

QUALITY CONTROL PROGRAM FOR LITEPRO, LLC MODEL TEKNOLITE™ TORCH SEALED SOURCE DEVICE

A. OVERVIEW

This Quality Control (QC) Program is applicable to the production and distribution of the Litepro, LLC Model Teknolite™ Torch Sealed Source Device (SSD). At the time of the development of this QC Program, the torch is scheduled to be manufactured, tested and packaged by Keen Tools, Inc. in Tainan Hsien, Taiwan, then shipped to a licensed distribution facility in Miami, Florida USA, and distributed from that facility as an exempted product.

Keen Tools, Inc. is scheduled to manufacture all components of the SSD and packaging except the Gaseous Tritium Light Sources (GTLs), which will be manufactured by mb-microtec in Niederwangen, Switzerland. Litepro, LLC, the registrant and license applicant, is scheduled to be the distributor in Miami, Florida.

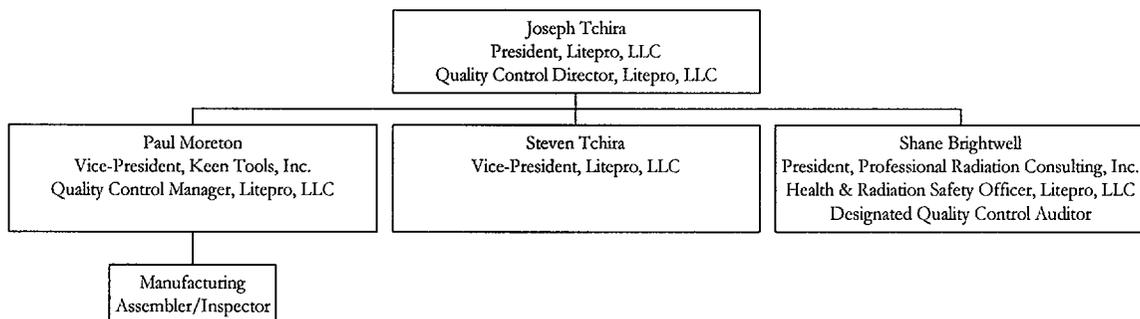
B. ORGANIZATION

Litepro, LLC is a small organization, consisting of a full-time President (Quality Control Director), full-time Vice-President (administrative), augmented Quality Control Manager (manufacturer's senior officer), and augmented contract Safety Officer.

1. Organization Chart

The following is an organization chart of the Litepro, LLC staff as it applies to the QC Program.

Litepro, LLC QC Program Organization Chart



2. Duties/Responsibilities

- Quality Control Director (QCD) - Has overall responsibility for the implementation of the QC Program. Reviews and approves any changes to the QC Program that may affect the device registration or exempt distribution. Not directly involved with SSD production.
- Quality Control Manager (QCM) - Responsible for the day-to-day operations of the QC Program. Performs routine audits of QC requirements during production. Not directly involved with SSD production.
- Designated Quality Control Auditor - Designated by QCD to perform scheduled audits and inspections of all aspects of the QC Program. Not directly involved with SSD production.
- Manufacturing Assembler/Inspector - Manufacturer employee(s) responsible for the day-to-day implementation of the requirements set forth in the QC Program during the SSD manufacturing process.

C. PERSONNEL

All personnel performing assembly and inspections of the SSD will be properly trained.

- This QC Program document and the standard operating procedure for SSD performance testing (Appendix B of the Application) will serve as the training documents for training all manufacturer's assembly, inspection, and testing personnel.
- Personnel performing assembly and inspections of the SSD will be trained and observed to satisfactorily perform the assembly/inspection procedures; training and observations will be documented accordingly (**Attachment QC-1**). Personnel performance will be re-evaluated and documented (**Attachment QC-1**) on an annual basis, or at an increased frequency at the discretion of the QCM.
- Personnel performing SSD testing (such as lot sample testing) will be adequately trained to operate all applicable equipment per facility-maintained training and procedures. These training records will be reviewed on an annual basis, or at an increased frequency at the discretion of the QCM, to assure adequate training and documentation of testing personnel.

