# Application and Review Checklist for Acceptance Review for SSD 01-028

**SUMMARY DATA**

**Name and Complete Mailing Address of the Applicant:**
**Litepro, LLC**
**3731 North Country Club Drive, Suite 525**
**Aventura, FL 33180**

**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:**
**Joseph Tchira, President**
**305-931-6990 (voice)**
**305-513-5927 (fax)**

**The Applicant is (check one):**

| | |
|---|---|
| | Custom User |
| | Manufacturer |
| X | Distributor |
| | Manufacturer and Distributor |

**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
**Keen Tools, Inc.**
**49-1 Feng Hwa, Feng Hwa Tsen**
**Shin Shyh Hsiang, Tainan Hsien**
**Taiwan, ROC**

**If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:**
**N/A**

**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:**
**GTLS manufacturer**
**mb-Microtec**
**Freiburgstrasse 624**
**CH-3172 Niederwangen**
**Switzerland**

**Model Number: Teknolite**

**Principal Use Code (see Appendix E):**

**Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):**

**For Use by:**

| | |
|---|---|
| | Specific Licensees Only |
| | General Licensees Only |
| | Both Specific and General Licensees |
| X | Persons Exempt from Licensing |

**Leak-Test Frequency:**

| | |
|---|---|
| x | Periodic Leak-Testing is Not Required |
| | 6 Months |
| | Attached is justification for a leak test frequency of greater than 6 months |

**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 30.19, 32.22**

**Radionuclides and Maximum Activities (including loading tolerance):**
**H-3, 156 mCi**

**CERTIFICATION:**

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 AND 32 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.

**Certifying Officer — Typed Name and Title**

**Signature:** **Date:**

## CHECKLIST

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | OK/DEF | COMMENTS |
|---|---|---|
| DESCRIPTION/CONSTRUCTION | | |
| If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so? | NA | |
| Device/source design with complete engineering drawings (dimensions, tolerances, list of materials) | x | |
| Assembly methods (screw, welds, etc.); verify integrity | x | |
| Source mounting (size and integrity) and security | x | |
| Is source classification sufficient (ANSI N43.6 or ISO 2919)?<br>Radiography - Unprotected . . . . . 43515<br>Radiography - In Device . . . . . 43313<br>Medical - Radiography . . . . . 32312<br>Medical - γ Teletherapy . . . . . 53524<br>Medical - Brachytherapy . . . . . 53211<br>Medical - Source Applicators . . . . . 43312<br>γ Gauges - Unprotected . . . . . 43333<br>γ Gauges - In Device . . . . . 43232<br>β Gauges, Low Energy γ Gauges, or X-ray fluorescence . . . . . 33222<br>Oil Well Logging . . . . . 56522<br>Portable Moist/Density . . . . . 43333<br>Neutron Applications . . . . . 43323<br>Calibration source activity > 30$\mu$Ci (1 MBq) . . . . . 22212<br>γ Irradiators (I) . . . . . 43323<br>γ Irradiators (II, III) . . . . . 43424<br>γ Irradiators (II, III, IV) . . . . . 53424<br>Chromatography . . . . . 32211<br>Static Eliminators . . . . . 22222<br>Smoke Detectors . . . . . 32222 | N43.4-2000 | |
| Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances | NA | |
| On-Off indicators (description, qty., location) | NA | |
| Safety interlocks, guards, etc. to prevent access to beam or high radiation levels | NA | |
| Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.) | x | |
| Shielding efficiency and integrity | x | |
| For medical devices: Was a 510(k) provided? (provide written notification to FDA) | NA | |
| Well logging sources must be nondispersible and nonsoluble. (see App. B for a list of approved well logging sources as of Nov. 1991) | NA | |
| See “ANSI and Other Standards” list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.) | N43.4-2000 | |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | OK/DEF | COMMENTS |
|---|---|---|
| LABELING | Def | |
| Copy of label | | |
| Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20) | | |
| Permanent attachment and location(s) - visible to users? | | |
| Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, “CAUTION - RADIOACTIVE MATERIAL” (Depleted Uranium information must be included) | | |
| CONDITIONS OF USE | | |
| Expected working life of the source/device (years, operations) | x | |
| Actions to be taken when product reaches end of its working life. | NA | |
| Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport) | x | |
| How the device will be used | x | |
| Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing | x | |
| PROTOTYPE TESTING/HISTORICAL USE | | |
| Tests methods and conditions (for source and device) | Def | RAI |
| Tests results | x | |
| Years of use (incidents, failures, etc.) | x | |
| Similarities to other sources/devices if they are used as basis. | x | |
| RADIATION PROFILES | OK | |
| Survey instrument used (type, window thickness, sensitivity, etc.) | | |
| Conditions: including environments, scatter (product in beam), and use of guards and shields | | |
| Distance from source/surface (per ANSI 538-1979) | | |
| Shutter Open and Closed/Source Shielded | | |
| Verify radiation surveys for γ radiation meet $inv^2$ law. | | |
| Verify radiation surveys for non-γ radiation have not been calculated using $inv^2$ law. | | |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | OK/DEF | COMMENTS |
|---|---|---|
| QUALITY ASSURANCE | Def | App. C & D are missing. |
| Materials, subassemblies, services | | |
| Assembly methods (screws, welding, etc.) | | |
| Dimensions and tolerances | | |
| Activity, radiation levels, leak tests | | |
| QA Manual and comparison of manual to Regulatory Guide 6.9 | | |
| INSTALLATION | | |
| Fixed, portable, movable, fixed installation but portable source housing | NA | |
| Inherent shielding, inaccessibility | x | |
| Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers | x | |
| Mounting integrity | x | |
| SAFETY INSTRUCTIONS | | |
| Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys | NA | |
| ACCOMPANYING DOCUMENTATION | | |
| Leak tests results and radiation surveys | | |
| Transportation documents | | |
| Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable | | |
| For Distribution to General Licensees:<br>Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations | | |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | | | | OK/DEF | COMMENTS |
|---|---|---|---|---|---|
| SERVICING | | | | | |
| The following activities may be performed by the persons indicated: | | | | | |
| Activity | by a General Licensee | Only by a Specific Licensee | Will be Offered by the Applicant | | |
| Installation | | | | | |
| Relocation | | | | | |
| Maintenance | | | | | |
| Repair | | | | | |
| Source Exchange | | | | | |
| Calibration | | | | | |
| Leak Testing | | | | | |
| Radiation Survey | | | | | |
| Training | | | | | |
| FOREIGN VENDORS | | | | Def | |
| Drop ship | | | | | |
| Who and where is source installed | | | | | |
| Leak test and radiation surveys | | | | | |
| QA in the U.S. | | | | | |

**Signature:** ***/RA/*** **Date:** 06/07/2001

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