030 20 43

VOID SHEET

Atty's 1
32 30
123521

TO: License Fee Management Branch

FROM: RI

SUBJECT: VOIDED APPLICATION

Control Number: 123521

Applicant: BERTHOLD SYSTEMS, Inc.

Date Voided: 9-20-96

Reason for Void: Licensee wants Apgee's license 37-28697-01 Amended not Berthold's. 37-21226-01. After review. Reference 123639.

Rebecca J. Brown 9/20/96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

~~No~~ Refund Due

Fee Exempt or Fee Not Required

Comments:

Log completed

Processed by: BB

OFFICIAL RECORD COPY MI 10

01

APGEE CORPORATION
Hopewell Business Park * 103 Corporate Drive * Aliquippa, PA 15001 * Tel. (412) 378-1900, fax. 1926

August 30, 1996

MS 16
P-3

Mr. John McGrath
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. McGrath,

I refer to your Docket Nos. 30-20043 and 030-21228, Control Nos. 123521 and 123522. We wish to respond to your request for information of August 8, 1996.

1. APGEE-BERTHOLD SYSTEMS RELATIONSHIP: You have asked us to explain the intended relationship between Apgee and Berthold Systems, Inc. (BSI). Apgee Corporation will manufacture shields and transfer to BSI for distribution in section 9A (authorized use) of Apgee's license 37-28697-01. Apgee made this request made in its letter to you of July 15th. We now note an error in that request. To that end, we herewith amend and attach the Apgee QA Manual, section 1.0.

2. ANNUAL AUDIT: We wish to confirm that our audit report will be provided to management, and corrective action documented. To that end, we herewith amend and attach the Apgee QA Manual, Section 15.3.

3. DEVICE DESIGN CHANGES: We wish to confirm that Apgee will notify the appropriate NRC headquarters office and the appropriate regional offices for amendment requests related to device design changes. To that end, we herewith amend and attach the Apgee QA Manual, section 7.3.1 (Notify NRC).

Please accept the attached revised Quality Assurance Manual, which incorporates the above changes. Also attached you will find our amendment application, and check number 14646 for amending Apgee License #37-28697-01.

Should you have further questions, please contact me or Mary Dedola.

Sincerely yours,

APGEE CORPORATION

G.M. (Bud) Smith, Jr.
President

Attachment: Quality Assurance Manual (Revision 1).
Application for Amendment.
Check #14646.

123521/123522

SEP - 5 1996

cc: Mary Dedola
Charlie Ferrin

OFFICIAL RECORD COPY ML 10

TELEPHONE CONVERSATON RECORD	Date: 8/29/96	Time: 1:15 PM
Mail Control Nos.: 123521 and 123522	License Nos.: 37-21226-01 37-21226-02G	Docket Nos.: 030-20043 030-21228
Person Called: Mary Dedola, RSO for Berthold	Licensee:Berthold/Apgee	Telephone No.: 412.378.1900
Persons Calling: John McGrath and Kathleen Dolce		
Subject: Deficiency Letter		
Summary: Ms. Dedola was confused as to which license needed amendment. She said that they made a mistake on the application and that Apgee is not the distributor. Apgee is the manufacturer and Berthold is the distributor. She asked where the Q/A manual should go and we told her that a Q/A Manual usually is tied to a Sealed Source Device registration which is then tied to the manufacturer. She said that she will inform Bud Smith, the president, that they need to amend Apgee's license instead of Berthold's licenses. A response is due September 8, 1996.		
Action Required/Taken: Inform Branch Chief		
Signature: K. Dolce		Date:8/29/96

AUG - 8 1996

License Nos.: 37-21226-01
37-21226-02G
Docket Nos.: 030-20043
030-21228
Control Nos.: 123521
123522

G.M. (Bud) Smith, Jr., President
Berthold Systems, Inc.
Hopewell Business and Industrial Park
101 Corporation Drive
Aliquippa, Pennsylvania 15001-4863

Dear Mr. Smith:

This is in reference to your letters dated July 15 and 30, 1996 requesting to amend License Nos. 37-21226-01 and 37-21226-02G. In order to continue our review, we need the following additional information:

1. Section 1.0 of the Quality Assurance Manual indicates that Apgee will distribute these products. Apgee's license does not authorize distribution. Your letter dated July 30, 1996 requests to amend Berthold's licenses and not Apgee's license. You informed the NRC that Apgee and Berthold are separate companies; however your letters dated July 15 and 30, 1996 interchange Apgee and Berthold. Please explain the Apgee-Berthold relationship in regards to manufacturing and distributing of these new shields.

2. Sections 2.0 and 15.3 of the Quality Assurance Manual describes the annual audit. Please confirm that your audit report will be provided to management and corrective actions documented.

3. Sections 4.5 and 7.3.1 of the Quality Assurance Manual indicates that the NRC will be notified when there is a device design change. Please confirm that you will notify the appropriate NRC headquarters office and the appropriate regional office for amendment requests.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control Nos. 122521 and 122522. If you have any technical questions regarding this deficiency letter, please call Kathleen Dolce at (610) 337-5251.

