

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

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Part A: Justification

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The Centers for Disease Control and Prevention (CDC) requests OMB approval of a peer-reviewed research study for the National Institute for Occupational Safety and Health (NIOSH) for a one year period.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) seeking 12 month approval from OMB. This study is being conducted by the National Institute for Occupational Safety and Health (NIOSH). Under Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C. 669) (Attachment A), NIOSH has the responsibility to conduct research to prevent occupational illness.

This research study relates to lung disease and respiratory impairment in the indium-tin oxide (ITO) industry. ITO is a sintered material consisting of 90% indium oxide (In_2O_3) and 10% tin oxide (SnO_2) [Medvedovski et al. 2008]. ITO is used in the manufacture of such devices as liquid crystal displays, touch panels, solar cells, and architectural glass. In these applications, a thin coating of ITO provides the dual properties of electrical conductivity and optical transparency. Sputtering, a process in which ITO ceramic tiles or “targets” are bombarded with energetic particles that atomize the material, is used to deposit a thin layer of ITO on the surface of interest.

Lung disease among indium workers has come to the attention of the scientific community only recently, with the rise of the ITO industry. From 2003 to 2010, ten cases of symptomatic disease, including two fatalities, were reported among indium workers involved in the production, use, and reclamation of ITO in Japan, the United States, and China [Omae et al. 2010]. Two of the cases and one of the fatalities occurred in workers at the ITO production facility that is the subject of this study [Cummings et al. 2010]. During an international workshop sponsored by NIOSH in 2010, expert clinicians identified pulmonary alveolar proteinosis, cholesterol clefts, cholesterol granulomas, and interstitial fibrosis as common features of the cases; emphysema was noted in some advanced cases [Cumming et al. 2012]. Workplace investigations have revealed that published cases occurred against a background of subclinical or undiagnosed lung disease in co-workers [Chonan et al. 2007; Hamaguchi et al. 2008; Nakano et al. 2009]. These findings are consistent with the results of animal studies that have demonstrated a spectrum of pulmonary lesions following exposure to a variety of indium compounds including indium oxide and ITO [Lison et al. 2009; Nagano et al. 2011].

Indium lung disease is thus an emerging occupational health issue. Research to date has emphasized establishing an association between occupational indium exposure and lung disease. That exposure to indium compounds can cause lung disease has been clearly demonstrated by a combination of case reports, workplace investigations, and animal studies [Omae et al. 2010]. Thus, rather than focus on whether exposure to indium compounds can cause lung disease, this study seeks to develop an understanding of the determinants of lung disease in indium workers that can inform preventive efforts. Questions include: Which indium compounds pose the greatest health risk? Do physicochemical form and particle size influence toxicity? What is the effect of workplace interventions used by the company (such as ventilation, machine enclosures, and personal protective equipment) on exposure and lung health? Ultimately, the goal is to provide evidence-based recommendations intended to reduce exposures and prevent indium lung disease in this workforce.

Innovative components include the use of air monitoring, physicochemical characterization of process materials, and novel blood biomarkers of lung inflammation to ascertain the factors that contribute to the development of lung disease and identify the interventions that successfully prevent disease.

This study builds on an established relationship with an ITO production company that has requested assistance from NIOSH in preventing indium lung disease. Thus, the findings are primarily intended to reduce exposures and prevent lung disease at this particular facility. To the extent that the industrial processes and exposures at this facility are relevant to some facilities in the United States and many more in Asia, the lessons learned may be useful to other workplaces here and abroad.

In a preliminary evaluation in 2010 using existing data collected by the company at its ITO production facility, NIOSH found an excess burden of lung abnormalities in the facility's workforce and discrepancies between traditional measures of exposure and health outcomes [NIOSH 2012; Cummings et al. 2013]. Subsequently, NIOSH collected medical and industrial hygiene data at the facility in 2012. Those data are currently being analyzed and will serve as a baseline for comparison. All prior NIOSH data collections at this ITO production facility were conducted under "Health Hazard Evaluations/Technical Assistance and Emerging Problems," OMB Approval No. 0920-0260, expiration 11/30/2014.

1.1 Privacy Impact Assessment

NIOSH proposes a one-time information collection using a questionnaire (Attachment C). The questionnaire is based on validated questions from the American Thoracic Society, the National Health and Nutrition Examination Survey, and the European Community Respiratory Health Survey. In particular, the smoking questions are from the American Thoracic Society/Division of Lung Diseases of the National Heart, Lung, and Blood Institute [Ferris 1978]. The questionnaire will be administered by trained NIOSH staff at the facility during normal working hours. Each participant will be interviewed individually in a private room. Responses will be entered into a laptop computer by the interviewer. Employees who are not available at the facility will be offered the opportunity to respond to the questionnaire at a later date by telephone. All data collected will be maintained according to CDC record schedule.

