Policy and Procedure Manual

ENTITY **American Epilepsy Society**	NUMBER **AES-IND**
MANUAL **Policy and Procedure**	EFFECTIVE DATE March 29, 2008
SUBJECT **Industry Presence at CME Activities**	STATUS CAC approved in August 2007, COE Approval Dec 2007. BOD approval March 28, 2008

1. POLICY

The American Epilepsy Society (AES) conducts CME Activities that serve as the Society's educational program. The purpose of these activities is to improve competencies, performance-in-practice, and/or improve patient care.

AES recognizes that Industry plays an important and valued role in the support of education. AES is committed to maintaining a fair and balanced partnership with Industry.

2. PURPOSE

Upholding the utility and credibility of the educational process and maintaining both the actuality and the appearance of propriety with regard to Industry presence is paramount to AES. AES wholeheartedly adopts the principles embodied in the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, American Medical Association (AMA) rules for the operation of the Physician's Recognition Award (PRA), and the Office of the Inspector General of the US Department of Health and Human Services (OIG) Guidance. These principles state that education must be free from influence, direct or indirect, that may be exerted from Industry; and that the environment in which continuing education takes place must be free from commercial bias.

Accordingly, AES has established standards and guidelines with regard to Industry presence at the CME Activities. These standards and guidelines have been established in order to:

2.1 Ensure the AES fulfills it responsibilities as required by ACCME Essential Areas and policies.

2.2 Monitor the influence that Industry may exert on individual learners at the AES CME Activities.

2.3 Help assure the general public that the practice of medicine is fair, balanced and free from commercial bias.

3. STANDARDS AND GUIDELINES

In order to meet its stated purpose with regard to Industry presence at the CME Activities, AES has established the following standards:

3.1 All AES CME Activities attendees will have full and appropriate access to the CME Activities in an environment that is free from commercial bias.

3.2 Because the AES CME Activities operate within several distinct domains, separate guidelines have been established to ensure that ACCME, AMA, OIG, and FDA guidelines with regard Industry influence are adhered to, and that the CME Activities overall is well-coordinated and productive both for the attendees and for Industry supporters. These distinct domains are:

3.2.1 **Public Domain** – The registration area, lobbies, general hallways and other areas of transit within the public areas of a hotel or meeting facility.

3.2.2 **CME Education Domain** – Those rooms or areas within a hotel or meeting facility in which formal CME activities are presented.

3.2.3 **Attendee Personal Domain** – Attendees' hotel sleeping rooms.

3.2.4 **Commercial Exhibit Domain** – Areas in which commercial exhibits are presented; located in a self-contained exhibit hall clearly distinct from the CME Education Domain.

3.25 **Scientific Exhibit Domain** – Areas in which Industry displays of various aspects of ongoing research and development of modalities (e.g., drugs, devices) for treatment or diagnosis of epilepsy are displayed as poster presentations; located in the exhibit hall or in another area clearly distinct from the CME Education Domain.

3.3 Industry will have equitable opportunities for support of activities and components of the CME Activities, subject to the following:

3.3.1 Opportunity to provide support for activities and components of the CME Activities is offered to Industry based on the most current membership needs assessment, emerging clinical information or treatments in the discipline, and the areas of interest of the commercial supporter—all subject to discussion and negotiation between the parties.

3.3.2 The American Epilepsy Society must approve in advance and in writing all plans regarding Industry presence at the CME Activities.

3.4 For each of the domains, AES has adopted distinct procedures and operational guidelines to govern Industry presence with regard to activities and promotional material.

4. PROCEDURES AND OPERATIONAL GUIDELINES

4.1 The Public Domain

The public domain is an area that shall remain free of any visible commercial presence. Specific exceptions to this policy are listed below.

4.1.1 Signs and printed materials that promote CME activities sponsored, co-sponsored, or jointly sponsored by AES are permitted in the public domain. In such materials, the name of the commercial supporter should appear in language in accordance with the ACCME *Standards for Commercial Support*, and be secondary to the messages on the content of the activity.

4.1.2 Distribution of printed materials produced by an industry supporter of a CME activity, and/or associated signage, is strictly prohibited.

