

Continuing Medical Education Policies and Procedures



PURPOSE:

The International Association for the Study of Lung Cancer (IASLC) Continuing Medical Education (CME) program's purpose is to promote lifelong learning for physicians and the health care teams they work with. The IASLC is a professional medical society that provides education about lung cancer and other thoracic malignancies to physicians and other professionals who care for their patients. IASLC believes such efforts "raise the bar" regarding quality patient care. The mission of the IASLC is to conquer lung cancer and other thoracic malignancies by studying their etiology, epidemiology, prevention, diagnosis and treatment; by disseminating information and providing education to the Association's members, to the medical community at large, and to the public; and by using all available means throughout the world.

IASLC programs are designed to improve the knowledge, competence, performance, and patient outcomes by improving the quality and safety of medical care. The IASLC is the only global organization dedicated to the study of lung cancer. Founded in 1972, the association's membership includes more than 7,000 lung cancer specialists in over 100 countries.

IASLC Department of CME is the administrative unit at IASLC responsible for ensuring compliance with the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support (SCS), as well as other regulations and laws as they relate to the provision of CME. IASLC CME Department also requires that the following policies and procedures be followed throughout the development and implementation of CME activities:

IASLC Providership and Requirement for CME Credit: All educational activities provided by IASLC and seeking CME credit must have credit awarded by IASLC CME Department with no exceptions.

Independence - In addition to SCS 1:

Each activity certified for credit by IASLC Department of CME will be in compliance with the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education.

Final authority for all areas relating to the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education will be retained by the IASLC Department of CME.

A commercial interest cannot be involved in any aspect of the activity nor provide meeting planning or faculty coordination functions. Information on the identity of

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learners at CME activities is considered to be the confidential property of IASLC Department of CME. Information on learners will only be released to third parties when learners have prospectively signed a document authorizing this release of information (e.g. MOC).

At the discretion of IASLC Department of CME, anonymous (sanitized) evaluation summaries of the supported activity may be shared with industry representatives.

Identification and Resolution of Conflicts of Interest - In addition to SCS 2:

IASLC Financial Relationships and Conflict of Interest Policy for Faculty Members, CME Committee, Planners, Reviewers, Moderators, Researchers et al. was designed to protect patient safety and welfare, safeguard the reputation and integrity of the institution, preserve the integrity of affiliated research, ensure fulfillment of obligations to faculty, planners and reviewers, and require disclosure of all relevant commercial financial relationships and conflicts of interest, while permitting the pursuit of relationships with for-profit entities that further the mission of IASLC.

Full disclosure is required of all involved and able to control or influence content of any given IASLC CME activity. IASLC Department of CME has established and implemented a disclosure policy for its program chairs, moderators, planning committee members, faculty (teachers/authors), and activity reviewer's et al. IASLC Financial of Commercial Support and Conflicts of Interest Disclosure Policy are made available to all prospective participants prior to the any given CME activity.

IASLC is required to have a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners. The primary mechanism is to have all individuals who are in a position to control or influence the content of an educational activity complete an attestation that they have read and agreed to abide by The IASLC policies and that any and all clinical recommendations that they make for patient care as part of their planning and/or CME presentation/activity materials will be based on the best available evidence, that they will give a balanced view of therapeutic options, and that the content will be in accordance with ACCME's Content Validation Statement (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/cme-clinical-content-validation>).

Additional and supplemental mechanisms to resolve conflicts of interest include a two-step process, but are not limited to: The conflicted individual indicates how they have resolved their own relationships for the activity on the disclosure form itself.

All conflicted faculty, author, planner, reviewer et al. disclosure forms are provided to the Program Reviewers to review the content of the activity a complete a resolution of conflict of interest for any disclosed relationships. Methods of resolution may include but are not limited to:

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Replace the Faculty: Faculty with potential conflicts may be asked to step down from their speaking role if a suitable resolution cannot be found or they refuse to work with the chair to resolve the COI.

In the case of a written or oral presentation, the primary reviewer could appoint another individual to exercise control over the content of the presentation or change the speaker assignment to a topic that does not present a potential Conflict.

Altering the financial relationship: Where a potential conflict arises out of a financial relationship, one option that the individual could pursue would be to change his or her relationship with conflicting commercial interest to the extent that the primary reviewer believes that would address the conflict. This would need to occur 12 months before the CME activity.

