Standard Operating Procedure

Title: Equipment Interproduct Cleaning and Clearance

SOP Number: 21529 **Revision Number: 02**

Supersedes: Revision 01 **Effective Date: SEP 13 2011**

Originator/Date: [redacted]

Originator/Date:

Approval/Date:

Approval/Date:

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1.0 Purpose

This SOP describes the procedure for defining and implementing cleaning, sampling and testing of process equipment between different products.

2.0 Scope

This procedure applies to BDP persons responsible for operation and cleaning of reusable process equipment.

PRECAUTIONS: **Operators must be familiar with safe handling of materials listed on batch production records and/or appropriate forms. Refer to the appropriate Material Safety Data Sheets and/or Safety Manual.**

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

3.0 Authority and Responsibility

3.1 The Director, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

3.2 Supervisors/Managers are responsible for ensures their staff are trained in this procedure and for reporting this training to the BQA Training Manager.

3.3 BQA is responsible for quality oversight of this procedure.

4.0 Guidelines

4.1 Procedures for cleaning of specific pieces of equipment are established, approved, and on file prior to the initiation of the remaining sections of this procedure.

4.2 Procedures describing sampling for verification of cleaning are established, approved and on file prior to initiation of the remaining sections of this procedure.

4.3 Procedures for testing cleaning verification samples are established, approved and on file prior to initiation of the remaining sections of this procedure.

5.0 Establishing the Interproduct Cleaning Process

5.1 Product-specific Issues

5.1.1 Prior to the initiation of Section 6.0, the Project Scientist, Product Requestor, or Supervisor of any affected areas, submits to BQA Engineering a completed Form 21529-01, Interproduct Cleaning and Testing Protocol, outlining the proposed protocol for interproduct cleaning and testing.

5.1.1.1 The submission should indicate if interproduct cleaning from similar products or process streams has previously been validated.

5.1.1.2 The submission will list all tests that are to be performed on samples taken from equipment that has been cleaned, as well as the maximum acceptable limit.

5.1.1.3 The submission will indicate which tests are appropriate for rinse samples, which are appropriate for swab samples and which are appropriate for both.

5.1.2 BQA Engineering approves the proposal.

5.1.3 The approved protocol becomes the official protocol for interproduct cleaning and testing for that product. If interproduct cleaning from a specific product is not similar to currently validated cleaning processes, all tests listed on the protocol must be performed for each sampling point outlined in Form 21529-02 (see 5.2) each time a product changeover is performed. Once the changeover process has been validated, the protocol is amended.

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5.2 Equipment Specific Issues

5.2.1 Prior to initiation of section 6.0, the Supervisor of the affected area submits to BQA Engineering a completed Form 21529-02, Interproduct Cleaning Sampling Schedule, outlining the type and location of samples to be taken from each specific piece of affected equipment. If any parts (such as diaphragms or O rings) are to be replaced during the changeover process, a completed Form 21529-04, Product Changeover Parts Replacement Schedule, which lists all parts to be replaced during product changeover and any additional steps that need to be taken, must also be submitted to BQA Engineering.

5.2.2 BQA Engineering reviews and approves the proposed sampling schedule and, if submitted, parts replacement schedule.

5.2.3 The approved sampling schedule becomes the official reference for obtaining cleaning verification samples for that piece of equipment and the approved parts replacement schedule becomes the official reference for changing out parts during the changeover process.

5.2.4 The sampling schedule is used during cleaning validation activities in obtaining samples for the purpose of validating interproduct cleaning activities. Once an interproduct cleaning process has been validated, it may no longer be necessary to sample all points. A reduction in sampling will be documented on Form 21529-02, which is equipment-specific.

6.0 Procedure

6.1 The Area Supervisor obtains a copy of Forms 21529-01, 21529-02 and 21529-04 (if applicable) relevant to a specific piece of equipment and product.

6.2 The Area Supervisor completes Section A of Form 21529-03 and assigns the cleaning task to the appropriate personnel.

6.3 A cleaning procedure is performed using the SOP pertinent to the specific piece of equipment, and the cleaning documentation is attached to Form 21529-03.

6.4 Samples are collected from the equipment locations specified on Form 21529-02 for the specified equipment and using the solvents and sample preparation methods specified on Form 21529-01 for the specific product. The persons collecting the samples complete the checklist on Form 21529-02 and attach the form to Form 21529-03

6.5 Samples are submitted to PA for the tests specified on Form 21529-01. The tests and PA numbers are recorded in Section B of Form 21529-03.

