PULMONARY FUNCTION TESTING COURSE APPROVAL PROGRAM
Regulation 29 CFR 1910.1043 (h) (1) (iii)
(0920-0138)

Request for Office of Management and Budget (OMB) Review and Approval
for a Federally Sponsored Data Collection
REVISION

Part A

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Table of Contents

PART A. Justification

A1. Circumstances Making the Collection of Information Necessary

This is a revision information collection request (ICR) requesting a 3 year approval from OMB. The revision includes a new one-time customer satisfaction survey to evaluate service to stakeholders, the effectiveness of program changes implemented since 2005, and the usefulness of potential Program enhancements. The current ICR (0920-0138) expires on August 31, 2014.

The National Institute for Occupational Safety and Health (NIOSH or the Institute) has the responsibility under Section 21 of the Occupational Safety and Health Act to conduct research to advance the health and safety of workers (Attachment 1). The Cotton Dust Standard [29 CFR 1910.1043], promulgated by the Occupational Safety and Health Administration (OSHA) gives the National Institute for Occupational Safety and Health (NIOSH) the responsibility to approve courses in spirometry for instruction of those individuals who will be administering screening pulmonary function testing to employees (Attachment 1a). Successful completion of a NIOSH-approved training course is mandatory for technicians performing lung function tests on workers exposed to cotton dust. To carry out its statutory and regulatory responsibilities, NIOSH maintains a Pulmonary Function Testing Course Approval Program.

The data collection associated with the course approval program consists of:

- an introductory course application that is submitted to NIOSH by potential course sponsors (Attachment 3),
- annual reports, which provide/supply information on course status (Attachment 4),
- a program renewal application for approved sponsors (Attachment 5), and
- a refresher course application for those sponsors already approved at the introductory instruction level (Attachment 6).

Course sponsors may also voluntarily submit requests for changes in course content or for additional faculty to be approved. There is no form for the sponsors to use when requesting changes in content or faculty. The sponsor submits their requests with documentation by postal mail or electronically (example in Attachment 7). Prior discussions with the sponsors indicate that this request process takes approximately 45 minutes. NIOSH is requesting sponsors and course directors to voluntarily complete a one-time customer satisfaction survey (Attachment 8) to evaluate our service to courses. Three sponsors and course directors reviewed the survey for clarity and provided feedback to NIOSH. The respondents indicated that the time needed to complete the survey was 12 minutes.

A1.1 Privacy Impact Assessment

Organizations wishing to conduct a NIOSH-approved course submit a completed application." The first items on the "NIOSH-Approved Spirometry Testing Course Application" (Attachment 3), "NIOSH-Approved Spirometry Testing Course Renewal Application" (Attachment 5), and "NIOSH-Approved Spirometry Refresher Course Application" (Attachment 6) request the name of the sponsoring organization, information related to course design, and curriculum information. NIOSH encourages these forms to be submitted electronically; very few organizations choose to submit their applications in paper format. Telephone calls and e-mails are sometimes used to assist applicants with completing the forms. The new "One-Time Customer Satisfaction Survey" (Attachment 8) is a web-based questionnaire.

No individually identifiable information will be collected.

A2. Purpose and Use of Information Collection

Occupational lung disease is one of the top eight research priority areas for disease and injury in NIOSH's National Occupational Research Agenda (NORA) program. NORA arose from a partnership between public, private, and government sectors to address the need to focus research in areas with the highest likelihood of reducing the significant toll of workplace injury and illness. Surveillance of workers, including screening spirometry, is critical to the identification of early detrimental changes in lung function among the hundreds of thousands of exposed workers who are at risk of developing occupational lung diseases, including silicosis, byssinosis, asbestosis, pneumoconiosis, and chronic obstructive pulmonary disease (COPD), often after 20 to 30 years of exposure.

If NIOSH did not conduct the course approval program, individuals may not have the opportunity to be adequately trained in accordance with the federal regulation and NIOSH would not fulfill its mandate under the law [(29 CFR 1910.1043 (h) (1) (iii)] (Attachment 1). Also, this program is of benefit to U.S. workers and employers as Occupational Safety and Health Administration (OSHA) compliance officers may utilize this information to make a determination as to whether individual technicians have taken a valid NIOSH-approved course (individuals must have a course certificate with a valid course date and approval number). In addition to providing the mechanism for individuals to complete a NIOSH-approved course, this program has stimulated the standardization and enhancement of spirometric testing for worker surveillance and screening across the country as well as in some foreign countries.

Agencies wishing to conduct a NIOSH-approved course submit a completed application to the Institute, along with the supporting course materials. Approximately three applicants submit materials for approval each year. The information contained in the application is

reviewed by a Course Approval Committee (made up of four NIOSH members who are experts in spirometry) within the Institute to determine whether the course meets minimum NIOSH/OSHA requirements for hours, instrumentation, content, technique, and faculty as set forth in the standard.

Course sponsors also submit any changes made to their courses during the approval period. These changes are reviewed by NIOSH to assure adherence to the minimum criteria. There is no form for the sponsors to use when requesting changes in content or faculty. The sponsors submit their requests with documentation by standard mail or electronically. The Institute receives about 12 requests per year from approved sponsors to change course content or add new faculty.