Questionnaire data to be collected includes:

- Individually identifiable information (name, date of birth, mailing address, and phone number, along with the name, address, and phone number of a friend or relative who can be contacted if the participant cannot be reached)
- Demographic data
- Medical information
- Employment information
- Smoking history

The questionnaire is quite similar to one used by NIOSH at the facility in 2012. That data collection was conducted under "Health Hazard Evaluations/Technical Assistance and Emerging Problems," OMB Approval No. 0920-0260, expiration 11/30/2014.

In addition to the collection of information in the questionnaire, the study includes medical testing (spirometry, diffusing capacity, total lung capacity, fractional exhaled nitric oxide, low-dose high resolution computerized tomography [HRCT] of the chest, blood indium concentration, blood biomarkers of inflammation) and personal air sampling (for respirable indium, tin, and dust). Participation is voluntary. Employees will be recruited to participate in the study with an invitation letter (Attachment D). The medical testing and personal air sampling will be conducted at separate times.

To participate in the medical testing (including the questionnaire), each employee will be required to review and sign an informed consent document (Attachment E). 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 (Attachment F). Participants will receive letters with their personal lung test results (Attachment G) and their personal blood test results (Attachment H).

To participate in the personal air sampling, each employee will be required to listen to the information in the informed consent script (Attachment I). A participant who wishes to receive a copy of his personal air sampling results will need to complete the contact information form, providing his name, mailing address, and phone number, along with the name, address, and phone number of a friend or relative who can be contacted if the participant cannot be reached (Attachment J). NIOSH staff will keep track of the air sampling devices using a log sheet (Attachment K). Participants who request personal air sampling results will receive letters with their personal air sampling results in a timely manner (Attachment L).

This project does not involve any web-based data collection methods with content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

This research project is funded through 2015 by the National Occupational Research Agenda (NORA) to understand and prevent a new occupational illness, indium lung disease. Data collection will be carried out by NIOSH staff and will only be performed one time. The data collected in this study will be analyzed by NIOSH researchers to understand the relationship between exposures in the ITO facility and lung disease. The findings will be used to develop recommendations for the facility's managers, health and safety officials, workers, and healthcare providers. Recommendations to individual workers could include follow-up with a pulmonary specialist for further evaluation, while recommendations to the company might encompass strategies for exposure reduction, changes to the existing corporate medical surveillance program, the personal protective equipment program, or the policy on relocating affected workers. Findings will also be disseminated to a global audience through mechanisms including scientific presentations in the United States and Asia and peer-reviewed publications in the scientific literature.

To date, most research on indium lung disease has been carried out in Japan. The Japanese investigations have greatly contributed to our understanding of this new disease. Yet there were multiple limitations to these studies that leave questions about the exposure-response relationship unanswered. Virtually no environmental measurements of indium were available with which to assess

safe levels of indium exposure, and the reliance on serum indium as a biomarker of exposure did not take into account the greater toxicity of ITO, in comparison with other indium compounds that contribute to indium body burden. In addition, the Japanese investigators could not assess process-related risk because workers had frequently worked in multiple processes with different types of indium compound exposures.

Given these gaps in our understanding, this study seeks to shift the research paradigm from the initial question of “Does indium exposure cause lung disease?” to the subsequent question of “How can indium lung disease be prevented?” The findings will allow NIOSH to make informed recommendations about disease prevention for this workplace and recommendations about exposure-response relations and interventions that will apply to a global industry that is expected to continue to grow on account of the demand for ITO for electronic devices. Thus the intended impact of this data collection is the prevention of a disabling and potentially fatal 21st-century occupational lung disease.

2.1 Privacy Impact Assessment

Some identifiable personal information (i.e., names, addresses, phone numbers, and date of birth) will be collected during this study. In addition, data such as information on current and past employment and health state will be taken. This information could have an effect on the respondent’s privacy if there were a breach of security. Therefore, privacy will be assured by using subject numbers and codes in all analysis work. In addition, individual level data from participants will only be available to study personnel. Subject files will be kept in a separate file location and any data entered into computer data bases will be entered only by subject number and code. Privacy is also enhanced through controlled access to the NIOSH facility and the office where the files will be stored along with the rest of the Field Studies Branch human subject data. The specific information derived from the participants in this study will be kept secure and will not be disclosed to others without written consent except as required by law. This information will be used for statistical and research purposes in such manner that no individual can be identified.