OFFICIAL RECORD COPY

ML 10

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
John R. McGrath

John R. McGrath
Senior Health Physicist
Division of Nuclear Materials Safety

cc:
Steven Baggett, NMSS

DOCUMENT NAME: R:\WPS\DLTR\L3721226.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N				
NAME	Dolce/kadl		McGrath					
DATE	08/09/96		08/ 8 /96		08/ /96		08/ /96	

OFFICIAL RECORD COPY

TELEPHONE CONVERSATON RECORD	Date: 8/5/96	Time: 1:13 PM
Mail Control Nos.: 123521 and 123522	**License Nos.:** 37-21226-01 37-21226-02G	**Docket Nos.:** 030-20043 030-21228
Person Calling: Mary Dedola, RSO for Berthold	**Licensee:Berthold**	**Telephone No.: 412.378.1900**
Person Called: Kathleen Dolce / (610) 337-5251		
Subject: License Amendment to manufacture new shields		
Summary: Ms. Dedola left a voice mail message which indicated that Apgee's name will be on the new shields.		
Action Required/Taken: Inform Branch Chief		
Signature:		**Date:**8/5/96

TELEPHONE CONVERSATON RECORD	Date: 8/2/96	Time: 1:45 PM
Mail Control No.: 123521	**License Nos.:** 37-28697-01 37-21226-01 37-21226-02G	**Docket Nos.:** **030-32518** 030-20043 030-21228
Person Called: Mary Dedola, RSO for Berthold	**Licensee:Apgee/Berthold**	**Telephone No.: 412.378.1900**
Person Calling: Kathleen Dolce / (610) 337-5251		
Subject: Apgee QA Manual on Berthold Licenses?		
Summary: Ms. Dedola indicated that their July 30, 1996 letter is correct. Apgee will manufacture shields, but the licensee wants this activity listed on both of Berthold's licenses (not Apgee's license). Ms. Dedola could not inform me which company name will go on the shield (Apgee or Berthold). She will get back to me on this issue.		
Action Required/Taken: Inform Branch Chief (FMC)		
Signature: K. Dolce		**Date:**8/2/96

Frank Costello says Berthold

OFFICIAL RECORD COPY ML 10

TELEPHONE CONVERSATON RECORD	Date: 7/22/96	Time: 11:00 AM
Mail Control No.:	**License No.:** 37-28697-01	**Docket No.:** 030-32518
Person Called: Charlie Ferrin, RSO	**Licensee:Apgee Corporation**	**Telephone No.:** 412.378.1900
Person Calling: Kathleen Dolce / (610) 337-5251		
Subject: License Amendment?		
Summary: Mr. Ferrin informed me that Apgee is spelled with a capital A only. He said he does not know how much the amendment would cost. I referred him to Brenda Brown of the NRC Fees Branch and gave him her number. He will submit this info to us by the end of the week.		
Action Required/Taken: Inform Branch Chief (FMC)		
Signature: K. Dolce		**Date:**7/22/96

TELEPHONE CONVERSATON RECORD	Date: 7/19/96	Time: 8:15 AM
Mail Control No.:	**License No.:** 37-28697-01	**Docket No.:** 030-32518
Person Called: Charlie Ferrin, RSO for Apgee	**Licensee:Apgee**	**Telephone No.:** 412.378.1900
Person Calling: Kathleen Dolce / (610) 337-5251		
Subject: Apgee QA Manual		
Summary: Ms. Dedola will not be in the office today. I spoke with Charlie Ferrin. Mr. Ferrin will write to us with the following: 1. the correct spelling of APGEE (or is it Apgee). 2. a sentence clearly stating that the submission of the QA Manual is an amendment request (accompanied with a check).		
Action Required/Taken: Inform Branch Chief (FMC)		
Signature: Kathleen Dolce		**Date:**7/19/96

Apgee Corporation

Hopewell Business & Industrial Park · 103 Corporation Drive · Aliquippa, Pennsylvania 15001 · Telephone: (412) 378-1900 · Fax: (412) 378-1926

July 30, 1996

Mr. Frank Costello
Chief, Nuclear Materials Safety Branch 3
Division of Nuclear Materials Safety
Region I
US Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

030-20043

Dear Mr. Costello:

Subject: APGEE AS SHIELD MANUFACTURER

This letter transmits our QA Manual for review, as required prior to our undertaking USA manufacture of shielding devices. This letter replaces my earlier letter of July 15, 1996, to which the QA Manuals were attached.

This QA manual is submitted as an addition to the Berthold Licenses, #37-21226-01 and 37-21226-02G. Attached is a check with the appropriate fees for amendment to these licenses.

Please pass to the appropriate NRC staff for review, so that we may proceed with local production. Through local production, we will bring jobs to Western Pennsylvania, improve safety by having tighter control over manufacturing, and allow the NRC greater influence relative to safety considerations.

Must we supply additional information? Please contact me or our Mary Dedola, and we will immediately respond.

