THE CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC)
2024 BIOSAFETY WORKGROUP

MEETING SUMMARY REPORT

Workgroup Charge

The CLIAC Biosafety Workgroup is charged with providing input to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on the potential additions to the CLIA regulations and the need for solutions that will improve the safety of laboratory professionals, their colleagues, and the environment.

Workgroup Agreements

1. The workgroup agreed that a standardized definition of a biosafety risk assessment should be developed and added to 42 CFR 493.2.
2. The workgroup agreed that language in the definition of a biosafety risk assessment should be comprehensive about the risk assessment, including hazard assessment, mitigation, management, and performance monitoring.
3. The workgroup agreed that laboratories should be required to perform a risk assessment on all instrumentation currently in use. Before implementation, laboratories should consider biosafety risks when purchasing new equipment and must complete a risk assessment (analogous to analytic verification).
4. The workgroup agreed that 42 CFR 493.1804(a)(2) should be expanded to clarify that laboratory workers and, in turn, the general population should be safeguarded.
5. The workgroup agreed that a Food and Drug Administration (FDA) requirement(s) on biosafety risk assessment for device approval would support clinical laboratory biosafety and the health of the public.
6. The workgroup agreed that it is the laboratory's responsibility to obtain the written equipment disinfection instructions and practices, preferably before purchase. Additionally, end users should incorporate the manufacturer’s detailed instructions and practices into their biosafety risk assessments and routine practices.
7. The workgroup agreed that CLIA requirements should be revised to include biosafety training as part of testing personnel competency requirements.
8. The workgroup agreed that there is a need for annual biosafety competency assessments.
9. The workgroup agreed that there is value in increased collaboration between equipment manufacturers, clinical and public health laboratories, and regulatory agencies to improve knowledge of instrument risks and hazards and effective mitigation and decontamination practices. Additional research is needed to determine the best path forward.

Workgroup Meeting #1 Summary - February 12, 2024

In vitro diagnostic product (IVD) instrument design plays a key role in mitigating biosafety issues that arise during routine use and maintenance schedules. How can interested parties better address biosafety for already established IVD instruments and IVD instruments currently under development?

a. What mechanisms/best practices do manufacturers currently use to assess biosafety considerations for established IVD instruments and IVD instruments currently under development?
   i. Are there current mechanisms where end users can discuss/highlight biosafety issues with established IVD instruments within the end-user community and/or with the manufacturer? If so, what are they? How can manufacturers be included if they are currently not included?
   ii. Are there mechanisms currently in place or that can be developed that would facilitate collaboration between manufacturers and a variety of clinical laboratory representatives during the use and maintenance of existing IVD instrumentation to incorporate or improve biosafety features?

b. When developing new IVD instrumentation, what considerations are typically given to biosafety with respect to instrument design (e.g., the robustness of instrument parts/materials to routine decontamination/sterilization procedures, use of disposable parts in areas of the instrumentation that are more at risk of contamination)?

c. c. Are there mechanisms currently in place or that can be developed to facilitate collaboration between manufacturers and a variety of clinical laboratory representatives during the design stage for new IVD instrumentation under development to incorporate or improve biosafety features?

Workgroup Discussion and Comments

- A consensus was reached that laboratories should have a requirement to perform a risk assessment on all instrumentation currently in use and also before purchasing new equipment.
  - There is not currently a framework to conduct a risk assessment, but an ideal framework would address safety across the entire pre-analytic, analytic, and post-analytic aspects of the test system.
  - The risk assessment will need to include instructions for using the equipment under normal conditions and during extended periods of time, such as surge testing periods, and should include guidance for decontamination and disinfection.
  - Guidelines and training on how to conduct a biological risk assessment should be developed.
- Laboratory equipment manufacturers do have protocols for disinfection and/or decontamination, but they are mainly from the standpoint of the instrument itself to avoid or prevent cross-contamination for the specific agent they are detecting.
- It was emphasized that often, these instructions are unclear and hard to locate and are focused on the patient versus the operator.
  - Decontamination guidance should be provided for an instrument and must address the actual design, aerosol prevention, cross-contamination, and exposure to risks and hazards.
    - This should be viewed as a shared responsibility, one on the design side and one on the assessment side.
    - The conversations with the manufacturer should be in the early phase about what type of materials they can use that would withstand several different types of decontamination materials or how it would undergo sterilization.

