STANDARD OPERATING PROCEDURE
LOT PERFORMANCE TESTING
FOR THE
LITEPRO TEKNOLITE™ MODEL FLASHLIGHT
CONTAINING
GASEOUS TRITIUM LIGHT SOURCES

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1.0 INTRODUCTION

1.1 Purpose

The purpose of this standard operating procedure (SOP) is to test, evaluate, and document the performance of a sealed source device.

1.2 Sealed Source Device

A sealed source device (SSD) is a product, item, etc. that incorporates radioactive material in the form of a sealed radioactive source. This SOP is specific to the following SSD:

SSD Name:	Litepro Teknolite™ Model Flashlight
SSD Owner/Company:	Litepro, LLC
SSD Manufacturer/Assembler:	Keen Tools, Inc.
SSD Description:	Rugged flashlight that incorporates 2-4 Traser® gaseous tritium light sources (GTLS) into its design
GTLS Manufacturer:	mb-microtec Traser® Part Number T 5372-1
GTLS Radionuclide:	Tritium (^{3}H)
SSD Total ^{3}H Activity (Maximum):	5.8 GBq (156 mCi), 1.4 GBq (39 mCi) per GTLS

1.3 Sealed Source (GTLS) Registration

The GTLS that will be incorporated into this SSD has already been approved and registered in the NRC's Registry of Radioactive Sources and Devices in accordance with 10 CFR 32. The Registration Number is NR-446-S-102-S, which includes Model Numbers 400/1, 400/2, 400/3, 400/4 400/5 and 400/6. These GTLS are currently approved for incorporation into SSDs such as luminous gunsights (Registration Number NR-418-D-101-E) and wrist watches (Registration Number NR-446-D-103-E), both of which are currently licensed for exempt distribution.

1.4 Regulatory Requirements and Guidance

In order to manufacture, use, distribute, etc. a device in the United States that incorporates radioactive material, certain licensing requirements have to be considered. In the case of this SSD, a distribution license issued by the Nuclear Regulatory Commission (NRC) is required. One of the requirements of the distribution license is a SSD safety evaluation and registration as specified in 10 CFR 32. NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," (1556v3) provides regulatory guidance for implementing the requirements in 10 CFR 32. 1556v3, Section 10.5, discusses appropriate testing methods.

The primary method that will be used in the SOP for SSD for testing and evaluation is lot testing in accordance with 10 CFR 32.110 at a lot tolerance percent defective (LTPD) of 5%.

1.5 Testing Standards Guidance

1556v3, Appendix G recommends using American National Standards Institute Committee Document N43.4-1975, "Classification of Radioactive Self-Luminous Light Sources" (ANSI N43.4-1975) as the bases for this SSD testing. ANSI/HPS N43.4-2000, "Classification of Radioactive Self-Luminous Light Sources," is a more recent version of ANSI N43.4-1975. ANSI/HPS N43.4-2000 was used as the basis for the development of this SOP.

1.6 SSD Classification Designation

ANSI/HPS N43.4-2000, Table 1 establishes a maximum activity for a GTLS of 1850 GBq (50 Ci). The GTLS classification is determined in Table 3, based on the SSD activity fraction/percentage of 1850 GBq (50 Ci). The SSD total activity is 5.8 GBq (156 mCi), which is 0.31% of 1850 GBq (50 Ci); therefore, the SSD qualifies as Class 2, which has an upper limit of 18.5 GBq (500 mCi).

Once the SSD classification has been established, the classification designation can be determined. The SSD classification designation is determined using the conditions in

ANSI/HPS N43.4-2000, Section 5, "Classification Designation." The resulting SSD classification designation, based exclusively on the criteria, is T2GC. Therefore, the SSD will be assigned and tested based on the following classification designation:

T2GC1222222

1.7 Documentation

All documentation generated pertinent to this test shall be in legible English.

Form A-1 in Appendix A contains the specifications for each test to be performed in this SOP. Form A-1 shall be used to document the results of each test. Additionally, Form A-2 in Appendix A shall be used to document additional notes, calculations, and etc. pertinent to the execution of this SOP.

2.0 LOT PERFORMANCE TESTING PROCEDURES

2.1 General

The lot testing procedures described below are acceptable and recommended procedures for conducting the performance tests prescribed in ANSI/HPS N43.4-2000. Procedures demonstrated to be at least equivalent are also acceptable. Any equivalent procedures shall be documented in detail on Forms A-1 and A-2.