Peer Review of faculty slides: An unbiased review of the speaker's or author's slides/written document(s) and lecture can be conducted prior to the activity to determine if the presentation or documents contain bias. The physician planner will invite a member of the CME Subcommittee member to perform this objective review. If bias is found, the speaker/author can be asked to remove the bias. Each final presentation should be confirmed to have a balanced approach to the discussion of drugs, devices, and treatment modalities. Also, presentations should be free of recommendations for care, particularly of specific drugs and devices.

The primary physician/non-physician planner will assume the responsibility for ensuring that the process for managing and resolving conflicts is implemented for each CME activity. Written records of disclosure and actions taken to resolve potential conflicts with the resolution are recorded. The individual(s) involved, or any IASLC member may refer a matter arising under this section of the policy to the CME Subcommittee or the Ethics Committee for further review. However, the decision of the primary planner stands and must be honored until confirmed or modified, if at all, by these two committees.

An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, author et al. of CME, and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CME activity (ACCME Standard 2.3).

Appropriate Use of Commercial Support – In addition to SCS 3:

IASLC Department of Education is responsible for the review and signing of all CME grant letter of agreements; the source of all support from commercial interests must be disclosed to learners prior to the activity beginning.

When commercial support is 'in-kind' (e.g., provision of equipment) the nature of the support must be disclosed. In order for commercial support acknowledgement to be made, the letter of agreement must be signed by both the commercial supporter

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representative and IASLC CME Department prior to printing/production/activity.

In the case of jointly provided activities, the grant letter of agreement will delineate the joint provider's name and contact information (* IASLC does not accept joint providership activities at this time).

In the event there are social events or meals at CME activities, they cannot compete with or take precedence over the educational event(s) and should comply with the American Medical Association's Guidelines on Gifts to Physicians: E-8.061 (<http://www.ama-assn.org/>).

To avoid activation of Sunshine Act reporting requirements, any food service should be paid with funds outside of funding received from commercial interests, not industry support grants.

Appropriate Management of Commercial Promotion - In addition to SCS 4:

Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

a) Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support). Exhibitors should sign IASLC's Exhibitor Letter of Agreement.

b) Exhibit fees shall be set by IASLC or the joint provider (if any), for each activity and will be standard for that activity; potential exhibitors shall have equal access to purchasing exhibit space (first come-first serve).

c) All exhibitors must be in a room or area separate from the educational activity and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the CME activity.

d) Commercial interest representatives may attend CME activities at the discretion of IASLC for the direct purpose of the representatives' own education; however, they may not engage in sales or marketing activities while in the space or place of the educational activity.

IASLC Department of CME will not utilize a commercial interest as the agent providing a CME activity to learners; e.g., distribution of CME activity brochures, distribution of programs for CME activities or arranging for electronic access to CME activities.

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Content Validation – In addition to SCS 5:

ALL IASLC CME activities will comply with ACCME's Content Validation Statement:

- a) All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients.
- b) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis. 2. Activities that promote recommendations, treatment, or manners of practicing medicine or pharmacy that are not within the definition of CME or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients will not be certified for credit.
3. Presentations and CME activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies must be used.

Criteria for Selection of Educational Formats:

Educational formats are based on the activity objectives and nature of the content as well as learner feedback and evaluation. Formats are chosen that are suitable for the venue and setting taking in consideration the targeted audience, and that will achieve the educational objectives and desired results.

The educational formats used in IASLC educational activities include manuscript review publications; abstracts from meeting sessions; book publications including staging handbooks and manuals; and live activities that offer the following formats: lectures/presentations; panel discussions; moderated small group discussion; and expert-led case studies. The Association also develops online, self-directed programs with associated live webinars. Evaluation of the formats through participant evaluation is part of the activity design and is used in the development of future similar programs.

Evaluation:

All IASLC activities are evaluated at the conclusion of the activity. A completed evaluation is required in order to receive CME credit/contact hours. The evaluation process assesses participant satisfaction including achievement of personal goals and objectives, faculty and session content, learning goal and objectives met, content of activity matched current scope of practice/educational needs, disclosure of financial relationships, communication of commercial support, intent to make changes in practice, anticipated barriers incorporating changes to current practice and how to overcome those barriers. An evaluation summary is compiled for

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each CME activity.

IASLC tracks information regarding the number of participants and number of certificates issued. Evaluation of the activity obtains learner response to gained knowledge, competence and performance in terms of implementation, and barriers to overcome in order to implement. All speakers are evaluated on the content they present. Additionally, participants are welcome to comment on activity presentations in terms of how valuable content was and any suggested changes for future educational activities.