        - Robust model systems and appropriate assays should be created to generate biologically meaningful decontamination data that can be extrapolated to an emerging pathogen situation.
        - Instrument cleaning and decontamination guidance should be standardized and easily identified in the instruction manual provided to the end user.
        - A centralized location, repository, or website that manufacturers can use to post such guidance would be useful.
    - It was agreed that the responsibility for the risk assessment is shared between the manufacturer and the laboratory, but it was noted that the laboratory needs information from the manufacturer to identify the critical parts of the instrument and specifically what to use for decontamination.

Laboratories receive and handle specimens that contain unknown pathogens routinely. How can interested parties ensure proper biosafety activities for end users are established, effectively provided/communicated, and followed?

a. Are there widely available training materials for laboratory professionals that focus on instrument operation and cleaning and disinfection practices?
    i. Do currently available biosafety training materials include sufficient information regarding instrument disinfection? If not, what minimum information should be included in these trainings?
b. Are there mechanisms in place or that can be developed by laboratories that would ensure annual biosafety training and/or competency assessment of laboratory staff?

Workgroup Discussion and Comments

- A consensus was reached that there is inadequate biosafety training related to instrument operation and decontamination.
    - Training should be developed to include service engineers, application specialists, trainers, and others who are not necessarily medical technology trained.
    - The laboratory director is responsible for ensuring that individuals entering the laboratory are trained in disinfection and decontamination cleaning procedures, especially maintenance procedures.
- Partnerships with manufacturers are essential in developing training for new instrumentation.
- Training should be provided for the entire laboratory process with people from different perspectives, i.e., surgical pathology, core facility, and hematology.
    - Ideally, the training will include case studies and provide the learner with a more basic understanding of where the dangers are coming from, how to identify those hazards, and how to start mitigation.
- It was acknowledged that no standardized mechanisms are in place to assess biosafety competency adequately, and they should be developed.

Workgroup Meeting #2 Summary - June 28, 2024

What additions to the CLIA regulations could be made to ensure that laboratories are required to have policies and procedures addressing laboratory biosafety?

a. Currently, the Facilities standard at §493.1101(d) indicates that "Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials." Should the CLIA regulations be updated to

include additional safety standards as related to facilities that could include, but not be limited to, the items listed below?

i. Proper workspace ventilation to safely handle contaminated specimens or pathogenic organisms at the appropriate biosafety level.
ii. Proper decontamination processes in place to help minimize contamination for the environment and instrumentation.
iii. Appropriate biosafety equipment and personal protective equipment are available in accordance with the appropriate biosafety level.
iv. Requirement to report results of highly infectious organisms, potential agents of bioterrorism, and unusual multi-drug resistant organisms to State Public Health laboratories or CDC as required by Federal, State, or local government authority.

b. Currently, the General Considerations Standard at §493.1804(a)(2) indicates that "To safeguard the general public against health and safety hazards that might result from laboratory activities." Should the CLIA regulations be updated to include additional safety standards related to General considerations?

Workgroup Discussion and Comments

- The workgroup discussed updating the CLIA regulations to include additional safety standards related to the facility.
- The workgroup acknowledged that revising CLIA guidelines might have cost implications for the laboratory and should be based on the risk assessment process to address the site-specific needs of each laboratory category.
- It was noted that a standardized definition of a 'risk assessment' is currently lacking and should be developed and added to 42 CFR 493.2.
- The workgroup reviewed 42 CFR 493.1101 and recommended clarifying that the risk assessment process should guide the establishment of safety procedures.
- An agreement among all that in an ideal scenario, a risk assessment should be performed in the laboratory and emphasized that the manufacturer, as part of the development process, should perform a risk assessment in anticipation of the end-user application in a typical hospital/clinical laboratory.
- The workgroup discussed the potential for incorporating a risk assessment requirement into the CLIA regulations at 42 CFR 493.1253 [Standard: Establishment and verification of performance specifications].
- It was agreed that the manufacturer should refine and provide the scope of decontamination of laboratory equipment through the risk assessment process and provide this information to the end user.
- The FDA agrees that it is a manufacturer's issue to provide decontamination instructions to the end user and is working with the CDC on ways the manufacturer can advise the end user on adequate decontamination procedures, including what chemicals can be used and a clear definition of responsibility.
- The workgroup agreed that PPE should be identified during the risk mitigation component of the risk assessment process, and training should be provided to staff on the correct use of PPE, and this correct use of safety PPE should be part of the competency assessment.
- An agreement was reached that reporting requirements for the identification of certain pathogens should be kept general but noted that better synthesis and coordination are needed from the agencies on reporting requirements.
- The workgroup agreed that 42 CFR 493.1804(a)(2) should be expanded to clarify that the laboratory worker should be safeguarded as well as the general population.