Each year, sponsors are asked to submit an annual report to keep the Institute appraised of course status. The NIOSH course approval number and identification of the sponsor's coordinating individual is requested. Individuals must log into a password protected site on a NIOSH internet web page using a unique UserID. The login procedure identifies the individual when the report is forwarded to the program coordinator. In addition, the timing and location of courses conducted in the year as well as numbers of students trained are requested. Using this information, NIOSH is able to maintain effective communication with the sponsors and also determine geographic regions where training may not be as readily available.

Refresher courses are recommended by several professional societies to maintain adequate skills and updated knowledge of standard practice guidelines for technicians administering spirometry tests in the occupational setting. The information contained in the refresher course application will be reviewed by the Course Approval Committee to determine whether the course meets minimum NIOSH requirements for hours and content.

Thirty-five NIOSH-approved courses are currently active throughout the country. Generally from one to three new applications are received each year. We do not anticipate more than three applicants per year over the next three years, but will submit a change worksheet should the number increase.

Since 2005, the NIOSH Pulmonary Function Testing Course Approval Program implemented changes in course administration, offered new refresher training, and developed new teaching resources for curriculum enhancement. The Program is seeking feedback from sponsors and course directors to evaluate our service to courses, the effectiveness of the program changes implemented, and the usefulness of potential Program enhancements.

2.1 Privacy Impact Assessment

At the conclusion of the data collection, a report summarizing aggregated survey data will be disseminated to course sponsors and faculty. The survey results will assist NIOSH to evaluate our service to certified courses, to better understand the effectiveness of the program changes implemented since 2005, and to evaluate the usefulness of potential Program enhancements to our stakeholders better understand. The proposed data collection will have minimal impact of respondent's privacy since no individually identifiable information will be collected.

A3. Use of Improved Information Technology and Burden Reduction

NIOSH has developed a pulmonary function testing manual for students enrolled in the course. It includes the required content (including the OSHA/NIOSH and American Thoracic Society recommended procedures and equipment for testing) as well as exercises for use in class. The manual has been placed on the NIOSH Internet site for public use (http://www.cdc.gov/niosh/docs/2004-154c/). This NIOSH manual considerably reduces the burden of developing the content and materials for individual sponsors. When new curriculum content is developed, it is made available to courses via downloaded files from the NIOSH internet. As new material is completed, it is organized into electronic files that can be inserted into existing Power Point presentations.

The application forms were developed to effectively describe the minimum criteria for each course, and also to enable the respondent to transmit only the materials that are necessary for NIOSH to make a determination of whether the course meets those criteria. There are no legal obstacles to reduce the burden. These forms are available in electronic formats. The applicant may also electronically submit accompanying materials (curriculum vitae, non-NIOSH course manual, and student exercises).

Electronic forms for annual reporting to NIOSH regarding the number of courses given and the number of students successfully completing the course are also available to sponsors via a password-protected program on the NIOSH Internet site.

The one-time customer satisfaction survey will be based on the internet.

A4. Efforts to Identify Duplication and Use of Similar Information

No other agency in the country is currently approving spirometry courses to train individuals to conduct testing according to the OSHA/NIOSH/American Thoracic Society criteria. Moreover, NIOSH is mandated by the Occupational Safety and Health Act and the Federal Cotton Dust Standard (29 CFR 190.1043) to approve this training.

Course approval and renewal applications contain information regarding course content, faculty qualifications, and equipment that will be used in the training courses. This

information is only available from the sponsor/applicant. The NIOSH-provided course manual is not a duplicate of other existing material.

A5. Impact on Small Businesses or Other Small Entities

Less than 50 % of the course sponsors are small business concerns. For these and all other sponsors, the burden of applying for course approval can be minimized by using the NIOSH-developed materials. Also, telephone calls and e-mail correspondence are utilized to assist sponsors in submitting applications.

A6. Consequences of Collecting the Information Less Frequently

NIOSH requires sponsors to apply once for training course approval and then every 5 years for sponsorship renewal. Following course approval, any proposed changes must be submitted and approved by NIOSH to ensure that the minimum course criteria are met. Sponsors are also asked to submit an annual report regarding course activity. Without this information, NIOSH would be unable to maintain current contact information or determine which courses remain in compliance.

Application for and maintenance of NIOSH approval is completely voluntary. It is not effective to conduct this information collection less frequently than presently done.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no circumstances that require this collection of information to be conducted in a manner inconsistent with 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The date of the Federal Register Notice publication was December 23, 2013, Vol. 78, No. 246, pages 77468 and 77469. A copy of the notice may be found in Attachment 2. There were no public comments.
B. NIOSH organized a meeting for course directors in May 2005 to receive input regarding 1) proposed curriculum changes to the introductory course, 2) limiting course approvals for a period of 5 years and require sponsor renewals thereafter, 3) limiting validity of student certificates to 5 years, and 4) proposed curriculum for the new NIOSH-Approved Spirometry Refresher Training Course. Directors unable to attend the meeting were given the opportunity to provide comments and suggestions. The proposed curriculum changes to the introductory course and new curriculum for the refresher course as well as limiting course approvals for 5 years were

unanimously agreed upon by course directors. All but one of the course directors agreed to limit the validity of student certificates to 5 years.

