

Information Collection Request for
“An Investigation of Lung Health at an Indium-Tin Oxide Production Facility”

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February 2014

Part B: Statistical Methods

Table of Contents

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Test of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

This information collection does not employ statistical methods to select respondents.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe

All current employees of the ITO production facility that requested NIOSH assistance will be invited to participate. This approach is preferable to using a sample of current employees because the total number of current employees is relatively small (100) and distributed across many (>10) departments with different types of exposures. Thus, any sampling strategy would risk being unrepresentative of the departments, limiting the range of exposures among respondents. Having a wide range of exposures among respondents is critical to detect associations between exposure and health outcomes in data analyses.

2. Procedures for the Collection of Information

A recruitment letter (Attachment D) describing the study will be mailed to all current employees by the employer. Data collection will take place at the workplace during normal work hours. To reduce the impact of the study on production, the questionnaire and medical testing will take place several weeks apart from the air sampling.

For the questionnaire and medical testing, trained NIOSH staff will meet with each employee to review the informed consent document (Attachment E) and the record release forms (Attachment F). Employees who wish to participate will be required to sign the informed consent document. Participants who wish to release medical records to NIOSH or to have NIOSH release the results of our medical testing to a personal physician will need to complete the appropriate records release forms.

A trained NIOSH interviewer will conduct the interview in a private room using a laptop computer to administer the questionnaire (Attachment C). Pregnancy status will be privately assessed by the study's medical officer using the questions at the end of the questionnaire (Attachment C) for all female participants of menstrual age (through age 50 years). Medical tests (Attachment N) consist of lung function tests and blood draw, which will take place at the workplace, and chest scan, which will take place at a nearby radiology center. Round-trip shuttle service between the workplace and the radiology center will be provided. Following medical testing, participants will receive letters with their personal lung test results (Attachment G) and their personal blood test results (Attachment H).

For the personal air sampling, trained NIOSH staff will use the informed consent script (Attachment I). Given the very low risk to participating in the personal air sampling, verbal (rather than written) consent will be utilized. Employees who wish to participate and would like to receive their personal results will be required to complete the contact information form (Attachment J). Participants will be fitted with a personal air sampler allowing for the measurement of respirable dust, indium, and tin (Attachment O). This process consists of clipping the air sampling equipment to the respondent's belt and lapel, and later unclipping the equipment. Participants will carry out their normal work activities while wearing the personal air sampler. NIOSH staff will keep track of the air sampling devices using a log sheet (Attachment K). Whenever possible, each participant will be monitored over the course of two shifts.

Following the air sampling, participants who request personal air sampling results will receive letters with their personal air sampling results (Attachment L).

We will use the available medical data to define adverse health outcomes. We will use the available industrial hygiene and blood indium data to define exposure. Potential variables include: job title, work area, tasks, cohort by hire date, employment tenure, form of indium (metal, hydroxide, oxide, unsintered mixture, ITO), and blood indium concentration (treated as both categorical and continuous variables). We will develop a job-exposure matrix that links results of air sampling to job category (such as job title, work area, or task). Full-shift personal sampling will be used to estimate average and cumulative exposures. Real-time personal sampling will be used to assess risk of peak exposure. We will use analytical methods including restricted cubic splines and generalized linear models to examine the relationship between health outcomes and exposure metrics. Ongoing analyses of data collected at the facility in 2012 are revealing health effects at low blood indium concentrations and relationships between adverse health outcomes and cumulative exposure estimates derived from personal air sampling. We expect that the new data collection will allow us to evaluate trends in health and exposure over time and the effectiveness, if any, of interim modifications to the workplace environment.

3. Methods to Maximize Response Rates and Deal with No response

Several components of the study are expected to maximize the response rate, including formal invitation letters, company endorsement, positive aspects of the medical testing (free of charge, onsite and near workplace, during working hours, confidential reporting of results), and the use of low profile air sampling equipment.

During previous data collection at this facility, participation was high (93%). Given the company's support for the project and willingness to allow employees to participate at the facility during normal work hours, a similarly high response rate is anticipated.

4. Tests of Procedures or Methods to be Undertaken

The questionnaire (Attachment C) was developed from standardized data collection instruments used by the American Thoracic Society and in the National Health and Nutrition Examination Survey. Similar questionnaires have been used extensively by NIOSH for health hazard evaluations and research studies. Furthermore, the questionnaire is quite similar to one used by NIOSH at the facility in 2012. That data collection was conducted under OMB Approval No. 0920-0260, expiration 11/30/2014. Following data collection and preliminary analyses, minor modifications to the 2012 questionnaire were made to minimize burden and improve the utility of the questionnaire.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The primary statistical consultant for the design of this project was:

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The data will be collected and analyzed by:
Field Studies Branch
Division of Respiratory Disease Studies
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Morgantown, WV