

POLICY ON CONTAINMENT FOR RISK GROUP THREE ORGANISMS

Date: *October 27, 2017*

Supersedes: *Policy on Containment for Risk Group Three Organism* dated October 7, 2014

I. PURPOSE

Exposure to “Risk Group Three” (RG3) organisms may result in serious or potentially lethal disease. Additionally, the release of RG3 organisms outside of containment could have serious public health implications. There have been several high profile laboratory acquired infections and incidents with these agents due to contamination of attenuated strains with wild type strains and removal of agents, which were not completely inactivated, from biosafety level three areas. Consequently, New York Medical requires all RG3 organisms to be handled at Biosafety Level 3 (BSL-3) and has instituted this policy to establish procedures that will prevent the release of these materials outside of BSL-3 containment.

II. POLICY

NYMC requires that all RG3 organisms be handled at Biosafety Level 3. The only exceptions to this are attenuated risk group three organisms and inactivated agents that are products of RG3 organisms. Confirmation of attenuation and/or inactivation must be performed at BSL-3 containment. Documentation that confirms attenuation of the organism must be presented to and approved by the Institutional Biosafety Committee (IBC) before the organism or agent may be removed from BSL-3 containment. Any inactivated agents that must be removed from BSL-3 containment must be inactivated using a validated protocol that has been fully approved by the IBC. Any failure to comply with this policy will result in disciplinary action, including the immediate suspension of IBC approval(s) to conduct research.

III. SCOPE

This policy applies to all NYMC faculty, staff, students, volunteers, space licensees, and contractors.

IV. DEFINITIONS

Attenuated Strain: a debilitated, weakened or less virulent virus, bacteria, other organism or toxin.

Biosafety Level 3 (BSL-3): classification of clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.

Inactivation: a process which renders an agent or nucleic acid as non-viable while retaining characteristic(s) of interest for future use.

Infectivity Testing: a protocol to confirm the inactivation procedure by demonstrating the nucleic acids are incapable of producing infectious forms of virus.

Toxicity Testing: a protocol to confirm the inactivation procedure by demonstrating the select toxins are non-toxic.

Validated inactivation procedure: a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable, but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Verification: confirmation by an individual or entity that the use by the individual of a validated inactivation or select agent removal procedure will result in an end product that achieves the expected results.

Viability testing protocol: a protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

Wild-Type Strain: a strain found in nature or a standard strain.

V. PROCEDURES

- A. Verification of Attenuated Strains from Inter-Entity Transfers.** Before engaging in any research with an attenuated RG3 organism, the Principal Investigator (PI) must register the research protocol(s) with the IBC. The IBC must grant the protocol (s) full approval before shipments of attenuated RG3 materials can be received and/or work with the attenuated organism may begin. The Department of Energy, Environment, Health and Safety (EEH&S) must be notified of all incoming shipments. Upon receipt, the package(s) must be transferred to the BSL-3 laboratory for verification of attenuation. Verification must be performed using an approved method to distinguish between the attenuated and wild type strain (e.g., PCR). Confirmation of the attenuation must be submitted to the IBC for final approval before the organism can be moved out of the BSL-3 laboratory into lower containment (i.e., Biosafety Level 2). If attenuation cannot be confirmed, the agent must be handled at BSL-3.
- B. Verification of Self-Attenuated Strains.** Before attenuating a wild-type RG3 organism the Principal Investigator must have a written attenuation protocol approved by the IBC. The attenuation protocol must include procedures that verify the attenuation. Verification must be performed using an approved method to distinguish between the attenuated and wild type strain (e.g.,

polymerase chain reaction “PCR”). Confirmation of the attenuation must be submitted to the IBC for final approval before the organism can be moved out of the BSL-3 laboratory into lower containment (i.e., Biosafety Level 2). If attenuation cannot be confirmed, the organism must be handled at BSL-3.

C. Validation of Inactivated Materials.

1. Before organisms can be removed from BSL-3 containment for work at lower containment, the Principal Investigator must have a written inactivation protocol approved by the IBC. The protocol must include viability, infectivity, or toxicity testing procedures and validation data that is able to demonstrate a lack of infectious material present in the sample after inactivation is performed. The inactivation protocol must be performed at least three times for validation of the protocol. Submissions to the IBC must include procedures for verification of the validated protocol. Once the protocol is approved, the Principal Investigator and his/her personnel must strictly follow the approved protocol, including the use of appropriate positive, negative, and process controls to ensure that samples are rendered non-infectious. If the inactivation procedure requires modification, the modified procedures must be validated and the results of the experimental validation must be submitted to the IBC for approval. No modified protocols may be utilized to reduce the requirement for BSL-3 containment until the modified protocol has been fully approved by the IBC. Validated inactivation protocols must be reviewed annually by the IBC and kept for three years.
2. Inactivation failures must be immediately reported to the Responsible Official (RO) or Alternate Responsible Official of the BSL-3 laboratory. The RO or ARO will investigate all inactivation failures and report to CDC all Select Agent validation failures that did not result from a deviation from the validated procedure.
3. A certificate, signed by the Principal investigator that includes the date of inactivation, the validated procedure used for inactivation, the name of the individual performing the procedure, and the location where the procedure was performed must be generated for each batch of materials that is inactivated and removed from the BSL-3 laboratory. A copy of the certificate must accompany the material during any inter-facility transfer.

VI. EFFECTIVE DATE

This policy is effective immediately.

VII. POLICY RESPONSIBILITIES

- A. Research Personnel
 1. Refrain from working with attenuated organisms and/or inactivated materials at a lower containment level until attenuation and/or inactivation has been demonstrated via an approved validated protocol;
 2. Report all shipments of attenuated BSL-3 organisms to EEH&S;
 3. Report any instances of non-compliance with this policy to EEH&S and/or the IBC.

- B. Principal Investigators
 1. Register and obtain IBC approvals for all research protocols that utilize RG3 agents (including attenuated strains);
 2. Register and obtain approval for all attenuation and/or inactivation protocols relating to RG3 organisms;

- C. Department of Energy, Environment, Health & Safety
 1. Ensures that packages of attenuated RG 3 agents are received and moved into the BSL-3 lab.
 2. Reports any non-compliance issues to the IBC.
 3. Reports inactivation failures not resulting from a deviation in procedure to the CDC.

- D. Institutional Biosafety Committee
 1. Reviews and approves protocols for confirmation of attenuation and approves protocols for inactivation.
 2. Assesses instances of policy non-compliance and develops action plans.

VIII. POLICY MANAGEMENT

Responsible Executive: Vice President of Operations

Responsible Officer: Director, Energy, Environmental, Health & Safety

Responsible Department: Energy, Environmental, Health & Safety

Approved by the Chancellor's Office, the Office of Energy, Environment, Health & Safety and the Director of Energy, Environmental, Health & Safety