D. EQUIPMENT

- The only sophisticated equipment requiring calibration that will be used in the manufacturing of the SSD is the equipment to be used in testing. This equipment will be calibrated at a frequency no less than that recommended by the manufacturer.
- If no manufacturer's calibration frequency is specified, the equipment will be calibrated annually, unless the QCM requires/approves an increased/decreased frequency.
- All calibration records will be maintained at the applicable facility and will be subject to inspection at all times. The calibration documentation will be reviewed at least annually to assure proper equipment calibration.
- Any sophisticated equipment that is new or has undergone maintenance that may affect the operating settings will be calibrated prior to use in satisfying requirements of the QC Program.

E. DESIGN AND DOCUMENT CONTROL

- The QCM is responsible for maintaining all documents, procedures, and records associated with manufacture and testing of the SSD.
- The QCD is responsible for maintaining all documents associated with the distribution of the SSD.
- Any changes to the QC Program that may potentially impact the applicability of the SSD registration or distribution licensing will be approved by the QCD. All other changes may be approved and implemented by the QCM.

F. ASSEMBLY AND INSPECTION PROCEDURES

The following procedures will be used to control the quality of the SSD during manufacturing.

1.0 Manufacturer's Inspection: Gaseous Tritium Light Source (GTLS)

The GTLS manufacturer, mb-microtec, will perform initial inspections of 100% of all GTLSs for leakage and contamination in accordance with the requirements of ANSI/HPS N43.4-2000, Section 8.3.2. The results of these tests will be maintained by mb-microtec and will be made available for review at all times.

2.0 Manufacturer's Inspection: SSD Components

Prior to assembly, the SSD manufacturer will inspect components of the SSD as follows:

- 2.1 100% of all GTLSs will be visually inspected under darkroom conditions for dim or non-luminous sources.
- 2.2 100% of all SSD lens caps will be visually inspected to verify
 - a) proper labeling in accordance with the SSD registration specifications, and
 - b) adequate depth and diameter of GTLS cavities in lens cap.
- 2.3 Any lens cap that does not meet the specified requirements will be segregated and will not be used in assembly pending further evaluation.

3.0 Assembly: SSD Lens Cap

The following steps will be used for assembly of the GTLS into the lens cap:

- 3.1 Invert the lens cap so that the cavities are accessible from above. Lens cap should remain inverted during this procedure until epoxy has dried.
- 3.2 Carefully insert GTLS into the lens cap cavity, preferably using soft-tipped utensils such as plastic tweezers.
- 3.3 Insert silicone disk, flat end first, until it fits snugly against end of GTLS.
- 3.4 Inject epoxy adhesive into remaining volume of cavity until it is flush with the lens cap lip.
- 3.5 Store the inverted lens cap for drying/hardening time specified by epoxy manufacturer.

4.0 Manufacturer's Inspection: Assembled Lens Cap

100% of all assembled lens caps will be inspected. The following steps will be used to verify that the GTLSs have been securely installed into the lens cap:

- 4.1 100% Inspection for Proper Assembly
 - 4.1.1 Visually inspect each lens cap to assure that all GTLSs have been installed and that epoxy level is flush with the lens cap lip.

- 4.1.2 Turn the lens cap over so that the lens is facing up; hold the lens cap, being sure not to cover the cavities, over a soft-covered, wide area surface; shake the cap rigorously to assure that none of the GTLSs are dislodged.
- 4.1.3 Any lens cap that does not meet the specified requirements will be segregated and will not be used in assembly pending further evaluation.
- 4.2 100% Visual Inspection for Proper Labeling
 - 4.2.1 Visually inspect each lens cap to assure that it is legibly and indelibly labeled with the radionuclide symbol and the identifying information for the U.S. distributor (initial transferor).
 - 4.2.2 Any lens cap that does not meet the specified requirements will be segregated and will not be used in assembly pending further evaluation.
- 4.3 100% Visual Inspection for GTLS Brightness (Leak Indication)
 - 4.3.1 Place all assembled lens caps in darkened room conditions. Allow inspector's eyes to adjust to darkened conditions.
 - 4.3.2 Compare each individual lens cap to a standard lens cap (one selected specifically for this inspection procedure that contains GTLSs of appropriate brightness). Rotate lens cap and inspect all GTLSs; identify any GTLS that emits light at a brightness level visibly lower than that of the standard as one that does not meet specified requirements.
 - 4.3.3 Any lens cap that does not meet the specified requirements will be segregated and will not be used in assembly pending further evaluation.

