

From: [Wilson, Scott](#)
To: [Jay Gupta \(jay@plusbrandsllc.com\)](mailto:jay@plusbrandsllc.com)
Cc: [Danny Evans \(dannyjevans@att.net\)](mailto:dannyjevans@att.net); [Ullrich, Elizabeth](#)
Subject: PLUS, LLC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR LICENSE, CONTROL NO. 585055
Date: Tuesday, December 23, 2014 12:17:00 PM

License No. 06-35183-01
Docket No. 03038780
Control No. 585055

Jay Gupta
Director
Plus, LLC
733 Summer Street, Suite 506
Stamford, Connecticut 06901

cc: Daniel J. Evans, Certified Health Physicist
Simple Smart Safety, LLC

SUBJECT: PLUS, LLC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR LICENSE, CONTROL NO. 585055

Dear Mr. Gupta:

This is in reference to your application dated October 1, 2014 (application), requesting a Nuclear Regulatory Commission License. In order to continue our review, we need the following additional information in a written letter signed by Plus, LLC management:

1. Item 9 of the application states that the business model involves shipment from an overseas storage/warehouse location in small quantities to the address listed in Item 3 (Plus, LLC's address above) and that the facilities and equipment are dedicated to the receipt, handling, storage, and packaging for transfer of the devices listed in Item 5 (radioactive materials). However, Item 10 of the application states that licensed activities planned under the license are limited to receipt of individual units for return, temporary storage of units prior to shipment to supplier, packaging and shipment of units to overseas supplier, and quality assurance checks. **Please clarify the purpose for the license. Are the items to be received and initially distributed from Plus, LLC's address above? Are returned items to be received by Plus, LLC and returned to the manufacturer from the address above?**
2. This item is for information only, you do not need to respond to this item. The application states that Plus, LLC plans to package and ship units to an overseas supplier. Export of radioactive materials and devices requires a license issued in accordance with the requirements in 10 CFR 110. The license applied for in Plus, LLC's application is for the possession of licensed material in accordance with 10 CFR 30. **Please note 10 CFR 110.23 authorizes individuals to export materials under a general license with certain restrictions on the type, amount per shipment, annual total, and with prohibitions on export to certain countries. Note also that**

tritium for recycle or recovery, and radioactive waste cannot be shipped under a general license issued in accordance with 10 CFR 110.23. If you have any questions regarding the general license requirements, please contact our office.

3. Section 8.7.1 of NRC's 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution' ([NUREG-1556, Volume 12](#)), states in part that radiation safety officer's (RSOs) must have training and specific experience with the types and quantities of licensed material to be authorized on the license. Section 8.7.1 also requires the applicant to provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience. The application you submitted provided the RSO's name but did not include information demonstrating that the proposed RSO is qualified by training and experience for the duties of an RSO for this type of license. **Please provide information demonstrating that the RSO is qualified and trained in the duties of RSO.** Typical RSO duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. The specific duties the RSO should be aware of and trained in include, in part, the following items listed in Appendix G of [NUREG-1556, Volume 12](#):
 - Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;
 - Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301;
 - Ensure security of radioactive material;
 - Post documents as required by 10 CFR Parts 19.11 and 21.6;
 - Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements;
 - Ensure program audits are performed annually;
 - Ensure access to appropriate survey instruments or ensure an agreement is in place with a qualified radiation protection professional who will survey as necessary;
4. Section 8.8 of [NUREG-1556, Volume 12](#), 'Training for Individuals Working in or Frequenting Restricted Areas' requires the applicant to submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. The application included a sample training outline, however, the outline did not include a description of the specific training regarding the applicant's program and operating and emergency procedures, or the frequency of training. **Please provide information describing each proposed authorized user's radiation safety training specific to your licensed activities with the requested licensed materials and the frequency of training.**
5. Section 8.10.1 of [NUREG-1556, Volume 12](#), 'Audit Program' requires the applicant to provide a description of its audit program. The application submitted did not include this description. **Please state that you will review the content and implementation of the Radiation Protection Program at least annually as required in 10 CFR 20.1101(c).**

The purpose of the review is to ensure compliance with NRC and DOT regulations and the terms and conditions of the license; occupational doses and doses to members of

the public are ALARA (10 CFR 20.1101) and dose reduction efforts have been considered; and to ensure that operating procedures are in place for activities which could potentially affect radioactive material or occupational dose (10 CFR 20.1101(a)). An audit program that promptly identifies potential violations of regulatory requirements and takes prompt, comprehensive steps to correct them, meets NRC's expectations. Elements of an effective audit program and an example audit form are provided in [NUREG-1556, Volume 12](#).

6. Section 8.10.6 of [NUREG-1556, Volume 12](#), 'Operating and Emergency Procedures' requires the applicant to state that operating and emergency procedures will be developed and documented before receipt of licensed material. The application submitted did not include this statement. **Please state that operating and emergency procedures will be developed, documented and implemented before receipt of licensed material to include what will be done if sealed tritium light sources are found damaged.**
7. Section 8.10.7 of [NUREG-1556, Volume 12](#), 'Surveys and Leak Tests' requires the applicant to describe its survey and leak test program. The application submitted did not include this information. **Please state one of the following:**

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix P to NUREG-1556, Vol. 12." If applicable, state: "We will perform contamination checks on all fabricated sealed sources prior to distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."

OR

State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R to NUREG-1556, Vol. 12." If applicable, state: "We will perform contamination checks on all fabricated sealed sources prior to distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix Q to NUREG-1556, Vol. 12."

OR

Because your license will only authorize tritium in a sealed form, an acceptable minimum alternate survey frequency is annual or if any damaged or leaking sources are identified or suspected. **Please submit a description of *minimum routine survey frequency procedures* you will use to evaluate a radiological hazard. Confirm that a survey will be performed if damage to watches is identified that**

may involve release of tritium from the sources and potential contamination of facilities. Include a description of the type of survey(s) that will be performed and the availability of suitable instrumentation or equipment for performing such surveys.

8. Section 8.10.2 of [NUREG-1556, Volume 12](#), 'Radiation Monitoring' requires the applicant to provide a description of the survey instrumentation to be possessed and used by the applicant. The application submitted did not include this description. **If you do not elect to commit to the Appendix P procedures listed above, please provide a description of the instrumentation to be used in case of emergency or state that when surveys are required, Plus, LLC will hire a radiation safety consultant to perform surveys and analyze wipe tests for contamination.**
9. Section 8.10.3 of [NUREG-1556, Volume 12](#), 'Material Receipt and Accountability' requires the applicant to develop a procedure for material accountability and to provide either a statement that "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license," or a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced. The application submitted did not include a statement regarding material accountability. **Please provide one of the statements above describing your material accountability program.**
10. Section 8.10.4 of [NUREG-1556, Volume 12](#), 'Occupational Dose' requires the applicant to respond describing how it will comply with the dose limits in 10 CFR 20. The application submitted did not address occupational dose. **Provide either of the following statements:**

"We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20."

OR

"We will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program – Occupational Dose' in [NUREG-1556, Vol. 12](#)."

Please note that you may reply to this e-mail by scanning a signed copy of your written response and submitting it as an attachment via e-mail. Alternately, you may respond in writing by letter to this office or by facsimile (610-337-5269).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 585055. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5136.

Thank you for your cooperation.

Scott Wilson
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