent to the topic area, is asked for nominations for the writing committee members. No more than 50% of the writing committee members may be from the recommending ACCF Committee. The parent task force also recommends individuals to serve on the writing committee, as well as identifies organizations to be invited to participate in the writing effort. The Chair of the CCS works with the Chair of the writing committee to determine final membership of the writing committee (based on suggestions given by the CCS). Writing committee members are required to attend meetings and conference calls pertinent to document development, adhere to document deadlines, transfer copyright to ACCF, and agree to follow CCS methodology.

Role of the Task Force Liaison

A member of the parent Task Force serves on each writing committee as the Task Force liaison. The liaison monitors the progress of the effort, participates fully in the committee as a working member, and provides feedback to the parent committee concerning any problems or issues that need to be addressed. This member has the responsibility of ensuring that the document under development is consistent with previously published ACC documents. This member also maintains close contact with other writing committees in progress pertinent to the topic and shares drafts. If there are significant differences among ongoing writing committees, this should be made known to the parent Task Force Chair and every attempt should be made to reach a compromise to ensure concordance of ACCF documents.

Role of the Task Force Lead Reviewer

The Task Force Lead Reviewer assumes the responsibility to conduct a thorough review of a particular document on behalf of the Task Force. All Task Force members have the opportunity to review the document, but the lead reviewer reviews the document as an “official” peer reviewer on behalf of the Task Force.

Subsequently, the Task Force Lead Reviewer receives a copy of:

- All peer review comments on the document (official, organizational and content)
- The detailed response to official reviewers prepared by the writing committee chair
- The revised document that has addressed all peer review comments

The Task Force Lead Reviewer reviews this material and makes a recommendation to the Task Force Chair whether the document is ready for board review, or whether there are outstanding issues that require resolution. The Task Force Lead Reviewer and/or the Task Force Chair then follow up with the writing committee chair to provide feedback if further revision is necessary. Once the Lead Reviewer believes the document is ready for board review, the reviewer either sends a brief letter (and copies staff) or e-mail message to the Chair (and copies staff) to indicate that the document is ready for board review. The task force chair then provides staff with final approval to send document for board review.

Writing Committee Member Relationships with Industry

The ACCF has taken a number of steps to improve the full disclosure of committee members' financial relationships with industry. Writing committee members are required to disclose any relationships with industry that may be perceived as real or potential conflicts of interest. Such relationships will be made known verbally and in writing to the writing committee at the first meeting and updated at each full-committee meeting and conference call thereafter.

The importance of strict adherence to this policy will be emphasized at the initial meeting of each writing committee by the Chair of the task force and/or the Chair of the writing committee. In addition, the following language will be included in the preamble of each published clinical document:

The ACC/AHA/ACP Task Force makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the Writing Committee. Specifically, all members of the Writing Committee are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These changes are reviewed by the Writing Committee and updated as changes occur.

Industry Support for Clinical Competence and Training Statements

The College does not accept money from pharmaceutical and device companies for development of clinical documents or policy statements, however financial assistance is accepted for the printing and distribution of pocket guidelines.

Publication of Peer Reviewer Names

In order to further strengthen the integrity of the writing effort and make the document development process more transparent to readers all CCS documents will include on-line appendices of peer review names and affiliations.

Document Development Guidelines

Currency of Clinical Competence and Training Statements

The CCS Task Force periodically reviews documents that fall under its purview to ensure that the documents are current. Documents that fall under its purview include all competence and training statements. If the documents are out-of-date, the TF oversees a process to determine whether the documents should be sunsetted or revised.

Time Line for Document Development

The CCS writing activity is budgeted to oversee two clinical documents in progress at any one time. Once a topic begins, it generally takes between 12 to15 months to develop the document from the time of identification of a writing committee chair to time of delivery for peer review.

The writing committee staff liaison drafts a time line that is reviewed with the writing committee chair. The proposed time line is shared with committee members and guides the work of the committee. The time line is revised, as needed, to accommodate changes in work flow.