Sincerely yours,

G.M. (Bud) Smith, Jr.
President

Attachment: Application for Material License
QA Manual (4 copies) - Attached to July 15, 1996 letter
Check # 14489 for $880.00

cc: Mary Dedola
Charlie Ferrin
Whit Little

123521

OFFICIAL RECORD COPY ML 10

AUG - 2 1996

APPENDIX A

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19405

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

030-20043

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 37-21226-01 & 02G
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Berthold Systems, Inc.
101 Corporation Drive
Aliquippa, PA 15001-4863

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Same as 2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mary Dedola

TELEPHONE NUMBER: (412)378-1900

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3N & 3P
AMOUNT ENCLOSED $880.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
X	G.M. Smith Jr	President	Aug 1, 1996

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REV

OFFICIAL RECORD COPY

123521

ML 10

AUG - 2 1996

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

APGEE CORPORATION

Hopewell Business Park * 103 Corporate Drive * Aliquippa, PA 15001 * Tel.(412) 378-1900, fax. 1926

July 15, 1996

Mr. Frank Costello
Chief, Nuclear Materials Safety Prank 3
Division of Nuclear Materials Safety
Region I
U.S. NUCLEAR REGULATORY COMMISSION
King of Prussia, PA 19406-1415

Dear Mr. Costello,

Subject: APGEE AS SHIELD MANUFACTURER

This letter transmits our QA Manual, required prior to our undertaking USA manufacture of shielding devices.

Please pass to the appropriate NRC staff for review, so that we may proceed during 1996 with local production. Through local production, we will bring jobs to Western Pennsylvania, improve safety by having tighter control over manufacturing, and allow the NRC greater influence relative to safety considerations.

Must we supply additional information? Please contact me or our Mary Dedola, and we will immediately respond.

Sincerely yours,

APGEE CORPORATION

G.M. (Bud) Smith, Jr.
President

Attachment: QA Manual (4 copies)

cc: Mary Dedola
Charlie Ferrin
Whit Little

APGEE CORPORATION Policy Procedure	Approved By: 7/15/96	Title: Quality Assurance Manual	Revision: 0
	Prepared By: 7/15/96	Date: July 15, 1996	Document #: AP 001

Quality Assurance Manual

Apgee Corporation

Table of Contents

0.0 PURPOSE

This document describes the Quality Assurance program implemented to provide control of product design, parts, manufacturing and testing by means of procedures and documents.

1.0 APPLICATION

The procedures stated in this document shall be applied to every product distributed by Apgee Corporation, hereafter referred to as "Apgee".

2.0 RESPONSIBILITIES

2.1 The Quality Manager is responsible for maintaining and distributing the Quality Assurance manual. The manual will be reviewed yearly and updated if needed, by the Quality Manager.

2.2 All employees of Apgee are responsible for producing product in accordance with this document.

3.0 DEFINITION

3.1 Device - Any product registered in accordance with 10 CFR 32.210.

3.2 Material - Any item which is raw material, subassembly , or component used in the production of Apgee products.

3.3 Product - Any device, instrument, or accessory manufactured or distributed by Apgee.

3.4 Quality Assurance (QA) - The policies and people that make up the overall plan for the company, to assure the quality of products and services delivered by Apgee.

3.5 Quality Control (QC) - The area of QA involved in the inspection of incoming materials and finished product.

4.0 ORGANIZATION

The organizational structure of Apgee as it relates to the QA Manual is illustrated by the Organization Chart on page 16. The positions and associated responsibilities as they relate to the QA Program is as follows:

4.1 QA Director

Responsible for ensuring the QA process is functioning properly, including auditing, implementation, improvement, effectiveness and adequacy of the QA program.

4.2 The QA Manager

4.2.1 Prevents deviations from quality standards.

The QA Manager is responsible for taking action when materials or products do not meet design or performance specifications. The manager is to work with other

departments to define the problem and initiate a solution. The QA Manager is also responsible for monitoring the corrective actions for effectiveness.

4.2.2 Responsible for maintaining and approving documents associated with the QA program.
The QA Manager is to review documentation associated with quality problems, solutions, and results. Also, the QA Manager shall be notified and must review any procedural changes which would affect material or product quality or inspections. The QA Manager must approve these procedural changes before implementation.

4.2.3 The auditing, approval, or disapproval of suppliers is to include the participation of the QA Manager.

4.2.4 Supervises the QC Inspectors.
The QC Inspectors provide the QA Manager with information on inspections of incomming material and finished product.

4.3 Vice President of Manufacturing
The Vice President in charge of manufacturing is responsible for the logistics of procurement, production and inventory control.

4.4 Manufacturing Engineer
The Manufacturing Engineer is responsible for maintaining the documentation for manufacturing. This documentation includes, but is not limited to, drawings, specifications, and assembly procedures. The equipment maintenance schedules, procedures, and records are also part of this documentation.

The supplier audits and selections are to include the Manufacturing Engineer.

4.5 NRC Contact
The NRC Contact is responsible for notifying the NRC and obtaining approval when there is a device design change. If there is a significant device defect, the Contact notifies the NRC of the defect and makes sure they receive a copy of the evaluation.

4.6 Development Engineers
The Development Engineers must provide the documentation and specifications necessary for the QA program and Documentation. This documentation includes, but is not limited to, drawings, specifications, inspection procedures.

An appropriate engineer is to be involved in the selection and auditing and approval or disapproval of suppliers.

4.7 Buyer or Outsourcing Manager
The Buyer is responsible for the procurement of materials from the approved suppliers. The auditing and selection of suppliers is to include the Buyer, QA Manager, and appropriate

Development Engineers.

5.0 PERSONNEL

All personnel who receive materials, assemble product, or service product shall have the necessary training to determine if the material is within specification.

