Analytical Worksheet Review Form

Lead Analyst: _______________________________ Date Analysis Reported: ______________

Sample Number: __________________ Product: ________________________________

Technologies Covered: ___________________________________________________________________

Type of Analysis: Original ☐ Check ☐ Additional ☐ Other ☐ __________ PAC _________
(Mark the selection below that applies) MICRO ☐ DRUGS ☐ OTHER ☐

Quality Factors

I. SAMPLE MANAGEMENT, ACCOUNTABILITY, CHAIN OF CUSTODY

☐ ☐ ☐ 1. LIMS transfer screen shows receipt and agrees with worksheet entry.
☐ ☐ ☐ 2. The analyst initiates a new worksheet whenever a sample is received from the Sample Custodian, or for check or additional analysis.
☐ ☐ ☐ 3. If an analyst uses a temporary seal to maintain sample integrity, the analyst records on the worksheet that a temporary seal was used, how it was used, and records the seal quote.

II. ANALYST’S WORKSHEET. INFORMATION ON THE WORKSHEET IS COMPATIBLE WITH THE COLLECTION REPORT AND OTHER SUPPORTING DOCUMENTATION.

☐ ☐ ☐ 1. The analyst describes the sample, seal inscription and seal condition as received, compares with the Collection Report (C/R), documents discrepancies.
☐ ☐ ☐ 2. The analyst states collection identification of sub samples and collector’s sub numbers and describes types and numbers of containers.
☐ ☐ ☐ 3. On the worksheet, product name is consistent with C/R terminology.
☐ ☐ ☐ 4. The analyst identifies each label with a sample number, date and initials directly on the label and identifies labels prior to copying the label.
☐ ☐ ☐ 5. Labels are properly stapled on mounting paper and two-sided labels are easily reviewed.
☐ ☐ ☐ 6. The analyst lists the code(s) with the applicable expiration date and notes any discrepancies with the collection report, and if the code is not present, but is given on the C/R, the analyst refers to the C/R on the worksheet.
☐ ☐ ☐ 7. All analysts involved in the sample analyses, sign the front sheet of the worksheet and each analyst dates and initials his/her work on the worksheet. If applicable, the analysts who broke the seal are shown in 12a.
III. THE ANALYST USES METHODS CONSISTENT WITH THE APPROPRIATE COMPLIANCE PROGRAM GUIDE, ASSIGNMENT OR SUPERVISOR’S SUPERVISOR’S INSTRUCTIONS.

1. The analyst lists the purpose of analysis and records the number of unit analyzed.
2. Sample analysis is consistent with C/R, program, and/or request.
3. The analyst lists the method of analyses containing the page # (s) or paragraph numbers (as applicable), edition or date of revision.
4. If an analyst develops a method, it is validated and contains the complete method on worksheet or the method is attached as a memo.
5. The analyst explains on the worksheet any deviations from the referenced method.
6. Methods quoted are compared with entries reported in LIMS.

IV. SAMPLE RESERVE OR DISPOSITION IS CORRECTLY REPORTED.

1. Describes the reserve sample clearly and includes the amount of reserve remaining to include the weight, volume or count.
2. Records any incompatibility between the amount received, amount used and the
3. If no reserve is remaining, the analyst writes, "No reserve” or "None” and should be on LIMS Sample Transfer Screen.
4. If the reserve sample is not returned to the sample custodian, how and why it was not returned to normal storage must be recorded on the worksheet.
5. Documents any sample or sample portions transferred among analysts within the laboratory on the worksheet noting what was provided, to whom, date, and reason for transfer.
6. Documents any sample or sample portions mailed outside the laboratory on the worksheet noting what was provided, to whom, date, how much, how it was sealed and the reason for mailing the sample or sample portions and has utilized “sample
7. If the analyst removes a seal from the sample package, the analyst submits the seal with the worksheet as an attachment and explains under Block #11, Reserve Sample, that the seal is attached.
8. LIMS Sample Transfer Screen shows return of sample to Sample Custodian (if applicable).

V. REPORTING LABORATORY DATA

1. Electronic templates/forms, spreadsheets and abbreviated worksheets have Laboratory Director written approval for use (approved H: drive versions
2. If an analyst makes an error, that analyst lines out the incorrect entry,
3. The analyst lines out discarded results on the worksheet, dates and initials and explains why the results were not used in the analysis.
4. If data is generated for a series of similar samples, the worksheet containing the original data is referenced on each subsequent worksheet package.
5. Sample #, date, and initials are included on attachments, worksheet backs, and/or mounting paper for attachments and labels.
6. Sample Analysis Data entered into LIMS agrees with worksheet.
7. Results are reported to include unit identification, correct number of significant figures, and compared with label declarations, published tolerances and standards, or other acceptable criteria.
WORKSHEET CALCULATIONS ARE ACCURATE, EASY TO FOLLOW AND ARE VERIFIED.

1. Calculation checks are performed, if applicable.
2. If a computer program is used to generate results, the name of the spreadsheet and version number is included on the worksheet.
3. The analyst records raw data directly on the worksheet or directly into a computerized spreadsheet.

VI. QA/QC DATA

Chemical methods (Quantitative):
1. Duplicate Standard within range specified.
2. Duplicate Sample within range specified.
3. Reagent Blank analyzed
5. Matrix/reagent spike recovery as specified.
6. Validation data of non-standard or new product is provided.

Chemical methods (Qualitative):
1. Blank analyzed.
2. Positive Control analyzed.
3. Spike prepared and analyzed.
4. Duplicate sample analyzed.

VIII. THE USE OF APPROPRIATE STANDARDS, REAGENTS, AND EQUIPMENT IS DESCRIBED ON THE WORKSHEET

1. The analyst lists instruments (ID number) and instrument settings on the worksheet or attaches instrument printouts containing this information.
2. The analyst lists full name, source, and lot number for all reference standards. If applicable, list any pertinent preparation conditions (e.g. drying).
3. Proper data entered on the calibration and maintenance charts for instruments/equipment used during analysis.

IX. OTHER

1. Sample analysis timeframes are met.
2. Laboratory classification is supported by the information on the worksheet and in LIMS and consistent with applicable guidelines. Check analysis is performed if necessary.
3. Analytical results are provided to appropriate individuals.

Comments/Investigation (including root cause):

Corrective Action (including Follow-up/ findings):

Reviewer’s Signature: ___________________________ Date: _______________
Laboratory Supervisor’s Signature: ___________________________ Date: _______________
Analyst’s Signature: ___________________________ Date: _______________
Quality System Manager’s Signature: ___________________________ Date: _______________