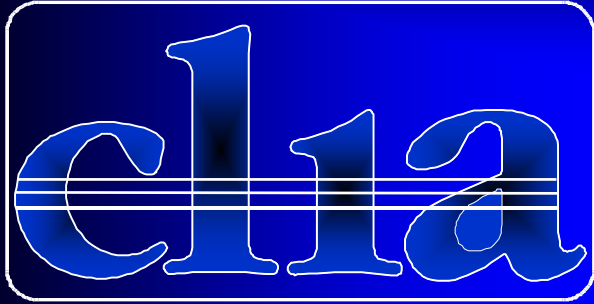


Test Systems Not Currently Regulated Under CLIA

Clinical Laboratory Improvement Advisory Committee
Workgroup Meeting
August 8, 2001

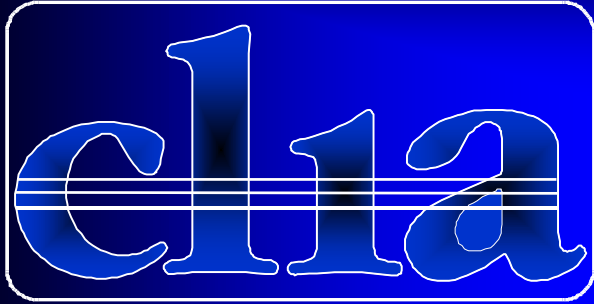
WORKGROUP REPORT



Breath Testing - Criteria

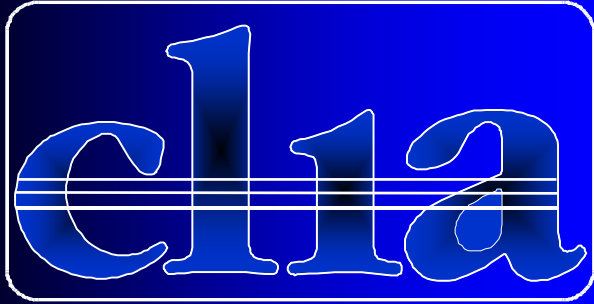
- **What mechanisms/criteria could be used to determine CLIA applicability?**
 - Test site
 - Test purpose
 - How and where test results are used

Note: Problems occur when unintended users perform testing, regardless of test system labeling or instructions



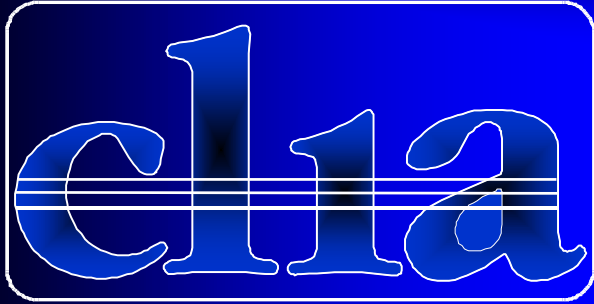
Breath Testing – Criteria

- Inclusion/exclusion criteria are useful, but different criteria may be needed depending on the test and its clinical utility
- For breath tests that detect or measure a specific analyte, consider separate categories (e.g. pulmonary, gastrointestinal)
- Consider the impact of federal regulations, as well as alternate oversight mechanisms



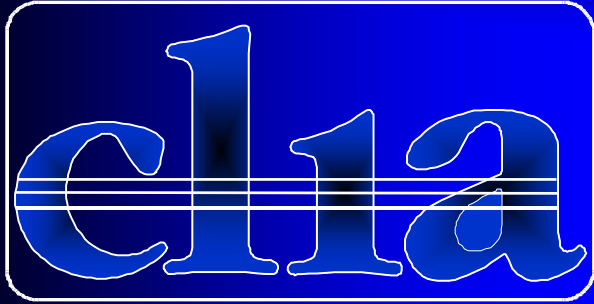
Breath Testing – Guidelines/Voluntary Standards

- Consider federal guidelines in lieu of CLIA regulations
- Consider incorporating existing professional organizations' voluntary standards/guidelines
- Depending on the level of federal regulation desired, current voluntary standards/guidelines may be adequate