3. Use of Improved Information Technology and Burden Reduction

NIOSH interviewers will use a computer-based questionnaire (Attachment C) to complete all interviews with participants. Responses will be recorded by the NIOSH interviewer directly into a laptop computer. This approach reduces the burden of participation and ensures accurate data collection. A participant who wishes to receive his personal air sampling results will need to complete the one page contact information form by hand (Attachment G). Using an electronic version of this form is unpractical, as would require that NIOSH staff bring laptop computers into the production areas where consent for personal air sampling is obtained. Furthermore, the burden of filling out this short form by hand is minimal and unlikely to be reduced by use of an electronic version.

4. Efforts to Identify Duplication and Use of Similar Information

NIOSH researchers have been leaders in the recent effort to describe the new lung disease that has occurred in the ITO industry. They have conducted thorough literature reviews. Through scientific collaborations and conferences, they have developed professional relationships with content experts in the United States, Japan, Korea, China, Taiwan, and the United Kingdom. They are aware of ongoing efforts in other countries to characterize exposure and health in the ITO industry. However, they are not aware of any other study as extensive as theirs. In particular, the high quality lung function testing, novel blood biomarkers, and comprehensive exposure assessment make this study unique. Furthermore, previous studies have been cross-sectional in nature, so have not been able to make conclusions about patterns over time. The availability of a NIOSH database from prior evaluations at this same facility will allow for a longitudinal analysis of both health and exposure data, key to identifying preventive strategies. The prior evaluations were conducted under "Health Hazard Evaluations/Technical Assistance and Emerging Problems," OMB Approval No. 0920-0260, expiration 11/30/2014.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The 60-day Federal Register Notice was published on Tuesday, November 19, 2013, Vol. 78, No. 223 (See Attachment B). There were no public comments.

B. We have sought the input of multiple subject matter experts. In 2010, when we were initially developing the protocol, we consulted:

Dr. Robert Tallaksen, Professor of Radiology at West Virginia University and a specialist in chest imaging. Dr. Tallaksen's phone number is (304) 293-3091 and his email address is rtallaksen@hsc.wvu.edu. Dr Tallaksen provided guidance on our low-dose protocol for HRCT scanning.

Dr. John Parker, Professor of Medicine at West Virginia University and a specialist in occupational lung disease. Dr. Parker's phone number is (304) 293-4661 and his email address is jparker@hsc.wvu.edu. Dr. Parker provided guidance on classification of HRCT scans for epidemiologic purposes and recommended a classification system that we incorporated into our protocol.

Dr. David Lynch, Professor of Medicine at University of Colorado and National Jewish Health and a specialist in chest imaging and epidemiological studies. Dr. Lynch's phone number is (303) 270-2810 and his email address is LynchD@NJHealth.org. Dr. Lynch provided comments on quality issues that informed our choice of type of CT scanner. He also provided information on scoring systems for lung abnormalities.

Dr. Bruce Trapnell, Professor of Pediatrics at the University of Cincinnati and a specialist in rare lung diseases including pulmonary alveolar proteinosis. Dr. Trapnell's phone number is (513) 636-6361 and his email address is bruce.trapnell@cchmc.org. Dr. Trapnell provided assistance in our selection of blood biomarkers, particularly granulocyte-macrophage colony-stimulating factor. He agreed to lend his expertise to the project by conducting all analyses of blood biomarkers in his laboratory.

Dr. Stephen Adjei, fellow in Pulmonary Medicine and Occupational Medicine at the University of Cincinnati. Dr. Adjei is now practicing in Louisiana, where his phone number is (225) 761-5200; we do not have his current email address. Dr. Adjei reviewed the entire protocol, and assisted with the development of our low-dose protocol for HRCT scanning.

Dr. Paul Enright, Professor of Epidemiology at the University of Arizona and a specialist in lung function testing and epidemiological studies. Dr. Enright's phone number is (520) 577-8254 and his email address is lungguy@gmail.com. Dr. Enright reviewed the entire protocol, providing insightful comments on informed consent language, lung function testing, and data collection.

In 2012, as we were preparing protocol amendments, we consulted:

Dr. Terrance Healey, Director of Thoracic Radiology at Brown University and a specialist in chest imaging. Dr. Healey's phone number is (401) 444-5184 and his email address is thealey@Lifespan.org. Dr. Healey provided input on our low-dose protocol for HRCT scanning, including recommendations about positioning and interslice gap. He agreed to lend his expertise to the project by overseeing the scanning and classifying all HRCT scans at a local radiology center.

