

APPENDIX E

PERFORMANCE EVALUATION AUDIT

CHECKLIST EXAMPLE

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PERFORMANCE EVALUATION AUDIT CHECKLIST EXAMPLE

The Computer Audit Checklist provides guidelines for evaluating the adequacy of a computer that could be used to calculate emissions, store inventory data, and generate tables of results for the final inventory report. The testing, calibrating, and evaluation of operating procedures of instruments are all important for assuring the quality of data; a computer is also an instrument and should be treated as such. Because of the dependence of the inventory staff on computers to complete the inventory, an assessment of the testing, operation, and use of the computer would be one of the most important audits conducted during the planning and development phases of the inventory.

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**AUDIT CHECKLIST
COMPUTER DATA ACCURACY**

Procedure: Select a date with results passing and not passing quality acceptance criteria, if possible. Determine if reported results accurately reflect the raw data. Use an alternate method to verify the accuracy of computer manipulations to yield calculated results.

	Yes	No	NA
1. Identify data maintained only on the hard drive <hr/> <hr/> <hr/> <hr/>			
2. Locate and identify data maintained on hard copies <hr/> <hr/> <hr/> <hr/>			
3. Are quality control data referenced to sample results? (standards, blanks, calibrations, replicates, duplicates, spikes, instrument conditions, surrogates, internal standards, etc.) - LAB DATA <hr/> <hr/> <hr/>			
a. Are the references to quality control data protected or can they be easily changed?			

	Yes	No	NA
b. Are the references sufficient to associate quality data with individual sample results?			
4. Are data outside of acceptance criteria flagged?			
a. If yes, are actions taken described?			
5. Are the detection limits for target analytes clearly defined or referenced in the raw data? (LAB)			
a. Are they accurately represented in the report?			
b. Were changes made to reflect dilutions?			
6. Are the data reduction steps defined in a written procedure?			
a. Is the procedure sufficient to recalculate results?			
b. Are the data sufficient to verify results?			
c. Were errors found in the data verified?			
If Yes, explain and identify results: _____ _____ _____ _____ (use additional comment sheet if necessary)			
7. Are the data accurately reported?			
a. Are the units accurate?			
b. Are the data accurately flagged to note bias or confidence in the results reported?			
8. Can results be traced back to the original data associated with a specific test article or data set?			
If not, describe problem: _____ _____ _____ _____			

**AUDIT CHECKLIST
COMPUTER PROGRAM DOCUMENTATION AND VALIDATION**

	Yes	No	NA
1. Are the following documents present			
a. Software management plan			
b. Software development plan and results			
c. Software test and acceptance plan			
d. Software User's operations document			
e. Software maintenance document			
f. Assessment of hardware			
2. Are the following documented:			
a. Program			
b. Table of definitions			
c. System size and timing requirements			
d. Definitions of subsystems			
e. Requirements for:			
-- Hardware			
-- Electricity			
-- Security			
f. Backup and disaster recovery procedures			
g. Quality requirements for:			
-- Reliability			
-- Maintainability			
-- Flexibility for expansion			
h. Testing procedures			
3. Does software management include the following:			
a. Independent validation			

	Yes	No	NA
b. Definitions/identifications of interfaces			
c. Definition of software tools			
-- Identification of program language			
-- Identification of network software requirements			
d. Configuration control (Control, release, and storage of master copies)			
4. Is there a flow chart or text showing functional flow?			
5. Are input and output fields identified?			
6. Are there written procedures for software revisions?			
a. Are revisions tested to determine how the entire program is affected? _____ _____			
b. How are revisions implemented? _____ _____			
c. Are revisions documented? _____ _____			
7. Does the User's Guide or software description include:			
a. Description of system (hardware)			
b. Identification of person to contact when problems occur			
c. How to access the system			
d. How to input data			
e. How to generate reports			
f. How to update data			
g. Description of error codes			
h. Procedures to follow if the system goes down			

	Yes	No	NA
8. Do testing procedures include the following:			
a. Description of test procedures to perform			
b. Expected outcome			
c. Documentation of results			
d. Recommendation for handling problems			
9. Has security be addressed (Statements or passwords to safeguard accuracy of computer program operation)?			
10. Can someone knowledgeable of the program language understand from reading the program what it does to the data to yield the expected or desired results (if not, explain on separate page)			

**AUDIT CHECKLIST
COMPUTER PROGRAM OPERATION**

	Yes	No	NA
1. Is a password required to access the system?			
2. Operator Training			
a. Are operators adequately trained?			
b. Is training documented?			
3. When testing the system, are there system delays that hamper the job?			
4. Are error messages given if an entry error is made (ex. data out-of-range)?			
5. Does the system prevent entry of data which are out-of-range?			
6. Are there prompts if fields are missed that are required for data manipulations?			
7. How are default parameters assigned by the system? _____			

