

Building Related Asthma Research in Public Schools (New)

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SUPPORTING STATEMENT

This is a new data collection, and we are seeking OMB approval for three years. We are requesting this ICR be expedited and considered a priority for review as data collection was planned to begin during the 2008 fiscal year. The funding source is directly linked to this time frame, and is not carried forward over fiscal years.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The National Institute for Occupational Safety and Health (NIOSH) will be conducting a study on work-related asthma in schools in New England. In order to achieve our goals of understanding relationships between indoor environmental quality issues associated with dampness and other contamination, we need to collect information as described in this OMB supporting statement. The Occupational Safety and Health Act, Public Law 91-596 (section 20[a][1]) authorizes NIOSH to conduct research to advance the health and safety of workers (see Appendix A).

A. School occupants

Currently, 2.97 million teachers and 2.63 million additional staff are joined by 47.3 million students in the 94,000 schools across the United States (U.S. Department of Education, National Center for Education Statistics, Common Core of Data, 2002-2003). These numbers are projected to increase to 3.47 million elementary and secondary school teachers instructing 55.2 million students by 2009 (U.S. Census Bureau, Statistical Abstract of the United States, 2004-2005). Thus, research aimed at reducing asthma incidence and exacerbation in schools would have a large impact.

B. Extent of school environmental problems

In 1995, the Government Accounting Office reported that 1 in 3 schools were in need of extensive repair or replacement of one or more buildings in poor condition, with projected repair costs of \$112 billion (GAO-HEHS-95-61, "Condition of America's Schools). A follow-up 1999 report from the U.S. Department of Education "Survey on the Condition of Public School Facilities" found that three-quarters of schools needed to spend money on repairs, renovations and modernizations. In 2000, the National Education Association estimated the cost of needed repairs to schools at \$322 billion. In that same year, the American School & University Official Education Construction Report estimated that elementary and secondary schools spent more than \$21.5 billion on construction.

Local school districts traditionally have received some of their operating funds from state governments, but construction projects have usually been funded locally through bond election. As conditions in schools have gained more public attention, many state governments and the federal government have stepped forward to help local communities build and repair schools. Most states now have some form of financial aid for school construction through flat or need-based grants to school districts; some states disburse monies based on equalized funding formulas that give the most money to the poorest districts. Even with these funding mechanisms, financial constraints may occur during all phases of design, construction, and operation of school buildings. Design of school buildings is often dictated by costs for construction. Decisions made to cut costs in construction sometimes do not consider material lifetime or subsequent maintenance

costs or requirements. Low-cost construction examples known to require higher maintenance and to have shorter functional lifetimes include flat roofs, prefabricated structural materials or components, and carpeting. Mechanisms for funding construction of school buildings may not include funding for maintenance of the buildings once built. Schools are frequently water-damaged due to these common design and maintenance difficulties.

The link between school facility conditions and the health and welfare of the occupants is increasingly recognized. The federal requirements for “No Child Left Behind” have mandated that school facilities be designed and maintained in a way that provides a safe and healthful learning environment for children (Section 5414 of the Elementary and Secondary Education Act as amended by the No Child Left Behind Act of 2001). Two large studies in Sweden on staff and students of schools found statistically significant relationships between asthma and measurements of exposure to fungi, bacteria and volatile organic compounds (Smedje et al. 1997a; Smedje et al. 1996). A review of the literature on the influence of indoor environments in schools on student performance concluded that poor indoor environmental quality in schools is “common and adversely influences the performance and attendance of students, primarily through health effects from indoor pollutants” (Mendell and Heath 2005).

C. Extent of asthma

In 2000, the estimated prevalence of asthma in school teachers, counselors and librarians was 12% (NIOSH 2003). Occupational asthma accounts for about 15-20% of adult-onset asthma (Balmes et al. 2003). The asthma burden in school employees is sizable because asthma is a common and increasing disease. In 2002, 20 million Americans had asthma and half reported an asthma attack or episode during that same year (National Center for Health Statistics). The annual direct health care cost of asthma in the United States is approximately \$11.5 billion; indirect costs (e.g. lost productivity) add another \$4.6 billion, for a total of \$16.1 billion dollars (National Heart, Lung and Blood Institute Chartbook, U.S. Department of Health and Human Services, National Institutes of Health, 2004).

