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| **University of Washington,** **Harborview Medical Center****325 9th Ave. Seattle, WA, 98104****Transfusion Services Laboratory****Policies and Procedures Manual** | **Original Effective Date:** **January 1, 2013** | **Number:** **F6007-1** |
| **Revision Effective Date:** | **Pages:**  |
| **TITLE: Procedure and Process Validation Checklist** |

**Procedure or Validation Title:**

**Validator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Acceptance Criteria:** Task can be performed correctly and completely with valid results obtained, using only this procedure or process for direction. All questions must be answered in the affirmative.

**Instructions:** *Complete the following checklist by placing a check mark by the appropriate response. Add comments as needed.*

*Questions 1-5 to be completed by validator*

1. Is the title of the procedure or process defined and specific? \_\_\_\_yes\_\_\_\_no

 Initials\_\_\_\_Date\_\_\_\_\_

2. Is the purpose clearly defined and specific? \_\_\_\_yes\_\_\_\_no

 Initials\_\_\_\_Date\_\_\_\_\_

3. Is text sufficiently detailed to be understood and followed by \_\_\_\_yes\_\_\_\_no

 Staff?

 Initials\_\_\_\_Date\_\_\_\_\_

4. Can the task be completed correctly by following the \_\_\_\_yes\_\_\_\_no

 Instructions?

 Initials\_\_\_\_Date\_\_\_\_\_

5. Do the procedure or process outcomes or results meet the \_\_\_\_yes\_\_\_\_no

 acceptance criteria?

 Initials\_\_\_\_Date\_\_\_\_\_

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*Questions 6-7 to be completed by Manager or Designee*

6. Is the procedure or process or revision in compliance with \_\_\_\_yes\_\_\_\_no

 Regulatory requirements, if applicable?

 Initials\_\_\_\_Date\_\_\_\_\_

7. Analysis and Evaluation:

Attach end product / recommendation. Reviewed by\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_