1. **Purpose**

This procedure provides instructions for evaluating Illumina MiSeq instrument software updates to determine necessary actions to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *“insert laboratory name here”*.

1. **Scope**

This document applies to Illumina MiSeqused within the *(Your Lab / Branch, etc.)* for DNA or RNA sequencing.

1. **Related Documents**

|  |  |
| --- | --- |
| **Title** | **Document Control Number** |
| MiSeq Software Update Form |  |
| Illumina MiSeq Software Release Notes | *include applicable version* |

1. **Responsibilities**

|  |  |
| --- | --- |
| **Position** | **Responsibility** |
| All laboratory staff | * Ensure software is updated according to established laboratory guidelines * Follow documented software update process |
| Branch Chief / Team Lead | * Ensure documented procedures for the evaluation of software updates are established * Ensure documented procedures are followed * Review and approve the MiSeq Software Update Form |
| Quality Manager | * Ensure documented software update procedures are available to the end user * Review and approve the MiSeq Software Update Form |

1. **Procedure**
   1. Any updates to the equipment software require evaluation and approval prior to installation.
   2. Obtain the MiSeq Software Update Form and the Illumina MiSeq Software Release Notes
   3. ***Complete the MiSeq Software Update Form***
      * 1. Record the current and new software versions.Note: There are multiple components to the MiSeq software, record the current and new version numbers for each.
        2. Document the Illumina sequencing workflow(s) currently used in the laboratory.
        3. Review each bullet point in the software release notes and evaluate the following:
           1. Determine if the update affects the sequencing workflow used in the laboratory.
           2. Determine if the update potentially affects the sequencing data output results.
        4. Evaluate the action required to ensure the equipment functions as expected following the software updates:

| **Updates affect the sequencing workflow?** | **Updates potentially affect the sequencing data?** | **Required Action** |
| --- | --- | --- |
| No | No | None |
| Yes | No | None |
| Yes | Yes | Verification |

* + - 1. Install the software updates as directed in the release notes.
      2. If verification is required, proceed to step **5.3.7**; otherwise proceed to step **5.3.8**.
      3. Complete a verification run as described below prior to releasing the equipment back into service.
         1. Using a standard, well-characterized sample previously ran in the laboratory, perform a sequencing run.
         2. If the sequencing data obtained with the new software versions are comparable to the data obtained with the prior software versions, no further action is needed.
         3. If the sequencing data obtained with the new software versions are not comparable to the data obtained with the prior software versions, conduct a revalidation of the assay.
      4. Attach additional information as needed (e.g. Release Notes documentation, Verification / Validation data) to the MiSeq Software Update Form.
      5. Sign, date, and obtain applicable reviews and approvals.

1. **Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Rev #** | **DCR #** | **Change Summary** | **Date** |
|  |  |  |  |

1. **Approval**

Reviewed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_