4.1.3 Supporters of activities certified by AES shall have no role in the administration of the activity whatsoever.

4.1.4 Bags, cases, or other give-away items are permitted if they serve to support the attendees in managing the materials from the conference, and are approved in advance and in writing by the AES. Industry names, logos, or product information may be printed on the inside surface of such items or on a surface detachable from the item. The outside of such items is reserved for the AES logo and other data relating to the CME Activities. The design and content of any information to be printed on or inside such items or on an associated detachable surface must be approved in advance and in writing by the AES.

4.1.5 As the AES is fully in control of all activities and events at its CME Activities and those messages it wishes to communicate to attendees, no independent industry-supported meeting information and communication services (such as Internet access, conference video program, or newspaper) may be distributed, shown or accessed in the public domain.

4.1.6 Industry-sponsored or supported events, receptions, dinners and other social events that are not associated with CME activities are allowed when held at specific times designated by AES (so as not to interfere with the CME Activities educational programming). Such events must be approved in advance by AES, and are subject to the following guidelines:

- Social events (e.g., dinners, receptions, or other events that have entertainment as their primary purpose) are allowed for groups of 100 or fewer event attendees. In accordance with AMA rules on gifts to physicians, the per-attendee value of the event shall not exceed AMA rule ($100).

- Each Industry supporter may sponsor one such social event during the CME Activities.

4.1.7 Focus groups or other similar meetings supported or sponsored by Industry are allowed, subject to the following:

- Focus groups or similar gatherings that have as their primary purpose opinion and/or market research will be scheduled to avoid conflict with CME activities or social events that are an official part of CME activities.

- Each Industry supporter may sponsor one or more focus group(s), so long as the total number of attendees of all the groups so sponsored does not exceed 50.

4.2 The CME Domain

Industry is strongly encouraged to support CME Activities Industry support that is received for a CME activity will be acknowledged as “an educational grant to the AES.”

4.21 Social events that are an official part of a CME activity are managed directly by the AES staff.

4.3 The Personal Domain

To protect the privacy of attendees' personal domains, content and means of delivery of materials (in any medium) related to the CME Activities must be approved in advance by the AES.

4.3.1 Any AES CME Activities video broadcasts shown on hotel room televisions is considered in the private domain and is governed by the following guidelines:

- The purpose of the AES CME Activities video broadcast is to provide information on CME Activities scheduling and AES activities, and to highlight clinical developments at the AES CME Activities.

- Producers may not utilize AES officials to endorse products directly or indirectly.

- Commercial messages are permitted at the beginning and/or the end of the broadcast only. Commercials are not allowed in AES conference video broadcasts when they are shown in the public domain.

- The AES Education Council and its CME Activities Committee will appoint a liaison to the AES video broadcast. The liaison will be responsible for reviewing and approving scripts and pre-broadcast materials.

4.4 The Commercial Exhibit Domain

Commercial exhibits are bound by the rules and regulations as set forth in the exhibit contract (see attachment).

4.4.1 The promotion of Industry presence in the Commercial Exhibit Domain must abide by the rules regarding promotional material or advertisements in the other meeting domains as specified in the above sections.

4.4.2 Promotion of Commercial Exhibits must be approved in advance by the AES.

4.4.3 The design and content of information to be displayed in or distributed from contracted booth space within the Commercial Exhibit domain must be approved in advance and in writing by AES.

4.5 The Scientific Exhibit Domain

Scientific exhibits are bound by the rules and regulations as set forth by the AES and detailed in the AES document entitled “AES Guidelines for Industry-Sponsored Scientific Exhibits” (see attachment).

4.5.1 The promotion of Industry presence in the Scientific Exhibit domain must abide by the rules regarding promotional materials or advertisements in the other meeting domains as specified in the above sections.

4.5.2 Promotion of Scientific Exhibits must be approved in advance by AES.

5. ACCOUNTABILITY FOR THESE POLICIES

As a condition of participation, each Industry participant and its agent(s) agree to observe these policies. Violations to the above policies will be reviewed and sanctions applied.