Some of the asthma burden in school employees is undoubtedly due to exposures in water-damaged school buildings. A clinical case series of 55 Connecticut teachers with work-related respiratory complaints found 23 cases of asthma, of which 20 were currently symptomatic and 7 had developed in the course of employment in their current school building (Dangman et al. 2005). The case series included four cases of granulomatous lung disease (two hypersensitivity pneumonitis and two sarcoidosis). The majority of teachers (33/55) worked in schools with documented water incursion. All seven incident asthma cases and all four patients with granulomatous lung disease worked in these wet buildings. A study in Finland found a cluster of asthma cases among teachers working in a mold damaged building. Of the eight cases that were reported, three were determined to be due to mold exposure at the school (Patovirta et al. 2004). In a Swedish study of schoolchildren, they found that a higher prevalence of current asthma was reported in schools with higher levels of viable bacteria and mold, although visible signs of dampness were not significantly related (Smedje et al. 1997b).

D. Dampness as a public health problem

The Centers for Disease Control and Prevention sponsored the Institute of Medicine to make an exhaustive review of the published literature relating exposures in damp buildings to health consequences. The committee findings, summarized in *Damp Indoor Spaces and Health* (Institute of Medicine of the National Academies of Science

2004), concluded that sufficient evidence exists for associating the presence of mold or other agents in damp buildings to nasal and throat symptoms, cough, wheeze, asthma symptoms in sensitized asthmatics, and hypersensitivity pneumonitis in susceptible persons. The committee also concluded that damp indoor environments constitute a public health problem. Identification of specific causal agents for these health outcomes in damp environments requires more investigation, and research and demonstration projects are needed to evaluate interventions in damp buildings.

2. Purpose and Use of Information Collection

This research project is funded by the National Occupational Research Agenda (NORA) to assess work-related asthma in relation to poor indoor environmental quality in schools. This study has been funded through the 2010 fiscal year. The purposes of this study are three-fold: 1) to document the time course of changes in respiratory health, sick leave, and quality of life in relation to building remediation for water incursion and dampness problems in public schools; 2) to validate the reporting of building-related lower respiratory symptoms in school staff with bronchial hyper-responsiveness by the use of serial spirometry to look for building-related patterns of air flow variability; and 3) to demonstrate that a toolkit comprised of a semi-quantitative index for assessing water damage and signs of moisture in schools, along with a short health questionnaire, can be used by school personnel to pinpoint specific problem areas and aid remediation efforts.

A major long term objective of this project is to help stakeholders be proactive in dealing with issues of dampness, poor indoor environmental quality and any associated adverse health effects such as onset or exacerbation of asthma. The New England region has placed an emphasis on both improving schools environments and reducing asthma in the region, and there are networks of organizations that have already made good progress in building capacity to achieve these goals. Since the stakeholders in New England have requested NIOSH collaboration in improving school environments, it is very important that we use this opportunity to translate our research into practical approaches.

NIOSH will partner with local and regional groups to achieve our outreach goals. The American Lung Association of New England will play a large role in facilitating the project locally and aiding in the dissemination of annual study update newsletters prepared by NIOSH researchers. They will use their extensive network of stakeholders in asthma as well as in indoor environmental issues to co-ordinate community, state and regional outreach.

In each of the school survey years NIOSH will hold meetings to update school personnel and management as well as community stakeholders and our partners in the project on progress of the work. As study results become available NIOSH will make presentations at appropriate meetings in the New England Region. Organizations that we will work through for dissemination of results are: the New England Asthma Regional Council, school nurses associations, departments of education, and state health departments. NIOSH will also make use of state and regional partners' websites and the NIOSH website to disseminate information on the project.

3. Use of Improved Information Technology and Burden Reduction

NIOSH interviewers will administer a questionnaire each year to all employees and staff in the school. All the interviews will be administered face-to-face, and the responses will be recorded by the NIOSH interviewer directly into a computer (see Appendix H.1). During the second and third years of the study, we will also interview

previous participants who have left employment at the school by a telephone interview (see Appendix H.2). We will invite these previous participants to take part in the telephone survey by using the contact information given by the participant in the initial questionnaire. For persons asked to participate in the serial spirometry portion of the study, we will ask them to use an EasyOne[®] portable spirometer. The EasyOne[®] spirometer is a small device in which the participant is first asked a series of questions (type of session (arising, awake hours, bedtime), location of testing, respiratory symptoms, medication use, and cigarette smoking) in which they will enter their responses directly into the spirometer (see Appendix J for protocol). After the set of questions, the participant is then instructed to blow into the spirometer. At the end of each day, the participant will cradle their spirometer on a modem, from which their data will then be downloaded onto a NIOSH computer.

