Update from NBIC Part 2 Committee

Working Group on Quick Acting Closures 21-25

Vincent Scarcella, CNA Risk Control Director

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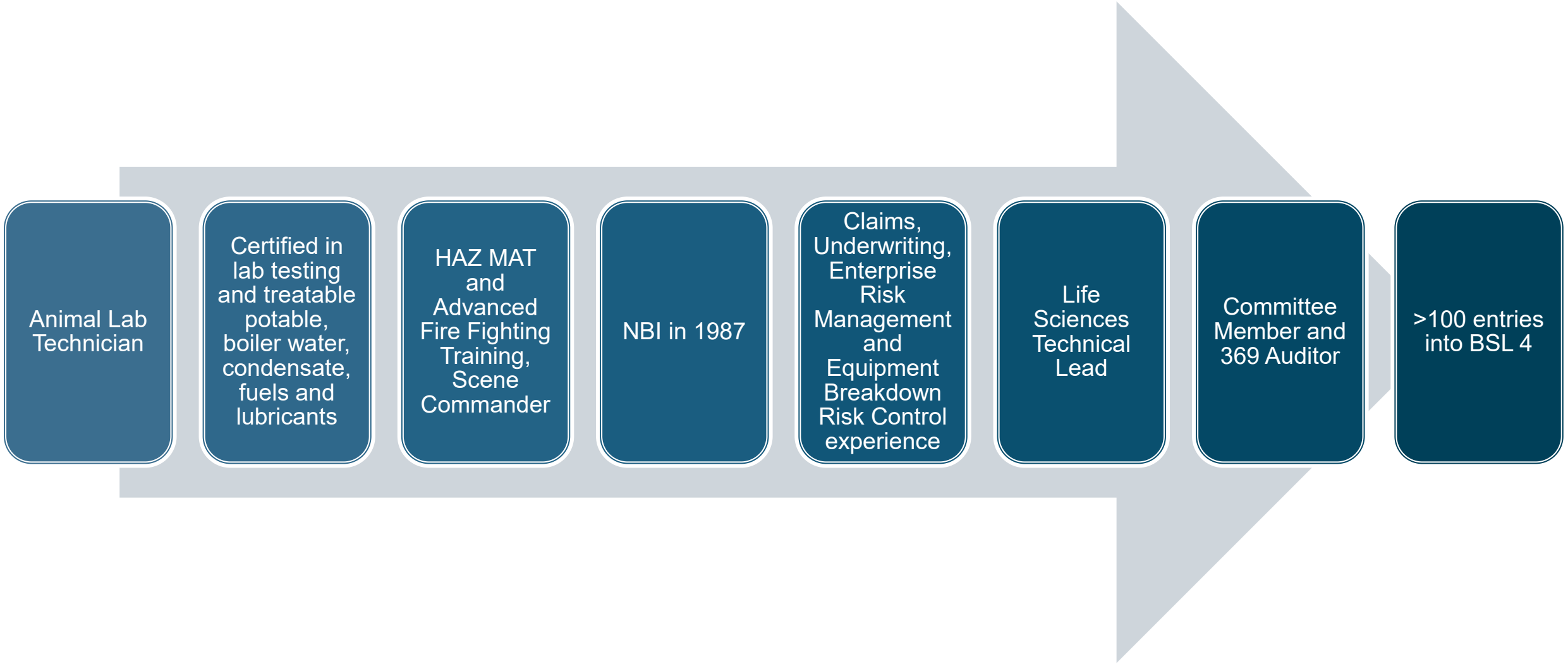
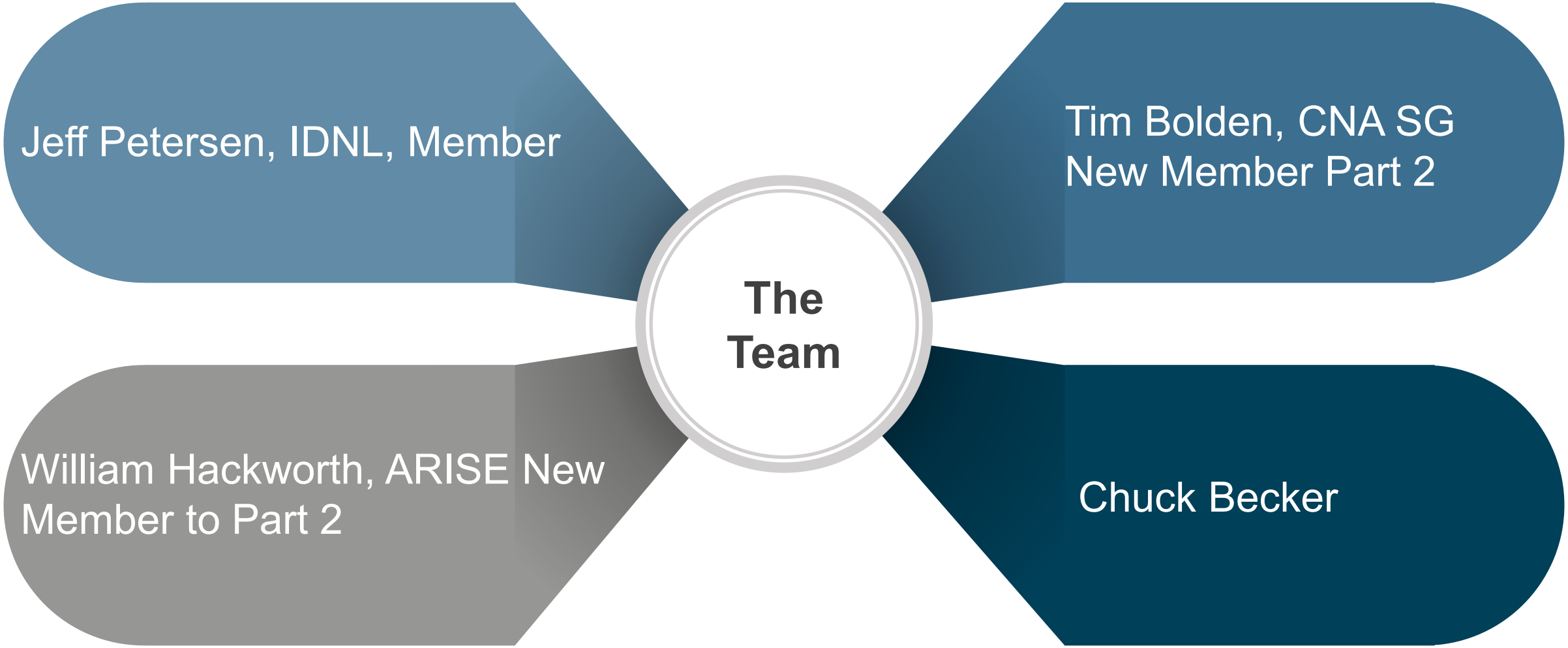
Legal Disclaimer

