COLD ROOM USE POLICY
MJIS 3052C – Weldon School of Biomedical Engineering
Version 1, 03092026

1. Purpose

The purpose of this policy is to define acceptable use, access controls, safety requirements, and segregation practices for the third-floor cold room located within the Martin Jischke Hall of Biomedical Engineering (MJIS 3052C). The cold room supports both academic research activities and selected collagen polymer production-support, testing, and controlled storage activities that are conducted under an approved Harbin Laboratory Quality Plan. This policy is intended to ensure personnel safety, material integrity, and institutional and quality-system alignment within a shared academic environment. See Appendix A for the current configuration of the Cold Room.

2. Scope

This policy applies to all faculty, staff, trainees, students, and visitors who request and are granted access to the cold room.

Two categories of activities are supported:

- **Research Use (RU):** Approved academic research and storage activities
- **Quality-Plan-Governed Activities (QP):** Production-support, testing, or controlled storage of raw and/or development-grade collagen polymer materials conducted under the Harbin Laboratory Quality Plan

For purposes of this policy, “Quality Plan” refers to the Harbin Laboratory Quality Plan.

3. Governing Principles

- The cold room is a controlled laboratory space and not a general shared storage area.
- Segregation of activities, materials, and equipment is required.
- Quality-Plan-Governed activities shall comply with this policy and any additional controls established in the Harbin Laboratory Quality Plan.
- Purdue University Environmental Health & Safety (EHS), MJIS, and Weldon BME policies take precedence where applicable.

4. Physical Segregation of Space

The cold room shall be divided into clearly labeled zones, as outlined in Appendix A:

- **Quality-Plan Zone (QP Zone)**
  - Storage, handling, production, and testing of QP-controlled equipment, resources, supplies, and raw and/or development-grade collagen polymer materials, as defined in and conducted under the Harbin Laboratory Quality Plan and approved SOPs
  - Restricted to authorized personnel trained and approved in accordance with the applicable Quality Plan
  - Marked: *“QUALITY PLAN CONTROLLED AREA – AUTHORIZED PERSONNEL ONLY”*
- **Research Use Zone (RU Zone)**
  - Clearly labeled areas designated for academic research use
  - Areas may be further subdivided to support the academic research activities of designated faculty laboratories
  - No Quality Plan materials permitted

Commingling of materials, equipment, supplies, or PPE between zones is prohibited.

5. Access Control and Training

- Access to RU Zone requires prior approval from the designated Cold Room Oversight Committee, which shall initially be comprised of Susan Hardy, Building Deputy, Weldon School of Biomedical Engineering; Prof. Sherry Harbin, Professor, Weldon School of Biomedical Engineering; and Prof.

Jackie Linnes, Associate Head for Research, Weldon School of Biomedical Engineering. Committee members may designate alternatives, as needed.

- In addition to receiving approval from the Cold Room Oversight Committee, QP Zone access is further limited to personnel with documented Harbin Laboratory Quality Plan and SOP training.
- Personnel not authorized for QP activities may not access QP Zones.

5.1. Access Request Procedure

Individuals requesting access to the cold room must complete the following steps:

1. Complete and submit the MJIS 3052C Cold Room Access Request Form to the Cold Room Oversight Committee for review and approval, describing:
    - Name, role, and affiliated laboratory
    - Intended use (Research Use or Quality-Plan-Governed Activities)
    - Anticipated duration of access
2. Complete required training, as outlined in the MJIS 3052C Cold Room Training and Policy Acknowledgement Form, including:
    - Weldon School of Biomedical Engineering Initial Safety Training Checklist and Laboratory Access Request Form, approved by Susan Hardy or designated departmental staff
    - Cold Room Policy Read and Acknowledge
    - Cold Room Safety Training & Orientation
        - To schedule this in-person training, please contact Rachel Morrison (morri107@purdue.edu) and Alexander Harbin (aharbin@purdue.edu)
    - Quality Plan and SOP training, if requesting QP access
3. Complete and submit the Cold Room Training and Policy Acknowledgment Form

Cold room access is granted on an individual basis only and is not transferable. Approved users may not grant access to or train non-approved individuals in cold room access. All individuals requiring access must complete the required training and receive prior approval as outlined in this policy.

Access approvals are granted for a defined purpose and specified duration, as documented in the approved access request. Changes in scope of use (e.g., change in personnel or types of activities) or requests for extended access require submission of a new or revised MJIS 3052C Cold Room Access Request Form and associated approval.

6. Area and Labeling Requirements

To ensure safe, orderly, and compliant use of the cold room, all materials, solutions, equipment, resources, and assigned work and storage areas within the cold room must be clearly and appropriately labeled. At a minimum, labels must include:

- Authorized individual owner (full name)
- Faculty PI laboratory affiliation
- Project or protocol identifier (as applicable)
- Date prepared, received, or placed in storage
- Expiration date (label “N/A” as expiration date if not applicable)
- Solutions, reagents, and working stocks: must also include the contents (full chemical or material name; no abbreviations)
- Activity category: Research Use (RU) or Quality-Plan-Governed (QP)

The following additional expectations apply:

- Labels must be legible, durable, and appropriate for cold room conditions.
- Items or areas with missing, illegible, or ambiguous labels may be treated as noncompliant.

