

**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  
**REINSTATEMENT**  
(with change)

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**SUPPORTING STATEMENT  
PULMONARY FUNCTION TESTING COURSE APPROVAL PROGRAM  
OMB No. 0920-0138**

**PART A. Justification**

**A1. Circumstances Making the Collection of Information Necessary**

This package remains unchanged except, as part of this reinstatement, approval is requested to include the sponsor's renewal application and a refresher course application.

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 and 29 CFR 1910.1043 (h) (1) (iii) for approving courses for training technicians in pulmonary function testing (Attachment A). 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 B),
- annual reports, which provide/supply information on course status (Attachment C),
- a program renewal application for approved sponsors (Attachment D);
- and a refresher course application for those sponsors already approved at the introductory instruction level (Attachment E).

Course sponsors may also voluntarily submit requests for changes in course content or for additional faculty to be approved (Attachment G). 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. Prior discussions with the sponsors indicate that this request process takes approximately 45 minutes.

**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 A). Also, this program is of benefit to U.S. workers as 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 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/Occupational Safety and Health Administration (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 apprised 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 update 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.

### **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. New curriculum content is being developed and will be 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.

#### **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 1910.1043) 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 viable.

Application for and maintenance of NIOSH approval is completely voluntary. It is not feasible 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. A copy of the Federal Register Notices is attached (Attachment F). The date of the publication was November 16, 2007, Vol. 72, No. 221, pg 64650-64651. No comments were received.
  
- 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/>).

In 2007, 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. Mary Townsend, M.C. Townsend Associates, Pittsburgh, PA  
(412) 343-9946 [mary.townsend4@verizon.net](mailto:mary.townsend4@verizon.net)
- b) Ms. Kathleen Bailey, Allenmore Hospital, Tacoma, WA  
(253) 459-6623 [Kathleen.Bailey@multicare.org](mailto:Kathleen.Bailey@multicare.org)
- c) Dr Carl Mottram, Mayo Clinic, Rochester MN  
(507) 284-6811 [mottram.carl@mayo.edu](mailto:mottram.carl@mayo.edu)

#### **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 from a Privacy Act and confidentiality perspective and it has been 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.

Section A.2 states that “agencies wishing to conduct a NIOSH-approved course submit a completed application.” The first items on the “NIOSH-Approved Spirometry Testing Course Application” (Attachment B), “NIOSH-Approved Spirometry Testing Course Renewal Application” (Attachment C), and “NIOSH-Approved Spirometry Refresher Course

Application” (Attachment E) request the name of the sponsoring organization. While faculty names, professional degrees, licensure and certifications are also requested, applications are submitted voluntarily and these items are considered to be matters of public record. Course sponsors may also voluntarily submit requests for changes in course content or for additional faculty to be approved (Attachment G).

Even though the Privacy Act is not applicable, records will be safeguarded. Data will be treated in a confidential 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.

**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:

Forms for Respondents	Number of Respondents	Number of Responses/ Respondent	Average Burden/ Response (in hrs)	Total Burden (in hrs)
Initial Application	3	1	4	12
Annual Report	35	1	30/60	18
Renewal Application	13	1	6	78
Refresher Course Application	10	1	8	80
Report for Course Changes	12	1	45/60	9
Total	73			197

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

B. Estimated Annual Cost to Respondents:

$$197 \text{ hours} \times \$19.00 \text{ hr.*} = \$3,743.00$$

\* Estimated at the government level of General Schedule (GS) 06/07 for typing and compiling materials. Salary is based on 2007 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 and change application  
\$486 per review X 3 applications 1458.00

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 \$37/hr*	444.00
E. Clerical time - (7 hours X \$19/hr*)	133.00
F. Compile/file information 12 hr X \$37/hr*	<u>444.00</u>
Total	\$7,759.00

\* Salaries are based on 2007 Office of Personnel Management GS and Locality Pay Tables for GS 12-8 (14.B, C, E) and GS 06/07 (14.D).

Total cost to government = \$7,759.00

#### **A15. Explanation for Program Changes or Adjustments**

The burden hours increased from 64 to 197 hours due to program changes. All collection instruments are available in electronic formats, which help to reduce the respondents' burden. Although there is a decrease in the number of active courses, two new collection instruments (Sponsorship Renewal Application and Refresher Course Application) are being requested to enhance the implementation of the program. The sponsorship renewal application (78 hours) provides information to NIOSH which is reviewed to ensure the sponsors are teaching the minimum curriculum content required by the OSHA and NIOSH and is consistent with the ATS guidelines and highlights any equipment changes made by the sponsor. NIOSH will begin to offer refresher training courses to individuals who have already taken the introductory course. These refresher courses are recommended by several professional societies (ATS, American College of Occupational and Environmental Medicine, and the American Association of Occupational Health Nurses) to maintain adequate skills for technicians administering spirometry tests in the occupational setting. The information contained in the refresher course application (80 hours) will be reviewed by the Course Approval Committee within the Institute to determine whether the course meets minimum NIOSH requirements for hours, content, and technique.