Biography


Animal Lab Technician
Certified in lab testing and treatable potable, boiler water, condensate, fuels and lubricants
HAZ MAT and Advanced Fire Fighting Training, Scene Commander
NBI in 1987
Claims, Underwriting, Enterprise Risk Management and Equipment Breakdown Risk Control experience
Life Sciences Technical Lead
Committee Member and 369 Auditor
>100 entries into BSL 4

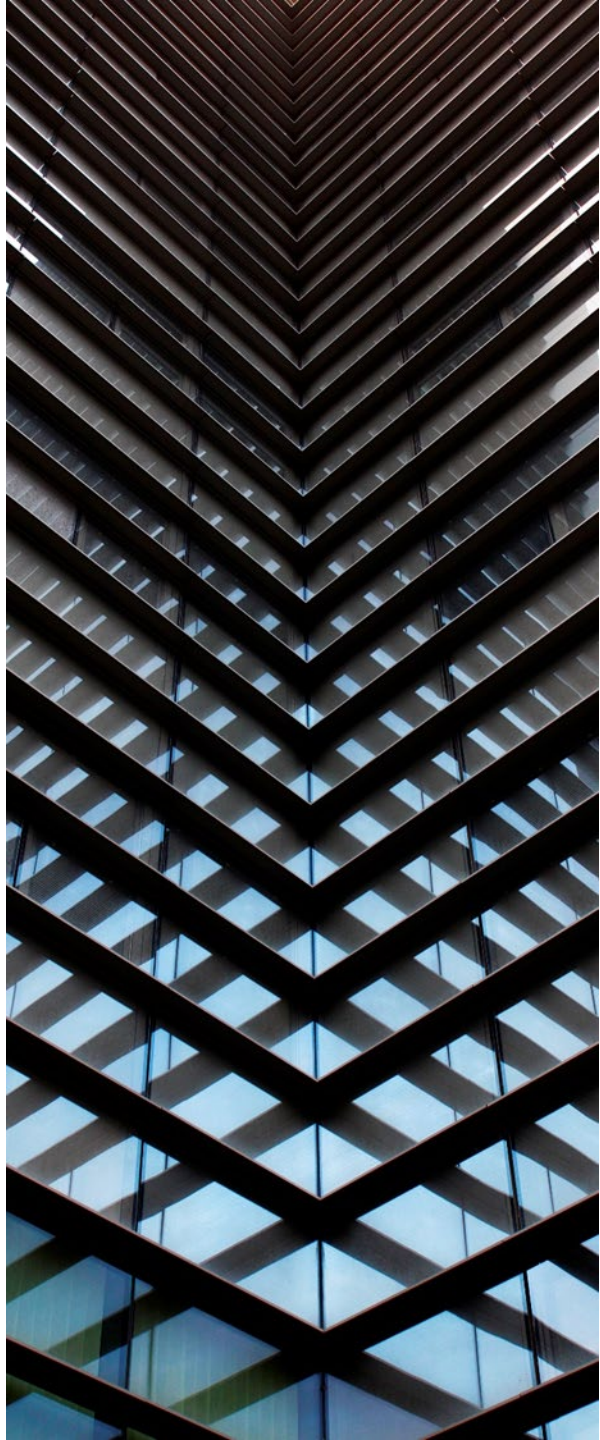
Working Group 21-25-Quick Acting Closures



Working Group 21-25-Quick Acting Closures

Scope of Work

- Autoclaves
- Sterilizers
- Retorts
- Vulcanizers
- Pressure Vessels for Human Occupancy
- Bio Reactor
- Isostatic Press



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Meeting minutes available from the National Board Secretary on request

The Nature of QAC

Failures of quick acting closures can cause collateral damage, in some cases quite extensive, due to the nature of the construction.*

Joint efficiencies in ASME welded pressure vessels are 90% or higher. With quick acting closures, the E can vary with the amount of force on the locking components. By nature of design, QAC are not permanent joints.

The application of repetitive force on the opening lock mechanisms adds stresses atypical to what is seen in the vast majority of construction. Because of this, ASME Section VIII[1] has a section specifically for these types of vessels.[2]

The human interface occurs at the quick acting closure, so people are often in proximity of the energy release.[3]

1. See ASME Section VIII UG has several sections dealing with joint efficiency, the value E representing efficiency is common in vessel construction.
2 See ASME Section VIII UG 35.2
3. ASME Section VIII Non Mandatory Appendix FF-3, paragraph 4
*ASME Section VIII Non Mandatory Appendix FF-7 talks about causes of “accidents”. It is the only place where the term “accidents” appears in ASME Section VIII.

Now More Than Ever

COVID is changing our exposure map

SARS-CoV-2 (COVID 19) Classified as a Risk Group 3 Biological Agent[1].

Labs handling Risk Group 3 must have Biosafety Level 3 (BSL) controls[2].

Aerosols*, transmissible variants, and zoonosis**: All of these risks must be contained by BSL 3 controls[2].

Jurisdictional objects can exist throughout laboratory facilities including solid and liquid waste stream, lab services and HVAC systems.

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1. Interactive: Who's funding the COVID-19 response and what are the priorities? https://www.devex.com/news/interactive-who-s-funding-the-covid-19-response-and-what-are-the-priorities-96833
2 Significance of High-Containment Biological Laboratories Performing Work During the COVID-19 Pandemic: Biosafety Level-3 and -4 Labs
Define BSL, Pathogen
- "A procedures potential to release microorganisms into the air as aerosols and droplets is the most important operational risk factor that supports the need for containment equipment and facility safeguards." BMBL Section 1 Page 5

**Zoonosis is the transmitting of a disease or parasite from an animal to a human. Reverse zoonosis is the opposite.

Bio Safety Levels (BSL)

1	2	3	4	5
Sterilizers and autoclaves can contain harmful pathogens; a review of applicable codes was a working group task.	Biosafety Levels are defined in Biosafety in Microbiological and Biomedical Laboratories (BMBL 6th Edition).	Published by the Center for Disease Control (CDC) and the National Institutes of Health (NIH), published by this name in 1984.	Evolved from WWII Army Standards, civilian version 1974.	International Standard for Biosafety Containment.