5.1 Training Methods

5.1.1 Initial Training

Some of the training is in a classroom setting but, a majority of the training is done on-the-job. Employees who are not qualified to inspect are instructed and/or will work with a qualified employee, until they exhibit the knowledge to become qualified.

5.1.2 Refresher Training

Yearly refresher training is held by the QA Manager for inspectors. This is a classroom style overview of applying inspection techniques and specifications to materials and products.

5.2 Training Records

5.2.1 Training sheets are kept for each employee. The Vice President of Manufacturing will maintain and keep a file of the training records. The training sheets are specific to the tasks expected of the employee's job position. Information on training sheets include the following information:

Name	Employee to be trained.
Date	Date training for the sheet is started.
Supervisor	Person responsible for ensuring the training was completed.
Tasks/Knowledge	List of the tasks the employee is to be qualified to do and knowledge the employee is to possess.
Completion Date	Date the employee exhibited qualifying competence.
Approved By	This is where the qualified training employee initials when the specific Task/Knowledge training is completed.

5.2.2 Refresher Class Sign-in Sheets

A sign-in sheet for the refresher training serves as a record of attendance of the yearly refresher courses. This form will have the topic of the training, date, who was the trainer, and the signatures of those who attended.

6.0 EQUIPMENT

6.1 Maintenance Log

Supervisors are responsible for the maintenance and calibration of all equipment in their area. A listing of every piece of equipment and the scheduled maintenance and calibration is on file with the QA Manager and Area Supervisor. The Maintenance Log contains the following

information:

Manufacturer of the equipment
Model and serial numbers
Calibration or maintenance procedure
Frequency of procedure
Persons qualified to perform the maintenance

The Area Supervisor consults the list monthly to make sure the maintenance is performed.

6.2 Sign-off Sheet

Each piece on the maintenance list has a sign-off sheet in close proximity of the equipment. The sign-off sheet contains the same information in the maintenance log for that piece of equipment. The sign-off sheet also contains a listing of dates the maintenance was performed and the initials of the person who performed the task. In the case of a portable piece of equipment which a sheet in close proximity is impractical, the Area Supervisor keeps the sign off sheet in a file.

6.3 Calibration

Equipment which requires calibration is to be calibrated when received new and according to the Maintenance Log. Equipment is also calibrated after maintenance which would affect the accuracy of the equipment.

6.3.1 Calibration Tags

Instruments scheduled for calibration have a calibration tag attached to the instrument with the last calibration, next calibration due date, and the person or company who performed the calibration. If it is impractical to attach a label to the piece of equipment, the tag is to be affixed to the case specific to the piece of equipment.

6.3.2 Calibration Certificates

Area Supervisors have a file of calibration certificates if the calibration is done by a supplier. The calibration certificates indicate by which standards the instrument was calibrated. The calibration certificates are kept on file by the QA Manager.

7.0 DESIGN AND DOCUMENT CONTROL

The purpose of Document Control is to ensure changes are not made with out proper review of the impact of the change, and to ensure the current revision of the document is being used.

7.1 Document Contents

Every document generated by Document Control has specific requirements for it to be an effective document. These requirements are an identifying number, revision level, creator and approver initials, and dates created and approved.

7.1.1 Drawings

All drawing are to have dimensions with tolerances and units, material, and specific

finish and label instructions if required. Approved suppliers are to be listed on the drawing. The materials and product drawings are to have the specifications and information necessary for a QC inspection. Some assembly reference drawings will not have dimensions or detailed specifications.

7.1.2 Bills of Materials
The bills of materials for assemblies list the materials used by part number, part description, and quantity. Also listed in the bills of materials are the reference materials used for assembly, including assembly procedures and reference drawings.

7.1.3 Procedures
Specific instructions for the assembly steps, cleaning of materials, finishes, labeling testing, and packaging are in the assembly procedures. Inspection and test procedures indicate the sampling rate, method of inspection, and acceptance and rejection criteria. The inspection procedures can be part of the drawing.

7.2 Document Files
Documentation Control maintains a list of all documents in the current file and the revision levels.

7.2.1 Current Files
The Current Files contain documents of the effective revisions and a Document Distribution List. The Document Distribution List contains the part number of the document and the people who are to receive an updated document if it is revised. All copies of documents are stamped with the date when distributed.

7.2.2 History Files
Each document has a History file containing a copy of the previous revisions and the DCR # which revised the document.

7.3 Document Creation and Revision Approval
No document is created or revised without being reviewed and approved by representatives from QC, Development Engineering, Purchasing, Manufacturing, and the NRC contact.

7.3.1 Document Change Request
The first step in creating or changing a document is for the person responsible for the action to submit a Document Change Request. The DCR contains the following information:

DCR #	Every DCR is numbered by Document Control for traceability.
Date	Date the DCR was submitted
Needed by	Date the change must be effective. If the change is not needed by a certain date, "Needed by" can be left blank.
Submitted by	Name of the person submitting the DCR.

Part No.	The document part number which will be revised. The creation of a new part or document will not have this filled in.
Description of Change	Complete description of the changes to be made.
Reason For Change	The reason the request has been made.
Part Numbers Affected	A list of materials of other assemblies which will be effected by the change.
Remarks	If there are comments or remarks from the reviewers, they are to be entered here.
Reviewed / Approved	This is a listing of the departments included in the document approval process with a space for the reviewer's signature and the date signed.
Notify Supplier	Indicate if the supplier should be notified. The Buyer is responsible for notifying a supplier if they are affected by the revision.
Notify Customer	Indicate if customers need to be notified and if so, who will notify them.
Notify NRC	If the part being revised is a part of a device registration or license application, the document change must also be approved by the Nuclear Regulatory Commission. The NRC contact is responsible for notifying the NRC and getting the document approved.
Final reviewer	The revised document is checked, usually by the person initiating the DCR.

7.3.2 Submitting the DCR Form

The DCR form is submitted to Document Control. Whenever possible, a marked-up copy of the document to be changed is included with the DCR form. The DCR is given a DCR# and entered in the DCR log. The log contains the DCR# , a description of the change, and the part numbers effected. The DCR is then routed to the reviewers from each department for comments and approval. If the revision is not approved by every department, the DCR is changed and rerouted.

7.3.3 Revised Document

After the revision has been approved by all department representatives, Document Control will make a revised document. The revised document will be checked by the DCR initiator to make sure it was changed correctly. The DCR and revised document are signed and dated by Document Control and the final reviewer. The final reviewer is to be someone other than the person who prepared the document. Policy affecting QA must have the QA Manger as the Final reviewer.

7.3.4 Effective Document

Document Control will copy the master document and distribute it to the people on the Document Distribution List and collect the old revisions. The previous revision master is moved to the history file and the new revision is placed in the current file.

8.0 MATERIAL AND SERVICE PROCUREMENT

The selection of suppliers is a process which includes the participation from QA, Development Engineering, Manufacturing, and the Outsourcing Manager.

8.1 Specifications

There needs to be effective documentation (drawings, spec. sheets. etc.) containing specifications for supplied material or services before an order is issued. This documentation is to specify the scope of the work, technical requirements, identification of documents the supplier should keep on file, QC inspection instructions, and an authorized signature. The documentation will serve as conditions for the supplier's obligation.

8.2 Inspection Instructions

It is important the same inspection procedure is used by the Supplier and by incoming QC. The sample size and rate as well as inspection methods must be made clear by the inspection instructions. The instructions are determined by the QA Manager.

All devices not completely manufactured by a NRC licensee must undergo an operational check and inspection. If testing is done by the supplier, the serial numbers of the materials and devices tested, and the test results will be supplied to Apgee.

8.3 Selection of materials suppliers

Suppliers which are approved to supply the materials are listed on the part drawing. Materials suppliers are selected based on several factors.

8.3.1 If the material is a simple, standard part (ex. screw, washer) a sample from the supplier and a satisfactory price may be all that is needed. If sample material meet the specifications and delivery is assured, the supplier can be used.

8.3.2 If the supplier has provided similar specialized materials in the past, and the delivery and quality history is acceptable, they might not be audited. Again, if the sample materials meet specifications and delivery is assured, the supplier can be used.

8.3.3 If the part is nonstandard and the quality of the part can not be determined through inspection or testing of samples, an audit of the supplier's operations is performed by QA, Purchasing, Development Engineering, and Manufacturing.

9.0 INVENTORY CONTROL

The flow of inventory must be controlled so that uninspected, nonconforming, and expired material is not used in product manufacturing.

9.1 Incoming QC Inspection

Material is placed in the "Incoming QC Inspection" area. The materials will be contained in this area until they have been inspected according to the inspection procedure.

9.2 Defective Material
Material which does not conform to the inspection specifications are labeled with a "Reject" label and a stamp on the shipping papers. The items are moved to "QC Holding".

9.3 Accepted Material
When material has passes the QC inspection, it is received in to stock both physically and numerically. The inspector will label the material and stamp the shipping papers as "Inspected". The date and the person who inspected the material are indicated on the label. The material is moved to the designated inventory location. The inventory locations are identified by part number and descriptions. The material is also received into stock inventory records.

9.4 Stock Rotation
Any stock with a shelf life is rotated and used on a first-in/first-out basis. Stock with an expiration date is to be checked periodically. If a material is used frequently, the expiration date is checked when it is used. If it is nearing the expiration date, the supervisor is to be notified and the material reordered. A list of materials with a shelf life which are not frequently used is kept by the QA Manager. The materials on this list are to be checked monthly for expiration dates.

10.0 PRODUCTION PROCEDURES AND PROCESSES
All product assemblies have documentation which, when followed, produce a product which is within specifications. An assembly might require all or any of the following controlled documents:

10.1 Bill of Materials
The Bill of Materials lists the necessary materials and reference documentation for the assembly.

10.2 Assembly Procedure
The Assembly Procedure includes the equipment required, detailed instructions, methods and techniques used for each step, and inspection and testing for the assembly. The Assembly Procedure contains the necessary forms for recording test data and serial numbers. It explains the consequences of improper assembly and a failed inspection or test. The Assembly Procedure instructs the assembler on what to do if the material fails the inspection or test. Packaging and labeling instructions are also in the Assembly Procedure.

10.3 Reference Drawings
Reference drawings are graphical support for the Assembly Procedure. The materials on Reference Drawings are identifiable by the Bill of Material.

10.4 Inspection or Testing Procedures
Most inspection and testing procedures are included in the Assembly Procedure.

11.0 INSPECTION AND TESTING
No material or product is to be put in stock or advance to the next stage of production until it has passed an inspection or test.

11.1 Inspection and Test Procedures.
The procedures for inspections and tests are the responsibility of the QA Manager. Each inspection instruction is to contain the following information when applicable:

Test equipment.
Location of the inspection in the production flow.
Sampling size and rate, including the method for determining it.
Characteristics and specification of the inspection.
Acceptance and rejection criteria.
What to do with nonconforming material (rework, reject, etc.)
Necessary forms or instructions for collecting test data and serial numbers.

If the material is critical to safety, 100 percent of the material is inspected or tested.

11.2 Incoming Materials
Incoming QC is responsible for ensuring only materials which are not defective are used in products. Incoming QC inspects and/or test all materials delivered from a supplier according to the Inspection Procedures. Samples are to be as random as possible. Inspection results are noted on the shipping papers by a stamp as either accepted or rejected.

Daily Inspection Reports containing information on the material inspected that day and the outcome of the inspection, are completed by incoming QC Inspector and submitted to the QA Manager. The QA Manager will use this DIR as a record of inspection and statistical analysis of accepted/rejected material.

11.3 In Process Inspections
Most inspection and testing procedures are in the Assembly Procedure. If the inspection or test procedure is not included in the Assembly Procedure, it will be referenced by the Bill of Material.

11.4 Final Inspection
The inspection instructions for shielding devices includes an operational check. 100 percent of the instruments are tested for functionality. Labeling is inspected on all final assemblies.

12.0 NONCONFORMING MATERIALS
Materials which do not conform to specifications are not to be allowed to be put into stock, used in production, or distributed.

12.1 Defective Material Report
A Defective Material Report is filled out and submitted to the QA Manager by a QC Inspector or Area Supervisor when nonconforming material is found. The DMR contains the following information:

Date
Material or Product and quantity

Serial number if serialized
Non-conformance
Root of defect if known
Name of the person who performed the inspection or test
Any additional comments

12.2 Incoming QC Rejections

All material rejected by Incoming QC is clearly labeled with a "Reject" label. The date, person who rejected the material, and the reason for reject are to be noted on the label. If the reason for the reject can not fit on the label, the label is to indicate where the reason can be found, usually the DMR#for the reject. The material is placed in the QC Holding area. A Defective Material Report is submitted to the QC Manager at the end of the day containing information on the material. The DMR along with past Daily Inspection Report are used to determine the action to be taken with the material.

12.3 In Process Materials and Completed Assemblies

If at any stage in the assembly process the materials do not meet the inspection or test specifications, the material is either reworked or scrapped according to the applying Assembly, Inspection, or Test Procedure. The procedure states if a Defective Material Report is needed to scrap the material. If the material is scrapped, a "Reject" label is put on the material with the date, name of the person rejecting the material, and the reason for the reject. The DMR and the material is given to the Supervisor.

12.4 Defective Devices

Devices which do not meet specifications are to be repaired, reworked, or scrapped. The contract Apgee has with the manufacturer holds the manufacturer responsible for producing and delivering devices within specifications. Repair, rework, or scrap costs are the responsibility of the manufacturer.

13.0 PACKAGING AND TRANSPORTATION

Measures have been taken to ensure the correct products are delivered to the customers in a timely manor with the proper information.

13.1 Customer Orders

A Shipping Report is generated to inform Shipping, Manufacturing, and Inventory Control as to what is known to be shipped on future dates.

13.2 Picking Ticket

A Picking Ticket is generated for each customer order. The Picking Ticket provides the Shipper with the information necessary for product shipment and delivery. Including customer and order information, shipping method, product, prices, and quantities as required. Special packing or shipping instructions are on the Picking Ticket. If a product is serialized, the Picking Ticket has a space for the Shipper to record the serial number. Someone other than the Shipper checks to ensure the serial numbers are valid for the product part numbers before they are shipped.

If a partial shipment was made to a customer, the Packing List identifies items shipped and items not shipped. A Picking Ticket with the remainder product will be generated.

13.3 Packing List

The Packing List is included with the shipment. It lists the customer information, shipping method, product, serial numbers, and quantity shipped. If an item was not available for shipment, the quantity will be zero.

13.4 Packaging

Product for shipment will be packed to ensure the material is received by the customer undamaged. If the Picking Ticket includes special packing instructions, the products will be packed according to the instructions. If the material is hazardous, it is packaged according the Federal regulations for the material.

13.5 Shipping Papers

The packing list is attached to the shipment. If the material is hazardous, a Shippers Declaration of Dangerous Goods is included. Any other papers required by Federal regulations for the material will accompany the shipment.

14.0 DEVIATIONS AND CUSTOMER COMPLAINTS

Customer complaints are an indication of deviations which were not detected by in house inspection and testing procedures.

14.1 Deviations

Daily Inspection and Defective Material R\ orts provide the QA Manager with information necessary to determine if there is a need t\ corrective action. Ongoing trend analysis of materials received and scrapped materials is essential to detecting the frequency of deviations, and the need and type of corrective action. The QA Manager is to prepare a report if there is a deviation of material requiring corrective action. The QA Manager will determine who will head the corrective action. If corrective actions implemented, the QA Manager is to monitor the corrective action for effectiveness.