- A minimum of two SSDs representing each SSD lot shall undergo each test in this SOP. The typical number of SSDs tested for each lot will be based on the table in 10 CFR 32.110 at a LTPD of 5% for the given lot size.
- Tests shall be run consecutively on each SSD in the order listed in this SOP and shown on Form A-1.
- Unless otherwise specified the tests shall be performed at 23°C ±10°C, at barometric pressure of 710-790 mm (28-31") mercury and at a maximum relative humidity of 80 percent. Temperature changes, unless otherwise specified, shall be gradual to reduce the possibility of thermal shock.
- Compliance with the tests shall be determined by:
    a. the ability of the SSD to maintain the GTLS in its initial secured condition, and
    b. the ability of the GTLS to maintain its integrity and brightness after each test performed, i.e., to retain its radioactive material and maintain, within the limits specified in this SOP, its physical and operating characteristics.
- In the event that any SSD or GTLS tested fails any test or the test series, the SSD shall be considered unacceptable.

2.2 Discoloration

2.2.1 Equipment

- Weatherometer or S-4 Sunlamp
- Corex D filter (or equivalent)
- Calcium chloride
- Glass container (8 liters or larger)

2.2.2 Procedure

a) Expose SSD in weatherometer for twelve hours, alternating one-half hour wet and dry cycles, or

b) Expose SSD for twelve hours to the light from an S-4 lamp, filtered by a Corex D filter, at a distance of 20 centimeters from the S-4 lamp.

All tests shall be performed in air with an ambient temperature of 27°C ± 10°C and a relative humidity of 95 to 100 percent. The SSD shall be irradiated with the light impinging on the translucent surface of the GTLS.

2.2.3 Evaluation

SSD shall be examined visually and any discoloration or other effects on the GTLS observed. The light spectrum and output after the test shall be compared with that before the test. When measured with a visual photometer or a color corrected photocell, no grater loss of luminosity than 20 percent shall be observed.

2.3 Temperature Test

2.3.1 Equipment

The heating or cooling equipment shall have a test zone volume (that volume at essentially constant temperature) of at least five times the volume of the SSD. The temperature of the test chamber shall be determined by at least two recently calibrated (within the past two years) temperature-measuring instruments, and the average of the readings shall be taken as the true temperature.

If a gas or oil-fired furnace is used for the temperature test, an oxidizing atmosphere shall be maintained at all times.

2.3.2 Procedure

Conditions

- All temperature tests shall be performed in air.
- High temperature or low temperature test can be performed in either order.
- High temperature:
  1. Heat SSD to a constant test chamber temperature of at least 50°C. Achieve this temperature in no more than 5 minutes.
  2. Maintain this temperature for at least 1 hour.
  3. Return the test chamber temperature to ambient. The SSD shall be allowed to remain in the test chamber until ambient conditions are achieved.
- Low temperature:
  1. Cool SSD to a constant test chamber temperature at or below 0°C. Achieve this temperature in less than 45 minutes.
  2. Maintain this temperature for at least 1 hour.
  3. Return the test chamber temperature to ambient. The SSD shall be allowed to remain in the test chamber until ambient conditions are achieved.

2.3.3 Evaluation

SSD shall be examined visually for any evidence of failure of the GTLS and its containment and, in the absence of any evident failure, shall be used in the succeeding thermal shock test. In the event of any uncertainty regarding possible failure, the person performing the test may, at his option, subject the SSD to the final immersion test before proceeding within the next test.

2.4 Thermal Shock Test

2.4.1 Equipment

Same as 2.3 – Temperature test.

2.4.2 Procedure

1. Heat the SSD using the high temperature procedure in Section 2.3.2 and hold at this temperature for at least 15 minutes.
2. Transfer the SSD, in 15 seconds or less, to the cold chamber, held at or below the minimum temperature specified in Section 2.3.2.

2.4.3 Evaluation

SSD shall be examined visually for any evidence of failure of the GTLS and its containment and, in the absence of any evident failure, shall be used in the succeeding pressure test. In the event of any uncertainty regarding possible failure, the person performing the test may, at his option, subject the SSD to the final immersion test before proceeding with the next test.

2.5 Pressure (Reduced) Test

2.5.1 Equipment

The apparatus used for the pressure test should consist of a vacuum pump, vented to a suitable exhaust system, and a suitable sealed chamber having means for visual observation of the SSD and GTLS under test. The pressure gauge shall be recently calibrated and should have a range at least 10 percent greater than the test pressure.

2.5.2 Procedure

The SSD shall be put into the chamber and exposed to the test pressure of 226 mm Hg absolute for four periods of 15 minutes each, the pressure being returned to atmospheric between each period.

2.5.3 Evaluation

SSD shall be examined visually for any evidence of failure of the GTLS and its containment and, in the absence of any evident failure, shall be used in the succeeding impact test. In the event of

any uncertainty regarding possible failure, the person performing the test may, at his option, subject the SSD to the final immersion test before proceeding with the next test.