Clear instructions and communication are key to addressing biosafety. Therefore,

a. How can manufacturers and clinical laboratories work together to provide clear, readily available biosafety instructions for each phase of testing, cleaning and disinfection practices, and maintenance of the instrument?
b. What resources are available for manufacturers to gain biosafety-related input to develop appropriate instructions (e.g., Environmental Protection Agency lists, Occupational Safety and Health Administration regulations)?
c. How can manufacturers gain input from biosafety professionals to aid in the development of supplemental biosafety testing instructions for end users and service representatives?
d. How can non-regulatory organizations (e.g., the Clinical and Laboratory Standards Institute, the International Organization for Standardization), professional societies (e.g., The American Biological Safety Association, The American Society for Microbiology), and other interested parties assist in facilitating the process for manufacturers and laboratories?

Workgroup Discussion and Comments

- The workgroup agreed that manufacturers should work with the end-user during the design stage and before regulatory approval to address possible biosafety implications. However, it was noted that the end user is not currently involved in the design phase.
- The workgroup suggested that the FDA should explore adding a requirement that the manufacturer provide biosafety guidance as part of product review and clearance.
- A common theme was the notion that a space should be created to serve as a centralized repository for biosafety information that both the manufacturers and end-users can access.
- The workgroup discussed updating CLIA requirements to include biosafety training as part of testing personnel competency requirements. It requested the development of an implementation guide.
- The workgroup emphasized the importance of hiring competent biosafety professionals with laboratory experience to work with manufacturers during the design process but noted it was beyond the scope of the workgroup.
- It was suggested that an organizational approach between the interested parties would be more appropriate for developing these resources.

Workgroup Meeting #3 Summary - August 23, 2024

Workgroup Discussion and Comments

- The workgroup discussed updating the CLIA regulations to include additional safety standards related to the facility.
- It was agreed that risk assessments are needed.
  - The group discussed linking the risk assessment into the test verification and validation process, although it might be redundant.
  - Risk assessment should occur on each test system, including those without instrumentation, for each testing stage.
- Risk assessment vs risk management was discussed, and it was noted that there is a lack of comprehensive understanding.
- Defining the range of risk assessment was emphasized. It was agreed that language should be comprehensive about the risk assessment, including hazard assessment, mitigation, and performance monitoring.
  - The need for resources and references was discussed, and it was agreed that these should be included in the summary report to provide background.

        - These will be included in the summary report as an Appendix.
        - All workgroup members were encouraged to provide resources that would benefit the group and give context to CLIAC.
- The workgroup again agreed that 42 CFR 493.1804(a)(2) should be expanded to clarify that laboratory workers and the general population should be safeguarded.
- It was reaffirmed that the FDA review does not include biosafety aspects but is more in the context of the potential for cross-contamination or cross-carriage of the samples themselves to determine if there's a potential for false positive or negative results.
- A consensus was reached that the equipment manufacturer's instructions must include disinfection practices.
- It was noted that test categorization, including if there's a public health emergency in the EUA process, is within the scope of the CLIA program and the CLIA regulations; however, medical device approval is within another regulatory statement law, the Federal Drug and Cosmetic Act.
- Increased collaboration between equipment manufacturers and clinical and public health laboratories was strongly encouraged.

Workgroup Meeting #4 Summary - September 13, 2024

Workgroup Discussion and Comments

- The summary from the previous meeting was reviewed, and items below were clarified:
    - It was clarified and reinforced that the manufacturer's instructions for use must be sufficient for users and manufacturers' service personnel to accomplish disinfection and provide sufficient detail to allow incorporation into the laboratory's site-specific risk assessment.
    - Collaboration between the manufacturers and equipment users was again stressed and recommended.
    - It was clarified that the assessment of biosafety competencies should be performed annually.
- The workgroup reviewed and refined the current list of workgroup agreements in preparation for the November 6-7, 2024, workgroup report and CLIAC discussion.

References Provided by Workgroup Members

Citation:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020)- Appendix N. Washington, DC: Government Printing Office.
- Delany, J. R., M. A. Pentella, J. A. Rodriguez, K. V. Shah, K. P. Baxley, D. E. Holmes, C. Centers for Disease and Prevention (2011). "Guidelines for biosafety laboratory competency: CDC and the Association of Public Health Laboratories." MMWR Suppl **60**(2): 1-23.
- Ned-Sykes, R., C. Johnson, J. C. Ridderhof, E. Perlman, A. Pollock, J. M. DeBoy, C. Centers for Disease and Prevention (2015). "Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories." MMWR Suppl **64**(1): 1-81.
- Herstein, J. J., S. A. Buehler, A. B. Le, J. J. Lowe, P. C. Iwen and S. G. Gibbs (2019). "Clinical Laboratory Equipment Manufacturer Policies on Highly Hazardous Communicable Diseases." Public Health Rep **134**(4): 332-337.
- Le, A. B., C. E. Figi, J. J. Herstein, P. C. Iwen, S. A. Buehler, J. J. Lowe and S. G. Gibbs (2024). "Clinical laboratory equipment manufacturers' lack of guidance for high consequence pathogen response is a critical weakness." Infect Control Hosp Epidemiol: 1-3.

ISO: International Organization for Standardization

- ISO 9001:2015, Quality management systems — Requirements
- ISO 15189:2012, Medical laboratories — Requirements for quality and competence
- ISO 15190:2003, Medical laboratories — Requirements for safety
- ISO 45001:2018, Occupational health and safety management systems — Requirements with guidance for use
- ISO Guide 73:2009, Risk management — Vocabulary
- ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- ISO 31000:2018, Risk Management – Guidelines

WHO: World Health Organization

- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition, and associated monographs).
- Decontamination and waste management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition, and associated monographs).
- Risk assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition, and associated monographs).

Other

- CEN Workshop Agreement 15793:2011, Laboratory biorisk management
- CEN Workshop Agreement 16393:2012, Laboratory biorisk management — Guidelines for the implementation of CWA 15793:2008
- APHL Laboratory Biosafety Competency Assessment Form https://www.aphl.org/programs/preparedness/Documents/APHL%20Approved%20Conversation-Based%20Biosafety%20Competency%20Assessment%20Form.pdf
- ABSA OSHA Alliance, Biological Safety Professional Competency Fact Sheet: https://absa.org/wp-content/uploads/2018/05/OSHABSOcompetencyFactSheet.pdf
- Sandia National Laboratories: *Core Biorisk Management Document Templates,* https://gcbs.sandia.gov/core-documents/
- The Canadian Biosafety Guideline – Local Risk Assessment: https://www.canada.ca/en/public-health/services/canadian-biosafetystandards-guidelines/guidance.html

Appendix A

CLIAC Biosafety Workgroup
Charge, Topics, and Discussion Questions
Workgroup Terms of Engagement