We will also be asking school facilities personnel to use a semi-quantitative assessment sheet to qualitatively assess rooms for water damage and mold. This assessment sheet has been used in previous NIOSH studies and is quick and easy-to-use (see Appendix G) (Park et al. 2004). A new sheet is completed for each room or area they evaluate. The reason why this assessment sheet is completed on paper instead of a computer is that it would be difficult for facility personnel to carry a laptop from room to room while doing the evaluations. NIOSH will complete all data entry of these assessment sheets to minimize burden on the facilities personnel.

4. Efforts to Identify Duplication and Use of Similar Information

NIOSH is in a unique position to study schools in New England through our collaboration with the American Lung Association of New England. To our knowledge, no other intervention studies have been conducted in New England similar to this one.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the study.

6. Consequences of Collecting the Information Less Frequently

We are proposing to conduct an initial cross-sectional respiratory health survey in three schools, which will consist of a questionnaire and spirometry lung function testing offered to all employees, as well as serial spirometry for a subset of the respondents (no more than 20 participants). The questionnaire and spirometry lung function testing will be repeated annually for the following two years. This is done to assess respiratory health in relation to time and intervention status in the schools. The serial spirometry and semi-quantitative assessment components of the study will be done only one time.

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

There are no special circumstances.

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

Attached is a copy of the Federal Register Notice (see Appendix B) which contains the request for comments on the proposed collection of information. CDC published the notice on June 28, 2007 (Volume 72, Number 124 (pages 35489-35490)).

A comment was received from an individual regarding the validity and usefulness of the study. A response was sent to this individual regarding CDC's mission and referring them to the CDC website (see Appendix B).

This project was subject to extensive external and internal review in 2005 when it was submitted as a NORA project. A copy of the NORA evaluation is provided in Appendix C.

9. Explanation of Any Payment or Gift to Respondents

Persons who participate in the serial spirometry portion of the project will receive remuneration for their time. The reason why we are providing remuneration for this portion of the study is due to the intensive time commitment by participants. We are asking persons to participate in two three-week sessions. Each day, the participant will be asked to conduct five serial spirometry sessions; each session takes approximately 10 minutes. The total time commitment for each participant, which includes both training and the daily spirometry sessions, is estimated to be about 37 hours. Previous studies which involved self-testing using a portable spirometer have had difficulty with patient compliance, so researchers in our division have found it necessary to provide remuneration to participants in order to reduce non-participation and ensure full compliance. At the end of each three week session, participants that successfully complete the serial spirometry will receive a \$25 gift card to a local merchant. No gift cards will be given until the serial spirometer is returned to a NIOSH representative.

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. The data collection will involve collecting sensitive and/or personally identifiable information, which includes: name, address and phone number, birth date, race/ethnicity, gender, and questions on health and well-being. NIOSH will use standard methods to ensure the confidentiality and protection of this 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 file rooms or cabinets; data access will be restricted to only NIOSH personnel and contractors that are involved in the study. This study has been approved by the NIOSH HSRB; a copy of the approval letter is attached (see Appendix D). Please refer to Appendices E, H, I, J for the consent forms, questionnaires, notification letters to participants, and all medical protocols for this study.

11. Justification for Sensitive Questions

There are questions on the survey instrument which may be considered sensitive. The address and telephone number will be for notifying participants of their lung function test results, as well as to contact participants if they end employment at the school during the study. Information on race, ethnicity, gender, age, and smoking status is necessary to collect so that we can compare health symptoms and physician diagnoses with the National Health and Examination Survey (NHANES) III data, which is stratified by race, gender, age, and smoking status (National Center for Health Statistics, 1996). Questions from the SF-12[®] Health Survey are included to obtain information on the participant's physical and emotional well-being, which will be compared between the schools as well as with national data (Ware et al. 2002).

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

We estimated that the maximum number of teachers and staff that we would have at the three schools would be 300. All teachers and staff in the schools will be offered the NIOSH-administered questionnaire and spirometry lung function test (see Appendix H.1 and J). No more than 20 who participated in the questionnaire will also take part in the serial spirometry portion of the study (see Appendix J for medical protocols).

For the former worker questionnaire, we estimated that approximately 10% (n=30) of the workforce would leave during the study period. During the second and third years of the study, we will interview 30 former workers by telephone (see Appendix H.2).