2.6 Impact Test

2.6.1 Equipment

- Steel plate rigidly mounted on an unyielding surface so that it will not deflect appreciably during the test. Plate should be of adequate surface area such that the SSD comes to rest on the plate following each impact.
- Support or shelf for SSD that will allow a minimum 1-meter free fall.

2.6.2 Procedure

1. Mount the SSD support above the steel plate at a height of at least 1 meter.
2. Place the SSD to be tested on the support and push the SSD from the support and allow it to free fall and impact the steel plate.
3. SSD should be observed to land such that first impact occurs between the lens cap and the surface at least once.
4. Perform the previous steps a minimum of 2 times.

2.6.3 Evaluation

SSD shall be examined visually for any evidence of failure of the GTLS and its containment and, in the absence of any evident failure, shall be used for the succeeding vibration test. In the event of uncertainty regarding possible failure, the person performing the test may, at his option, subject the SSD to the final immersion test before proceeding with the next test.

2.7 Vibration Test

2.7.1 Equipment

The equipment shall be capable of providing a simple harmonic motion having an amplitude of 0.075 cm (0.03") and a maximum total excursion of 0.15 cm (0.06"), the frequency being varied uniformly between the approximate limits of 10 and 55 hertz (Hz).

2.7.2 Procedure

SSD shall be subjected to the above simple harmonic motion for a minimum of 10 minutes. The entire frequency range, between 10 Hz and 55 Hz and return to 10 Hz, shall be traversed in approximately 1 minute.

2.7.3 Evaluation

SSD shall be examined visually for any evidence of failure of the GTLS and its containment and, in the absence of any evident failure, shall be used for the succeeding immersion test.

2.8 Immersion Test

2.8.1 Equipment

- Hot and cold baths. Bath volume, or temperature control, shall be such that bath temperature does not change by more than ±3°C during the test cycle.
- A dye may be used to observe any gross penetration.

2.8.2 Procedure

1. Immerse the SSD in a water bath, maintained at 0°C, for 15 minutes.
2. Immediately (1 minute maximum) transfer the SSD to a hot water bath, maintained at 50°C, for 15 minutes.
3. Immediately (1 minute maximum), transfer to the cold bath for 15 minutes.
4. Perform Steps 2 and 3 twice (2 cycles).

2.8.3 Evaluation

1. SSD shall be examined visually for any evidence of failure of the GTLS and its containment.
2. The total ^{3}H activity in the hot and cold bath liquids shall be determined. The total ^{3}H activity in all liquids as a result of the presence of a single SSD shall not exceed 1850 Bq (50 nCi).

3.0 EVALUATION

After each SSD has been subjected to the entire test sequence, determination of compliance with the performance test requirements shall be made in accordance with the procedures described below. These evaluations shall be made in addition to the evaluation procedures specified for the individual tests.

- The SSD shall be examined visually for any evidence of failure, visible leakage or degradation.
- The SSD shall be subjected to brightness measurements and the loss of luminosity shall not exceed 20 percent of that observed prior to testing.
- The SSD shall be tested for loss of radioactive contents as follows:

  Each SSD shall be soaked tested for 24 hours in a volume of water about equal to 10 times the volume of the SSD. The SSD shall be removed and the total ^{3}H activity in the liquid measured. The total activity in the liquid shall not exceed 1850 Bq (50 nCi).

APPENDIX A

FORM A-1

FORM A-2

Form A-1: This form shall be used to document the results of each test. Additional information pertinent to this SOP shall be documented on Form A-2.

Test		Specification[1]	Evaluation[2]
2.1	Ambient Conditions	Temperature = 23±10°C	
		Barometric Pressure = 710-790 mm Hg	
		Humidity ≤ 80%	
2.2	Discoloration	12-hour lamp	
2.3	Temperature	0°C and +50°C	
2.4	Thermal Shock	0°C to +50°C	
2.5	Pressure (Reduced)	226 mm Hg absolute	
2.6	Impact	1 meter free fall to steel plate 2 times	
2.7	Vibration	Simple harmonic motion	
		Amplitude of 0.075 cm	
		Maximum total excursion of 0.15 cm	
		Frequency varied uniformly between limits of 10 Hz to 55 Hz and back to 10 Hz in about 1 minute	
		Duration = 10 minutes	
2.8	Immersion	0°C to +50°C for 2 cycles	

[1] Refer to applicable SOP test section for detailed specification.
[2] Use Form A-2 to document additional evaluation information.

Page Number: A-2-_____

Form A-2: This form shall be used to document additional notes, calculations, and etc. pertinent to the execution of this SOP. If more than one page is needed, number pages consecutively.