BACKGROUND

From a historical perspective, laboratory biosafety was initially designed to address the dangers of working with dangerous pathogens in research laboratories. For years, laboratory biosafety efforts were almost exclusively focused on research facilities. Recently, there's been a broader recognition that clinical laboratories may encounter dangerous pathogens, which can be present in patient specimens without the laboratory staff's knowledge. A laboratory accident or laboratory-acquired infection could affect the laboratory staff, others around them, and their environment, and fears about inadequate biosafety can paralyze a clinical laboratory and jeopardize patient care. The underlying weakness of clinical laboratory biosafety in the United States became clear when Ebola spread from West Africa to the United States in 2014. Soon after the first Ebola patient appeared in the United States, many of the largest commercial laboratory companies, all well-versed in handling specimens that contain dangerous pathogens, publicly announced they would not accept blood or tissue samples from suspect Ebola patients. Many laboratory instrument manufacturers followed suit. Some indicated that their warranties called for the incineration of their equipment after use with samples from suspect Ebola patients. Others explained that their technicians would not service equipment from isolation wards used for suspected Ebola patients. In 2014, CAP surveyed 28 health systems and more than 350 hospitals during the Ebola crisis. Only four of 17 respondents indicated they would allow suspected or confirmed Ebola virus disease specimens into their laboratories. Of those four, one would restrict testing to a BSL-3 laboratory and strongly discourage sending clinical specimens to the laboratory for testing. This almost complete shutdown of clinical laboratory testing in the US for suspected Ebola patients had significant consequences. Between July and November 2014, local health departments and healthcare providers acknowledged that complete blood counts, liver function tests, and serum chemistries were regularly deferred until a negative Ebola virus test result was obtained. Individuals who had recently traveled to or from Africa with fever and malaise symptoms were routinely refused malaria testing until Ebola had been ruled out. As a result, most malaria patients did not receive the proper and timely intravenous antiviral treatment. According to one Centers for Disease Control and Prevention (CDC) study, at least two persons who tested negative for Ebola died from other causes because of severely delayed diagnoses and treatment. The gaps discovered during the Ebola outbreak are documented in *Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future*, which discusses critical gaps in clinical laboratory biosafety, including issues related to the use and disinfection of laboratory instruments.

Over the last 20 years, infectious disease outbreaks, epidemics, and pandemics have occurred, putting clinical laboratories at the forefront of laboratory testing and diagnosis. The clinical specimens required for testing could have contained infectious agents that could cause disease in laboratory professionals if the exposure occurred during testing. During the Ebola outbreak of 2014, real and perceived concerns about instrument safety emerged and led laboratories to delay their testing – or refuse to test altogether.

Now, mainly because of the COVID-19 pandemic, our understanding of "clinical laboratories" has evolved to include testing in nursing homes, schools, shelters, correctional facilities, and parking lots. All of these settings could present biosafety risks to personnel. Therefore, we must broaden our application of biosafety, including guidance and training, to address all clinical testing locations.

In 2016, the Clinical Laboratory Improvement Advisory Committee (CLIAC), a federal advisory committee, issued the following recommendation:

CLIAC considers the matter of biosafety in clinical laboratories as an urgent, unmet national need. We, therefore, recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that:

- *Includes stakeholders from all areas of clinical laboratories (including professional societies), the diagnostic instrumentation industry, other relevant federal agencies, and patient/clinician representatives.*
- *Recommends areas requiring further research in clinical laboratory safety.*
- *Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and emerging infectious diseases.*
- *Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and solicit input from the clinical laboratory and broader medical communities.*
- *Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety.*
- *Develops a framework for implementing good clinical practices that also address transparent evaluation and monitoring of biosafety practices.*

On June 24, 2022, CDC's Division of Laboratory Systems hosted the CDC Town Hall Meeting on Laboratory Biosafety – Use of Laboratory Instruments in collaboration with clinical and public health laboratory partners and instrument manufacturers. The purpose of this meeting was to provide an overview and discussion on laboratory biosafety when using laboratory instruments to test human and biological specimens. As a result of the town hall discussions, the CLIA program agencies, CDC, the Food and Drug Administration (FDA), and the Centers for Medicare & Medicaid Services (CMS) agreed to the formation of a new CLIAC workgroup to bring together the diagnostic instrument manufacturers, clinical and public health laboratory professionals, federal partners, and industrial hygienists to continue the discussions on biosafety issues with laboratory instrumentation revealed during the recent outbreaks and the pandemic.

CHARGE

The CLIAC Biosafety Workgroup is charged with providing input to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on the potential additions to the CLIA regulations and the need for solutions that will improve the safety of laboratory professionals, their colleagues, and the environment.

