DEPARTMENT OF HEALTH & HUMAN SERVICES

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September 30, 2014

LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Site Audit Program Questions and Answers

As part of the respirator approval program, the National Institute for Occupational Safety and Health (NIOSH) conducts site audits of all approval holders' facilities. The audit process ensures that approval holders continue to meet the quality requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84). This letter presents some basic questions and answers to help explain the site audit program.

Q1. NIOSH already tested our product. Why do you need to visit our facilities?

A1. Conformance of product samples is only one part of the respirator approval program (or process). Applicants are required to submit details of their quality system, and site audits are a method used to verify that this quality system is adequate, effective, and operates as described in the approved documentation. This helps safeguard that manufactured product continues to meet the performance requirements.

Q2. What gives NIOSH the right to conduct site audits?

A2. The approval regulations in 42 CFR 84.43(b) provide that NIOSH may inspect an approval holder's facilities and records as well as interview employees to evaluate its quality system.

Q3. We are audited as part of our ISO 9001 or ISO 13485 registration. Why does NIOSH need to conduct its own audit instead of just accepting our certificate?

A3. While such registration is valuable, there are NIOSH-specific requirements that are not included in ISO quality standards. A separate audit is the best way to confirm the NIOSH-specific requirements are met.

Q4. We hold NIOSH approvals, but have not manufactured any of the approved respirators in the past two years. Will NIOSH still need to perform an audit?

A4. Yes. <u>All</u> current NIOSH approval holders, regardless of manufacturing status, will have periodic site audits conducted. Approval holders have the option of requesting to have their NIOSH approvals voluntarily rescinded. This means that the respirator may no longer be manufactured and labeled as NIOSH-approved. Additionally any respirators of that model (including those already sold) will no longer be considered a NIOSH-approved respirator.

Q5. Which of our facilities will you need to visit?

A5. NIOSH auditors may visit any of the approval holder's facilities where functions relating to the quality system for approved respirators occur. The site visits are not limited to manufacturing, but also include activities such as design and purchasing. The facilities of subcontractors will also be visited as described in the April 7, 2005 letter to manufacturers titled "Clarification of Supplier and Subcontractor Relationships."

Q6. We are not selling respirators into the U.S. market. Do you still need to perform an audit?

A6. Yes. The requirements apply to facilities identified for the manufacturing of any respirator labeled as NIOSH-approved, regardless of where the product is sold.

Q7. How will we be informed of a site audit?

A7. NIOSH will send a pre-audit survey, requesting basic information, to the approval holder's primary contact along with a proposed timeframe. This should be completed and returned as soon as possible. The lead auditor will then e-mail or telephone the primary contact to schedule specific audit dates. After a mutually agreed upon schedule is determined, NIOSH will send a formal letter announcing the audit along with the audit plan two to four weeks before the audit.

Q8. May we request a specific date for the site audit?

A8. Audits are usually performed as part of a trip to visit multiple sites. The schedule is made to accommodate the availability of all of these sites and the auditors. It is very important for approval holders to list all dates that are <u>not</u> available in response to the pre-audit survey. A request for a specific date must only be made in addition to, not instead of, a list of unavailable dates. We will try to meet such requests if possible, but this is often prevented by scheduling conflicts.

Q9. Who will perform the site audit?

A9. The audit team members will be listed as part of the audit plan for each specific site visit. The audit may be conducted by NIOSH employees, contracted auditors, or both. You may always contact NIOSH to verify the identity of a contract auditor. Our contracts require that all auditors maintain the confidentiality of approval holder information. You may also request that a contract auditor sign a specific confidentiality agreement. For those sites producing respirators approved jointly by NIOSH and the Mine Safety and Health Administration, a representative of that organization may also be present for the audit.

Q10. May we request that a NIOSH employee perform an audit instead of a contract auditor?

A10. Approval holders may ask that a NIOSH employee perform the audit or accompany a contract auditor, but our audit planning and travel schedule often makes it impossible for us to

honor such requests. If requested in advance, it is usually possible for a NIOSH employee to attend the audit opening meeting and/or closing meeting by telephone.

Q11. How often are site audits performed?

A11. Currently, the typical schedule is once every two years. Sites where no production occurs (such as design centers or corporate offices) may have this extended to once every four years. Note that these are approximate intervals and may vary depending on circumstances.

Q12. How long will a site audit take?

A12. Site visits normally are completed in one to two full working days. This will be detailed in the audit plan sent to you prior to the audit.

Q13. What areas will the audit cover?

A13. The audit criteria include the approved quality documents (including the quality manual and product quality control plans) and the requirements of 42 CFR 84. This includes production, testing, design, management review, purchasing, and other areas. Audits are similar in structure to a typical ISO 9001 audit, but will focus on NIOSH-approved respirators and NIOSH requirements rather than the ISO requirements.

Q14. What will happen after the site visit?

A14. An audit report will be sent by NIOSH to the person designated by the approval holder as its primary contact. If any nonconformance issues were found during the audit, corrective action is necessary and specific instructions on how to respond will be provided in the report.

For further information regarding the site audit program, contact Mr. Vance Kochenderfer at vck6@cdc.gov or at 412-386-4029.

Sincerely yours,

/s/

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