

PULMONARY FUNCTION TESTING COURSE APPROVAL PROGRAM
(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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- Attachment A – Legislative Authority
- Attachment B – 60 Day Federal Register Notice
- Attachment B2 – 60 Day FRN comment
- Attachment C – Spirometry Initial Testing Course Application
- Attachment D – Annual Report Form
- Attachment E – Spirometry Course Sponsorship Renewal Application
- Attachment F – Spirometry Refresher Course Application
- Attachment G – Example of E-mail Request for Course Change
- Attachment H – One-time Sponsor Survey
- Attachment I – IRB Determination

- **Goal:** The primary goal of this data collection is to adhere to the NIOSH duties outlined in the OSHA Cotton Dust Standard [29 CFR 1910.1043]. NIOSH is mandated to provide educational materials, oversight, and approval to course sponsors who provide spirometry training to individuals who perform spirometry testing on our nation's workers exposed to cotton, coal mine, and respirable crystalline silica dusts.
- **Intended Use:** The data collection activities will allow NIOSH to continue to receive information from course sponsors. This information allows NIOSH to maintain spirometry training standards as outlined under Section 21 of the Occupational Safety and Health Act and 29 CFR 1910.1043 (h) (1) (iii). This program is used by course sponsors to provide a mechanism for individuals to complete a NIOSH-approved course, enhance the quality of worker spirometry testing, and to nationally standardize spirometry surveillance and screening within the workforce.
- **Methods:** NIOSH provides educational materials and curriculum content review to course sponsors to ensure that NIOSH-approved spirometry training maintains current regulatory and professional standards for occupational spirometry testing. Additionally, we mandate that course sponsors undergo periodic curriculum renewals and site-visits to oversee course content. NIOSH also safeguards that those who teach the NIOSH approved-courses have the necessary professional expertise to provide cogent, effective, and high quality spirometry training.
- **Population:** NIOSH-approved Spirometry Training Course Sponsors
- **Data Analysis:** Annual tallies regarding faculty status, course attendance, and successful completion of spirometry training are maintained by NIOSH.

PART A. Justification

A1. Circumstances Making the Collection of Information Necessary

This package (0920-0138 expires 11-30-2020) contains minor revisions and requests an approval for revision for 3 years. The complete list of revisions is included as Attachment A2. 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 occupational spirometry 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. In addition, 42 CFR §37.95(a) specifies that persons administering spirometry tests for the national Coal Workers' Health Surveillance Program must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses. Also, 29 CFR § 1910.1053(i)(2)(iv), 29 CFR § 1910.1053(i)(3), 29 CFR § 1926.1153(h)(2)(iv) and 29 CFR § 1926.1153(h)(3) specify that pulmonary function tests for initial and periodic examinations in general industry and construction performed under the respirable crystalline silica standard should be administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course.

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 C),
- annual reports, which provide/supply information on course status (Attachment D),
- a program renewal application for approved sponsors (Attachment E), and
- a refresher course application for those sponsors already approved at the introductory instruction level (Attachment F).

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 G). 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 H) to evaluate our service to courses.

A2. Purpose and Use of Information Collection

Revision of 0920-0138 will allow the on-going NIOSH Pulmonary Function Testing Course Approval Program to continue to receive information from our NIOSH-approved course sponsors. This information allows NIOSH to maintain spirometry training standards as outlined under Section 21 of the Occupational Safety and Health Act and 29 CFR 1910.1043 (h) (1) (iii) through initial review and periodic renewal of course curricula, materials, and faculty. NIOSH also collects course sponsor information pertaining to the number of courses being conducted annually and the number of students being successfully trained. This allows NIOSH to quantify its impact in our stated goal to

disseminate information that helps to facilitate quality spirometry testing within our nation's workforce. For example, in 2018, 371 courses were conducted by NIOSH course sponsors in 12 countries, 45 states, and 1 US territory and Washington, D.C. During the three-year period between 2015 and 2017, 998 Spirometry Training courses were conducted by NIOSH course sponsors and 10,269 attendees received a spirometry training Certificate of Completion in accordance with the standards set by the 1978 Cotton Dust Standard (OSHA 29 CFR 1910.1043).

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 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.

Agents 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 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 35 requests per year from approved sponsors to change course content or add new faculty.