5.0 Manufacturer's Inspection: SSD Body and LED Assembly

Random samples (~10%) of all SSD bodies and LED assemblies should be inspected immediately prior to SSD assembly to assure that they are complete and contain all necessary components:

- a) proper markings visible and legible on outside of body;
- b) copper contact strip in-place with rubber spring at bottom;
- c) o-rings in-place;
- d) LEDs secure in LED holder, and
- e) hydrogen catalyst secure in LED holder.

Any SSD body or LED assembly that does not meet the specified requirements will constitute 100% inspection by this procedure of all applicable components in that production lot. Any SSD body or LED assembly that fails specified requirements will be segregated and not used in assembly pending further evaluation.

6.0 Assembly: SSD

The following steps will be used for assembly of the SSD:

- 6.1 Place the LED assembly, light first, into the open end of the lens cap; verify that the LED assembly is properly seated.
- 6.2 Screw the lens cap securely onto the body until the lip is flush with the SSD body seat.
- 6.3 Unscrew the lens cap approximately one (1) full turn.
- 6.4 Store/segregate successfully assembled SSDs for further requirements.

7.0 Assembly Inspection: SSD

Random samples (~10%) of all SSDs awaiting assembly will be assembled with the batteries installed to verify proper operation. The following steps will be used for assembly inspection of the SSD:

- 7.1 Place the LED assembly, light first, into the open end of the lens cap.
- 7.2 Install three (3) AA batteries into the body with the positive (+) terminals facing the open end.
- 7.3 Screw the lens cap securely onto the body until the lip is flush with the SSD body seat; verify that the LED lights are on.
- 7.4 Unscrew the lens cap approximately one (1) full turn; verify that the LED lights are off.
- 7.5 Unscrew lens cap completely, remove batteries, screw the lens cap securely onto the body until the lip is flush with the SSD body seat, unscrew the lens cap approximately one (1) full turn.
- 7.6 Any SSD that does not meet the specified requirements will constitute 100% inspection by this procedure of all applicable components in that production lot. Any SSD body or LED assembly that fails specified requirements will be segregated and not considered for distribution pending further evaluation.

8.0 Segregation

All SSDs will be segregated into applicable categories to assure appropriate handling during the next phase.

- a) All SSDs in a single lot that have been fully assembled and have passed all applicable assembly inspections will be segregated and stored together in storage containers that are clearly and accordingly labeled so that the lot can be identified on the storage container.
- b) All SSDs that have been segregated because they did not pass applicable assembly inspections will be segregated and stored in storage containers that are clearly and accordingly labeled; these SSDs should be stored in a location that assures that they will not be confused with passing SSDs.

NOTE: This same philosophy will be used in the segregation of individual assembly components that have passed/failed applicable inspections.

G. TESTING PROCEDURES

1.0 Testing Conditions

Following successful assembly, each production lot will undergo testing. The following are conditions under which SSD lot testing will be performed:

- 1.1 Lot testing will be performed in accordance with the applicable requirements set forth in 10 CFR 32.110, "Acceptance sampling procedures under certain specific licenses."
- 1.2 The Lot Tolerance Percent Defective (LTPD) value is five percent (5%). 10 CFR 32.110, Table 6 (reproduced below) will be used to determine sample size for the specified lot size.

| Lot Size | Sample Size | Acceptance Number* |
|----------------|-------------|--------------------|
| 1 - 30 | All | 0 |
| 31 - 50 | 30 | 0 |
| 51 - 100 | 37 | 0 |
| 101 - 200 | 40 | 0 |
| 201 - 300 | 43 | 0 |
| 301 - 400 | 44 | 0 |
| 401 - 2,000 | 45 | 0 |
| 2001 - 100,000 | 75 | 0 |

* Acceptance number for all lot sizes is zero (0).