Changes made to course requirements are sent to all sponsors by an electronic distribution list, when available, and are posted on the spirometry course topic page on the NIOSH website (http://www.cdc.gov/niosh/topics/spirometry/training.html).

In 2013, three course sponsors were contacted to ascertain whether the burden has increased and whether any problems existed in the program, and none were reported. The sponsors included:

a) Dr. Rebecca Moreland, RF Moreland, LLC; Palmetto, FL
(410) 215-9305 OccHealthNow@aol.com

b) Dr. Micky Sullivan, OMI; Houston, TX
(800) 869-6783 info@occupational.com

c) Dr. Mary Townsend, M.C. Townsend Associates, LLC; Pittsburgh, PA
(412) 343-9946 mct@mctownsend.com

A9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

A10. Assurance of Confidentiality Provided to Respondents

This project has been reviewed by the NIOSH PRA contact who has determined that the Privacy Act *is not* applicable. The primary method for retrieval of applications is by the course approval number issued to a sponsoring organization, and the Privacy Act does not apply to organizations.

Even though the Privacy Act is not applicable, records will be safeguarded. Data will be treated in a secure manner, unless otherwise compelled by law. Paper documents are kept in locked file cabinets in locked rooms and electronic data are kept in password protected files. Access is limited to NIOSH personnel with a bona-fide need for the data to perform their official duties.

Institutional Review Board (IRB) approval is not required for this activity (see Attachment 8).

A10.1 Privacy Impact Assessment Information

A. The CDC's Information Collection Review Office has reviewed this application and has determined that the Privacy Act is not applicable. No individually identifiable information will be collected. Survey invitees will be informed in the invitation letter that their participation in the survey is voluntary.

B. Access to data will be limited to authorized NIOSH project staff. NIOSH facilities have 24 hour security and all electronic data will be stored on secure servers accessible only with passwords. Survey data will be electronically submitted to NIOSH using password protected encryption techniques.

C. Respondents will be provided with information that will explain the intended use of the information collected and inform them that their participation is completely voluntary. Consent is implied when the respondent begins the survey.

D. Respondents will be informed that their participation is voluntary, and that they may discontinue the survey at any time. The Privacy Act does not apply. No individually identifiable information is being collected.

A11. Justification for Sensitive Questions

There are no questions of a sensitive nature on the application.

A12. Estimates of Annualized Burden Hours and Costs

A. Burden for this information collection is associated with the forms listed below. NIOSH encourages electronic submission of all instruments.

Estimate of annual respondent burden:

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Potential	NIOSH-Approved Spirometry Testing Course Application	3	1	3.5	11
	Annual Report	35	1	30/60	18
	NIOSH-Example	12	1	45/60	9

Sponsors	of e-mail request for course change				
	NIOSH-Approved Spirometry Course Sponsorship Renewal Application	13	1	6	78
	NIOSH-Approved Spirometry Refresher Course Application	10	1	8	80
	One-Time Customer Satisfaction Survey	23	1	12/60	5
Total					201

The calculation of burden hours is based on past experience and consultation with sponsors.

B. Estimated Annual Cost to Respondents:
201 hours X $22.00/hr* = $4,422.00

* Estimated at the government level of General Schedule (GS) 06/07 for typing and compiling materials. Salary is based on 2013 Office of Personnel Management GS and Locality Pay Tables.

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No capital or maintenance costs to the respondents are anticipated.

A14. Annualized Cost to the Federal Government

A. Review of introductory course application
$450 per review X 3 applications 1350.00
B. Review of renewal application
$60 per review X 13 applications 780.00
C. Review of refresher course application
$450 per review X 10 applications 4500.00
D. Telephone/e-mail inquiries

	1 hr/month X $48/hr*	576.00
E.	Course change requests	
	15 min/review X $48/hr* ($12/review) X 12 requests	144.00
F.	Clerical time - (7 hours X $22/hr*)	115.00
G.	Compile/file information	
	12 hr X $48/hr*	576.00
	Total	$8,041.00

* Salaries are based on 2013 Office of Personnel Management GS and Locality Pay Tables for GS 13-7 (14.D, E, G) and GS 06/07 (14.F).

Total cost to government = $8,041.00

A15. Explanation for Program Changes or Adjustments

The burden hours increased from 196 to 201 hours due to program changes. All collection instruments are available in electronic formats, which help to reduce the respondents' burden. There is one new collection instrument; a One-Time Customer Satisfaction Survey will be administered over the internet.

A16. Plans for Tabulation and Publication and Project Time Schedule

This collection of information will not result in a publication for statistical use. The purpose of this program is to provide NIOSH approval for pulmonary function training courses for technicians performing lung function tests on workers exposed to cotton dust. Course sponsors periodically contact NIOSH by phone or e-mail to receive updates, or to discuss arising issues. They voluntarily submit information on courses held, numbers of students, and other descriptors of the courses.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval is not being sought to remove the OMB expiration date.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement