

Date: INSERT DATE  
To: INSERT PARTICIPANT NAME  
From: American College of Chest Physicians  
Subject: Agreement between ACCP and INSERT PARTICIPANT NAME and INSTITUTION



## Interventional Bronchoscopy and Diagnostic Bronchoscopy Memorandum of Understanding

### I. INTRODUCTION

#### **AQURE Registry Purpose**

The American College of Chest Physicians (ACCP) have developed the ACCP Quality Improvement Registry, Evaluation, and Education (AQURE Registry). The ACCP AQURE Registry is a Web-based quality improvement tool for chest physicians developed by chest physicians. The ACCP AQURE Registry is designed to assist the chest physician to meet increasing demands placed upon them by the public, credentialing bodies, regulatory agencies, payers, and the institutions in which they practice. Monitoring real data is becoming compulsory for participation in recertification, maintenance of certification, reimbursement programs, privileging, CME activities, etc.

The ACCP AQURE Registry enhances the practice of chest medicine through the application of useful data reports and peer comparisons. Data reports and peer comparisons can be used to:

- obtain CME, MOC, and manage other professional practice requirements
- engage in quality improvement programs
- monitor resource utilization
- assess and monitor practice patterns overtime
- compare to national trends
- communicate with payers and regulatory agencies

#### **AQURE Registry Bronchoscopy Module**

The ACCP AQURE Registry, currently consists of two registries: (1) the Bronchoscopy Interventional Registry; and (2) the Bronchoscopy Diagnostic Registry. The main goal of these registries is to collect standardized multicenter data on various bronchoscopic interventional and diagnostic procedures.

## **AQulRE Registry Bronchoscopy Module Data Elements**

The ACCP AQulRE Registries on Diagnostic and Interventional Bronchoscopies are the only national registries collecting data on a myriad of bronchoscopic interventional and diagnostic procedures. Furthermore, the ACCP is proven to be a trusted and supportive resource for chest clinicians and their patients. This provides a sustainable model to assess which outcomes are optimal for pulmonary device surveillance.

The ACCP has developed a standardized format in which to collect procedural and de-identified patient data.

The Bronchoscopy Interventional Registry collects the following information:

- General patient information (de-identified)
- Procedure information for the following:
  - Ablative Therapy (Laser, APC, electrocautery, PDT, etc.)
  - Dilation
  - Stent Placement
  - Stent Removal
  - Valve Placement
  - Valve Removal
- Indications for Interventional Procedures (malignant or non-malignant diseases);
- Quality of Life Indicators pre-procedure, peri-procedure or 30 days post-procedure /Co morbidities/ mortality/Medication Use/Lifestyle assessment.

The Bronchoscopy Diagnostic Registry collects the following information:

- General patient information (de-identified)
- Procedure information for the following:
  - BAL- Bronchoalveolar lavage
  - Transbronchial Biopsy
  - Wash
  - Cytology Brushing
  - Endobronchial Forceps Biopsy
  - Transbronchial Needle Aspiration (TBNA)
  - Endobronchial Ultrasound (EBUS)
- Indications for procedure, periprocedural morbidity information (e.g., bleeding, pneumothorax, and airway injury), Co morbidities/ mortality/Medication Use/Lifestyle assessment and are collected.
- Diagnostic outcomes

## **II. PURPOSE & OBJECTIVES**

1. Provide a tool for ACCP members to readily implement in their practice when continuous performance assessment becomes a mandatory component of recertification, reimbursement, hospital privileging, and CME programs.
2. Provide a tool for ACCP members to engage in projects that improve the delivery of patient care.
3. Develop an objective source of data, which can be used to influence health policy, performance measure development, and reimbursement decisions as they related to pulmonary, critical care, and sleep medicine.
4. Develop a tool that objectively assesses the impact of ACCP educational interventions and resources, and provides opportunities for the ACCP enhance educational and clinical offerings as necessary.

### III. RESPONSIBILITIES OF PARTICIPATING ORGANIZATIONS

#### Data Collection

- Agree to enter data on bronchoscopic procedures for a 30-day trial period, based on the participants identified level of participation.
  - At the end of 30 days the Participant may:
    - Commit to furnishing clinical data directly to the AQuIRE Web-site on an ongoing basis for a twelve (12) month period, according to the selected level of participation.
    - Modify their level of participation, and commit to furnishing clinical data directly to the AQuIRE Web-site on an ongoing basis for a twelve (12) month period
    - Agree not participate in the AQuIRE Bronchoscopy Registry(ies). In which case, all data will be eliminated from the registry(ies) and not utilized for any analysis.
- Submit regular data within the “call for data period” after the close of each calendar quarter according to the Data Harvesting Timeline provided and updated annually.
  - Submit a data record on each patient who receives medical care and who is eligible for inclusion in the registry, based on your level of participation. The goal is to collect and enter data on 100% of your bronchoscopic case volume, as indicated by your level of participation and ultimately enter a complete unbiased and scientifically valid cohort of patients.
  - Use registry-specific data elements, definitions, as published in the current AQuIRE Code Book, and utilize collection tools approved by the ACCP for each respective registry provided to your site.
- Ensure that data collection is be performed by individuals, who have been trained to use the registry.
  - Ensure individuals entering data in the AQuIRE Registry have been trained by the ACCP and utilize instructional manuals developed by the ACCP.

#### AQuIRE Registry Contacts

- Participant will serve as or designate a Registry Site Manager who will serve as the primary point of contact for each Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports, and act as direct liaison with ACCP.
  - ACCP recommends that the Registry Site Manager be an experienced clinical professional; and if ACCP determines that any Registry Site Manager is not sufficiently trained or credentialed in this manner, Participant will identify an alternate individual to serve in that capacity.
  - Participant also agrees to notify ACCP within ten (10) working days of any change in the Registry Site Manager.
  - Participant hereby acknowledges that ACCP will use the e-mail address of the Registry Site Manager to communicate pertinent information regarding Registry-specific issues.
- Maintain an updated institutional profile, ensuring that ACCP has a valid e-mail address for the Registry Site Manager, individuals responsible for data entry and/or the participating physician at all times.

## **Data Accuracy and Completeness**

- Participant will furnish to AQuIRE independent corroboration, in a form satisfactory to ACCP in its sole, reasonable discretion, that all eligible patients' records have been submitted, based upon case volume counts or similar data from Participant's admitting/registration, bronchoscopy log, billing, and/or medical records information or other hospital/practice-based information system.
- Participant agrees that their submitted patient data will be audited for accuracy and completeness by or on behalf of ACCP.
  - In addition, all submissions are required to meet the AQuIRE inclusion threshold as defined in the current AQuIRE Code Book release provided to Participant, and as updated by AQuIRE from time to time, in order for Participant's data to be included in the national averages.
  - Participant understands and agrees that auditing may include an onsite review of patient medical records and additional supporting documentation.
    - The onsite audit process will consist of an audit of randomly selected charts and an evaluation of the process for data collection.
  - In the event that a Participant is selected for an audit, the initial audit will be at the expense of ACCP, and Participant agrees to cooperate in such audit through making available documentation and access to Participant's staff.
  - Participant agrees that if an audit process finds the data do not conform to ACCP standards, as a condition of continued participation in AQuIRE, the Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACCP, to correct such data issues, as well as, in the sole discretion of ACCP, submit to an onsite audit conducted by a third-party auditor chosen by ACCP at the Participant's sole expense.
  - Non-conforming data submitted by the Participant will be withheld from the AQuIRE Registry data analysis until such data is brought up to standard and re-submitted to AQuIRE by the Participant.
  - During any such correction period, while Participant may receive information comparing its data to general data from a Registry, ACCP makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.
- Permits AQuIRE to perform comparisons of Participant data with national or regional summary data to aid Participants in their data completeness and consistency programs and other efforts to improve patient care.
- If Participant voluntarily chooses to have additional external data audit. The Participant can contract with the ACCP or other ACCP approved auditor, for an additional fees. The results shall be available to both Parties. If such voluntary audit reveals data do not conform to ACCP standards or this Agreement, the process described above shall be enforced.

## **Safeguarding Data**

- Participant shall maintain appropriate procedures to safeguard data confidentiality on the AQuIRE Registry Web site. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder.
  - Participant agrees to maintain appropriate liability insurance.
  - Ensure that each participating physician utilize the AQuIRE Registry Patient Log to maintain a record of each participant in the registry.

- All unique patient identifiers should be kept on this log and stored in a secure location.
- Not submit any data to the AQUIRE Registry if doing so would violate HIPAA or any other applicable law.

### **Use of Names and Logos**

- Without the express prior written consent of ACCP, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol ACCP, CHEST, AQUIRE or any trademarks or service marks of ACCP, CHEST, and ACCP business partners, or make any reference to ACCP, CHEST, and ACCP business partners in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to participant, or in any other manner, including, without limitation, press releases or lists.

## **IV. ACCP RESPONSIBILITIES:**

### **Data Collection**

- ACCP agrees to accept Participant's clinical data, subject to review by ACCP, except where the submitted data does not conform to this Agreement.
  - In such cases, ACCP reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet the required ACCP standards.

### **Data Analysis and Reports**

- Agree to generate reports for each Registry based on Participant's submitted data, and to distribute reports periodically.
  - Reports include aggregated demographic, general procedural information, and patient outcomes in a form made available by ACCP to Participants, and as updated by ACCP from time to time.
  - Data Quality Reports will be distributed on a quarterly basis.
- Analyze Participant's submitted data records by means of electronic data checks, consistency checks, and range checks to review data accuracy and completeness and determine aggregate completion rates and return Data Quality Reports to Participant within 45 days after the calendar quarter.
  - Answer questions regarding the use of the AQUIRE Registry.
- ACCP may, at its option, audit submitted patient data to review its accuracy and completeness.

### **Maintenance of Data Elements**

- Produce, disseminate, and periodically revise the data elements, definitions, formats, and data collection tools that allow Participants to directly transmit patient data to AQUIRE.

## **Training**

- ACCP will provide a self-training document to guide Participant's data collection activities as well as one session with ACCP Staff to instruct on the use of the AQuIRE Web site.

## **Use of Names and Logos**

- Without the express prior written consent of Participant, ACCP shall not use the logos, trademarks or service marks of Participant or Participant's institution.

## **V. DATA COPYRIGHT AND OWNERSHIP**

### **Individual Patient Data**

- The Participant shall maintain ownership of data for individual patients submitted by that Participant, subject to the rights, if any, of HIPAA or any other applicable laws.
  - Participant hereby agrees the return of that information is not feasible once it has been entered into the AQuIRE Registry.
  - Participant grants to ACCP a perpetual, enterprisewide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of individual patients submitted by Participants in ways that will inform clinical and health services research, inform quality of care, inform care standards, provide benchmarking opportunities, inform health care reimbursement and resources utilization, maintenance of certification and licensure, competency and education. And to the extent ACCP develops de-identified or similar data that is not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACCP shall exclusively own such data, and any derivative works from it, as Intellectual Property Rights owned by ACCP.

### **Intellectual Property; Aggregate Data**

- All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, AQuIRE, Registries, any data submitted and accepted by ACCP for use in the AQuIRE Registry, aggregate data and the compilation of the same with any other data received in connection with the AQuIRE program, and any derivative works using the AQuIRE Registry, including, without limitation, any reports, calculations and models based thereon, and Deidentified Data, including, without limitation, all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with ACCP and its respective vendors.
- For purposes of this Agreement, "Intellectual Property Rights" means all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including, without limitation, any and all now known or hereafter existing, in and to
  - (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or logos;
  - (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data;
  - (iii) patents and patent applications, patentable ideas, inventions and innovations;

- (iv) know-how and trade secrets; and
  - (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing.
- ACCP reserves the right to use De-identified Data and Protected Health Information (“PHI”) in electronic or other format whether or not contained in a Limited Data Set, including, without limitation, to support ongoing improvements and enhancements to AQuIRE Registry.
  - Once Participant data is accepted by ACCP into AQuIRE for analysis and reporting, this data becomes part of the AQuIRE Registry aggregate data and it cannot be retracted from AQuIRE by Participant.