Bio Safety Levels (BSL)

1

Four ascending levels based on risk analysis, CDC classed COVID as BSL 3.

2

How infectious is the disease? Is the average person at risk? Is the risk limited to persons with compromised immune systems?

3

How severe is the disease? Is an infected person likely to have permanent damage, hospitalization or die from the disease?

4

Standard operating procedures, security, architectural envelope and equipment used for containment (including spare equipment – N+1) are essential.

5

The goal is to avoid Lab Associated Infections (LAI).

6

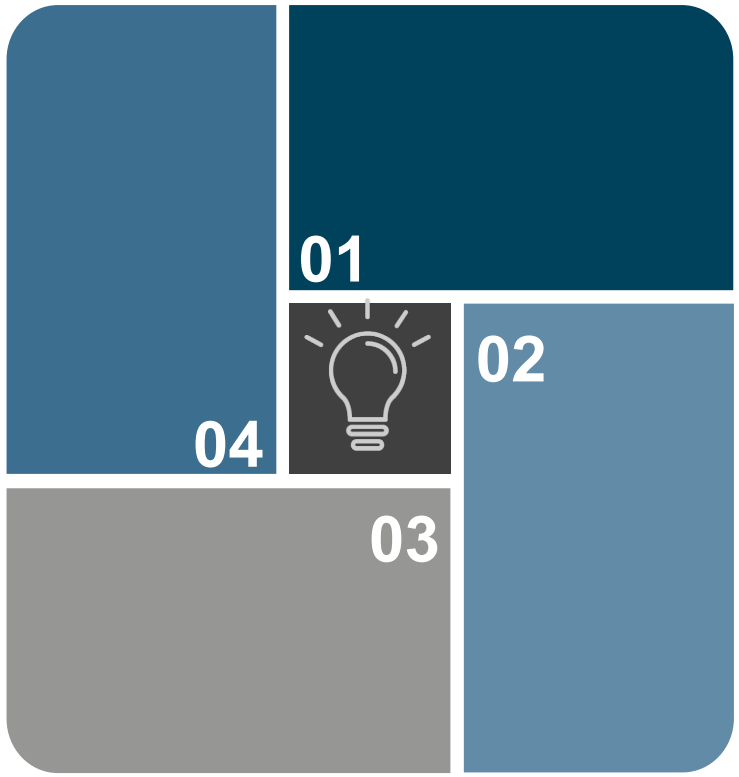
BMBL handles the pathogen side and the requirements; NIH does the infrastructure.

Inspector Exposure Points

Containment is key; The Center for Disease Control and the National Institutes of Health provide guidelines

04 Typically all the equipment other than the autoclave is outside the containment zone.

03 Services such as hot water heat exchangers, compressed air and vacuum systems.



01 HVAC systems that maintain directional, heat exchangers and boilers*.

02 Autoclaves[1] that sterilize waste.

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1 NIH Design Requirements Manual Section 2.5 Biocontainment Facility Predesign 2.5.0

*You can and will have bulk gas and cryogenic systems but they are topics on their own

Pressure Vessels/Autoclaves

- Most commonly used for supplying heat and hot water to decontaminate waste and other materials.
- Autoclaves can be required on each floor in large facilities; multiple units should be used to reduce travel distance and the room shall have negative pressure[1].
- Must incorporate suitable protections to prevent release or exposure[2].
- Designed to prevent escape of chamber contents. Relief valves shall discharge to a safe area in accordance with the risk assessment. Bio seals bridging a flange welded to the full circumference of the equipment.