- 1.3 Acceptance number for all lot/sample sizes is zero (0). If any tested device fails, the entire lot will be subject to reevaluation, which could result in
- a) rework;
 - b) recycle, or
 - c) 100% lot testing on the specific testing item(s) on which the tested sample failed.

2.0 Manufacturer Lot Testing Requirements

The following are the applicable requirements for manufacturer lot testing:

- 2.1 The applicable requirements in ANSI/HPS N43.4-2000 will be used to perform SSD lot testing. These requirements are incorporated into the procedure "Performance Testing for the Litepro Teknolite™ Model Flashlight Containing Gaseous Tritium Light Sources." This procedure is part of the SSD registration application.
- 2.2 Each sample is selected randomly and uniformly from the entire volume of the applicable lot being tested.
- 2.3 Each sample unit is subjected to all tests in the specified order.
- 2.4 All samples must pass all applicable tests prior to the lot being candidate for distribution.

NOTE: Any lot that is candidate for distribution should be segregated and stored separate from those awaiting testing results or additional evaluation.

3.0 Manufacturer Lot Testing Certification

Manufacturer lot testing results will be documented on the "Manufacturer Certificate of Quality Control Testing" (Attachment QC-2).

4.0 U.S. Distributor Lot Testing Requirements

The U.S. distributor will perform 5% LTPD lot testing for leakage (instead of removable contamination) and design conformity. U.S. distributor will perform lot testing in accordance with the requirements in Section 1.0 of this part. These tests will be satisfied by visual inspections of the intact individual SSD final packagings at the U.S. distributor's facility, prior to distribution, using the following procedures.

- 4.1 Each sample is selected randomly and uniformly from the entire volume of the applicable lot being tested. Each selected sample will be subjected to both of the following inspections.
- 4.2 Visual Inspection for Proper Labeling

- 4.2.1 Visually inspect each lens cap to assure that it is legibly and indelibly labeled with the radionuclide symbol and the identifying information for the U.S. distributor (initial transferor).
- 4.2.2 If any lens cap does not meet the specified requirements, the entire lot will be inspected. Failures will be segregated and will not be candidate for distribution pending further evaluation, which could result in return to the manufacturer for rework or recycle.
- 4.3 Visual Inspection for GTLS Brightness (Leak Indication)
 - 4.3.1 Place all selected samples in darkened room conditions. Allow inspector's eyes to adjust to darkened conditions.
 - 4.3.2 Compare the brightness of each individual GTLS in the lens cap of each SSD sample to a standard SSD (one selected specifically for this inspection procedure that contains GTLSs of appropriate brightness). Rotate lens cap and inspect all GTLSs; identify any GTLS that emits light at a brightness level visibly lower than that of the standard as one that does not meet specified requirements.
 - 4.3.3 If any GTLS does not meet the specified requirements, the entire lot will be inspected. Failures will be segregated and will not be candidate for distribution pending further evaluation, which could result in
 - 4.3.4 return to the manufacturer for rework or recycle, or
 - 4.3.5 on-site waste handling/disposal requirements in accordance with conditions set forth in the applicable possession license program.

5.0 U.S. Distributor Lot Testing Certification

U.S. distributor lot testing results will be documented on the "U.S. Distributor Certificate of Quality Control Testing" (Attachment QC-3).

H. PACKAGING, SHIPPING, AND DISTRIBUTION

1.0 Packaging

Packaging of the SSDs for shipment to the initial U.S. Distributor will be as follows:

- 1.1 Each SSD will be packaged, along with applicable information and peripheral materials, into a clamshell-type package following successful completion of lot testing and subsequent lot certification.

