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## 1.0 Purpose

This procedure describes the labeling of equipment for cleaning status used specifically by Late Process Sciences for mammalian, bacterial, and virus purification. This SOP is to be used in conjunction with other equipment specific cleaning procedures that outline the cleaning process and required documentation that need to be completed for equipment cleaning.

## 2.0 Scope

This procedure applies to, but is not limited to, personnel working with purification equipment at the ATRF.

## 3.0 Authority and Responsibility

3.1 The Director, Technical Operations, Late Process Sciences (LPS), Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 The Manager, Technical Operations, Purification, BDP is responsible for training personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 The Manager, Technical Operations, BDP is responsible for the implementation of this procedure.

3.4 BDP personnel are responsible for performing operations in compliance with this SOP.

3.5 BQA is responsible for quality oversight of this procedure.

## 4.0 Procedure

4.1 The cleaning status of product contact equipment is to be displayed using equipment status labels that are color coded to facilitate the identification of equipment that is either dirty, cleaned and pending release, or cleaned and ready for use (see complete descriptions below). The label should be placed on the equipment in a way that makes it highly visible so that the assessment of its status can be made quickly and easily.

4.2 Label information includes:

- Pre-Production or Post-Production Cleaning Status
- Project Name and Project Number
- Lot Number the equipment was released for or has been used for
- Resin Type (Columns Only)
- Viral Use (Yes or No) (If yes, affix “Infectious/Potentially Infectious sticker). (This only applies to Red and Yellow Status labels).
- Operator Initials and Date
- Date Cleaned
- A section for any additional notes

4.3 Dirty Status Labels (red labels).

These labels indicate that the equipment status is “To Be Cleaned.” The label will also indicate if the following activities have been performed (**Form 14150-01**)

- Salt Test (Columns Only, If Applicable)
- 0.5 NaOH Flush
- WFI Flush
- Storage Buffer

4.4 Cleaned - Quarantined (Not Released for Use) Status Labels (yellow labels). These labels indicate that the equipment has been cleaned per procedure and is not available for use, pending the completion of Process Analytics testing. The label will also include (Reference **Form 14150-02**):

- Testing Performed for Equipment Release
- PA Request Numbers of Release Testing

4.5 Cleaned - Released For Use Status Labels (green labels).

These labels indicate that the equipment has been cleaned, release testing has been completed, the results are within acceptable parameters, and this equipment is ready to be used. The label will only have the information listed in Section 2.2 (**Form 14150-03**).

4.6 Special notes or comments may also be included on the label such as: ***EQUIPMENT NOT IN SERVICE, EQUIPMENT NOT FOR CGMP USE***, etc.

## 5.0 Documentation

5.1 If cleaning a piece of equipment before a purification run, then the labels should be notated as Pre-Production cleanings. If the cleanings are to be performed after a purification run, then the labels should be notated as Post-Production.

5.2 After a purification run has been completed, a red "Dirty - To Be Cleaned" label will be placed directly onto the primary container or equipment, complete with any activities done prior to cleaning. The Green Status Label will be removed and any previous information erased.

5.3 After the equipment has been cleaned, according to an appropriate SOP and/or MPR, a yellow "Cleaned -Quarantined (Not Released For Use)" label will be placed onto the primary container or equipment, including any release testing to be done and the associated PA test request numbers. The Red Status Label will be removed and any previous information erased.

5.4 Once the tests confirm that the equipment is clean, according to an appropriate SOP and/or MPR, a green "Cleaned: Released for Use" label will be placed directly onto the primary container or equipment. The Yellow Status Label will be removed and any previous information erased.

5.5 If the piece of equipment is to be used for Virus purification, it should be noted on the label, and an Infectious/Potentially Infectious sticker should be placed onto the label.

5.6 Performance of the above status labeling procedure will be documented in the MPR as prompted or on other appropriate records.

5.7 Record equipment operations according to ***SOP 21531, Equipment Logs***.

## 6.0 References and Related Documents

6.1 **BDP SOP *21531*** *Equipment/Facility Logs*

6.2 **Form 14150–01** *Dirty to be cleaned*

6.3 **Form 14150–02** *Cleaned quarantined*

6.4 **Form 14150–03** *Cleaned released for use*

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