1 NIH Design Requirements Manual Section 4.6.1.12
2 NIH Design Requirements Manual Section 4.9.10

Autoclaves: The Codes

- International Mechanical Code (IMC), ASME Section VIII shall be followed. Also ASME BPE (Bioprocessing Equipment)
- Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) for boilers, pressure vessels, HVAC and numerus other pieces of equipment[1]
- QC and testing are covered in the Project Validation Master Plan (PVMP)[2]
- All hardware shall be in strict conformance with ASME Codes per ASME BPE
- Relevant sections of ASME B31 apply

1 NIH Design Requirements Manual Section 13.15.7 & 13.15.8 Commissioning/FAT & SAT
2 NIH Design Requirements Manual Section 13.16.2

National Board Inspection Code Part II

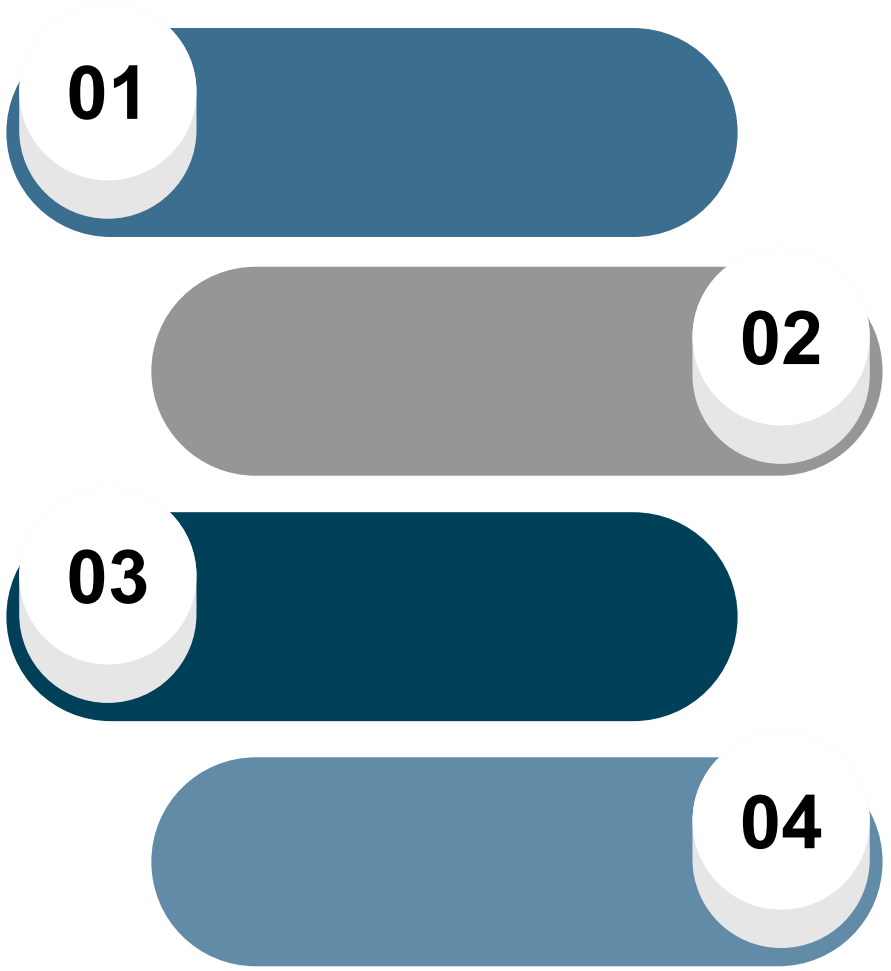
Working Group 21-265: Requirements for Integrity Testing Program

Integrity Testing Program

Non-destructive Examination Program shall be developed by a professional equivalent to a level 3 engineer per ASME Section V and ASME BPE (Bio Processing Equipment).

Test Interval

The NDE test interval should be at a minimum of every five years, more often if deemed necessary by the Original Equipment Manufacturer (OEM), equivalent professional, inspector or jurisdiction.



Non Destructive Examination Program

Non Destructive Examination Program shall be developed by a professional equivalent to a level 3 engineer per ASME Section V and ASME BPE (Bio Processing Equipment).

Photos and Drawings

Enhance drawings and photos of closure mechanisms.

National Board Inspection Code Part II

At a minimum, add to NBIC Part I, the requirement for the following safety devices:

Pressure vessels with quick-actuation closers: A safety interlock device that prevents the opening mechanism from operating unless the vessel is completely depressurized.

Automatic dump to safe point on door travel safety switch or occupant activation switch.

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These are proposed changes developed by the Working Group introduced at the January 2022 committee meeting

Thank You