- 1.2 The SSD packages may be bundled into shipping boxes that include anywhere from six (6) to twelve (12) SSD packages.
- 1.3 The shipping boxes may be bundled onto pallets that contain from six (6) to twelve (12) boxes (36-144 SSDs) each; the pallet should be regarded as an individual shipping unit.

2.0 Shipping

In accordance with DOT and IATA shipping regulations, the quantities of radioactive materials in the previously specified shipping units and their subsequent classification should not require special hazardous materials packaging, manifesting, or transportation provisions. The shipping units may be shipped to the initial U.S. Distributor using any combination of ground, air, or water vessel transportation.

3.0 Distribution

- 3.1 Once the initial U.S. Distributor receives the shipping unit, it will be properly inventoried and stored in a facility that is licensed for possession by the appropriate regulatory agency.
- 3.2 The possession licensee or designee will inspect any shipping unit that appears to be damaged; any SSD found to be damaged to the extent that it does not operate in accordance with specifications will be segregated for further evaluation.
- 3.3 All SSDs will be distributed under the conditions set forth in the applicable distribution license issued by the U.S. Nuclear Regulatory Commission.
- 3.4 SSDs may be shipped by U.S. Distributor for distribution as palleted units (as received from the manufacturer), in boxes, or as individual packages.

I. RECORDS, DOCUMENTATION, AND REPORTING

All records and documentation associated with production and distribution of the SSD will be maintained such that the reporting requirements in 10 CFR 32.25(c) can be satisfied.

1.0 Manufacture

All records and documentation generated as a result of manufacturing, including assembly, inspection, testing, and shipping, will be maintained at the manufacturer's facility under the custody of the QC Manager.

2.0 Distribution

All records and documentation generated as a result of distribution, including shipping and distribution records, will be maintained at the distributor's facility under the custody of the QC Director.

J. AUDITS

Two audit categories will apply to this QC Program:

1.0 Routine Audits

1.1 Routine audits will primarily be performed on the processes associated with manufacturing; they should evaluate the day-to-day operations, including inspections and assembly, segregation and storage, lot testing, and record keeping.

1.2 These audits can be performed by the QCM, QCD, or QCD Designee.

1.3 The audit frequency should initially be on a monthly basis; the frequency can be increased at the discretion of the QCM; a decrease in frequency should be approved by the QCD and should be based on the merit of program performance. The maximum duration between routine audits will be quarterly, not to exceed four (4) months.

1.4 The QCM will report the results/findings of each audit activity, in documented form, to the QCD for review; any items that are not in compliance with the requirements of this QC Program will result in (a) prompt corrective action under the authority of the QCM, and (b) documented corrective action report (CAR) that will be submitted to the QCD for review and approval.

1.5 Original routine audit documentation should be maintained at the manufacturer's facility under the custody of the QCM; copies should be maintained by the QCD.

2.0 Program Audits

2.1 Program audits will be performed on all aspects of the production and distribution process.

- 2.2 These audits can be performed by the QCD or QCD Designee.
- 2.3 The audit frequency should initially be on a semi-annual basis; the frequency can be increased or decreased at the discretion of the QCD and should be based on the merit of program performance. The maximum duration between routine audits will be annually, not to exceed fourteen (14) months.
- 2.4 The results/findings of each program audit will be documented and submitted to the QCM for review; any items that are not in compliance with the requirements of this QC Program will result in prompt corrective action under the authority of the QCD and implementation by the QCM (for manufacturing facility items) and implementation by the QCD (for distribution facility items); a documented corrective action report (CAR) that will be submitted to the QCD for review and approval.
- 2.5 Original program audit documentation should be maintained by the QCD; copies should be maintained under the custody of the QCM.



Attachment QC-1: Employee Training/Evaluation

This form should be used to document any training or evaluation (such as annual review) of an employee's performance with respect to the manufacture and distribution of the SSD.

