**INFORMATION**

1. **Auditing Organization**

AO:  AOID#:

AO HEAD OFFICE ADDRESS:

1. **Assessment Program Manager (APM)**

Name:

Agency:

1. **Reason for the Technical Review**

[ ]  Initial recognition

[ ]  Annual technical review

[ ]  Re-recognition

[ ]  Escalation of AO nonconformity report

[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Results of Verification and Evaluation of the Assessment Reports**

 Y = Yes or N/A = Not Applicable; N = No; P/I = Partial/Inadequate; U = Unclear

**APPLICATION REVIEW FORM**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Y  | N | P/I | U |
| Current version of the form used? |  |  |  |  |
| Review Check list is completed? |  |  |  |  |
| If clarification needed, is there evidence that it was provided? |  |  |  |  |
| Comment: |
| Form signed and dated? |  |  |  |  |
| Comment: |

**STAGE 1 ASSESSMENT REPORT**

**Report #:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Y  | N | P/I | U |
| Current version of the Assessment Report used? |  |  |  |  |
| General Information accurate? |  |  |  |  |
| Assessment Findings clearly documented? |  |  |  |  |
| Recommendations with regards to Stage 2 On-Site Assessment clearly documented? |  |  |  |  |
| Assessment Report signed and dated? |  |  |  |  |
| Comment: |

**HO/CL STAGE 2 / SURVEILLANCE ASSESSMENT PLAN**

**Assessment Plan Reference: HO:**

**CL # 1:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Y  | N | P/I | U |
| Current version of the Assessment Plan form used? |  |  |  |  |
| General Information accurate? |  |  |  |  |
| Assessment dates and duration indicated in the plan confirmed in the reports? If not, was explanation provided |  |  |  |  |
| Comment:  |

**Head Office STAGE 2 / SURVEILLANCE ASSESSMENT REPORT**

**Report #**

[ ]  Stage 2 [ ]  Surveillance #\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  Y | N | P/I | U |
| Current version of the Assessment Report form used? |  |  |  |  |
| General Information accurate? |  |  |  |  |
| Assessment plan followed as approved and objectives met? If not, was justification provided? |  |  |  |  |
| Comment:  |
| Recommendations from Stage 1 were followed? |  |  |  |  |
| Comment:  |
| Assessment Findings clearly documented? |  |  |  |  |
| Comment: |
| Is the conclusion clearly documented? |  |  |  |  |
| Comment:  |
| Assessment Report signed and dated? |  |  |  |  |
| Major changes clearly documented? |  |  |  |  |
| Comment:  |
| **FINDINGS BY ASSESSMENT PROCESS** |
| MANAGEMENT PROCESS |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Any discrepancies or inaccuracies? |  |  |  |  |
| Comment:  |
| USE OF EXTERNAL RESOURCES |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment:  |
| MEASUREMENT, ANALYSIS & IMPROVEMENT |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment: |
| COMPETENCE MANAGEMENT |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment: |
| AUDIT & CERTIFICATION DECISION |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment:  |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment: |
| INFORMATION MANAGEMENT |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below |  |  |  |  |
| Comment: |

**Critical Location STAGE 2 ASSESSMENT REPORT**

[ ]  Not Applicable [ ]  Applicable

If applicable, copy; paste the *HO STAGE 2 ASSESSMENT REPORT**checklist*, including the applicable processes.