## VI. PUBLICATION AND DATA USE

- If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by ACCP, or produced in connection with or derived from AQuIRE, with the exception of strictly internal use within the Participant, Participant must first obtain the prior express written consent of ACCP. This requires adherence to the AQuIRE Publications Policy.
- To the extent Participant is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by ACCP prior to publication, per the publications policy.
- Participant may request customized reports to answer specific research questions. Such data requests must be submitted to the ACCP for approval. The ACCP has developed specific processes to review such requests.
- Participant may use aggregate data or reports provided by the ACCP for internal uses or advertisement of services. Participant must follow AMA policy on Advertising and Publicity (E-5.02) found in Appendix B of this agreement.

## VII. TERM, ENFORCEMENT, TERMINATION

- This Agreement shall be effective for 12 months from the date of initial data enrollment, then renew automatically for additional one (1) year terms unless the Participant provides ACCP with ninety (90) days’ advance written notice of its desire to terminate the Agreement at the end of the then-current term.
- The Parties agree that this Agreement may be enforced or terminated with respect to any particular AQuIRE Registry, without initiating or impairing any Party’s right to enforce any right with respect to any other Registry or this Agreement as a whole.

## VIII. UPDATES AND AMMENDMENTS TO MOU

Updates and amendments can take place. In the event that a proposed change, a new signature page verifying the understanding of such changes may be required.

VI. MOU AGREEMENT

This Memorandum of Understanding is submitted by the American College of Chest Physicians for participation in the **“AQulRE Registry Bronchoscopy Module”**. This agreement represents the understanding of both parties with respect to the items covered in the agreement and supersedes any prior written or verbal communication between the parties regarding these items.

<b>APPROVED AND AGREED BY:</b>
<b>Principle Investigator:</b>
Print Name: _____
Signature Name: _____
Date: _____
<b>Participant Physician:</b>
Print Name: _____
Signature Name: _____
Date: _____
<b>Participant Physician:</b>
Print Name: _____
Signature Name: _____
Date: _____
<b>Participant Physician:</b>
Print Name: _____
Signature Name: _____
Date: _____

**I. Initial Commitment to a AQuIRE Bronchoscopy Module Level of Participation**

Individuals participating in the AQuIRE Bronchoscopy Module have the option to participate at six different levels. These levels are listed in section IV of this policy.

- Commitment to participate at one level must be the time of enrolment in the registry.
- Participants will be given a 30-day trial period at their selected level of participation to determine if they are able to fulfill the obligations required at the particular level.
- At the end of the 30-day trial period, AQuIRE participants will have the option of (1) continuing at their level of participation, (2) changing their level of participation, or (3) discontinuing participation with the AQuIRE Bronchoscopy Module.
  - If the participant chooses not to continue participation all data entered during the 30-day trial period will be eliminated from the registry.

**II. Annual Recommitment of AQuIRE Bronchoscopy Module Level of Participation**

At the end of Quarter 3 of each year all participants will be required to recommit for the upcoming year.

- During this period participants may choose to commit at a different level of participation for the coming year.
- The ACCP will make record of the date to ensure that appropriate steps are taken with regard to data analysis.

**III. Modifying AQuIRE Bronchoscopy Module Levels of Participation**

Under extenuating circumstances a participant may request in writing to change their level of participation.

- All requests must be submitted to Joyce Bruno Reitzner, MBA, MIPH at [jbruno@chestnet.org](mailto:jbruno@chestnet.org).
- The Bronchoscopy Module Executive Committee will review all requests and make a determination as to whether the request will be approved.
- Upon approval of such a request the ACCP will make record of the date to ensure that appropriate steps are taken with regard to data analysis.