14.2 Customer Complaints

Customer complaints are to be addressed as quickly and effectively as possible. It is important the person recording the customer complaint collects all information necessary for Service and Engineering to evaluate the complaint. Each significant complaint associated with product quality or safety is recorded on a Customer Complaint Form. This form contains the following information:

Date of Complaint
Product type and model information
Serial number when applicable
Name of complainant
Complaint
Environmental conditions
Reply to complaint

Corrective action taken
Root cause of failure if known
Does the complaint involve a device?
Can this failure be a substantial safety hazard?
Departments responsible
Are other customers affected by the failure?

The QA Manager maintains a file of customer complaints.

14.3 Evaluation
If a device is deviated or could cause a substantial safety hazard, the failure is to be evaluated by the manufacturer to determine if it is such, and what actions are to be taken. This evaluation is to be conducted with in 60 days of the discovery of the failure.

14.4 Notification
All notifications will be made in writing, either by interoffice memo or facsimile.

14.4.1 Departments
The departments responsible for the defective material are to be notified of the customer complaint or failures within 5 working days of the discovery by the QA Manager. They are also to be notified of the evaluation results and any corrective actions taken or to be taken.

If defective product or material is part of a device, the NRC contact needs to be notified.

14.4.2 Nuclear Regulatory Commission
The NRC is to be notified of significant device defects by the NRC contact. The NRC receives a copy of the evaluation within 60 days of the discovery of the failure. If the evaluation can not be completed within the 60 days, an interim is prepared and submitted to the NRC. This interim report describes the deviation and failure to comply and state when the evaluation will be completed.

14.4.3 Customers
Customers affected by significant defects are notified of the defect, any corrective actions, and the results of the evaluation.

15.0 AUDITS
The CEO is responsible for organizing and/or performing all internal audits. The QA Manager will appoint supplier auditors. The audits of suppliers are to be, in most cases, a joint effort of QA manufacturing, engineering, and purchasing. A auditor is appointed by the QA Manager to prepare an audit report.

15.1 Internal Audits
The basis of the internal audit is the Apgee Quality Assurance Manual and the policies and procedures for the department. The audit is to determine if procedures are followed,

personnel training is adequate, equipment maintenance and calibration is up to date, documentation is current and complete, and inspections and tests are properly performed. Internal audits are conducted yearly. If there is reason, the QA Manager may request additional audits be conducted within the year.

15.2 Supplier Audits

Representatives of the departments associated with the material or services the supplier is expected to deliver, audit the area which they are most qualified to evaluate. The frequency of supplier audits is determined by the QA Manager.

The areas to be evaluated are as follows:

Area	Evaluations
Quality Program	Are the QA manual, procedures, and documentation of inspections satisfactory?
Personnel	Do they have the education, qualifications, records and general competency to perform the job?
Equipment	Are the calibration and maintenance procedures, and practices, being followed? Are the records current?
Design and Document Control	Are there procedures associated with document control? Check the current as well as history documents for continuity and thoroughness.
Material and Service Procurement	Examine the procedure by which the supplier selects their supplier.
Inventory	Is inventory set up in a manor which prevents material from being used in production before it is inspected or is defective?
Production Procedures	Are the current revision of the production procedures being used? Are the procedures thorough, and do they include in process and final inspections and testing?
Nonconforming Material	Does procedures inform steps to be taken with nonconforming material? What is the likelihood and consequences of a undetectable safety hazard failure?
Packaging and Transportation	Is the shipper provided with enough information to ensure proper packaging and shipping of an order. Are thorough records kept?
Deviation and Customer Complaints	Does the procedures for handling deviations and customer complaints include corrective actions and notifying affected customers?
Audits	Does the supplier conduct internal and supplier audits, and what do the audits examine?

15.3 Audit Reports

The Audit Report includes the audit goals, acceptance criteria, the areas of deficiencies, the corrective action which must be taken, and the signature of the person responsible for the area of the being audited. Any check list or information used for the audit is included in the report. An auditor is to follow-up to verify if the corrective actions have been implemented.

16.0 RECORDS AND DOCUMENTATION

It is important for everyone to know who is responsible for individual records and documents and where they are kept.

16.1 QA Manual

The QA Manual is a controlled document, therefore, the master copy is kept with the controlled documents. The QA Manager has a copy of the QA Manual and is responsible for maintaining it.

16.2 Training Records

Training records for each employee are kept by the employee's supervisor. These records include the Initial Training sheets and the Refresher Training sign-in sheets. If an employee changes positions in the company, the training sheets stay with the original supervisor.

16.3 Equipment Maintenance Log

The Equipment Maintenance log for an area is kept by the area supervisor or the Manufacturing Engineer.

16.4 Maintenance Sign-off Sheet

The Sign-off sheets are kept in close proximity to the equipment it is for. If it is not possible to keep it by the equipment, the sheet is filed by the QA Manager and Area Supervisor.

16.5 Calibration Certificate

The calibration certificates are kept on file by the QA Manager.

16.6 Controlled Documents

Maintaining and filing of controlled documents is the responsibility of Document Control. These include drawings, bills of materials, and procedures.

16.7 Document Change Requests (DCR)

Maintaining information on the history and changes of controlled documents is the responsibility Document Control.

16.8 In Process Data

Test and inspection results from production procedures are the responsibility of the Manufacturing Engineer. This information must be readily accessible to the QA Manager.