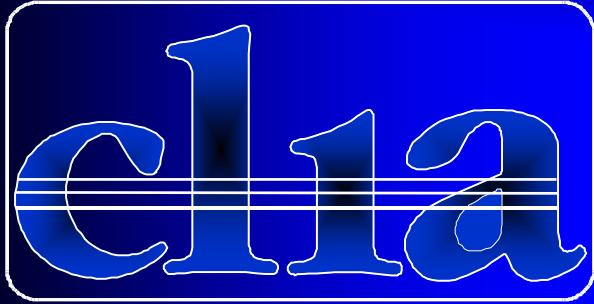
Breath Testing – Professional Organizations

- AAMI, Association for the Advancement of Medical Instrumentation
- AARC, American Association for Respiratory Care
- ASA, American Society of Anesthesiologists
- ASATT, American Society of Anesthesia Technologists and Technicians
- ASCCM, American Society of Critical Care Medicine
- ASTM, American Society for Testing Materials
- ATS, American Thoracic Society
- JCAHO, Joint Commission on Accreditation of Healthcare Organizations
- NCCLS
- NCQA, National Committee for Quality Assurance
- NPSF, National Patient Safety Foundation
- Others?



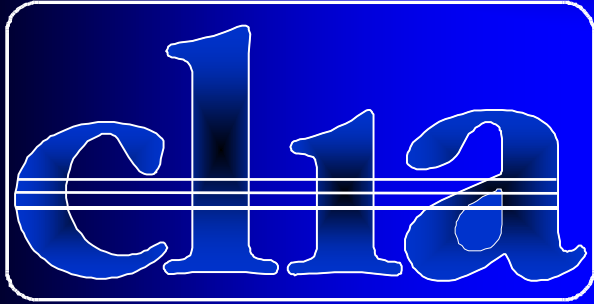
Breath Testing - Standards

- For CLIA testing, consider deemed status where applicable
- Mandating professional organizations' voluntary standards/guidelines through regulation would strengthen the standards and improve quality and testing practices



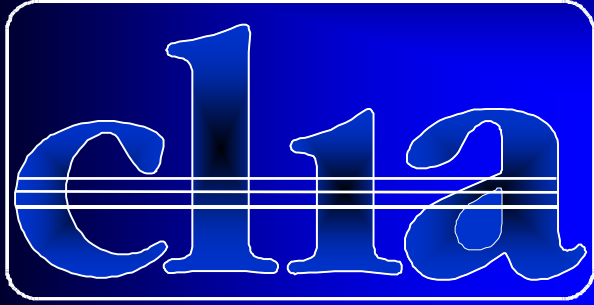
Breath Testing

- Should pulmonary function tests such as spirometry, use of ventilators, or lung volume tests be regulated under CLIA?
 - Spirometry - No
 - Use of ventilators – Need decision
 - Lung volume tests – Need decision



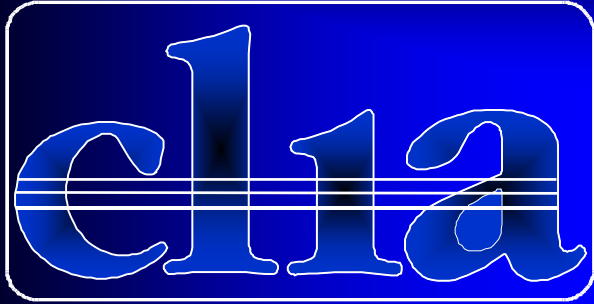
Other Tests Not Currently Regulated - Criteria

- **What mechanisms/criteria could be used to determine CLIA applicability?**
 - Clinical value of test result
 - Clinical accuracy needed for test result
 - Risk (to patient) of inaccurate results
 - Testing methodology
 - Testing site consideration (when not in a traditional lab setting)
 - Pre- and post-analytical test performance requirements
 - Other – obtain input from professional organizations