6.6 All parts specified in Form 21529-04 (if applicable) are changed. Parts do not need to be changed between consecutive campaigns of different components that will be combined by the BDP to form the final product. The person changing the parts complete the checklist on Form 21529-04 and attaches that form to Form 21529-03.

6.7 If any parts are changed, a second cleaning procedure is performed using the SOP pertinent to the specific piece of equipment and the cleaning documentation is attached to Form 21529-03.

6.8 The test results are reviewed by the Area Supervisor to confirm that they are below the acceptable limits as specified on Form 21529-01.

6.8.1 Equipment cannot be cleared for use in subsequent GMP production processes until all test results have been obtained and the results are below the acceptable limits.

6.8.2 If any results are above the acceptable limits, the cleaning procedure must be repeated and samples re-taken from all specified locations for the specific test for which the acceptance criteria were not met.

6.9 The Area Supervisor completes Part B of Form 21529-03, summarizing the results for each test specified in Form 21529-01 as "Pass" (at or below acceptable limits) or "Fail" (above acceptable limits). If equipment is re-cleaned and re-tested, this is noted by appending "re-test" to the entry in the "Test" column on Form 21529-03.

7.0 Documentation

7.1 This procedure is documented on Form 21529-03, with additional forms attached as supporting documentation.

7.1.1 A copy of Form 21529-01 is attached to specify the current testing requirements.

7.1.2 Copies of cleaning documentation are attached to document the cleaning operations.

7.1.3 A copy of Form 21529-02 is attached to document the samples that were taken from the equipment.

7.1.4 A copy of Form 21529-04 is attached to document the parts that were changed (if applicable).

7.1.5 A copy of all test results are attached.

7.2 Completed documentation consisting of the documents specified in 7.1 are assembled and reviewed by the Area Supervisor for each interproduct cleaning/changeover process.

7.3 Submit complete, reviewed documentation specific to each interproduct cleaning/ changeover to BQA Documentation for storage.

8.0 Attachments

8.1 **Attachment 1** Form 21529-01, Interproduct Cleaning and Testing Protocol

8.2 **Attachment 2** Form 21529-02, Interproduct Cleaning Sampling Schedule

8.3 **Attachment 3** Form 21529-03, Interproduct Cleaning Worksheet

8.4 **Attachment 4** Form 21529-04, Product Changeover Parts Replacement Schedule

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Attachment 1

NCI-Frederick
Form No.: 21529-01
SOP No.: 21529
Revision 02:

Interproduct Cleaning and Testing Protocol

Protocol No.: _____ Product: _____

Validated Process? (Circle One) Yes No Protocol No.: _____

Rinse Solvent: _____

Swab Solvent: _____

Rinse Sample Preparation: _____

_____

Swab Sample Preparation: _____

_____

Sample Storage Conditions: _____

Assay(s):

Assay	Sample Type (Swab, Rinse, Swab and Rinse)	Acceptance Criteria

_____
Prepared By/Date

APPROVALS

_____ _____
Production Date

_____ _____
Project Scientist Date

_____ _____
BQA Date

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Attachment 2

NCI-Frederick
Form No.: 21529-02
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Interproduct Cleaning Sampling Schedule

Sampling Schedule No.: _____ Equipment MEF: _____

Equipment Cleaning SOP: _____

Describe the location of each sample to be taken below. Attach drawing(s) as necessary to aid in thoroughly describing sampling locations. The right-most column is completed when samples are taken.

Location ID	Description	Rinse or Swab	Samples Taken By/Date	Verified By/Date

Drawings attached? (Circle one) Yes No

_____
Proposed By/Date

BQA Approval/Date:_____

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Attachment 3

NCI-Frederick
Form No.: 21529-03
SOP No.: 21529
Revision 02:

Interproduct Cleaning Worksheet

A. Pre-Operation Information

Equipment to be cleaned:	
Sampling Schedule No.:_____	Product Protocol No.:_____
Parts Replacement Schedule No.:_____	

_____
Supervisor Signature/Date

B. Operation Information

Equipment Cleaned:_____

_____
Performed By/Date

Sample Summary (attach results)

Test	Result (Pass/Fail)	PA QCTR No.

_____
Performed By/Date

_____
Document Reviewed By/Date

Attachment 4

NCI-Frederick
Form No.: 21529-04
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Product Changeover Parts Replacement Schedule

Parts Replacement Schedule No: _____ Equipment MEF: _____

List all parts to be changed during a product changeover process in the table below. Below the table, list any additional steps to be taken as part of the changeover process. The rightmost column is completed when parts are replaced and/or steps are performed.

Part No.	Component Description	Item Description	Quantity	Performed By/Date	Verified By/Date

_____ Proposed By/Date

BQA Approval/Date_____