**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

## **B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

Data collection procedures are outlined below. This collection of information does not employ statistical methods. The following procedures are used to collect information:

Parties interested in becoming a sponsor for the NIOSH-approved spirometry training program request an application and the program office forwards an electronic copy by e-mail. Approved sponsors submit requests to NIOSH when they have a change in curriculum or new faculty to be approved by the program committee. Sponsors submit an annual report of classes completed to NIOSH using the NIOSH internet. A course renewal application and supporting documentation is submitted by approved sponsors once every 5 years if they choose to continue teaching. Approved-sponsors interested in teaching the refresher training course submit an application and supporting materials.

### **B1. Respondent Universe and Sampling Methods**

The respondent universe includes sponsor applicants and NIOSH-approved course sponsors.

### **B2. Procedures for the Collection of Information**

The data collection associated with the course approval program consists of an introductory course application that is submitted to NIOSH by potential course sponsors; annual reports in which approved sponsors provide information on the status of their courses; a program renewal application for approved sponsors; and a refresher course application for those sponsors already approved at the introductory instruction level. Course sponsors may also voluntarily submit requests for changes in course content or for additional faculty to be approved.

Parties interested in becoming a sponsor for the NIOSH-approved spirometry training program request an application and the program office forwards an electronic copy by e-mail. The party returns the application and supporting materials to the program office at their convenience. The program chairperson checks the submitted materials to determine if the package contains all of the requested information. If any information is missing, the chairperson contacts the applicant to forward the requested material.

All sponsors receive an electronic notification at the end of the calendar year that annual reports are due. Sponsors submit their reports electronically via the NIOSH internet. Any sponsor who fails to submit a report is contacted by the program chairperson by e-mail or telephone to ascertain if they are still teaching courses and is requested to submit their report if they are teaching.

A sponsor's 5-year renewal process will be initiated by the NIOSH program office. Each sponsor will receive a notification with the application 9 months prior to their approval expiring. The sponsor will return the application and any supporting documentation to the program office. The sponsor will choose to submit materials by either regular postal mail or electronically. The program chairperson will check the submitted materials to

determine if the package contains all of the requested information. If any information is missing, the chairperson will contact the sponsor to forward the requested material.

Sponsors who choose to have their refresher course approved by NIOSH will submit an application and any supporting materials by either regular postal mail or electronically. The program chairperson will check the submitted materials to determine if the package contains all of the requested information. If any information is missing, the chairperson will contact the sponsor to forward the requested material.

There is no instrument for a sponsor to request a change to their curriculum or for a new faculty member to be approved. Sponsors send their requests via e-mail to the program office. The program chairperson checks the submitted materials and may ask the sponsor to provide more documentation in accordance with the qualification criteria posted on the NIOSH spirometry training course web page. These qualification criteria were distributed to all sponsors following a meeting with course directors in 2005.

### **B3. Methods to Maximize Response Rates and Deal with Non-response Rates**

This section does not apply to this data collection because 29 CFR 1910.1043 (h) (1) (iii) is a federally mandated regulation requiring administration of this program. All submissions are voluntary on the part of the sponsors and new entities wishing to become sponsors.

### **B4. Tests of Procedures or Methods to be Undertaken**

The NIOSH project officer routinely discusses the use of the data collection instruments with program sponsors and has updated all instruments so they may be submitted electronically if the sponsor so chooses.

### **B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

This project has been ongoing since NIOSH was given the statutory authority under 29 CFR 1910.1043 (h) (1) (iii).

The purpose of this collection is to provide information that will be used by NIOSH staff to determine whether the courses meet minimum NIOSH/OSHA requirements for hours, content, instrumentation, technique, and faculty as set forth in the OSHA standard, and are consistent with standard practice guidelines for administering spirometry tests as set forth by the American Thoracic Society.

## **LIST OF ATTACHMENTS**

- Attachment A. Legislative Authority**
- Attachment B. NIOSH-Approved Spirometry Testing Course Application**
- Attachment C. NIOSH-Approved Spirometry Course Sponsorship Renewal Application**
- Attachment D. Electronic Annual Report**
- Attachment E. NIOSH-Approved Spirometry Refresher Course Application for Approval**
- Attachment F. Federal Register Notice**