Designing Instruments with Safety in Mind

CDC Town Hall Meeting on Laboratory Biosafety—Use of Laboratory Instruments

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Disclosures

- Employee of Bio-Rad Laboratories
- Industry Liaison to CLIAC
  - On behalf of AdvaMedDx
- Compilation of points and suggestions by members of Diagnostics Task Force, AdvaMedDx working group of IVD manufacturer regulatory experts

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About AdvaMedDx

- AdvaMedDx – a Division of the Advanced Medical Technology Association (AdvaMed)
  - www.advamed.org/advameddx/
- Represents over 75 manufacturers of IVDs in the U.S. and abroad, including multiple instrument manufacturers
  - Promotes innovation and expanded access to quality testing

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About AdvaMedDx, continued

- Involved in areas including:
  - Coding, Coverage, and Payment
  - Collaboration with regulatory bodies to understand and clarify regulations
  - Promotion & communication of the value of IVDs
  - COVID-19 Response
  - Supply Chai

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Goal Today

- Present a snapshot of how instrument manufacturers incorporate biosafety when designing an instrument and when modifying biosafety protocols to address emerging pathogenic threats.

- Not intended to be comprehensive

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Regulations & Standards Governing Biohazards and Instrument Design

- Instrument manufacturers follow well-established regulations and harmonized international consensus standards to protect users from reasonably foreseeable biohazards during normal use.

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Relevant International Standards

- ISO 14971 Medical devices—Application of Risk Management to Medical Devices
  - Processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment, and the environment. For example,
    - C.2.27: Information for safe use to be provided to the end user;
    - D. 5.1: Risk control options analysis including protective measures for the operators;
    - H2.1.1: Risk analysis performed on intended users: (i) operator, (ii) healthcare providers, and (iii) patients.
- ISO 62366 Medical Devices—Application of usability engineering to medical devices

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Applicable FDA Regulations and Guidance

- FDA Requirement of Design Controls per 21 CFR Sec. 820.30
- FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
  - "Eliminating or reducing design-related problems that contribute to or cause unsafe or ineffective use is part of the overall risk management process" (p. 4)
  - Includes "biological hazards (e.g., allergens, bio-incompatible agents and infectious agents)" as one of the hazards traditionally considered in risk analysis and management (p. 5)

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Applicable European Requirements

- IVDD
  - Annex I, B.8.7(s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature. *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331 of 7 December 1998.*
- IVDR
  - Annex I, Chapter II. 9 Infection and Microbial contamination; 19. Protection against the risks posed by devices intended for self-testing or nearing patient testing. *European Parliament. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision.*

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Regulations and Standards Protecting against Biohazards as part of lab operations

- In addition to regulations, standards and guidance discussed above involving biosafety and instrument design, regulations and standards regarding laboratory operations further protect users from biohazards.
  - CLIA
  - OSHA
  - Clinical & Laboratory Standards Institute (CLSI) M29-A3: Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline – Third Edition

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Biosafety in Instrument Design in Practice

- In practice, biosafety design considerations are incorporated into
  - Workflow
    - Materials and components selected
    - Decontaminants recommended
  - Use environment
    - CLIA complexity
    - Professional vs. Layperson
    - POC vs. Clinical Laboratory
  - Usability
    - User Interface
    - Prevention of foreseeable misuses
    - Avoidance of cuts and punctures

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Biosafety in Instrument Design in Practice, continued

- In practice, biosafety design considerations are also incorporated into
  - Labeling
  - Instructions for routine maintenance, cleaning, and disinfection
  - Warnings and Precautions (ISO symbols are used)
  - Training

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Challenges when designing for decontamination, generally

- Wide variety of decontaminants
- Some decontaminants are harmful to parts of the instrument, like tubing
- Some decontaminants should not be used with certain transport media, e.g., bleach
- May vary depending on where intended to be used
- Manufacturer will validate the decontamination

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Challenges of Designing for Decontamination in Emerging Crisis

- Challenge of designing for unknown pathogens
- Must understand pathogen and what renders it safe
- Must be able to test various processes with pathogen
- Manufacturer has to validate contamination procedure before informing instrument users

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The News is more than the Headlines

- The USA Today story: Latest Ebola fear: Safety of lab equipment
- Para 2: Mfrs reportedly refuse technical service & one reportedly said to destroy the POCT instrument after use
- Para 19: Company CEO said the recommendation to destroy the instrument was the "dumbest thing" and replaced it with a validated decontamination procedure
- Para 23: Manufacturers policies will evolve as fear and misinformation subsides
- Still later, some labs limited to testing to patients who were certified Ebola-free *for staff and patient safety*

Similarities to early AIDS epidemic and to some extent Coronavirus pandemic

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Closing thoughts

- Numerous regulations, standards and guidelines provide a robust framework for biosafety protection
- Novel outbreaks may be subject of fear and misinformation
- Instrument manufacturers are required to validate decontamination procedures before dissemination
- Manufacturers’ scientists are hard at work to understand new pathogens and how to keep lab professionals safe
- Protecting IVD instrument operators from biohazard is a shared responsibility among IVD manufacturers, public health authorities, and laboratory communities.

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We welcome this forum …

…and hope to achieve a greater understanding of the challenges of novel outbreaks and how to increase collaboration and face those challenges as partners.

We continually ask ourselves

- What safety measures can be done before the pathogen is well characterized?
- What safety measures can be added while manufacturers are validating decontamination procedures?
- What mechanisms should be employed to disseminate that information?

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