Document Length

The targeted document length for CCS is 11 to 16 published pages, including tables, figures, and references. The Task Force has discretion regarding document length depending on document scope. Writing committees may recommend to the Task Force that additional material not included in the published version of a document (e.g., glossary of terms, additional background material, resource list) be posted on the web site along with the document. The Task Force must approve these requests.

References

Reference Guidelines: Generally, references should be limited to one to four current, relevant references to support individual statements. A few historical references may be appropriate in a document but should be used selectively.

Reference Verification: All references (including journals, abstracts, books, government publications and monographs) included in the reference list are either electronically (eg, PubMed, NLM Locator Plus) or manually verified by staff.

Journal references: Staff verifies most journal citations through PubMed which provides the "citation of record" for the document. If a journal reference does not appear in PubMed, authors are asked to provide a copy of the front page of the article to staff for manual verification.

Books and Reports: All whole book and book chapter information must be verified by staff. Whole book references require a specific page number reference to the cited material. Book chapters require chapter information (i.e., chapter title, authors, page range) as well as the publisher information for the book. If this material is unavailable to staff electronically (NLM Locator Plus) or in the ACC library, authors will be required to forward the book copyright page and the table of contents for manual verification by staff.

In Press: "In Press" articles may not be used in a document unless the article publishes *before* our document publishes *or* staff is provided a copy of the letter of intent to publish from the publisher to the lead author. In Press articles must be clearly identified in the reference list. Staff will update "In Press" citations with full citation information if the article publishes prior to web posting of our document.

Abstracts: When citing abstracts, authors must clarify in the text that the information is "preliminary." Abstracts should be identified in the reference list by using [abstr] in the citation. Abstract references older than two years must be replaced with a published article. Staff will verify abstracts through using ACC library resources. If the abstract is unavailable, authors will be requested to forward the page on which the abstract appears that includes the corresponding journal information (name, year, volume, page number).

Oral Presentations at Major Internationa/ Scientific Meetings: Statements referencing a presentation at a major scientific meeting may be included in the document under the following circumstances: 1) the statement must indicate that it is based on preliminary information; 2) the *presenter* must review and verify the accuracy of the statement in the document prior to publication; and 3) the statement must be referenced in parentheses in the text, e.g., (Lamas G, oral presentation at North American Society for Pacing and Electrophysiology Scientific Sessions, Boston, MA, May, 2001).

Personal Communication: Personal communication is not to be cited in the reference list but may be referenced in parentheses in the text of the document, e.g., (personal communication from <identify person, company, and date>). A copy of the communication should be forwarded to staff for manual verification.

Instructions for Adding and Deleting References: Staff use a reference manager database (RefMan) to manage references for all clinical documents. Therefore, when editing references, authors are asked to follow the attached instructions. Authors should not renumber references.

Finalizing the Document

At the final stages of document development, writers should re-examine the original goals regarding the scope of the clinical document. Any identified gaps should be addressed before the document is sent to peer review. The writing group will be asked to give formal approval of the document both before peer review and after peer review edits have been incorporated.

Building Consensus Through Group Decision-Making

Consensus building is an agreement-seeking process that enables a group of people to satisfy everyone's primary interests and concerns.

Writing committee discussions and consensus development are ongoing at all stages of document development. Since ACCF clinical statements are written by committee, agreeing on the scope, clinical objectives, evidence tables, text, and recommendations occurs throughout document development. Subsection writers often come to consensus through phone calls or e-mail exchanges of information.

Consensus development is often most important around topics that have no literature base. Writing groups are faced with the challenge of addressing an important clinical question despite a lack of data. The document development process allows for the incorporation of minority opinions if consensus cannot be reached.

It is the writing committee Chair's responsibility to do everything possible to try to come to resolve conflict within the group. If consensus can not be resolved, then the topic should be referred back to the parent task force with the parent task force chair and task force liaison outlining the objections. If, however, consensus cannot be obtained, a statement similar to the following can be used: "The majority of the members of the Writing Group could not come to agreement (would not recommend) … because …." The purpose of the statement is to indicate to the readers of the document that full-committee consensus could not be reached.