16.9 Daily Inspections Report (DIR)

Inspection results from Incoming QC are kept on file by the QA Manager.

16.10 Defective Material Reports (DMR)

Defective Material Reports generated by QC Inspection are filed by the QA Manager. DMRs from production processes are the filed by the supervisor and a copy is given to the QA Manager.

16.11 Customer Complaint Forms

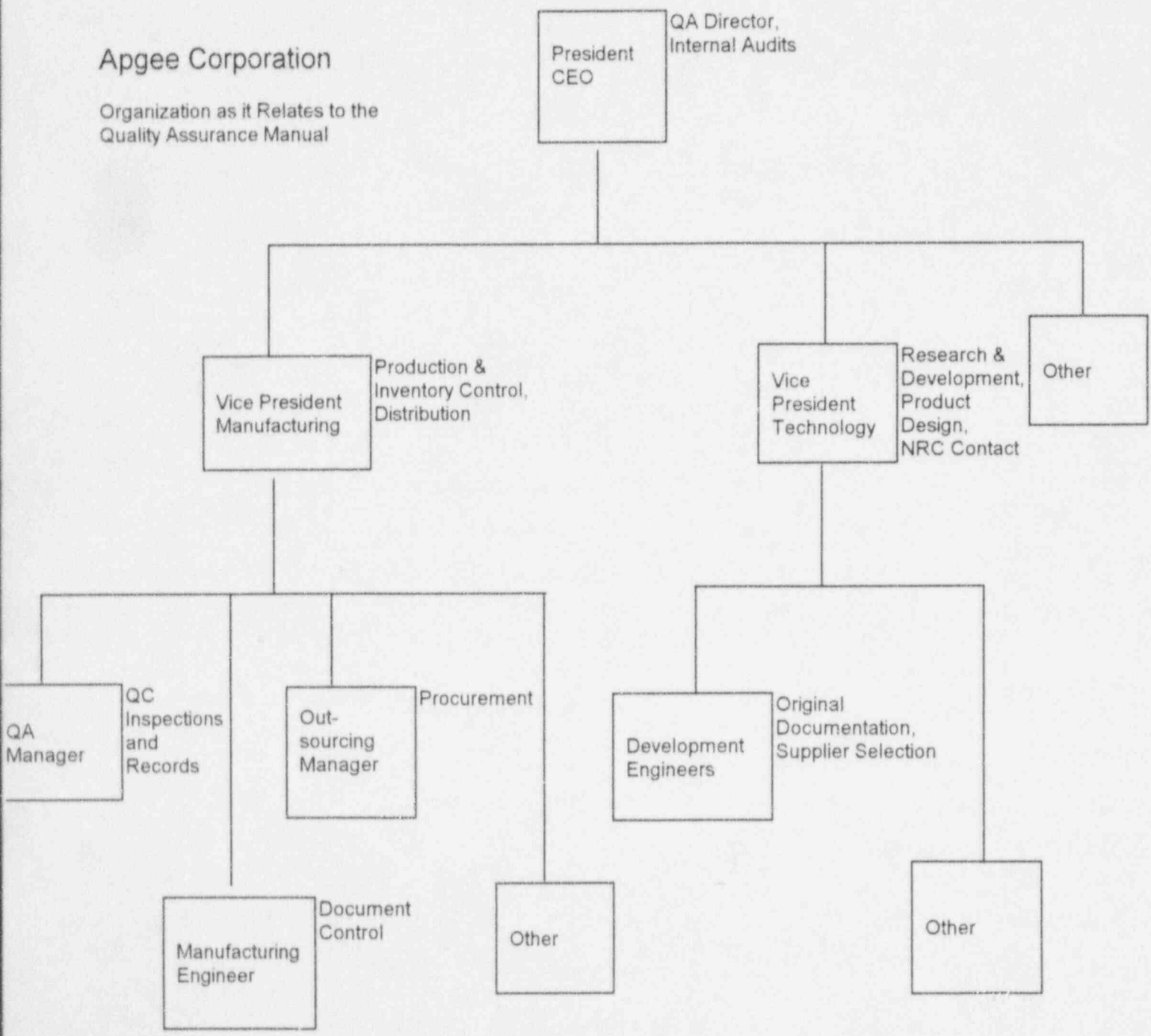
The QA Manager maintains the customer complaint file.

16.12 Audits

The QA Manager maintains the internal and supplier audit file.

Apgee Corporation

Organization as it Relates to the Quality Assurance Manual



BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03214
STATUS CODE: 0
FEE CATEGORY: 3N 3P
EXP. DATE: 20041231
FEE COMMENTS: SERV & DIST 7/90
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: BERTHOLD SYSTEMS, INC.
RECEIVED DATE: 960802
DOCKET NO: 3020043
CONTROL NO.: 123521
LICENSE NO.: 37-21226-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $ 880.00
CHECK NO.: 14489

3. COMMENTS
Ref. 123522.

SIGNED M. A. Perkins
DATE 8/14/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: (3N) 3P $590

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

I (90)
Log Aug 8
Receipt
Check No. 14489
Amount $880 $590 - Remainder applies to Control 123522
Fee Category (3N) 3P
Type of Fee Amend
Date Check Rec'd 8/8/96
Date Completed
By BB

(Also see 123522)

ZO-MAIL-7 AM 11:02