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Regulatory Guide 6.9 - Appendix A

Checklist for Auditing QA Programs

The checklist in this appendix is designed as an aid in auditing an applicant's quality assurance (QA) program. The checklist is designed as an aid and may not be all-inclusive. In addition, certain items may not be applicable to all applicants.

The checklist is designed to assign different ratings to the adequacy and implementation of each component of an applicant's QA program. Y = yes, N=no, N/A = not applicable

	Rating* Program/Implementation		Comments
1. Does the vendor have a QA manual or set of instructions defining the QA program?	y	y	
2. Is the manual up to date?	y	y	
3. Is the manual approved and signed by a designated official from each department?	y	y	
ORGANIZATION			
4. Is the organizational structure of the applicant documented in the QA manual?	y	y	
5. Are all the QA personnel listed, along with all their responsibilities?	y	y	
6. Is the QA Director someone in upper management not directly responsible for manufacturing or production?	y	y	Chris Hill
7. Does the QA Director have continual involvement in the QA program?	y	y	

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	Rating* Program/Implementation		Comments
8. Is the NRC Contact listed and up to date?	y	y	
9. Do the QA Manager and QA Director have the authority to halt production?	y	y	
PERSONNEL			
Does the applicant have procedures to ensure up-to-date records of:	y	y	
10. All employees' qualifications?	y	y	
11. All employees' training?	y	y	
12. All employees' indoctrination?	y	y	
13. All employees' medical records?	Y	Y	Health information form only
14. All training procedures?	y	y	
15. All indoctrination procedures?	y	y	
16. All employees qualified to perform special procedures or testing?	y	y	
17. Are items 10 through 16 up to date?	y	y	
EQUIPMENT			
18. Does the applicant have a historical log of all its equipment?	y	y	
19. Does the log include manufacturer, model and serial number, and instructions for use?	y	y	
20. Are there procedures for and records of routine and unscheduled maintenance of equipment?	y	y	

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	Rating* Program/Implementation		Comments
21. Does the applicant have a calibration log that includes: • manufacturer? • model and serial number? • calibration procedures? • frequency • qualified calibration personnel? • date calibrated • date due for calibration?	y*	y*	*except qualified Personnel
22. Are all calibrations, either performed by the applicant or supplier, traceable to the National Institute of Standards and Technology or equivalent?	y	y	NIST or UKAS
23. Are all calibration cycles reasonable and less than 1 year?	y	y	
24. Does the calibration ensure that all equipment is recalibrated before its expiration date?	y	y	
25. Is all equipment marked with calibration date, due date, and the person who performed the calibration?	y*	y	Not person
26. Is all equipment traceable back to calibratio record?	y	y	
27. Where applicable, is equipment labeled with special handling or storage instructions?	y	y	
28. Is all new equipment or equipment that has undergone maintenance calibrated before use?	y	y	

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	Rating* Program/Implementation	Comments
DESIGN AND DOCUMENT CONTROL		
29. Are there procedures for ensuring that all documents contain all pertinent information and conform to all pertinent regulations and specifications?	y	y
30. Are there procedures for handling document and design changes?	y	y
31. Do the procedures ensure that all appropriate departments are notified of the changes?	y	y
32. Do the procedures ensure that documents under revision are not used?	y	y
33. Are all changes documented?	y	y
34. Do the procedures ensure the documents and changes are checked and approved before released?	y	y
35. Do the procedures include notifying regulatory agencies of any changes?	y	y
36. Do the procedures ensure alternative approaches in the absence of specifications?	y	y
37. Is there a history file, for each document, that includes previous versions, document changes, and reasons for the changes?	y	y
38. Are the copies on file of all up-to-date documents for each job?	y	y

