**Questions & Answers**
**for**
**Implementation of the BEST Standard**

In the course of preparing for certification under the Better Environmental Sustainability Targets (BEST) Standard 1001, lead battery companies have raised several questions and requested clarification on certain criteria in the standard. To help facilitate the certification process, we have compiled a list of these inquiries below.

**Q: I understand that we need to audit our battery component suppliers but we are unsure about the scope of these audits. What is the meaning of 'applicable portions' in criteria 3.7.b of the BEST Standard?**

**A:** This criteria only applies to suppliers that provide items that DO NOT contain lead. Therefore there are few applicable portions relative to the entire BEST Standard. These portions are only found under Objectives 2 and 3. For example the "applicable" portions may include:

a. Criteria 2.7 and 2.8 on worker training;
b. Criteria 3.1 on air and water emissions and waste disposal and chemical storage;
c. Criteria 3.3 on emergency response;
d. Criteria 3.4 on water and energy consumption;
e. Criteria on greenhouse gas emissions;
f. Criteria 3.9 on disclosure.

A checklist for conducting such audits in non-lead supplier facilities is attached to help simplify the process.

**Q: At present we have a relationship with one registered recycler/smelter for the collection of used batteries. Will the BEST auditors be required to visit the recycling facility to see whether they are collecting and maintaining records of used batteries from our dealers?**

**A:** In regards to battery collection, records must be kept by the battery manufacturer to document the return rate (similar to Indian Government/MOEF reporting form requirements). No visit to battery collectors or recyclers is anticipated to be part of the audit process.

**Q: Before we have our initial third-party audit, what is the sample size of data collected and the duration of records required to prove compliance to auditors?**

**A:** Very few criteria require an annual average. The ambient air quality requirements for example require a full year average. These criteria must be satisfied with regular records at the specified interval. If a test has been conducted at some regularity for a full year, but not at the frequency specified in the BEST standard, the auditor would need to determine if the available data is in substantial compliance based on the results, number of tests, and the explanation provided by the battery manufacturer.

**Q: We do not have past data on personal air monitoring, but we will be initiating this very soon. Will this affect certification?**

**A:** Air monitoring can be conducted simultaneously in multiple areas over a short time frame (with enough air sampling pumps) and results can be reported by most laboratories in a number of days. We do not believe that the lack of such data collection until now would result in any substantial delay in demonstrating compliance with the BEST Standard.

**Q: We are currently conducting blood lead level measurements of workers for the first time. Will this affect certification?**

**A:** Again one-time whole blood lead level readings from all workers should be sufficient for the initial audit. However, written documentation must specify that there is a plan in place to conduct future testing at the more frequent intervals specified in the BEST standard. In some cases repeat testing is required on the same worker depending upon

the initial result (e.g., under medical removal). The auditor would need to see the results of these repeat tests if any are required.

**Q: Collecting batteries from government bulk buyers is very difficult because they typically send used batteries for auctioning. How should we address this provision of the BEST Standard under these circumstances?**

**A:** Annexure I specifies what language must be in contracts with bulk buyers to ensure that used batteries will be returned. However, some government buyers may have standard contract language that is not flexible and is not in conformance with these provisions. In addition, some long-term contracts that were agreed to in the past may not allow for changes or renegotiation of this nature. The battery manufacturer should identify which customers do not allow for the company to take back used batteries or include the required provisions as per the BEST standard. The refusal on the part of the government purchaser should be documented and provided to the auditor.

In the long term, it is our goal to work with you and bulk purchasers so that the provisions in the Standard are acceptable to all buyers. Battery companies cannot be held responsible for the inability or unwillingness on the part of the bulk purchaser to agree to these terms. However, the battery manufacturing facility is still required to comply with the minimum (e.g. 20%) take back target rate.

**Q: We are currently in the process of creating a half-day training class for our workers, but at present we are only conducting a 2-hour training course. Will this affect certification?**

**A:** The decision of equivalency for any given training program will be evaluated by the accredited auditors. First the curriculum must be reviewed to determine if the training course covers all required topics as per the BEST Audit Protocol, Indicator 2.8.b. If the course included all required topics but was shorter than required, it may be accepted and noted as an "opportunity for improvement" provided that the facility has committed that all training going forward (including the annual refresher training) will be at least a half-day program.

**Q: Having workers change out of their work clothes and back into their street clothes before entering the lunchroom is very time consuming. Is there an easier way to accomplish this to comply with Indicator 2.4.f. of the BEST Standard?**

**A:** In this situation, having workers put on a disposable protective jumpsuit before entering the lunchroom would suffice. Of course, the washing of hands and face would also be necessary.