Trainee: _____

Department: _____

Duties/Responsibilities (circle all that apply):

Inspector Assembler Tester Shipper Auditor Trainer Other _____

TRAINING TOPICS

A. OVERVIEW (0.25 hrs)

- Product development, production, and distribution summary
- General discussion of manufacturing facility's role and responsibilities

B. ORGANIZATION (0.25 hrs)

- Organizational chart
- Personnel responsibilities

C. PERSONNEL (0.5 hrs)

- Training requirements
- Training documentation (Attachment QC-1)

D. EQUIPMENT (2.0 hrs)

- GTLS inspection equipment
- Standard SSD assembly equipment
- Lot testing equipment
- Testing equipment calibration requirements, documentation

E. DESIGN AND DOCUMENT CONTROL (0.5 hrs)

- Applicable documents (procedures, records, etc.)
 - Manufacturing facility
 - Distribution facility
- QC Program changes

F. ASSEMBLY AND INSPECTION PROCEDURES (4.0 – 6.0 hrs)

- 1.0 Discussion of GTLS manufacturer's testing/inspection
- 2.0 SSD manufacturer's inspection of GTLS
- 3.0 SSD lens cap assembly
- 4.0 Assembled SSD lens cap inspection
- 5.0 SSD body and LED inspection
- 6.0 SSD assembly
- 7.0 Assembled SSD inspection
- 8.0 Segregation
 - 8.1 Inspection passes
 - 8.2 Inspection failures

G. TESTING PROCEDURES (6.0 - 8.0 hrs)

Manufacturing Facility

- 1.0 Testing conditions
 - 1.1 Acceptance sampling (10 CFR 32.110)
 - 1.2 Lot Tolerance Percent Defective (LTPD)
 - 1.3 Acceptance number, SSD failures

2.0 Testing requirements - Standard Operating Procedure: "Performance Testing for the Litepro Teknolite™ Model Flashlight Containing Gaseous Tritium Light Sources" (ANSI/HPS N43.4-2000)

2.1 Detailed training on implementation of SOP

2.2 Documentation of testing results on Forms A-1/A-2

3.0 Lot testing certification (Attachment QC-2)

U.S. Distribution Facility

4.0 Visual inspection of packaged SSD for labeling, brightness

- LTPD
- Acceptance criteria
- Acceptance number, SSD failures
- Inspection procedure
- Documentation of inspection results (Attachment QC-3)

H. PACKAGING, SHIPPING, AND DISTRIBUTION (3.0 hrs)

1.0 Packaging

1.1 Individual SSD packaging

1.2 Bulk packaging

1.3 Shipping unit packaging

2.0 Shipping

3.0 Distribution

3.1 Receipt, inspection

3.2 Segregation

3.3 Exempt distribution requirements

3.4 Exempt distribution packaging

I. RECORDS, DOCUMENTATION, AND REPORTING (2.0 hrs)

- 1.0 Manufacturer's facility – maintained by QC Manager
- 2.0 U.S. distribution facility – maintained by QC Director
- 3.0 Reporting requirements (10 CFR 32.25(c))

J. AUDITS (2.0 hrs)

1.0 Routine operational audits

- 1.1 Audit components
- 1.2 Authorized auditors
- 1.3 Frequency
- 1.4 Audit results, actions
- 1.5 Documentation, reporting

2.0 Program audits

- 2.1 Audit components
- 2.2 Authorized auditors
- 2.3 Frequency
- 2.4 Audit results, actions
- 2.5 Documentation, reporting

Trainee is required to undergo classroom-type training on the above specified topics. Trainee will then be required to take and pass a written exam prior to practical application training and performance.

Exam Score: _____% (minimum passing score is 75%) Pass/Fail

_____ Trainer/trainee exam review (trainee's initials)

PRACTICAL APPLICATION TRAINING

Following the successful completion of classroom-type training and testing, trainee will undergo practical application training. Practical application training will consist of a combination of the interactive performance, by both trainer and trainee, of all applicable QC Program procedures. Authorized auditors and trainers will also undergo training focused on performing QC audits and personnel training as an interactive part of the practical application training.