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	Rating* Program/Implementation		Comments
39. Are there procedures for verification of the adequacy of suppliers?	y	y	
40. Are there records of all audits of suppliers?	N/A	N/A	
41. Are audits of suppliers performed at intervals less than 3 years?	N/A	N/A	
42. Are there procedures for receipt inspection?	y	y	
43. Do receipt inspection procedures verify: • correct sizes? • quantity? • document and specification conformance? • paperwork?	y	y	
44. Are there procedures for receipt of nonconforming material?	y	y	
45. Are there records of receipt inspections, including nonconforming material?	y	y	
46. Do all purchase orders contain: • scope of work? • technical requirements? • identification of the documents that must accompany the order? • identification of the records that the applicant must keep? • signature of the appropriate individual?	y	y	
47. Are there records of all purchases?	y	y	
48. Are there inventory procedures?	y	y	

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	Rating* Program/Implementation		Comments
49. Do inventory procedures include: • special handling? • marking? • tagging? • labeling? • segregating? • paperwork procedures? • handling of nonconforming material?	y	y	
50. Does the inventory system have provisions for material with shelf life?	y	y	
51. Does the inventory system have provisions to ensure that the correct material is used in production?	y	y	
52. Are periodic physical inventories performed?	y	y	
53. Does the system ensure that products that are marked or segregated as complete have passed their final inspections and testing?	y	y	
54. Are there procedures that describe production processes?	y	y	
PRODUCTION PROCEDURES AND PROCESSES			
55. Do the procedures include: • machinery and equipment to be used? • qualifications of workers? • equipment settings? • hold points for inspection and testing?	y	y	

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	Rating* Program/Implementation		Comments
56. Is there a flowchart describing the flow of material and inspection hold points?	y	y	
57. Are there procedures for in-process and final inspection and testing of the device?	y	y	
58. Do inspection procedures include: • acceptance criteria? • receipt criteria? • at what points to perform in-process inspections and tests? • procedures for determining sample sizes? • procedures for final inspection and testing? • provisions for nonconforming material?	y	y	
59. Are there records for inspections of production procedures?	y	y	
60. Are there records of all inspections and testing, including date and person performing inspection or test?	y	y	
61. Is there a system for marking or segregating items that have been inspected or tested?	y	y	
62. Does final inspection include operational check and removal contamination test of 100% of the devices?	y	y	
NONCONFORMING MATERIALS			
63. Are there procedures for handling nonconforming items received from a supplier or customer or found during production?	y	y	
64. Are nonconforming materials tagged or segregated from production?	y	y	

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	Rating* Program/Implementation		Comments
65. Are there procedures for disposition of nonconforming materials and for introducing materials back into production?	y	y	
66. Are there records of nonconforming material?	y	y	
PACKAGING AND TRANSPORTATION			
67. Are there procedures for inspecting packaging and the form of transportation?	y	y	
68. Do these procedures ensure that all paperwork and manuals are included with the shipment or are being shipped separately to the customer?	y	y	
69. Are there records of all packaging and shipping reports and inspections?	y	y	
DEVIATIONS AND CUSTOMER COMPLAINTS			
70. Are there procedures for evaluating deviations and customer complaints?	y	y	
71. Are there procedures for informing the appropriate members of the organization and the NRC of deviations	y	y	
72. Are there procedures for informing customers of devices that may contain a deviation?	y	y	
73. Are there records of all deviations and customer complaints?	y	y	

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	Rating* Program/Implementation		Comments
74. Do customer complaint records contain: • name of complainant? • nature and date of complaint? • corrective action taken? • cause of failure? • model and serial number of the device?	y	y	
75. Are there procedures for trend analysis of deviations and complaints?	y	y	
76. Is trend analysis performed at intervals that do not exceed 1 year?	y	y	
AUDITS			
77. Does the applicant have procedures for auditing its QA program?	y	y	
78. Do the procedures include acceptance criteria?	y	y	
79. Do the procedures ensure that all records and procedures are up to date?	y	y	
80. Do audits include verification of audits of suppliers?	N	N	
81. Is the auditor responsible for any of the matters being audited?	N	N	Auditor not responsible
82. Do records include deficient areas in the program and corrective action taken?	y	y	
83. Are all deficient areas corrected?	y	y	

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	Rating* Program/Implementation		Comments
84. Are all records signed and dated by the appropriate member of the organization?	y	y	

Max Allsworth

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Date