The checklist in this appendix is designed to help the applicant or the Sealed Source and Device license reviewer in reviewing quality assurance (QA) programs for completeness. The checklist is designed as an aid and may not be all-inclusive. In addition, certain items may not be applicable to all applicants.

Table G.1 Checklist for Reviewing QA Programs

Questions	Program/Implementation		Comments
	Yes	No	
1. Does the vendor have a QA manual or set of instructions defining the QA program?	✓		
2. Is the manual up to date?		✓	is a draft
3. Is the manual approved and signed by a designated official from each department?		✓	
ORGANIZATION			
4. Is the organizational structure of the applicant documented in the QA manual?	✓		
5. Are all the QA personnel listed, along with all their responsibilities?	✓		
6. Is the QA Director someone in upper management not directly responsible for manufacturing or production?	✓		
7. Does the QA Director have continual involvement in the QA program?	✓		
8. Is the NRC contact listed and up to date?	✓		Is this applicable for the foreign manufacturer or the U.S. distributor
9. Do the QA Manager and QA Director have the authority to halt production?	✓		

RAM QA program reviewed by

6/14/2013

John Jankovich 6/18/2013

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
PERSONNEL			
10. Does the applicant have procedures to ensure up-to-date records of all employees' qualifications?	✓		
DESIGN AND DOCUMENT CONTROL			
11. Are there procedures for ensuring that all documents contain all pertinent information and conform to all pertinent regulations and specifications?	✓		
12. Are there procedures for handling document and design changes?	✓		
13. Do the procedures ensure that all appropriate departments are notified of the changes?	✓		
14. Do the procedures ensure that documents under revision are not used?	✓		
15. Are all changes documented?	✓		
16. Do the procedures ensure the documents and changes are checked and approved before release?	✓		
17. Do the procedures include notifying regulatory agencies of any changes?	✓		
18. Do the procedures ensure alternative approaches in the absence of specifications?	✓		

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
19. Is there a history file, for each document, that includes previous versions, document changes, and reasons for the changes?	✓		
20. Are copies on file of all up-to-date documents for each job?	✓		
21. Are there procedures for verifying the adequacy of suppliers?	✓		
22. Are there records of all audits of suppliers?	✓		
23. Are audits of suppliers performed at intervals less than 3 years?	✓		
24. Are there procedures for receipt inspection?	✓		
25. Do receipt inspection procedures verify:			
• correct sizes? • quantity? • document and specification conformance? • paperwork?	✓		
26. Are there procedures for receipt of nonconforming material?	✓		
27. Are there records of receipt inspections, including nonconforming material?	✓		

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions		Program/Implementation		Comments
		Yes	No	
28.	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?		NR*	
29.	Are there records of all purchases?		NR	
30.	Are there inventory procedures?	✓		
31.	Do inventory procedures include:			
	• special handling? • marking? • tagging? • labeling? ✓ • segregating? • paperwork procedures? • handling of nonconforming material? ✓		NR	
32.	Does the inventory system have provisions for material with shelf life?	✓		
33.	Does the inventory system have provisions to ensure that the correct material is used in production?	✓		

* NR – Not Reviewed for performing the SSD safety evaluation

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
34. Are periodic physical inventories performed?	✓		
35. Does the system ensure that products that are marked or segregated as complete have passed their final inspections and testing?		NR	
PRODUCTION PROCEDURES AND PROCESSES			
36. Are there procedures that describe production processes?	✓		
37. Is there a flowchart describing the flow of material and inspection hold points?	✓		IO-100
38. Are there procedures for in-process and final inspection and testing of the device?	✓		
39. 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?		NR	
40. Are there records for inspections of production procedures?	✓		

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
41. Are there records of all inspections and testing, including date and person performing the inspection or test?		NR	
42. Is there a system for marking or segregating items that have been inspected or tested?		NR	
43. Does final inspection include an operational check and removal contamination test of 100% of the devices?		NR	
NONCONFORMING MATERIALS			
44. Are there procedures for handling nonconforming items received from a supplier or customer or found during production?		NR	
45. Are nonconforming materials tagged or segregated from production?		NR	
46. Are there procedures for the disposition of nonconforming materials and for the introduction of materials back into production?		NR	
47. Are there records of nonconforming material?		NR	
PACKAGING AND TRANSPORTATION			
48. Are there procedures for inspecting packaging and the form of transportation?		NR	

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Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
49. Do these procedures ensure that all paperwork and manuals are included with the shipment or are being shipped separately to the customer?		NR	
50. Are there records of all packaging and shipping reports and inspections?		NR	
DEVIATIONS AND CUSTOMER COMPLAINTS			
51. Are there procedures for evaluating deviations and customer complaints?	✓		
52. Are there procedures for informing the appropriate members of the organization and the NRC of deviations?	✓		
53. Are there procedures for informing customers of devices that may contain a deviation?		NR	
54. Are there records of all deviations and customer complaints?		NR	
55. 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?	✓		

Table G.1 Checklist for Reviewing QA Programs (continued)

Questions	Program/Implementation		Comments
	Yes	No	
56. Are there procedures for trend analysis of deviations and complaints?		NR	
57. Is trend analysis performed at intervals that do not exceed 1 year?		NR	
AUDITS			
58. Does the applicant have procedures for auditing its QA program?	✓		
59. Do the procedures include acceptance criteria?	✓		
60. Do the procedures ensure that all records and procedures are up to date?	✓		
61. Do audits include verification of audits of suppliers?	✓		
62. Is the auditor responsible for any of the matters being audited?		NR	
63. Do records include deficient areas in the program and corrective action taken?		NR	
64. Are all deficiencies found during audits corrected in a timely manner?		NR	
65. Are all records signed and dated by the appropriate member of the organization?		NR	