**IV. Bronchoscopic Procedures and Interventions Collected***Diagnostic Procedures:*

- BAL- Bronchoalveolar lavage
- Transbronchial Biopsy
- Wash
- Cytology Brushing
- Endobronchial Forceps Biopsy
- Transbronchial Needle Aspiration (TBNA)
- Endobronchial Ultrasound (EBUS)

*Interventional Procedures:*

- Ablative Therapy (Laser, APC, electrocautery, PDT, etc.)
- Dilation

- Stent Placement
- Stent Removal
- Valve Placement
- Valve Removal

## V. AQuIRE Bronchoscopy Module Levels of Participation

Individuals participating in the AQuIRE Bronchoscopy Module have the option to participate at six different levels. Participants may choose a combination of two levels.

- For instance, a participant may choose to participate in Level 3- interventional procedures and Level 6, where only data on select diagnostic procedures are collected and reported.

### Level 1-

#### Full Level - **Without** Interventional Health Status Data Collection

- Physicians must aim to collect and enter data on 100% of their diagnostic and interventional bronchoscopic case volume. The ultimate goal is to enter a complete, unbiased, and scientifically valid cohort of patients.
- All diagnostic and interventional procedures must be collected and entered unless the center does not offer a particular procedure at their facility.

### Level 2-

#### Full Level - **With** Interventional Health Status Data Collection

- Requirements outlined in Level 1
- The participating physician also aims to collect and enter follow-up health status data on 100% of their interventional bronchoscopic case volume. The ultimate goal is to enter a complete, unbiased and scientifically valid cohort of patients.

### Level 3-

#### Interventional Only- **Without** Health Status Data Collection

- Physicians aim to collect and enter data on 100% of their therapeutic bronchoscopic case volume. The ultimate goal is to enter a complete, unbiased and scientifically valid cohort of patients.
- All interventional procedures must be collected and entered unless the center does not offer the procedure at its facility.
- AQuIRE currently collects data on the following interventional procedures:
  - Ablative Therapy (Laser, APC, electrocautery, PDT, etc.)
  - Dilation
  - Stent Placement
  - Stent Removal
  - Valve Placement
  - Valve Removal

### Level 4-

#### Interventional Only - **With** Health Status Data Collection

- Requirements outlined in Level 3
- The participating physician also aims to collect and enter follow-up health status data on 100% of their interventional bronchoscopic case volume. The ultimate goal is to enter a complete, unbiased and scientifically valid cohort of patients.

*Level 5-*

*Diagnostic Only*

- Physicians aim to collect and enter data on 100% of their diagnostic bronchoscopic case volume. The ultimate goal is to enter a complete, unbiased and scientifically valid cohort of patients.
- All diagnostic procedures must be collected and entered unless the center does not offer the procedure at its facility.
- AQUIRE currently collects data on the following diagnostic procedures:
  - BAL- Bronchoalveolar lavage
  - Transbronchial Biopsy
  - Wash
  - Cytology Brushing
  - Endobronchial Forceps Biopsy
  - Transbronchial Needle Aspiration (TBNA)
  - Endobronchial Ultrasound (EBUS)

*Level 6-*

*Diagnostic- Procedure Basis*

- Physicians aim to collect and enter data on 100% of any one of the diagnostic procedural cases featured in the registry.
- The ultimate goal is to enter a complete, unbiased and scientifically valid cohort of patients.
  - For instance, if you perform EBUS at your institution you must enter 100% of your EBUS cases.

**AQIRe Bronchoscopy Module Levels of Participation  
Commitment/Recommitment Form**

**1. Participant Name:** \_\_\_\_\_

**2. Institution:** \_\_\_\_\_

**3. Institution Principal Investigator Name:** \_\_\_\_\_

**4. Commitment/Recommitment period (choose one):**

- Initial Commitment*      Date of initial commitment (m/d/yy): \_\_\_\_\_  
End of 30-day trial (m/d/yy): \_\_\_\_\_
- 30-day Recommitment*      Date (m/d/yy): \_\_\_\_\_
- Annual Recommitment*      Date (m/d/yy): \_\_\_\_\_  
For upcoming year (enter year): \_\_\_\_\_