The following training topics outlined above will be covered in practical application training:

- D. EQUIPMENT (1.0 - 2.0 hrs) – Inspectors, assemblers, testers, auditors, and trainers
- F. ASSEMBLY AND INSPECTION PROCEDURES (4.0 – 6.0 hrs) - Inspectors, assemblers, auditors, and trainers
- G. TESTING PROCEDURES (6.0 - 8.0 hrs) – Testers, auditors, and trainers
- H. PACKAGING, SHIPPING, AND DISTRIBUTION (3.0 hrs) – Shippers, auditors, and trainers
- I. RECORDS, DOCUMENTATION, AND REPORTING (2.0 hrs) – Inspectors, assemblers, testers, auditors, and trainers
- J. AUDITS (Continuous throughout course of training) - Auditors

Trainer will observe trainee’s independent performance of all applicable practical application procedures and requirements. It will be the trainer’s responsibility to use professional judgment to determine that the trainee has satisfactorily performed all applicable requirements of this QC Program prior to such trainee being authorized to perform them independently.

Trainer’s Observations: _____

I have completed QC Program training/evaluation on ____/____/____(date). I understand that it is my responsibility to independently perform all specified duties in accordance with such training and the contents of the QC Program.

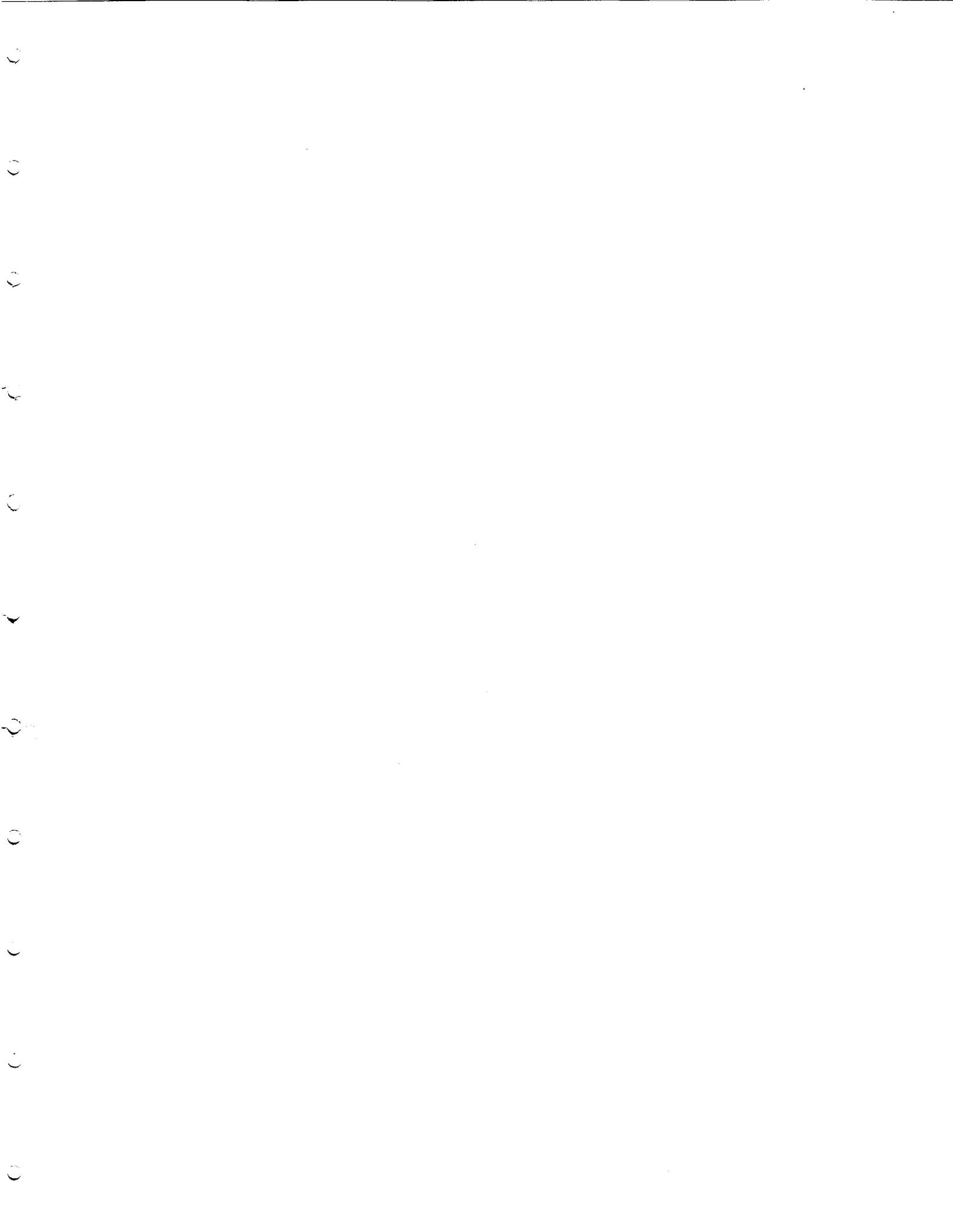
Trainee Signature

Trainer Signature

Title

Quality Control Manager Approval

____/____/____
Date



Attachment QC-2: Manufacturer Certificate of Quality Control Testing

Sealed Source Device (SSD) - Litepro Teknolite™ Torch Containing Gaseous Tritium Light Sources (GTLS)

SSD Production Lot Number: _____

SSD US NRC Registration Number: _____

SSD US NRC License Number: _____

| | | |
|---------------------|---------------|---------------|
| SSD Model: | Teknolite™ #2 | Teknolite™ #4 |
| SSD # of GTLSs: | 2 | 4 |
| SSD Total Activity: | 78 mCi | 156 mCi |

*Cross-out
inapplicable
model*

1. Requirements for GTLS used in SSD