In addition, upon completion of an approved duration of cold room access, RU users are responsible for removing all equipment, resources, supplies, and materials associated with their work from the cold room. Failure to do so may result in removal and disposal of such items during routine inspections.

7. Area and Resource Inspection

Research Use (RU) Areas: To ensure compliance with space designation, use, storage, and labeling requirements, routine inspections of RU areas within the cold room will be conducted at least on a quarterly basis by the Cold Room Oversight Committee or its designee. During these inspections, items that are improperly labeled, expired, or abandoned may be removed and discarded. Where feasible, reasonable efforts will be made to notify the responsible individual and faculty PI prior to disposal; however, advance notification is not guaranteed.

Quality-Plan-Governed (QP) Areas: QP areas, resources, and activities are subject to separate inspection, control, and disposition procedures as defined in the Harbin Laboratory Quality Plan and associated SOPs.

8. Cold Room Cleaning Practices

Users are responsible for maintaining a clean and orderly workspace within the cold room. Cleaning must be performed after each use and prior to leaving the cold room.

Cleaning should be appropriate for the activity performed and generally includes:

- Wiping down work surfaces, shelves, and equipment used during the activity
- Removing used supplies, packaging, and temporary materials
- Ensuring that no residues, spills, or contamination remain in shared areas
- Confirming that any remaining materials are properly labeled in accordance with this policy

Qualified, non-residue, non-aerosol cleaning agents (e.g., 80% ethanol, 70% isopropanol alcohol) will be provided. Failure to maintain appropriate housekeeping standards may be treated as a policy deviation or non-compliance.

Upon leaving the cold room, users must ensure that the door is fully closed and secured to maintain temperature control, and that lights are turned off.

9. Cold Room Safety Practices

- All applicable Purdue University EHS and MJIS safety policies must be followed at all times, including minimum PPE requirements:
    - Closed-toe, closed-heel shoes
    - Long pants
    - Lab coat
    - Gloves appropriate to the task
    - Eye protection
- Biohazard materials (BSL2 or higher) are prohibited in the cold room. Please refer to the Biological Safety Manual (see Section 12) for further information
- High-hazard chemicals are prohibited in the cold room. This includes, but is not limited to:
    - Highly reactive, acutely toxic, or corrosive chemicals
    - Large volumes of flammable materials (>1L)
    - Any chemicals that require chemical fume hood ventilation or are restricted to use in well-ventilated areas. Please refer to the Chemical Hygiene Plan (see Section 12) for further information
- Chemicals may not be stored in the cold room without prior review and approval by the Cold Room Oversight Committee
- Users are responsible for ensuring that chemicals and materials are handled, stored, and disposed of in accordance with approved EHS practices and this policy
- Materials that are not suitable for humidified cold room environments and are prone to degradation or mildew growth (e.g., cardboard, wood, paper products) should be avoided whenever possible
- As much as possible, limit exposure time to prevent cold stress
- Keep exits and emergency equipment unobstructed
- No food or drink permitted

9.1. Chemical Spills and Emergencies

- Follow Purdue EHS and MJIS spill response procedures
- Report major incidents to EHS and building management contacts listed on the door signs
- Current laboratory/building contacts:
    - Dr. Rachel Morrison: morri107@purdue.edu
    - Alexander Harbin: aharbin@purdue.edu
    - Prof. Sherry Harbin: harbins@purdue.edu
    - Susan Hardy, Building Deputy: hardy13@purdue.edu

10. Policy Deviations

Any errors or deviations from this policy occurring within the RU or QP Zones must be reported to the Cold Room Oversight Committee, including:

- Susan Hardy, Building Deputy: hardy13@purdue.edu
- Prof. Sherry Harbin: harbins@purdue.edu

Deviation reports should include:

- Date of occurrence
- Location (RU or QP Zone)
- Description of the incident or deviation
- Corrective action taken, if any, including cleanup of affected areas
- Preventative action taken, if any, to mitigate future occurrences

Failure to comply with this policy may result in suspension of access and escalation to department or institutional leadership.

11. Policy Review

This policy will be reviewed at least annually or upon changes to Weldon School or institutional requirements.

12. Reference Documents

Purdue EHS Website: https://www.purdue.edu/ehps/rem/

Purdue Chemical Hygiene Plan: https://www.purdue.edu/ehps/rem/laboratory/hazmat/chp.html

Biological Safety Manual: https://www.chem.purdue.edu/chemsafety/bio/index.html

APPENDIX A: MJIS 3052C Cold Room Configuration