**5. Level of Commitment (choose all that apply):**

- Level 1- Full Level- **Without** Interventional Health Status Data Collection*
- Level 2- Full Level - **With** Interventional Health Status Data Collection*
- Level 3- Interventional- **Without** Health Status Data Collection*
- Level 4- Interventional Only - **With** Health Status Data Collection*
- Level 5- Diagnostic Only*
- Level 6- Diagnostic- Procedure Basis (select all procedures you will collect and enter data for)*
  - BAL- Bronchoalveolar lavage
  - Transbronchial Biopsy
  - Wash
  - Cytology Brushing
  - Endobronchial Forceps Biopsy
  - Transbronchial Needle Aspiration (TBNA)
  - Endobronchial Ultrasound (EBUS)

**6. Indicate procedures you are able to perform at your facility, regardless of your level of participation:**

*Diagnostic Procedures:*

- BAL- Bronchoalveolar lavage
- Transbronchial Biopsy
- Wash
- Cytology Brushing
- Endobronchial Forceps Biopsy
- Transbronchial Needle Aspiration (TBNA)
- Endobronchial Ultrasound (EBUS)
- I do not perform diagnostic procedures

*Interventional Procedures:*

- Ablative Therapy (Laser, APC, electrocautery, PDT, etc.)
- Dilation
- Stent Placement
- Stent Removal
- Valve Placement
- Valve Removal
- I do not perform interventional procedures

**7. Participant Signature:** \_\_\_\_\_

## **Appendix B**

### **E-5.02 Advertising and Publicity**

There are no restrictions on advertising by physicians except those that can be specifically justified to protect the public from deceptive practices. A physician may publicize him or herself as a physician through any commercial publicity or other form of public communication (including any newspaper, magazine, telephone directory, radio, television, direct mail, or other advertising) provided that the communication shall not be misleading because of the omission of necessary material information, shall not contain any false or misleading statement, or shall not otherwise operate to deceive. Because the public can sometimes be deceived by the use of medical terms or illustrations that are difficult to understand, physicians should design the form of communication to communicate the information contained therein to the public in a readily comprehensible manner. Aggressive, high-pressure advertising and publicity should be avoided if they create unjustified medical expectations or are accompanied by deceptive claims. The key issue, however, is whether advertising or publicity, regardless of format or content, is true and not materially misleading. The communication may include (1) the educational background of the physician, (2) the basis on which fees are determined (including charges for specific services), (3) available credit or other methods of payment, and (4) any other non-deceptive information. Nothing in this opinion is intended to discourage or to limit advertising and representations, which are not false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act. At the same time, however, physicians are advised that certain types of communications have a significant potential for deception and should therefore receive special attention. For example, testimonials of patients as to the physician's skill or the quality of the physician's professional services tend to be deceptive when they do not reflect the results that patients with conditions comparable to the testimoiant's condition generally receive. Objective claims regarding experience, competence, and the quality of physicians and the services they provide may be made only if they are factually supportable. Similarly, generalized statements of satisfaction with a physician's services may be made if they are representative of the experiences of that physician's patients. Because physicians have an ethical obligation to share medical advances, it is unlikely that a physician will have a truly exclusive or unique skill or remedy. Claims that imply such a skill or remedy therefore can be deceptive. Statements that a physician has an exclusive or unique skill or remedy in a particular geographic area, if true, however, are permissible. Similarly, a statement that a physician has cured or successfully treated a large number of cases involving a particular serious ailment is deceptive if it implies a certainty of result and creates unjustified and misleading expectations in prospective patients. Consistent with federal regulatory standards, which apply to commercial advertising, a physician who is considering the placement of an advertisement or publicity release, whether in print, radio, or television, should determine in advance that the communication or message is explicitly and implicitly truthful and not misleading. These standards require the advertiser to have a reasonable basis for claims before they are used in advertising. The reasonable basis must be established by those facts known to the advertiser, and those, which a reasonable, prudent advertiser should have discovered. Inclusion of the physician's name in advertising may help to assure that these guidelines are being met. (II) Issued prior to April 1977; Updated June 1996.