Dr. Carrie Redlich, Professor of Medicine at Yale University and a specialist in occupational lung disease. Dr. Redlich's phone number is (203) 737-2817 and her email address is carrie.redlich@yale.edu. Dr. Redlich reviewed the study as part of an external peer review of the Field Studies Branch of the Division of Respiratory Disease Studies at NIOSH. She provided comments that were highly supportive of the study plan.

Dr. Patrick O'Shaughnessy, Professor of Occupational and Environmental Health at the University of Iowa and a specialist in inhalational toxicology. Dr. O'Shaughnessy's phone number is (319) 335-4202 and his email address is patrick-oshaughnessy@uiowa.edu. Dr. O'Shaughnessy reviewed the study as part of an external peer review of the Field Studies Branch of the Division of Respiratory Disease Studies at NIOSH. He provided comments that were highly supportive of the study plan.

In addition to these subject matter experts, we have been in regular contact with the ITO company's management and employee representative. As per NIOSH policy, they have been given multiple opportunities to review and comment on the protocol throughout its development.

There have been no major problems that could not be resolved during consultation.

We are aware of two related projects within DHHS. The first is a NIOSH Division of Surveillance, Hazard Evaluations, and Field Studies project to document use of indium compounds in the United States. This project recently concluded with publication of the results in a peer-reviewed journal [Hines et al. 2013]. The second is a National Institute of Environmental Health Sciences project to examine the experimental toxicology of indium compounds. Results from this project were recently published [Gwinn et al. 2013]. Our study does not impact these two projects, as they do not involve interaction with ITO workers, collection of health data, or collection of personal air sampling data. We are not aware of other related DHHS projects or programs.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift from NIOSH for participation.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by ICRO, who has determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0147, "Occupational Health Epidemiological Studies." The data collection will involve collecting individually identifiable information, including name, date of birth, mailing address, and phone number. All collected data will be transmitted to NIOSH. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

On the day of data collection, each participant will be assigned a subject identification (ID) number. Response data will be collected in identifiable form but de-linked from identifiers and subsequently retrieved by NIOSH data analysts using the subject ID number. NIOSH will maintain the linkage between name and ID number in a secure network file. The linkage will be maintained for as long as the records are maintained per the CDC record schedule.

NIOSH owns the data and collaborators will not have access to the linking information. Blood samples will be analyzed by contract laboratories. The contract laboratories will receive de-identified samples labeled only with the assigned code (subject identification number). The contract laboratories will report results to NIOSH using the assigned code. Chest HRCT scanning will be conducted at a contract radiology center. As a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), the contract radiology center will collect and maintain identifiable information in accordance with HIPAA requirements. The contract laboratory will report results to NIOSH using identifiers.

The data collection has been reviewed and approved by the NIOSH Institutional Review Board (IRB). A copy of the approval letter is included (Attachment J).

10.1 Privacy Impact Assessment

Individuals are informed that participation is voluntary in the informed consent document for the questionnaire and medical testing (Attachment E) and in the informed consent script (Attachment F). Individuals are given the opportunity to share and submit information by signing the informed consent document (Attachment E) and by completing the contact information form (Attachment G).

NIOSH will use multiple methods to ensure the security and privacy of the data. All data with personal identifiers will be stored on password protected computers; any paper copies with personal identifying information will be stored in locked rooms or cabinets; data access will be restricted to only NIOSH staff involved in the study. Security is also enhanced through controlled access to the NIOSH facility.

To maintain the data collected in this study, a system of records is being created under the Privacy Act.

11. Justification for Sensitive Questions

Information on race, ethnicity, and smoking history will be collected for the purpose of evaluating the results of the lung function tests. 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). Asking questions to assess pregnancy status is necessary because HRCT will not be offered to pregnant women, due to the potential risks of radiation to the fetus. Social security number will not be collected.

12. Estimates of Annualized Burden Hours and Costs

The facility is expected to have 100 employees at the time of the study. These 100 employees will be recruited to participate in the study with a recruitment letter (Attachment D) that will take about 5 minutes to read. We anticipate a high participation rate, as the 2012 study at this facility had a participation rate of 93%. Thus, the maximum number of respondents is estimated to be 95.

Prior to questionnaire administration and medical testing, respondents will be asked to review the informed consent document (Attachment E). The informed consent document will take about 15 minutes to review and sign. Respondents 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 (Attachment F). Completing all three records release forms will take no more than 5 minutes. The questionnaire (Attachment C) will take about 20 minutes to complete. The medical testing (Attachment M) will take 100 minutes.

