Item No	Checklist for Reviewing QA Programs for compliance with NUREG 1156 vol 3 revision 1 Appendix G	Y/N	Comments
1	Does the applicant have a QA manual or a set of instructions defining the QA program?		
2	Is the manual up to date?		
3	Is the manual approved and signed by designated official from each department?		
	ORGANIZATION		
4	Is the organizational structure of the applicaant 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 and production		
7	Does the QA director have continual involvement in the QA program?		
8	Is the NRC contact listed and up to date?		
9	Do the QA manager and the QA director have the authority to halt production		
	PERSONAL		
10	Does the applicant have the procedures to ensure up-to date records of all employee qualifications?		
	DESIGN AND CONTROL DOCUMENT		
11	Are there procedures for ensuring that all docuemnts contain all pertinent information and conform toa ll pertinent regulations and specificaitons?		
12	Are ther procedures for handling document and design changes?		
13	Do procedues ensure that all appropiraite departements are notified of the changes?		
14	Do procedures ensure that documents under revision are not used?		
15	Are all changes documented?		
16	Do the procedures ensure that documents and changes are checked and approved before released?		
17	Do the procedures ensure include notifying regulatory agencies of any changes?		
18	Do the procedures ensure alternative approaches in the adbsence of specifications?		
19	Is there a history file for each document that includes previous versions, document changes, and reasons for the changes?		
20	Are the copies on file of all up-to date documents for each job?		
21	Are there procedures for vertification of the adequacy of suppliers?		
22	Are there records of all audits of suppliers?		
23	Are audits of suppliers pertformed at intervals of less than 3 years?		
24	Are ther procedures for receipt inspection?		
25	Do you receipt inspections verify: correct sizes? quantity? document and specification conformance? paperwork?		
26	Are there procedures for receipt of non-conforming materials		
27	Are there records of receipt inspections, including non-conforming material?		
28	Do all purchase orders contain scope of work? technical requirements? identification of the docuemnts that must accompany the order? identification of the records that the applicant must keep? Signature of appropriate individual?		
29	Are there records of all purchases?		
30	Are there inventory procedures?		
31	Do inventory procedures include: special handling? marking? tagging? labeling?		

serregating?
paperwork procedures?
handling of non-conforming material?

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?
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

PRODUCTION PROCEDURES AND PROCESSES

36 Are there procedures that descibe production processes?
37 Is there a flowchart describing the flow of material and inspection hold points
38 Are there procedures for in-process and final and testing of the deviceDo inspection procedures:
39 Do acception criteria 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 non-conformig material
40 Are there records for inspection of production procedures?
41 Are there procedures for handling nonconforming items received from a suplier or customer or found during production?
42 Is there a system for marking or segregating items that have been inspected or tested?
43 Does final inspection include operational check and removal contamination test of 100% of devices?

NONCONFORMING MATERIALS

44 Are there procedures for handling nonconforming items received from a suplier or customer or found during production?
45 Are nonconforming materials tagged or segregated from production?
46 Are there procedures for disposition of non-conforming materials and for introducing materials back into production
47 Are there records of nonconforming materials?

PACKAGING AND TRANSPORTATION

48 Are there procedures for inspecting packaging and the form of transportation?
49 Do these procedures ensure that all paperwork and manual are included with the shipment or are being shipped separately to the customer?
50 Are there records of all packaging and shipping reports and inspections

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 deviation?
54 Are there records of all deviations and customer complaints?
55 Do customer complaint records contain
Name of complaintant?
Nature and date of complaint?
Corrective action taken?
Cause of failure?
Model and serial number of the device?
56 Are there procedures for trend analysis of deviations and complaints?
57 Is trend analysis performed at intervals that do not exceed 1 year?

AUDITS

58 Does the applicant have procedues for auditing its QA program?
59 Do the procedures include exceptance criteria?
60 Do the procedures ensure that all records and procedures are up to date?

61 Do audits include verification audits of suppliers?
62 Is the auditor responsible for any of the matters being audited?
63 Are all records signed and dated by the appropraite member of the organization?