

Standard Operating Procedures



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- **SOPs are vital to ensure processes are completed in the same way over time and should be:**
 - Clear and Concise
 - Complete
 - Consistent
 - Controlled
 - Current



- **SOPs should be written in plain language.**
- **Any highly technical jargon should be avoided or clearly defined**
- **Steps should be explained thoroughly, but concisely.**
 - Avoid long sentences or paragraphs explaining tasks.



– Inspecting the Isolator For Damage

- Check the entire outside of the isolator to include all connection ports and adaptors for damage
 - Report damage to the Production Support supervisor
- Inspect all welded seams in both the isolator and within the ports to check for signs of leakage to include air, light or moisture passing through the seam and/or build-up of residue
 - Report damage to any welded seams to the Production Support supervisor



- **Ensure all steps are accounted for within the process**
- **It can be helpful to reference other SOPs or materials as opposed to re-stating**
 - Equipment manuals
 - Material Safety Data Sheets
 - Personal Protective Requirements



- **3.0 SAFETY AND HANDLING**

- Refer to Document SE1202 - Personal Protective Equipment Requirements and Document SE1207 – Preparation of Approved Sterilants/Disinfectants.

- **5.0 REAGENTS AND PREPARATION**

- Approved sterilant/disinfectant (refer to manufacturer's instructions and Document SE1207) See appropriate MSDS



- **Format, font, tone should be the same from SOP to SOP**
- **Layout and flow should be the same**
- **Level of detail should be similar**



- **1.0 QUALITY ASSURANCE**
- **2.0 DESCRIPTION AND REFERENCES**
 - Description
 - The purpose of this standard operating procedure is to detail the steps required to reprocess an IBS Park Bioservices isolator. Reprocessing involves the removal of animals and supplies as well as the cleaning and sterilization of the dirty isolator.
 - 2.2 References**
 - 2.2.1 Document SE1202 – Personal Protective Equipment Requirements
 - 2.2.2 Document SE1207 – Preparation of Approved Sterilants/Disinfectants



- **A person or small group should maintain ownership**
- **Revisions should be routed through owners and approved by relevant parties (Vet, IACUC, etc.)**
- **Steps should be taken to ensure old versions are removed from all areas and that only the most recent version is available**



- **SOPs should be re-visited on a regular basis**
 - Review for current best practice
 - Review for regulatory changes
 - Ensure equipment and materials are still accurate



- **GI0501-Procedure For Taking Samples In Isolators For Microbiological Monitoring**
- **GI0532-Packing and Receiving Procedures For Germ Free Shippers**
- **GI0536-Gnotobiotic Technique For Closing Ports**
- **GI0541-Gnotobiotic Technique For Hooking Up Cylinders and Entering and Exiting Supplies**
- **GI0542-Gnotobiotic Technique For Entering Water Flasks**
- **GI0595-Gnotobiotic Husbandry For Isolators**
- **GI0597- Procedure For Building an Isolator**
- **GI0602-Reprocessing 2x2x5 Isolators**
- **GI0608-Preparation of Gnotobiotics Spray Cart**
- **GI0616-Isolator Contamination Prevention**
- **MH0997-Wrapping Cylinders and Isolator Air Filters With Media**
- **MH0999-Preparation of Feed and Bedding For Supply Cylinders**

Partial SOP list for Semi-rigid Isolators



- **IBS0209 - Schedules for IBS Facility Sanitation**
- **IBS0210 - Documentation of Significant Events for Semi-Rigid Isolators**
- **IBS0213 - Raw Materials Flow - Distribution/Release of Raw Materials Entering IBS Productions Areas**
- **IBS0214 - Materials Flow - Return of Materials from the IBS Production Areas to the Wash Area for Cleaning**
- **IBS0224 - Isolator Tear Down Procedure for IBS Isolators**
- **PD1017 - SBS Guidelines for Observation Logs**
- **PD1032 - Contract Breeding Services Documentation and Line Review - From Receipt to Production**
- **PD1050 - Biopsy Collection - Taconic with Transnetyx**
- **QA0510 - Raw Materials Quality Assurance System**
- **SE1202 - Personal Protective Equipment Requirements**
- **SE1207 - Preparation and Use of Approved Sterilants/Disinfectants (H)**
- **VS8016 - Necropsy Evaluation and Reporting of Abnormal Animals**
- **VS8032 - Colony Health Monitoring - Maintenance and Selection of Sentinel Animals**
- **VS8035 - Identification and Evaluation of Pain and Distress in Laboratory Rodents**



- **The Germ Free Animal in Biomedical Research**
 - Edited by Marie E. Coates and Bengt E. Gustafsson
- **Isolation Technology: A Practical Guide**
 - By Tim Coles
- **50 Years of Laboratory Animal Science**
 - AALAS Publication