All GTLSs used are taken from production lots exhibiting leakage of less than 50 nCi of tritium per 24 hours per batch of a minimum of 16 sources tested. Results of 100% testing per ANSI/HPS N43.4-2000, Section 8.3.2 are on file at mb-microtec, Inc., Niederwangen, Switzerland.

2. Requirements for Production Lots of Assembled SSDs

- 2.1 100% visual inspection of assembled lens caps for proper assembly.
- 2.2 100% visual inspection of lens caps for proper markings/labeling (design conformity).
- 2.3 100% visual inspection of GTLSs in lens caps for proper brightness (leakage).
- 2.4 Random sample lot testing (5% LTPD) per 10 CFR 32.110, ANSI/HPS N43.4-2000.



Attachment QC-3: U.S. Distributor Certificate of Quality Control Testing

Sealed Source Device (SSD) - Litepro Teknolite™ Torch Containing Gaseous Tritium Light Sources (GTLS)

SSD Production Lot Number: _____

SSD US NRC Registration Number: _____

SSD US NRC License Number: _____

SSD Model:
SSD # of GTLSs:
SSD Total Activity:

| |
|---------------|
| Teknolite™ #2 |
| 2 |
| 78 mCi |

| |
|---------------|
| Teknolite™ #4 |
| 4 |
| 156 mCi |

*Cross-out
inapplicable
model*

1. Manufacture Requirements for Production Lots of Assembled SSD

All SSDs used are taken from production lots that have been accepted by the manufacturer as meeting all requirements set forth in the QC Program.

2. Exempt Distribution Requirements of Production Lots of Assembled SSD

Visual inspections of final packaged SSD in accordance with the LTPD requirements of the QC Program, Part G, Section 4.0:

- 2.1 Visual inspection of lens caps for proper markings/labeling (design conformity).
- 2.2 Visual inspection of GTLSs in lens caps for proper brightness (leakage).

Inspection Results

Lot Size = _____ units

Sample Size = _____ units

Acceptance Number = 0 units

2.1 Visual inspection of lens caps for proper markings/labeling: Pass / Fail

2.2 Visual inspection of GTLSs in lens caps for proper brightness: Pass / Fail

Comments: _____

Production Lot Number _____ is Accepted / Rejected

Quality Control Director Signature

Certification Date