**Witness Audit Assessment Report (WA #1)**

**Report #**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  Y  | N | P/I | U |
| Was current version of the Assessment Report form used? |  |  |  |  |
| General Information accurate? |  |  |  |  |
| Comment:  |
| Assessment Findings summary (section 3.) clearly documented? |  |  |  |  |
| Comment: |
| Is the conclusion clearly documented? |  |  |  |  |
| Comment:  |
| Is the Audited Organization information accurate? |  |  |  |  |
| Comment:  |
| ASSESSMENT FINDINGS – AUDIT PLANNING AND AUDIT TEAM PREPAREDNESS |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment:  |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment:  |
| ASSESSMENT FINDINGS – AUDIT TEAM COMPETENCE AND BEHAVIOUR |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment:  |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Is there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below |  |  |  |  |
| Comment: |
| ASSESSMENT FINDINGS – MDSAP AUDITING APPROACH |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment:  |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment: |
| Are there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment: |
| ASSESSMENT FINDINGS – NONCONFORMITY AND FINAL REPORT |
| Is there enough evidence in support of the conclusion?  |  |  |  |  |
| Comment: |
| Is the conclusion adequate and reflecting the assessment evidence? |  |  |  |  |
| Comment:  |
| Are there any discrepancies or inaccuracies? If yes, please describe in the “comment” section below  |  |  |  |  |
| Comment:  |
| Is the Assessment Report signed and dated? |  |  |  |  |
|  |  |  |  |  |
|  |

**Witness Audit Assessment Report (WA #2)**

**Report #**

[ ]  Not Applicable [ ]  Applicable

If applicable, copy; paste the *Witness Audit Assessment Report checklist*.

**Witness Audit Assessment Report (WA #3)**

**Report #**

[ ]  Not Applicable [ ]  Applicable

If applicable, copy; paste the *Witness Audit Assessment Report checklist*.

**Special On-site Assessment Report**

[ ]  Not Applicable [ ]  Applicable

If applicable, copy; paste the *HO STAGE 2 ASSESSMENT REPORT checklist*, including the applicable processes.

**Review of Non-Conformities Status**

Fill the table below according to the following criteria:

1. The nonconformity comply with the requirements in clause 6.2 of IMDRF/MDSAP WG/N11FINAL:2014;
2. The grading of nonconformity complies with the requirements in clause 6.3 of IMDRF/MDSAP WG/N11FINAL:2014;
3. The remediation plan for Grade 1 or Grade 2 nonconformity has been deemed acceptable and complies with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014;
4. The remediation plans for Grade 3 or Grade 4 (result of recurrence) nonconformity(s) comply with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014 and has been deemed acceptable. The evidence that the actions have been implemented as planned was verified.

| **Activity** | **NC Report #** | **NC Grade** | **Verification of the above criteria** | **Resolution Status** | **NC****Status** | **Date of Closure** |
| --- | --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** |
| Stage2 HO |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
| Comments: |
| Stage2 CL |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
| Comments: |
| Surveillance #\_\_\_ |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
| Comments: |
| WA #1 |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
| Comments: |
| WA #2 |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
| Comments: |
| WA #3 |  |  |  |  |  |  |  |  |  |
| Comments: |
|  |  |  |  |  |  |  |  |  |
|  | Comments: |

**Recommendation by Assessment Program Manager**

**Check list for the analysis of the assessment activities and nonconformity reports**

**Please indicate “Not applicable” in the comments section when appropriate**

1. [ ]  All written nonconformities comply with the requirements in clause 6.2 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. [ ]  The grading of nonconformity(s) complies with the requirements in clause 6.3 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. [ ]  The remediation plans for Grade 1 or Grade 2 nonconformity(s) has been deemed acceptable and complies with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. [ ]  The remediation plans for Grade 3 or Grade 4 (result of recurrence) nonconformity(s) comply with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014 and has been deemed acceptable. The evidence that the actions have been implemented as planned was verified.

Comments:

1. [ ]  The TRRC and RAC have been informed if there was evidence of possible fraud, misrepresentation or falsification of evidence resulting in a Grade 4 nonconformity;

Comments:

1. [ ]  The TRRC and RAC have been informed if there was any complaint, or appeal from the Auditing Organization on a particular nonconformity and its outcomes;

Comments:

1. [ ]  Verify decisions on closure of any nonconformity and any appropriate follow-up which may include Special Remote Assessment or Special On-site Assessment.

Comments:

1. [ ]  Verified other information relating to a recognition decision.

Comments:

1. [ ]  Verified that conditions applied to a decision have been followed up.

Comments:

1. [ ]  Confirm or review of the assessment program.

Comments:

**Conclusion**

****

 APM

Date (YY-MM-DD):

****

 TRRC Chair

Date (YY-MM-DD):

**AIDE MEMOIRE: IMDRF N11 Rules**

**6.2 Nonconformity Reporting**

* Worded with factual and precise language;
* Enable the reader to comprehend the actual non-fulfillment that was detected during the assessment.

Each statement of nonconformity should:

* Identify the specific requirement which has not been met or adequately fulfilled.
* State how the specific requirement was not fulfilled; be supported by objective evidence (identify the extent of evidence (e.g. number of records) and - what exactly was found or not found, with an example(s); identify the location or basis (source document) for the evidence (e.g. in a record, procedure, interview, or visual observation)

Nonconformities identified against particular regulatory requirements may be raised under Clauses 6.1.1 (current audit practices and knowledge of medical device technologies), 8.2.1 (audit reports and certification documents) or other relevant clauses of IMDRF MDSAP WG N3.

**6.3 Grading Assessment Nonconformities**

The guiding principles for grading assessment nonconformities are the following:

* All nonconformities cited against ISO/IEC 17021:2011 will start as a minimum Grade 1;
* All nonconformities cited against IMDRF N3 and N4 will start as a minimum Grade 2. (N3 and N4 contain regulatory requirements);
* Assessors may elevate any minimum grade to a Grade 2, 3, or 4 if in their assessment they believe the grading rules below are met;
* If there is a recurrence of nonconformity of grade 1, 2 or 3 then the grade is escalated by one;

Grade 1 nonconformity: **unlikely** to have a direct impact on the Auditing Organization’s.

Grade 2 nonconformity: **likely** to have a direct impact on the Auditing Organization’s; and is **unlikely** to allow deficiencies in the manufacturer’s quality management system, or its implementation, to have a direct impact on the safety and performance of the medical device.

Grade 3 nonconformity: **likely** to have a direct impact on the Auditing Organization’s; and is **likely** to allow deficiencies in the manufacturer’s quality management system, or its implementation, to have a direct impact on the safety and performance of the medical device; Or when an Auditing Organization operates outside of the recognized and designated scope.

Grade 4 nonconformity: evidence involving possible fraud, misrepresentation or falsification of evidence of conformity per IMDRF/MDSAP WG/N3 Final:2013 clause 5.1.

**6.5 Remediation Plan**

Remediation plan includes: Investigation and cause analysis of the nonconformity(s) to date; Correction plan, as appropriate; and, Corrective action plan to include plans for systemic corrective actions and verification of effectiveness, as appropriate.

The documented remediation plan must be submitted within 15 working days from the day the nonconformity(s) was issued. Upon request, additional time may be granted by the recognizing Regulatory Authority for responses to Grade 1 or 2 nonconformities.

The Auditing Organization shall subsequently provide the recognizing Regulatory Authority(s) with evidence of implementation of correction and corrective actions for any nonconformities graded 3 or 4, according to the timeline confirmed by the recognizing Regulatory Authority(s) as an outcome of the review of the remediation plan. Any nonconformities graded 1 or 2 will be followed up on the next Assessment.

**6.6 Review of the Remediation Plan**

The recognizing Regulatory Authority(s)’s assessment team shall review the Auditing Organization’s remediation plan and determine if it is acceptable, in terms of: cause of nonconformity, actions identified, and the timeline for implementation of those actions. This review shall be documented. If deemed necessary, the recognizing Regulatory Authority(s) may require adjustments to the time limits specified in the submitted remediation plan to provide evidence of its implementation and effectiveness.

**6.7 Recommended Closure of Nonconformities**

The recognizing Regulatory Authority(s) assessment team shall recommend closure of the nonconformity only when the following criteria are met:

* for all nonconformities, the remediation plan, including the investigation and cause analysis has been deemed acceptable; and,
* for nonconformities graded 3 or 4, the recognizing Regulatory Authority(s) has verified the evidence that the actions have been implemented as planned.