Prior to exposure monitoring, respondents will be asked to listen to an informed consent script (Attachment I) that will take no more than 5 minutes. Respondents who choose to participate in the personal air sampling and want to receive their personal results will need to complete the contact information form (Attachment J). This contact information form will take no more than 5 minutes to complete. The burden of exposure monitoring (Attachment N) consists of clipping the air sampling equipment to the respondent's belt and lapel, and later unclipping the equipment, which together will take at most 5 minutes. Thus, the total burden time per participant is a maximum of 2 hours and 40 minutes.

Estimated annualized burden hours

Type of Respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Current ITO production facility employees	Recruitment letter	100	1	5/60	8
	Consent to participate in a research study	95	1	15/60	24
	Authorization to disclose health information	95	1	5/60	8
	Indium facility questionnaire	95	1	20/60	32
	Medical testing	95	1	100/60	158
	Script for collection of industrial hygiene samples	95	1	5/60	8
	Personal air sampling results contact information form	95	1	5/60	8
	Exposure monitoring	95	1	5/60	8
	Total				

Estimated annualized burden cost

Type of Respondents	Form name	Total burden (in hours)	Hourly wage rate	Total respondent cost
Current ITO production facility employees	Recruitment letter	8	\$15.00	\$120.00
	Consent to participate in a research study Informed	24	\$15.00	\$360.00
	forms Authorization to disclose health information	8	\$15.00	120.00
	Indium facility questionnaire	32	\$15.00	\$480.00
	Medical testing	158	\$15.00	\$2370.00
	Script for collection of industrial hygiene samples	8	\$15.00	\$120.00
	Personal air sampling results contact information form	8	\$15.00	\$120.00
	Exposure monitoring	8	\$15.00	\$120.00
	Total			

The value assigned for the hourly wage rate is based on the average U.S. hourly wage rate for production occupations from the Current Population Survey, Bureau of Labor Statistics, U.S. Department of Labor. Median weekly earnings of full-time

wage and salary workers by detailed occupation and sex. Available at: <http://www.bls.gov/cps/cpsaat39.htm>. (Accessed October 2013)

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

The estimated annualized cost to the government is \$305,161. This cost includes pro-rated salary and benefits for the NIOSH staff involved in data collection and analysis; supplies; contractual agreements with laboratories, a radiology center, and a statistical consultant; and travel to the facility for data collection.

Item	Cost
Personnel	\$224,000
Supplies	\$5,640
Contractual	\$46,625
Travel	\$28,886
Total	\$305,161

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Immediately following OMB approval, invitation letters will be sent to respondents. Data collection will be conducted about one to six months later, depending on production schedules at the facility and NIOSH staff availability. Reporting individual results to respondents will be a priority following data collection and should be completed within two to three months. Subsequently, the focus will turn to aggregate analyses of the data, with a primary goal of understanding the relationship between exposure and lung health outcomes in this facility.

Descriptive statistics will be used to illustrate the distribution of adverse health outcomes. For questions on our questionnaire derived from the National Health and Nutrition Examination Survey, we will compare the proportion of participants with adverse health outcomes to the proportion expected in the general population. Specifically, we will determine standardized morbidity ratios (SMRs), accounting for race, sex, age, cigarette smoking status, and body mass index. Univariate and multivariate regression techniques will be used to examine predictors of the adverse health outcomes. Potential predictor variables will include: smoking history and indices of workplace exposure. We will use recursive partitioning and cubic splines to explore relationships between health outcomes and predictor variables. Regression coefficients and odds ratios will be reported.

Results of the aggregate analyses will first be reported to the company and the employee representative. The information may be used by the company to guide preventive efforts. For instance, the results may suggest that certain areas of the facility, certain forms of indium, or certain industrial processes pose a higher risk of lung disease. If so, the company could increase ventilation for implicated areas, require higher levels of respiratory protection for handling implicated indium compounds, or enclose implicated machines. Later, the results will be presented at scientific meetings and prepared for publication in the scientific literature, so that the findings can inform preventive efforts at other facilities.

Project time schedule

Activity	Time schedule
Invitation letters sent to respondents	Immediately after OMB approval
Data collection	1-6 months after OMB approval
Individual results reported to respondents	3-9 months after OMB approval
Analyses	4-12 months after OMB approval
Aggregate results reported to company and employee representative	12-16 months after OMB approval
Presentation at scientific meetings	14-18 months after OMB approval
Publication	24-36 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

19. References

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