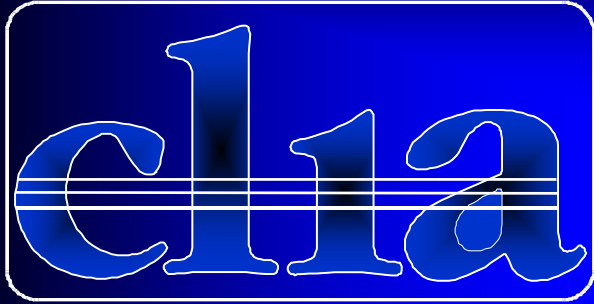
Other Tests - Criteria

- Criteria overlap and none can be used exclusively for decision-making
- Specimen type or manner of specimen collection should not be considerations



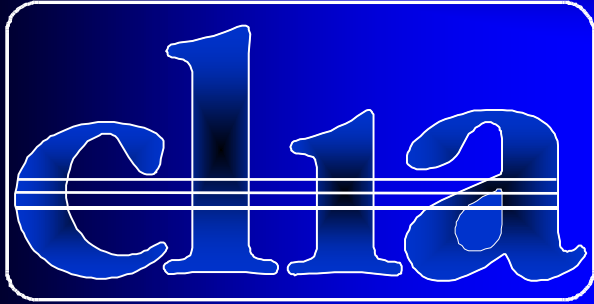
Other Tests - Criteria

- Should test systems using in-dwelling devices for in-vivo testing or involving transcutaneous measurements be regulated under CLIA?
- The degree to which a test is invasive should not be used to determine CLIA applicability
 - Consider instead:
 - Is the test diagnostic?
 - Does it involve a sample?
 - Conceptually is it a lab test?
 - Is CLIA the appropriate oversight mechanism?



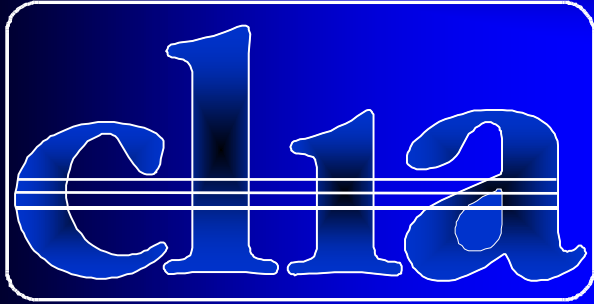
Other Tests - Criteria

- **Are there unique testing contexts for which CLIA regulation is not appropriate?**
 - **CLIA may interfere with patient care in some settings (including ICU, CCU, surgery, cardiovascular and cath. labs, etc.) where physicians and others perform testing or monitoring and provide direct patient care**
 - **Testing context is important, but should not be used exclusively to determine CLIA applicability**
 - **Appropriate education and training of testing personnel is a critical factor**



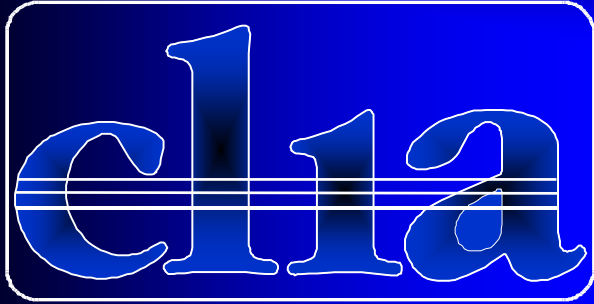
Other Tests - Voluntary Standards

- Are existing voluntary guidelines or standards adequate to ensure the quality of testing, especially in non-traditional testing sites?
 - For some testing, regulations mandating voluntary standards would strengthen the standards and improve quality and testing practices
 - Consider international standards and the International Laboratory Accreditation Cooperation (ILAC) guidelines
 - Support a CLIA recommendation concerning compliance with voluntary standard in lieu of regulations
 - Regulatory agencies need to evaluate the voluntary standards/guidelines for appropriateness