DELIVERABLE

The output of the workgroup will be a summary report or periodic reports to CLIAC based on information gathered during meetings and discussions. The report will specifically address the priority topic areas and related questions. The workgroup Chair will present the reports at future CLIAC meetings for Committee deliberation and potential recommendations to HHS. The report may result in

CLIAC developing practical recommendations for potential solutions to address issues or gaps in laboratory instrumentation biosafety that may help improve outbreak and pandemic preparedness. The report may also result in CLIAC recommendations for HHS to consider for future rulemaking to update the CLIA regulations to ensure that laboratories are required to have policies and procedures addressing laboratory biosafety.

DISCUSSION QUESTIONS/THEMES

1) In vitro diagnostic product (IVD) instrument design plays a key role in mitigating biosafety issues that arise during routine use and maintenance schedules. How can interested parties better address biosafety for already established IVD instruments and IVD instruments currently under development?

a. What mechanisms/best practices do manufacturers currently use to assess biosafety considerations for established IVD instruments and IVD instruments currently under development?

i. Are there current mechanisms where end users can discuss/highlight biosafety issues with established IVD instruments within the end-user community and/or with the manufacturer? If so, what are they? How can manufacturers be included if they are currently not included?

ii. Are there mechanisms currently in place or that can be developed that would facilitate collaboration between manufacturers and a variety of clinical laboratory representatives during the use and maintenance of existing IVD instrumentation to incorporate or improve biosafety features?

b. When developing new IVD instrumentation, what considerations are typically given to biosafety with respect to instrument design (e.g., the robustness of instrument parts/materials to routine decontamination/sterilization procedures, use of disposable parts in areas of the instrumentation that are more at risk of contamination)?

c. Are there mechanisms currently in place or that can be developed that would facilitate collaboration between manufacturers and a variety of clinical laboratory representatives during the design stage for new IVD instrumentation under development to incorporate or improve biosafety features?

2) Laboratories receive and handle specimens that contain unknown pathogens on a routine basis. How can interested parties ensure proper biosafety activities for end users are established, effectively provided/communicated, and followed?

a. Are there widely available training materials for laboratory professionals that focus on instrument operation and cleaning and disinfection practices?

i. Do currently available biosafety training materials include sufficient information regarding instrument disinfection? If not, what minimum information should be included in these trainings?

b. Are there mechanisms in place or that can be developed by laboratories that would ensure annual biosafety training and/or competency assessment of laboratory staff?

3) What additions to the CLIA regulations could be made to ensure that laboratories are required to have policies and procedures addressing laboratory biosafety?

a. Currently, the Facilities standard at § 493.1101(d) indicates that “Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.” Should the CLIA regulations be updated to include additional safety standards as related to facilities that could include, but not be limited to, the items listed below?

- Proper workspace ventilation to safely handle contaminated specimens or pathogenic organisms at the appropriate biosafety level.
- Proper decontamination processes in place to help minimize contamination.
- Appropriate biosafety equipment and personal protective equipment available in accordance with the appropriate biosafety level.
- Requirement to report results of highly infectious organisms, potential agents of bioterrorism, and unusual multi-drug resistant organisms to State Public Health laboratories or CDC as required by Federal, State, or local government authority.

b. Currently, the General Considerations Standard at § 493.1804(a)(2) indicates that "To safeguard the general public against health and safety hazards that might result from laboratory activities." Should the CLIA regulations be updated to include additional safety standards related to General considerations?

4) Clear instructions and communication are key to addressing biosafety. Therefore,

a. How can manufacturers and clinical laboratories work together to provide clear, readily available biosafety instructions for each phase of testing, cleaning and disinfection practices, and maintenance of the instrument?

b. What resources are available for manufacturers to gain biosafety-related input to develop appropriate instructions (e.g., Environmental Protection Agency lists, Occupational Safety and Health Administration regulations)?

c. How can manufacturers gain input from biosafety professionals to aid the development of supplemental biosafety testing instructions for end users and service representatives?

d. How can non-regulatory organizations (e.g., the Clinical and Laboratory Standards Institute, the International Organization for Standardization), professional societies (e.g., The American Biological Safety Association, The American Society for Microbiology), and other interested parties assist in facilitating the process for manufacturers and laboratories?

Appendix B

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC)
BIOSAFETY WORKGROUP ROSTER

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