Review Process for Clinical Documents

I. Peer Review

Prior to forwarding a document for board review/approval, the document must undergo external peer review. Official, content, and organizational peer reviewers participate in the process. Official and content reviewer panels should be comprised of an appropriate mix of experts, general cardiologists, practitioners, academia, geography, and age.[1]

Pre-Consensus Peer Review: At the discretion of the writing committee chair/co-chairs, individuals with specific expertise may be invited to read, review, and comment on specific sections of a draft document to provide the committee with additional insights that are not present among the writers or when writers request additional clarification on an issue. The pre-consensus review occurs prior to final writing committee sign-off on the document in preparation for peer review.

Peer Reviewer Categories:

Official Reviewers: Three official reviewers from the ACC are identified. ACC official reviewers include one from the BOT (selected by the ACC President), one from the Board of Governors[2] (selected by the BOG Chair), and one from the ACC/AHA Task Force on Practice Guidelines (selected by the Chair of the Guideline Task Force). These reviewers in effect serve as a subcommittee of the Board and Executive Committee to review the documents. The CCS

[1]An appropriate balance on peer review panels will help to ensure that perspectives of different end users and those with various backgrounds can provide feedback on the guidelines. There has been little research into who makes a good peer reviewer, but the qualifications listed above are reflective of the end users of the document. In addition, a recent study looking at the question of reviewer qualifications did find that age influenced the quality of a review. (Black, N. "What makes a good reviewer and a good review for a general medical journal." JAMA 1998; 280:231-3.)
[2]The Board of Governors' review process includes one *official* reviewer on behalf of the BOG, supported by 3 to 6 secondary reviewers representing a geographical diversity (these may be a BOG member or the member's designee within his/her state). Secondary reviewers of the document forward their comments to the primary reviewer who assimilates the information into one master BOG review. The master review is then forwarded to the writing committee chair for consideration.

Task Force also provides an official reviewer—the lead Task Force reviewer—who coordinates CCS Task Force review (see #5 below). The writing committee chair must provide a detailed response to all official reviewers regarding the handling of their comments (see #6 below).

Content Reviewers: Writing committee chairs have the option of sending the document to experts in the content areas of the document to further strengthen the review process. Appropriate ACCF, AHA and ACP scientific committees participate in content review of the document. Chairs may solicit suggestions for additional content reviewers from their writing committees. Responses to content reviewers are not required.

Organizational Reviewers: If an organization participates in a writing effort through providing a representative to serve on the writing committee, the organization is invited to peer review the document. A form asking the organization whether it would like to see the final, board-approved document for endorsement consideration also accompanies the peer review draft. Organizations that did not have a representative on the writing committee may also be requested to peer review the document and consider potential endorsement. The writing committee and/or parent task force should identify these organizations.

Peer Review Process

Copies of CCS are provided to reviewers who are asked to respect a two- to three-week turn-around time (depending on the length of the document) and informed that reviews received after the deadline *may* not be incorporated into the document. Organizations are given a four-week turn-around time to coordinate their review.

The writing committee chair will prepare a "response to official reviewers." This may be in the form of individual letters or may be combined into one response for all reviews. ACC staff will disseminate the response to the official reviewers, as well as to the lead reviewer from the parent task force who ensures that official peer review comments have been adequately addressed.

A primary reviewer from the parent task force will be appointed and assume the following roles:

- Conduct an initial comprehensive review of draft on behalf of the parent task force