**Q: Can serum blood lead testing be conducted for lead analysis?**

**A:** For the purposes of obtaining an accurate blood lead levels, it is required that only **whole blood** samples be analyzed for lead analysis. Only whole blood samples can provide an accurate determination of blood lead levels. Serum is the clear fluid that separates from the whole blood sample when placed into a centrifuge. This clear fluid does not contain any of the blood cells, platelets, or fibrogen that lead particles can bind to.

**Q: Can we test blood lead levels using the hand-held LeadCare device if we are collecting venous puncture samples for this purpose?**

**A:** The use of the LeadCare device is limited to blood lead levels with a maximum concentration of 65 ug/dl. As lead battery workers may exceed this level, this LeadCare device cannot be used as the sole testing method. However, if the battery company has a written medical surveillance plan specifying that the device shall be used as a screening tool for levels up to 65 ug/dl and the remaining portion of samples exceeding that level are analyzed by an independent facility, then it may be deemed acceptable. However, provisions must also be in place to avoid possible cross-contamination of samples during storage and handling. The samples over 65 ug/dl shall not count as the 10 percent duplicate samples analyzed for validation purposes.

**Q: Must the analytical equipment used in our on-site laboratory be the same as that used at an independent accredited laboratory for the 10 percent duplicate samples for validation purposes?**

**A:** No. The independent laboratory need only be accredited by the respective National Accreditation Authority for biological/medical testing, which certifies that the reported results are accurate to a confidence level of 95% (+/- 5%). Only test methods specified in the BEST Audit Protocol may be used at the independent laboratory.

**Q: Is filter paper test method (analyzed with graphite furnace atomic absorption spectrometry) conducted on venipuncture blood samples an acceptable method for blood lead testing under the BEST Standard?**

**A:** Filter paper testing is an accepted analytical method for screening lead levels in children. The method is generally intended for use with finger prick (capillary) blood lead testing. Capillary blood lead testing is very susceptible to cross-contamination especially in the occupational setting where lead is being handled. Even for children such tests require confirmation with a venous puncture if results indicate that levels are elevated. In addition, the process of transferring a sample from a venipuncture tube to the filter paper can also introduce contamination.

There are at least ten published papers addressing the validity of the filter paper method. A review of these papers reveals that the focus of most of these studies is the comparison between finger prick (i.e. capillary blood) on filter paper to venous blood samples on filter paper (collected from the same individuals) assayed for blood lead. These papers indicate that there is a strong correlation between the two methods ($r = 0.80$ to 0.99.3). However, no published studies compare split venipuncture samples on filter paper taken in an occupational setting.

Only one paper was identified that examined the validity of the filter paper method between laboratories using venipuncture blood samples to prepare filter paper tests from subjects with known occupational lead exposures. To minimize the possibility of environmental contamination, the specimen preparation was performed in a laboratory "trace metal clean room."

Due to the lack of studies clearly validating the use of filter paper testing in the context of the method proposed in the question, the BEST Audit Protocol does not list this method and it is therefore not currently an acceptable method for the measurement of lead in blood for lead battery workers under the BEST Standard.

**Q: Can filter paper test methods conducted on venipuncture blood samples be used for the purposes of having an independent, accredited laboratory analyze 10 percent of duplicate samples for validation purposes?**

**A:** Two U.S. based laboratories specializing in this test method that were consulted do not recommend the use of filter paper testing within the confines of a lead battery manufacturing facility for blood lead analysis. Both laboratories expressed serious concerns over the likelihood of cross-contamination, potentially resulting in false positive results. Both laboratories stated that filter paper sampling is considered a "screening method" for children and not a "diagnostic method" for occupational exposures. Given the incompatibility with the methods utilized by "in-house" battery company laboratories and the filter paper method, its use would introduce more variability and not allow for reliable validation of the performance of the in-house facility. Therefore the use of this method for validation purposes is not allowed under the BEST Standard.

**Q: Which laboratories are "Nationally Accredited" to conduct blood lead testing in India?**

**A:** Currently, there are only 3 nationally accredited laboratories within India that can test blood lead levels:

1. **Lister Metropolis Laboratory & Research Centre Pvt. Ltd.**
   3, Jagannathan Road, Nungambakkam,
   Chennai, Tamil Nadu, 600034
   Tel No. 044-28278971 / 28234229 / 28202666
   Fax No. 044 - 28258242
   Email lister@vsnl.net

2. **St. John's Laboratory Services**
   St. John's Medical College and Hospital, John Nagara,
   Bangalore, Karanataka, 560034, India
   Tel No. 080 22065000
   Fax No. 080-5530070
   Email: sjmch@vsnl.com

3. **The Secunderabad Diagnostic & Research Centre (SDRC)**
   Shop No. 1-1-58/7/3, Srinath Commercial Complex, SD Road,
   Secunderabad, Andhra Pradesh 500003, India
   Tel No. +91-40-40200097, 98, 99.
   Fax No. +91-40-40200332.
   Email: info@sdrc.in
   Web: http://www.sdrc.in