Each year, sponsors are asked to submit via email 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. Dates 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. The number of Refresher Course application requests have decreased. On average, 2 requests annually were made between 2017 and 2019.

Thirty-four 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 non-substantive change request 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.

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 downloadable files from the NIOSH internet. As new material is completed, it is organized into electronic files that can be inserted into existing PowerPoint presentations.

The application forms were developed to effectively describe the minimum criteria for each course, and 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. All course sponsor submissions are collected via electronic submission (100%). Course Sponsor forms are available in electronic formats. The applicant may also electronically submit their accompanying materials (curriculum vitae, non-NIOSH course manual, and student exercises).

In the past, annual report forms were uploaded by course sponsors to a password-secured Secure Access Management System (SAMS), then submitted to a linked email, which is no longer operable. To save sponsors' time, a dedicated email account was set up for direct annual reporting via email. Sponsors can choose to attach the form (or a similar formatted spreadsheet), or insert the totals in the body of the email. The email submission saves sponsor time by allowing flexibility and bypassing the need to log into SAMS and type data into the form. The form has been updated to reflect the easier

submission process.

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 (SAMS), which is accessible via the NIOSH Spirometry Training Program web pages.

The one-time customer satisfaction survey will be an internet-based survey located on the password-protected NIOSH course sponsor website.

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 June 2nd, 2020, Vol. 85, No. 106 pages 33676 and 33677. A copy of the notice may be found in Attachment B. We received one non-substantive comment (Attachment B2).
- 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 course director 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 2020, 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) Martha Horike-Pyne, University of Washington, Seattle, WA
(206) 221-0971 mjpyne@u.washington.edu
- 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NIOSH's Information Systems Security Officer reviewed this submission and determined that Privacy Act does not apply. 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 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. 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. The One-Time Customer Satisfaction Factors Survey (Attachment 8) does not ask for any identifying information.

Even though the Privacy Act is not applicable, records will be safeguarded. NIOSH will treat information in a secure manner and will not disclose 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. Institutional Review Board (IRB) and Justification for Sensitive Questions
IRB Approval**

The NIOSH Pulmonary Function Testing Course Approval Program has been determined that the data/information collected is not research involving human subjects. Therefore, IRB approval is not required (Attachment I).

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. The number of respondents to the annual report increased from 32 to 34. Annual report response time decreased from 30 to 28 minutes due to a simplified submission process that eliminates the need to log into the password-protected SAMS course director site and enter data line-by-line on an electronic form. Now, sponsors can submit totals in the body of an email or as an attachment and send to a dedicated mailbox. Consequently, total Annual Report hours remained the same. 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)
	Initial Application	3	1	3.5	10.5
	Annual Report	34	1	28/60	16
	Report for Course Changes	24	1	30/60	12

Potential Sponsors	Renewal Application	13	1	6	78
	Refresher Course Application	3	1	8	24
	One-Time Customer Satisfaction Survey	32	1	12/60	6
Total					147

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

B. Estimated Annual Cost to Respondents:
146.5 hours X \$23.00/hr* = \$3369.50

* Estimated at the government level of General Schedule (GS) 06/07 for typing and compiling materials. Salary is based on 2020 Office of Personnel Management GS and Locality Pay Tables. https://www.federaljobs.net/salarybase.htm#SALARY_TABLE_2015-RUS Accessed 3-11-20

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	\$240 per review X 3 applications	720.00
B. Review of renewal application	\$407 per review X 13 applications	5,291.00
C. Review of refresher course application	\$541 per review X 3 applications	1,623.00
D. Telephone/e-mail inquiries	4 hr/month X 12 X \$34/hr*	1632.00
E. Course change requests	15 min/review X \$34/hr* (\$8.50/review) X 24 requests	204.00
F. Clerical time	7 hours X \$17.00/hr*	119.00
G. Compile/file information	12 hr X \$34/hr*	408.00
TOTAL		9,997.00

* Salaries are based on 2020 Office of Personnel Management GS and Locality Pay Tables for GS 11-4 and GS 9-3 https://www.federaljobs.net/salarybase.htm#SALARY_TABLE_2015-RUS Accessed 3-11-20

Total cost to government = \$9,997.00

A15. Explanation for Program Changes or Adjustments

The annual report hours increased from 32 to 34 but the burden hours remain at 147.

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, coal mine dust, or respirable crystalline silica 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

“The display of the OMB expiration date is not inappropriate.”

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.