An outcomes measurement survey is sent to attendees 4-5 weeks after the CME activity to assess if learners made practical changes based on the learned knowledge, competence and performance. Information regarding the difficulties participants may be having in implementing practical changes is also obtained.

Off-Label Use Disclosure:

Faculty (speaker, presenter, or authors), activity medical directors, and moderators et al. are required to disclose to the learners when products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved); and any limitations on the information that is presented, such as data that is preliminary or that represents ongoing research, interim analyses, and/or unsupported opinion. This is important due to the nature of ongoing oncology research.

Faculty Honoraria and Travel Reimbursement:

It is the IASLC's policy that IASLC faculty cannot be paid honoraria for speaking at IASLC-provided CME events in which IASLC assumes financial liability. The decision as to whether honoraria will be paid to guest faculty is made by the Director of Education. If the program Director chooses to provide honoraria, the Honorarium Policy for Faculty must be followed.

Honoraria paid to guest speakers will be paid by the IASLC CME Department Guidelines Institutional Policy. "It is ...not to exceed \$1,000 per visit. Up to \$5,000 per visit for exceptional speakers or events. Amounts above \$5,000 require the CEO's prior approval."

The IASLC reimburses reasonable travel, accommodations, and meals for external faculty. Internal faculty expenses are also reimbursed when the conference is held outside a 50-mile radius of Denver. Reimbursement guidelines are established by IASLC Honoraria Policy Agreement.

All requests for faculty honoraria and travel reimbursements are approved by IASLC CME Department. Without the approval, payment is not allowed.

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All payments are handled by wire transfer or check from the IASLC Finance Department.

Auditability:

For directly provided CME activities, IASLC CME Department is responsible for maintaining auditable records in accordance with the policies and procedures of IASLC Finance Department. The IASLC does not participate in Joint-Provided activities.

Attendance and Record Keeping for CME Activity File:

Physician registration, evaluation submission, and CME credit information are retained in a secured data file for six years or longer as part of the activity files/records of educational programs. As an accredited CME provider, the IASLC will continue this process as part of its management of educational activities. If a participant in an IASLC educational activity requests information concerning credits obtained, the CME manager will verify the number of credits by sending stated verification.

Internet:

The IASLC-provided activities only appear on websites identified by IASLC CME as appropriate; they cannot be posted on a pharmaceutical or medical device manufacturer's website.

Links from IASLC CME-approved websites to the websites of pharmaceutical and medical device manufacturers are permitted before or after the educational content of an IASLC CME-provided activity but shall not be embedded in the educational content of the CME activity. The learner must be clearly notified that s/he is leaving the educational website.

The IASLC prohibits advertising of any type within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.

Review of CME Mission Statement and CME Policies:

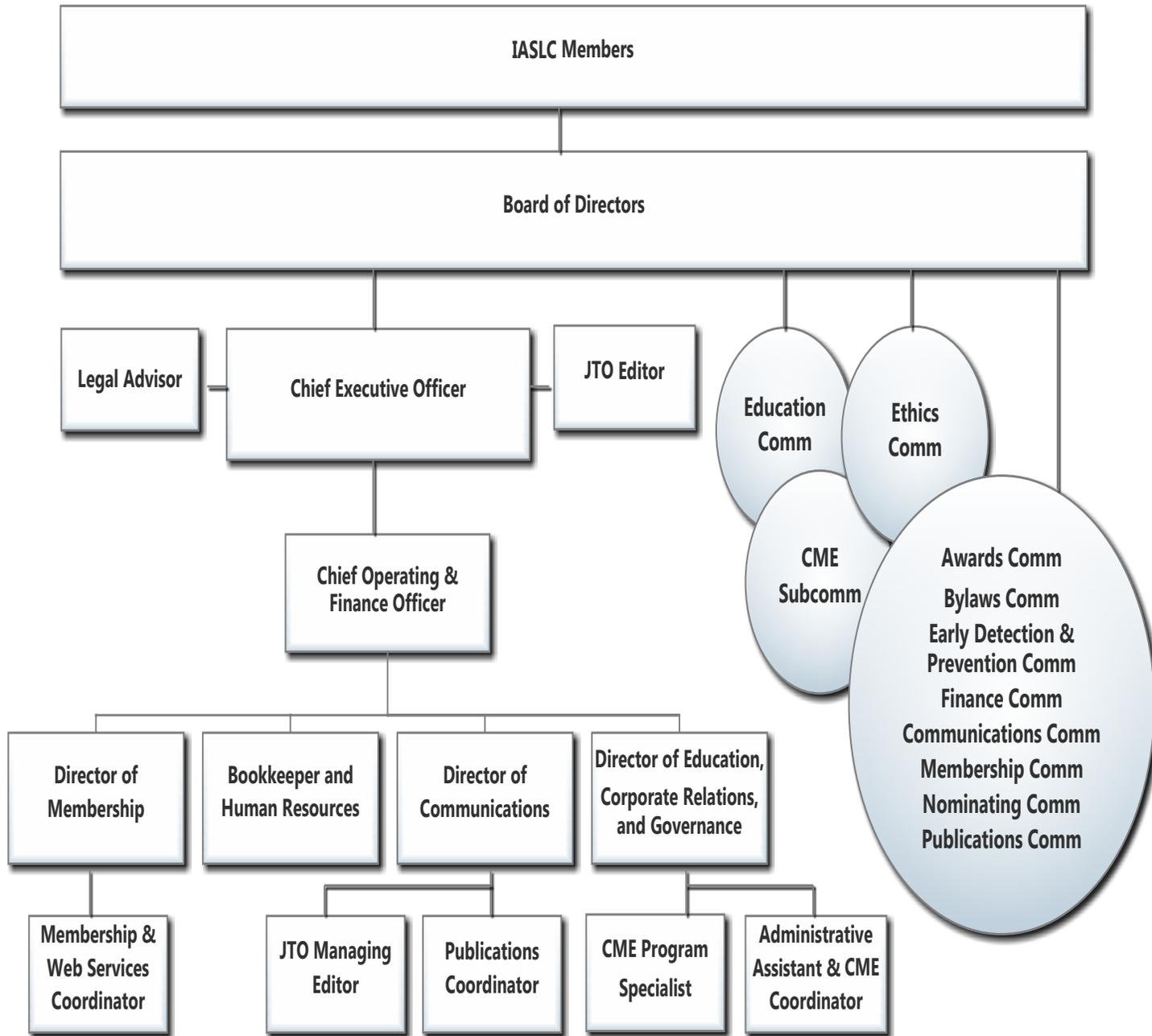
The IASLC CME Mission Statement is reviewed on an annual basis by the CME Committee to ensure that the CME Mission is current with the IASLC's mission. The CME Committee will recommend updates and changes to the IASLC CME Mission Statement to the Education Committee and the Board of Directors when it deems them to be warranted and necessary.

The IASLC CME policies will also be reviewed for updating, if necessary, to meet the [ACCME criteria](#) and [Standards of Commercial Support](#). A summary of the CME

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Committee's annual review of these policies and any recommendations for changes will be provided to the Education Committee and the Board of the Directors for their information and approval, when warranted.

IASLC CME Organizational Chart:



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CME Committee Purpose and Responsibilities:

To ensure that the IASLC's educational programs address the Association's CME mission and comply with the Essential Areas and Standards of the ACCME:

- Provide overall guidance and define the mission and policies for IASLC 's CME program.
- Review individual educational programs for compliance with ACCME requirements.
- Review IASLC's CME activities evaluation data.
- Annually review the overall CME Program, including the Association's CME mission statement, and recommend changes as necessary to keep them consistent with the overall mission and strategic plan of the Association.
- Bring forward innovations and new ideas in CME education.
- Support the Director of Education in overseeing the preparations for reaccreditation of the Association by the ACCME.
- Liaise with the Education Committee, the Ethics Committee, and any other committee to best support the needs and requirements of the IASLC CME program.

Definitions:

Commercial Interest: Any entity producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical services directly to patients to be commercial interests.

Commercial Support: Monetary, or in-kind, contributions given by a commercial interest, which are used to pay all or part of the costs of a CME activity.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

Continuing Medical Education (CME): Educational activities that serve to maintain, develop, or increase the knowledge, skills, professional performance, and relationships a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public. (Sources: ACCME and AMA).

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Exhibit Fee: A fee paid by a commercial interest to purchase display space and promote its products. Exhibit fees are considered a business transaction (e.g., they are not considered "commercial support").

Financial Relationships: Those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options, or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to include the financial relationships of a spouse or partner.

a) **Personal Financial Relationships:** 'Contracted research' includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

b) **Financial Relationships with Commercial Interests:** When a person divests himself of a relationship it is immediately not relevant to conflicts of interest, but it must be disclosed to the learners for 12 months.

c) **Relevant Financial Relationships:** Financial relationships in any amount occurring within the past 12 months that creates a conflict of interest (per ACCME). ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be relevant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Joint Provider: A non-ACCME accredited entity that plans and presents a CME activity in partnership with an ACCME accredited provider.