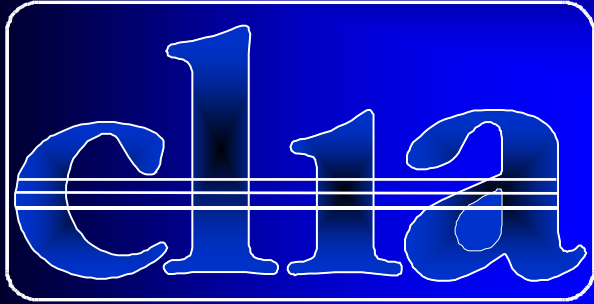
Issues for Further Discussion

- **Have all types of testing available been addressed?**
 - New technologies are constantly evolving, increasing the difficulties of developing appropriate standards
 - Regulations need to be flexible and applicable to testing, present and future
- **Are there tests currently not addressed by voluntary standards?**



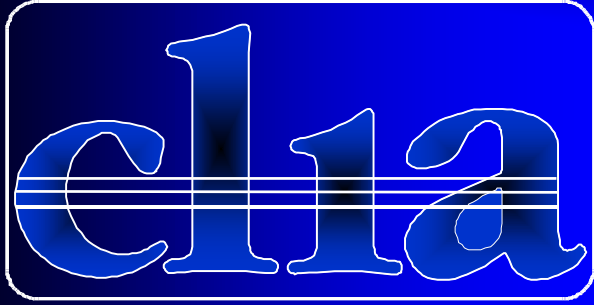
Monitoring Compliance

- **What special considerations would be needed concerning compliance evaluations for currently unregulated testing?**
 - Consider flexibility of the regulations/guidelines, and ability to monitor compliance
 - Improvements and advances in information technology will provide opportunities, alternative mechanisms for monitoring testing quality



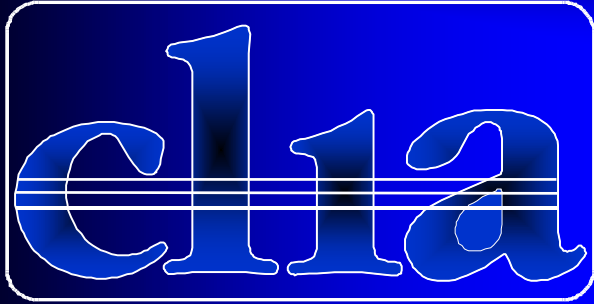
Standards

- If certain tests should be regulated under CLIA, what standards should apply?
 - Standards that emphasize quality systems/processes
 - QC/PT or process assessment (QA)
 - Personnel qualifications, especially education and training of testing personnel
 - Require testing personnel to follow manufacturers' instructions
- An option to provide flexibility under CLIA - create a “new” category (such as Provider- Performed Microscopy - PPM) with unique requirements for personnel qualifications, quality control (QC), proficiency testing (PT), etc.



Other Sources of Information

- JCAHO standards related to patient safety
- Radiological community on testing applications of MRI and other technologies
- Gastroenterology practitioners and nutritionists



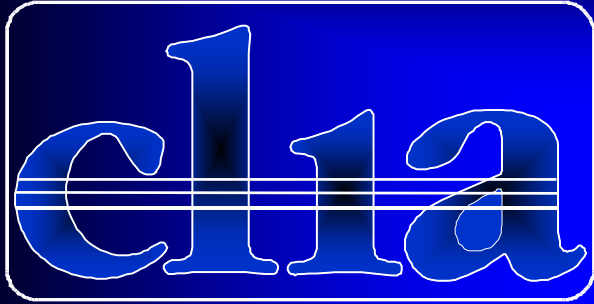
Value of CLIA Oversight

- Improve quality of testing
- Improve patient care, promote safer testing
- Increase standardization of testing, improve standards of practice
- Mandate compliance with voluntary standards/guidelines
- Consider potential impact due to inaccurate results from unregulated tests



Impact of Regulations

- Reimbursement may be affected
- Test result reporting and/or documentation requirements may change
- Possible increase in operating costs and higher costs for test devices resulting from requirements for built-in QC, fail-safe mechanisms, etc.



Alternatives

- Are there more appropriate ways to oversee testing in lieu of CLIA?
 - Strengthen existing voluntary standards/guidelines
 - Encourage professional organizations and manufacturers to develop standards/guidelines for testing