Form Group:	Facility Inspection
Packet ID:	FI-
Location:	
Date:	
Closed:	

A. Facilities	
Yes, No, N/A	
1. Facility is of suitable size:	
2. Adequate working areas:	
3. Facility appears clean/well maintained:	
4. Satisfactory facilities for sanitation:	
B. Test Control and Reference Substance	
Yes, No, N/A	
5. Are there separate areas for: :	
a. receipt and storage of test/control/reference substances?:	
b. storage of test/control/reference substances mixtures? :	
c. test substance mixing? :	
6. Receipt and usage:	
a. receipt and condition upon receipt documented:	
b. bulk inventory log maintained:	
c. adequate usage/accountability documentation:	
d. SOP followed:	
7. Storage::	
a. limited access:	
b. environmentally controlled if necessary:	
c. Is temperature continuously monitored? :	
d. calibration of temperature monitoring device per SOP.:	
e. temperature range adequate for compound integrity:	
f. storage area adequately ventilated:	
8. Test/control/reference substances properly labeled. :	
a. name, CAS or code number:	
b. batch number:	
c. expiration date:	
d. storage conditions:	
9. Test/control/reference substance storage neat and organized:	
C. Equipment	
Yes, No, N/A	
10. Equipment cleaned as per SOP.:	
11. Equipment designed as per SOP:	
12. Equipment located as per SOP. :	

13. Equipment appears to be in good repair:	
14. Equipment adequately stored when not in use:	
15. Maintenance logs on equipment up-to-date:	
a. contains standardization/calibration records:	
b. specifies routine and non-routine maintenance:	
c. specifies whether or not SOP was followed for routine maintenance:	
d. specifies nature of defect or routine maintenance :	
e. specifies how and when defect was discovered:	
f. specifies remedial action taken in response to defect:	
16. Maintenance/calibration/standardization/cleaning per SOP. :	
17. Owner's manual easily accessible:	
18. Maintenance logs easily accessible:	
D. Test System Sample Storage	
Yes, No, N/A	
19. Separate from test/control/reference standard storage area:	
20. Clean, organized free from contamination:	
21. Limited access:	
22. Tracking/accountability system in place and adequate:	
23. control/treated adequately separated:	
24. Temperature continuously recorded:	
25. Recording devices adequately calibrated/standardized:	
26. Maintenance logs on freezers up to date:	
a. Specifies routine and non-routine maintenance:	
b. Specifies whether or not SOP was followed for routine maintenance:	
c. Specifies nature of defect for non-routine maintenance:	
d. specifies how and when defect was discovered:	
e. specifies remedial action taken in response to defect.:	
27. Maintenance log readily available:	
E. General Laboratory	
Yes, No, N/A	
28. Work area neat, clean, uncluttered:	
29. Proper storage of clean glassware:	
30. SOP book available in work areas:	
31. Appropriate dress procedures are followed:	
32. All reagents/solutions properly labeled:	
a. identity:	
b. titer/concentration:	
c. storage conditions:	
d. expiration date:	

33. No reagents/solutions out of date:	
34. Proper storage maintained for all reagents/solutions:	
35. Have SOPs addressing safety issues been followed?:	

F. Standard Operating Procedures
Yes, No, N/A

36. Have SOPs been approved by management according to IR-4 Operational Handbook (IR-4 Regional Management)?:	
37. Is there an effective date for each SOP?:	
a. Did CRO TFM review SOP?:	
38. Is there a revision number? :	
39. Are SOPs appropriately retained after revision?:	
40. Are there procedures in place for replacing revised SOPs and ensuring that old SOPs are not available for use?:	
41. Are required SOPs in place (160.81)?:	
a. test system area preparation:	
b. test system care:	
c. receipt, ID, storage, handling, mixing & method of sampling test/control/reference substances:	
d. test system observations:	
e. laboratory or other tests:	
f. handling of test system found dead during study:	
g. necropsy:	
h. collection and ID of specimens:	
i. histopathology:	
j. data handling, storage & retrieval:	
k. maintenance & calibration of equipment:	
l. transfer, proper placement & ID of test systems:	
42. Do SOPs accurately reflect current procedure?:	
43. a. Are there procedures in place for periodic review of SOPs to maintain accuracy?:	
b. Are SOP review intervals being followed?:	
44. Is there an index for the SOPs?:	
45. SOP available on each piece of equipment:	
a. routine inspection/maintenance intervals specified:	
b. calibration/standardization procedures specified:	
c. remedial action to be taken in case of malfunction or power failure specified:	
d. person responsible for performance of each operation:	
46. SOPs readily available:	

G. Personnel Records

Yes, No, N/A	
47. Training Records:	
a. are current:	
b. are being reviewed periodically as per SOP:	
c. document recent GLP training:	
d. document procedural training as per SOP. :	
48. CV's:	
a. provide adequate detail of past experience:	
b. provide adequate detail of education:	
c. provide adequate detail of formalized training/meetings:	
d. have been updated according to SOP:	
49. Current job descriptions available for all personnel:	
50. GLP personnel files maintained after departure:	
H. Management of Facility Yes, No, N/A	
51. Had an EPA/FDA inspection:	
52. Have all deficiencies been corrected?:	
53. Is organization chart available? :	
54. Does organization chart adequately describe reporting structure?:	
55. Is a floor plan available?:	
56. Is the facility adequately staffed?:	
I. Archives Yes, No, N/A	
57. Are the archives adequate?:	
a. limited access:	
b. neat and orderly:	
c. environmentally controlled:	
58. Have precautions to prevent deterioration of the raw data been addressed?:	
59. Are procedures in place for logging data in and out?:	
60. Is the material indexed to expedite retrieval?:	
61. Is there a designated archivist? :	
62. Is a backup archivist designated?:	
63. How long are raw data maintained?:	
J. Quality Assurance Yes, No, N/A	
64. Is there an independent QA unit reporting directly to management?:	
65. Does the QA conduct periodic facility inspections:	
66. How often?:	
67. Does QA inspect critical phases of each study?:	
68. Does QA audit all reports? :	

69. How much of a data check is done (comment)?:	
70. Are Study Directors and testing facility management allowed to see all QA findings?:	
71. Does the QA maintain a copy of the Master Schedule?:	
72. Is the status of each study adequately documented? :	
73. Are all required elements on the Master Schedule?:	
a. indexed by test substance:	
b. test substance identified:	
c. nature of the study:	
d. date study was initiated:	
e. current status:	
f. identity of sponsor:	
g. name of study director:	
74. Are all QA records easily accessible and properly indexed?:	
75. Is the QA statement included in the report?:	
76. Are QA SOPs adequate?:	
78. Is the QA adequately staffed?:	
77. Does the QA offer periodic GLP training?:	
79. Does the QA appear to have management support?:	
81. Does the QA have a copy of the final regulation?:	
80.Does the QA maintain a copy of all signed approved protocols?:	