Role Definitions for CME Activities:

The Accreditation Council for Continuing Medical Education (ACCME) requires that anyone in a position to control or influence the content of an educational activity must disclose to the accredited Continuing Medical Education (CME) provider any relevant financial relationships that the individual and/or their spouse/partner have with ACCME-defined commercial interests. This disclosure is part of a process to ensure that the content is free of commercial bias.

A person may take on one or more of the following roles during the planning, development and execution of a CME-certified activity. A disclosure of relevant financial relationships would be required for these roles.

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Primary Course Director: A physician who has overall responsibility for ensuring that the activity complies with the ACCME Accreditation Criteria and Standards for Commercial Support, AMA policies and Stanford policies. He/she has direct oversight and supervisory responsibility for the planning, implementation and evaluation of the CME activity. This includes compliance with all the criteria listed on the Course Director Responsibility Agreement Form. If there are Co-Course Directors for an activity, all must sign the Course Director Responsibility Agreement Form.

Planner: An individual who participates in the planning and development of the educational content in collaboration with the Course Director. He/she has control of the curriculum and works with the Course Director on identifying:

- Professional practice gaps and the underlying educational needs from peer-reviewed literature,
- hospital data or other sources,
- the target audience,
- the ACGME/ABMS/IOM Core Competencies that will be addressed,
- learning objectives for the course,
- expected educational outcomes and measurement methods,
- format and design of the course,
- factors and barriers that would prevent successful application of the education to practice, and
- strategies to address or overcome these factors or barriers.
- They may also review the content to ensure that it achieves the expected results.

Content Reviewer: There are two types of Content Reviewers. In either case, the content reviewer(s) must have no relevant financial relationships with any commercial interests in the content area of the activity.

A physician that reviews and resolves any reported relevant conflicts of interest for an individual who has control over content for that CME activity (i.e. planner, speaker). The reviewer also ensures that: 1) educational content is fair, balanced, and free of commercial bias toward any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, and 2) patient treatment recommendations are supported with the best available evidence and generally accepted by the scientific community.

A content expert, typically a physician, who reviews a pre-existing enduring material to determine if the content continues to be up-to-date and accurate for the purposes of renewing the activity. Non-physician reviewers are acceptable when the content is not clinically focused (e.g., statistics, leadership).

Author: An individual who creates educational content and develops slides, modules and presentations, but does not verbally deliver content.

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Speaker/Faculty: The individual who is responsible for verbally presenting the educational content of an activity to learners. This person may also be involved in the development of said content or may work with content developed by authors.

Learner: An individual in attendance at a CME activity.

Moderator: The individual moderating or hosting the CME activity (introduces the presenters, facilitates question & answer sessions and/or panel discussions, etc.).

Program Chair: The IASLC faculty member in charge of planning, implementing, and evaluating the CME activity and who is responsible for collaborating with IASLC's CME Department to ensure compliance.

Provider: The ACCME-accredited provider certifying an activity for continuing education credit and, therefore, responsible for ensuring compliance with the ACCME Essential Areas, Elements, Criteria, and Standards for Commercial Support of CME. The ABIM MOC accreditation statement is as follows:

“Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to [XX] MOC points [and patient safety MOC credit] in the American Board of Internal Medicine’s (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC point’s equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider’s responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.”

For CME/ MOC activities you will have to use the ACCME accreditations statement and the ABIM’s MOC accreditation statement.

The ACCME accreditation statement is as follows:

For directly provided activities: “The (name of accredited provider) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.”

For jointly provided activities: “This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the ACCME to provide continuing medical education for physicians.”

IASLC Non-Endorsement Statement:

The content and views presented in this educational activity are those of the faculty and do not necessarily reflect the opinions or recommendations of IASLC. Inclusion in this activity does not constitute approval or endorsement of any commercial products or services. These materials have been prepared based on the best available information but are not exhaustive of the subject matter. Participants are advised to critically appraise the information presented and encouraged to consult the available literature for any commercial products mentioned.

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IASLC ADA/OEO Nondiscrimination Policy:

IASLC considers all applicants and activity participants without regard to race, color, national origin, age, religious creed, sex, or sexual orientation. IASLC is an Equal Opportunity Employer. IASLC does not discriminate on the basis of a disability in admissions, access to treatment, or employment in their programs and activities as identified in the Americans with Disabilities Act. Please let us know in advance if you require any accommodations.

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