8. Does the system carry over data from one screen to the next in order to minimize entry errors?			
9. Are data entered into the central database via a computer readable media? If yes, does the data include information concerning:			
a. The source of the data			
b. When the data were collected			
c. Conditions under which collected			
d. Pointers to link data to quality control data			

	Yes	No	NA
e. Quality control (QC) flags indicating the level of data acceptability			
10. If the data are entered by prompting the system to access a previously existing data file, are the data validated by			
a. Comparison of #/size of files transferred			
b. A log which documents files transferred			
c. Documenting or creating a record of the data, date, and name of the person transferring the data			
d. Periodic audits of data transfer			
-- Are audits documented?			
11. Are data entered into the central data system via a link from an instrument? If yes, is the following information given			
a. Data generated			
b. Date and time generated			
c. Identification of the instrument			
d. QC flags indicating the level of acceptability of the data			
e. Instrument conditions (operating) (Lab)			
12. If data are entered by direct link from an instrument is the data validated by...			
a. Voltage or calibration checks			
b. Comparison of results			
c. Comparison of hardcopy output with database contents			
d. Are data reasonableness checks either built into the data capture system or instruments?			
13. Data changes			
a. How are the data corrections made? _____			
b. Are corrections verified?			

	Yes	No	NA
c. Are corrections documented on a written log (who, when, authorization)			
d. Is there a computer generated record of the changed and unchanged data?			
e. If changes were made to data transferred from another source, was the original source corrected?			
f. If changes are made in flags from a central data base -- Who determines the need to make the change? _____			
-- Is authorization for revision documented?			
-- Is the change adequately documented?			
14. Data Reduction, Analysis and Assessment			
a. If data quality flags are used, are they defined			
b. Are qualifying flags correct?			
c. Can new flags be created? If so, how are they created? _____ _____ _____			
d. Are the mathematical expressions used by the system available in a written format?			
e. Were the mathematical expressions reviewed for accuracy?			
f. Was the validation of mathematical expression documented?			
g. Did revisions affect the over-all performance of data manipulations?			
h. If mathematical expressions are modified, -- Is the reason for the modification documented?			
-- Are old data recalculated with new formulas?			

	Yes	No	NA
i. Are printouts of report modifications routinely checked for accuracy? -- By whom _____ -- Documented _____ -- Percent checked ____%			
15. Data output			
a. Are there written procedures for generating data output (graphs, charts, reports)			
b. Are the data used to generate the output adequately identified			
c. After final output are generated, is the database "locked" so that no further changes can be made without managerial consent			
d. Are output generated in a timely fashion (unusual delays be database)			
e. Are final copies of output properly archived			
-- Secure			
-- Precaution against fire			
-- Limited access			
f. Are reports electronically generated?			
g. If reports are electronically generated, how is it done?			
-- Direct computer link			
-- Magnetic media			
-- Verified upon transmission			
16. Backups			
a. Are system backups performed?			
b. If backups are performed, indicate frequency _____			
c. Are backups partial or total?			

	Yes	No	NA
d. Is there an individual responsible for backups? If so, who? _____			
e. On what media are backups stored			
-- Magnetic tape			
-- Disks			
-- Diskettes			
-- Other _____			
f. Are media storing backups properly labelled?			
g. Are backups documented?			
-- Written log			
-- Project identified			
-- Computer system identified			
-- Other _____			
h. How are data from backups stored short term _____			
i. How are backup data stored long term _____			
j. Are the backup data arranged for expedient retrieval from the storage area(s)?			
k. Are long-term backup data stored off site or in a location other than the original data?			
l. Is the data storage area adequate?			
-- Security assured			
-- Access limited			
-- Fire precautions			
-- Environmentally controlled			

	Yes	No	NA
17. Hardware maintenance			
a. Are there procedures for conducting and documenting preventative maintenance?			
b. Is there a regularly scheduled preventative maintenance program? Frequency _____			
c. Is preventative maintenance documented (who, what, when)? _____			
d. Is non-routine maintenance performed by in-house staff? If yes, how is it documented? _____ _____ _____			
e. How is non-routine maintenance documented? _____ _____ _____			
f. What provisions, if any, are made for system downtime? _____ _____ _____			

	Yes	No	NA
g. Has downtime adversely affected the project? If yes, explain _____ _____ _____			
h. If the system fails because of electrical glitches or power outage what happens to the system? _____ _____ _____			
-- Backup power source available _____			
-- Backup starts automatically or manually _____			
-- How are power failures indicated if the system is running? _____			
-- Does the system lose the data being processed? _____			
-- Does the system start where it left off? _____ _____			

	Yes	No	NA
-- If data are lost, does the system indicate the loss? _____			
-- While the system is running, is there a backup procedure to minimize the data loss if the system goes down? _____			
-- If the system goes down is the time down and time restored easy to determine? _____			

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