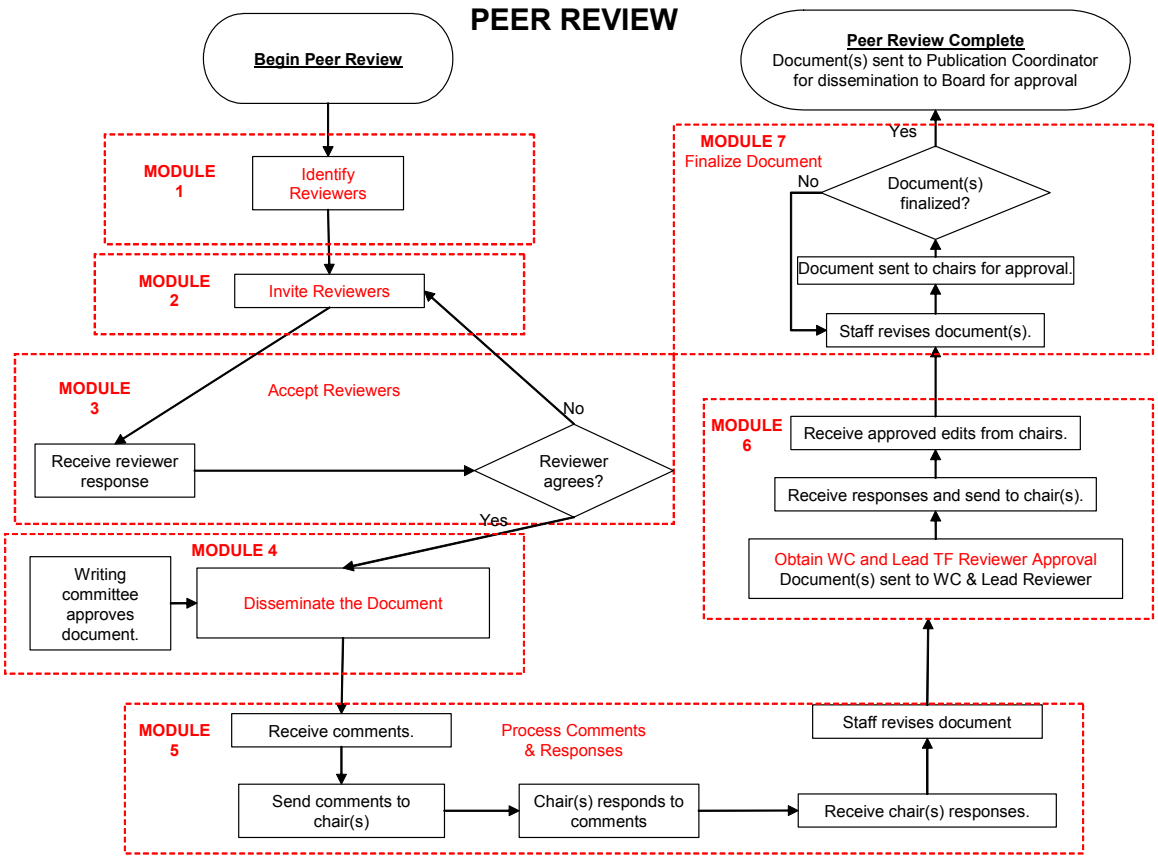
Once the post-peer review draft is complete:

- Review all peer review comments
- Review the revised draft to ensure that peer review comments have been adequately addressed
- Review the response to official reviewers to ensure that all issues have been adequately addressed
- Recommend to parent task force chair whether the document is ready to go forward for board review or identify remaining issues that require resolution. If there are remaining issues, work with writing committee chair and/or task force chair to resolve final issues.
- Sign off of the document on behalf of parent task force should be done in writing (brief letter or e-mail to task force chair with a copy to staff)
- Participate in the ACCF Board of Trustees conference call to discuss the document

Publication of Peer Review Process: A brief description of the peer review process will be included in the introduction of the document that highlights the number of official reviewers from cosponsoring organizations, the number of content reviewers, as well as names of organizations that participated in the review process. On-line appendices will be posted with the document that highlights peer reviewer names and affiliations.

TYPES OF DOCUMENT REVIEW

PRE-CONSENSUS REVIEW	PEER REVIEW
•Optional •Need additional expertise to supplement WC •Conducted prior to formal peer review process •Acceptance of reviewer's suggestions is at discretion of chair •Conducted by outside experts •Obtain approval & publish names	•Required •Official •Post-consensus (after writing committee sign- off of document) •Response required to official reviewers •Equal representation by cosponsoring orgs. •Obtain approval to publish names



II. Board Review/Approval Process

ACCF Board of Trustees' (BOT) Review

Clinical documents are forwarded to the BOT by mail ballot for review, discussion, and preliminary vote. A conference call is scheduled to offer Board members opportunity to raise concerns they may have about a document. Materials forwarded to the Board include 1) responses to official peer reviewers, 2) the document, and 3) a tracking form identifying writing committee chair/members, official peer reviewers, content peer reviewers, and a list of organizations that have peer reviewed the document. Although the conference call is open to all Trustees, participation is not required unless Trustees have a specific concern that needs to be addressed. If Trustees want to participate but are unable due to scheduling difficulties, they are requested to FAX written comments to the writing committee chair (via staff) so that conference call participants may discuss the concern on the call.

All Board members are asked to return their Consensus Form to indicate preliminary approval of or opposition to the document by a designated date following the conference call. The ACCF President decides whether any changes made at the board level warrant board revote or whether

the changes do not substantially alter the document and therefore do not require further review by the BOT.

Present on the call are:

- President, American College of Cardiology
- Chair, Parent Task Force
- Lead Reviewer, Parent Task Force
- Chair, Writing Committee
- Board members with concerns or interest in document discussion

Formal ACCF Approval of Clinical Documents

The ACCF Executive Committee formalizes approval of clinical documents via teleconference based on the results of preliminary consensus of the BOT.

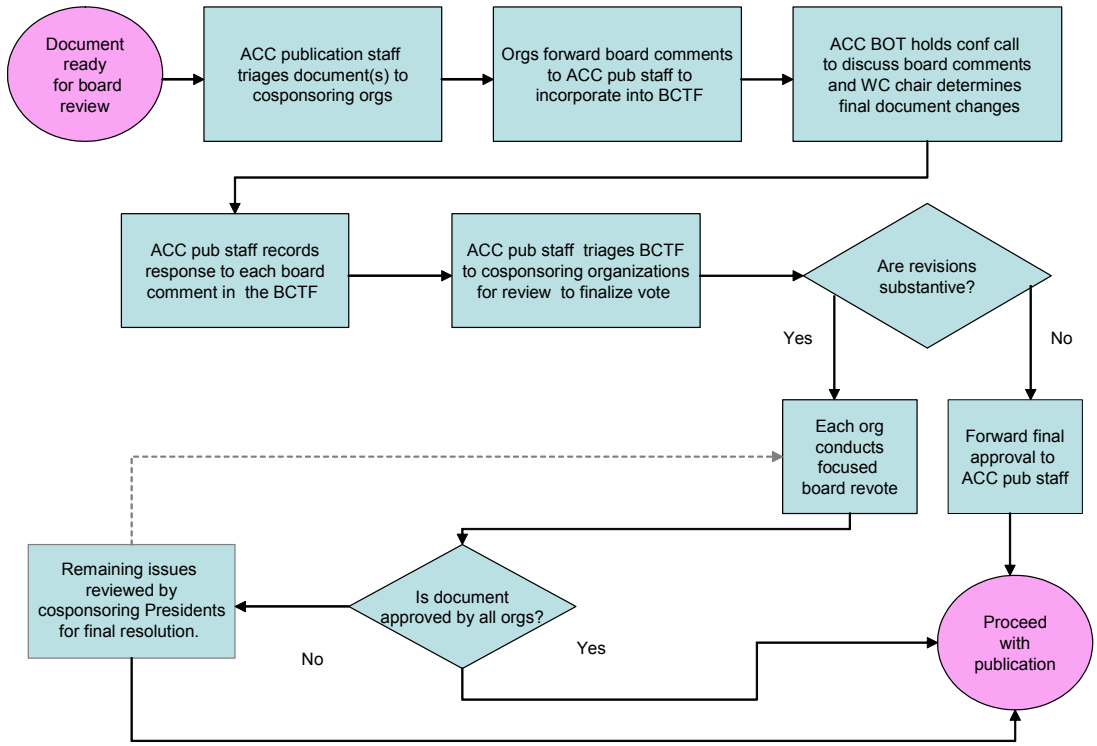
AHA Science Advisory and Coordinating Committee (SACC) Review:

AHA SACC review occurs simultaneous with ACCF BOT review. AHA staff receives a copy of 1) responses to official peer reviewers, 2) a copy of all peer review comments (official, content, organizational), 3) the draft document, and 4) a tracking form identifying writing committee chair/members, official peer reviewers, content peer reviewers, and a list of organizations that have peer reviewed the document. AHA conducts its own board review/approval process and contacts ACC staff with any concerns raised during the review. ACC staff facilitates a process to reconcile final issues by working with the Presidents and staff of both organizations and the writing committee chair. Depending on the nature of the board concerns, the writing committee chair may need to confer with writing committee members via mail ballot or conference call to resolve final issues.

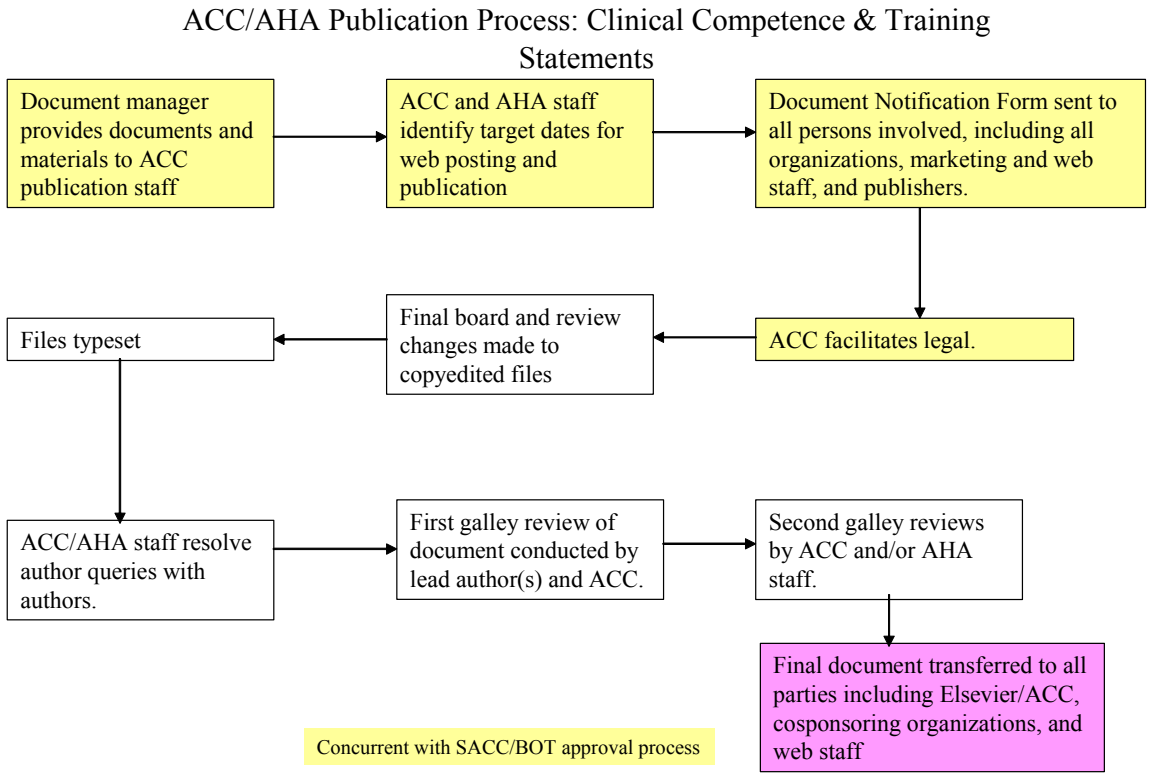
ACP Review and Approval Process:

The American College of Physicians sends clinical documents to its Education Committee for review and comment prior to board approval. All documents must be submitted and ready for the biannual meetings to be incorporated on their board agenda. ACP is not able to review and vote on documents via mail ballot.

Board Approval Process



BCTF = Board Comment Tracking Form; Cosponsoring orgs = ACC, AHA, ACP or other orgs, if applicable; Pub = publication; WC = writing committee

Publication Process:

All clinical competence documents are published in the *Journal of the American College of Cardiology*, *Circulation* and the *Annuals of Internal Medicine* if they participated and approved the document. See the flow chart below for the detailed explanation of this process.