Type of Respondents	Forms	No. of Respondents	No. of Responses per Respondent	Average burden per response (in hours)	Total burden hours
Teachers and staff	NIOSH-Administered Questionnaire	300	1	45/60	225
Former teachers and staff	Former Worker Questionnaire (Years 2 & 3 only)	30	1	9/60	4.5
Teachers and staff	Spirometry	300	1	15/60	75
Teachers and staff	Serial Spirometry	20	1	37	740
Facility personnel	Semi-Quantitative Assessment Sheet	3	1	5	15
	Total				1,059.5

B. Estimated Annualized Burden Hours

These estimates are calculated from the U.S. Department of Labor’s National Industry-Specific Occupational Employment and Wage Earnings in May 2005 for the average hourly rate of all occupations in the Elementary and Secondary School industry group.

Source: http://www.bls.gov/oes/current/naics4_611100.htm#b00-0000

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Elementary and Secondary School Employees	1,059.5	\$18.94	\$20,067

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

There are none.

14. Annualized Cost to the Government

The annualized cost to the government ranges between \$285,160 for the first year to \$297,000 for the final two years. Equipment and supplies for the project include glucan kits for an in-house analysis of (1 → 3)-β-D-glucan, a fungal cell wall component, and other general industrial hygiene supplies. Equipment and supplies costs for FY08 also include compensation for participants who participate in the serial spirometry portion of the study. Contractual costs include both contracted personnel and the costs to analyze environmental samples collected during the three environmental surveys. Travel includes the costs for the environmental and medical surveys, as well as travel to other stakeholder and national meetings. We expect about 11 government employees will be needed to conduct the environmental and health surveys.

Item	FY 2008	FY 2009	FY 2010	Total
Equipment and supplies	\$11,500	\$10,500	\$10,500	\$32,500
Contractual	\$216,893	\$229,733	\$229,733	\$676,359
Travel	\$56,767	\$56,767	\$56,767	\$170,301
Annualized estimate of federal costs	\$285,160	\$297,000	\$297,000	\$879,160

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Project Time Schedule

After we receive approval from OMB, we plan to notify schools within a month of the upcoming surveys with a study announcement (see Appendix F). The following month we will conduct the environmental and health surveys (questionnaire, spirometry lung function testing, and serial spirometry) at the schools. At the same time, we will also train facility personnel in the use of the semi-quantitative assessment sheet and nurses in using a short health questionnaire. We expect to have notification letters of the spirometry lung function testing (see Appendix I) sent to all participants approximately one month after our health survey. We will continue the environmental and health surveys (questionnaire and spirometry lung function testing only) for the next two years. After data collection is finished, we will begin preparation of our results for publication in a peer-reviewed journal. We expect to submit for publication about 48 months after receiving OMB approval.

Activity	Time Schedule
Notification of study to respondents	1 month after OMB approval
NIOSH-administered questionnaire, spirometry lung function testing, environmental evaluations by facility personnel and NIOSH, and training school nurses in the use of the short health	2 months after OMB approval

questionnaire (Year 1)	
Serial spirometry training	2 months after OMB approval
Serial spirometry	2-5 months after OMB approval
Letters to respondents of lung function results	3 months after OMB approval
Questionnaire and environmental evaluation, former worker questionnaire (Year 2)	14 months after OMB approval
Questionnaire and environmental evaluation, former worker questionnaire (Year 3). End of data collection.	26 months after OMB approval
Publication in peer-reviewed literature	48 months after OMB approval

B. Statistical analysis

1. Analyzing environmental indices with semi-quantitative assessment tool

Since all objective environmental measurements are continuous variables, we will use linear regression models to examine the associations of objective measurements as dependent variables with semi-quantitative indices of dampness as independent variables within a school as well as among the three schools. We will use total scores for dampness indices as a continuous variable in these models. We will examine the association of individual indices for water stains and visible mold with objective measurements of dampness-related contaminants because we found in previous studies that those two measures dominated the scores in damp buildings and played the most important roles in predicting health outcomes. Mold smells and presence of wet material added valuable information to overall indices of dampness. To confirm if increasing dampness indices are associated with linear increases of objective measurements, we will categorize indices of dampness by tertiles and compare the mean levels of objective environmental measurements (dependent variables) among tertiles of dampness indices (independent variable) using linear regression models within a school and among all schools. We will also use graphical analysis to examine linear trends. To examine differences among schools in average dampness indices and objective exposure measurements, we will use linear regression models with the environmental measurement as a continuous dependent variable and school as a categorical independent variable in pooled data from all schools for each measurement and index. Estimated least squares means of the environmental measurements from the regression models will be compared to examine if there is any linear trend among the schools.

2. Analyzing the agreement between facility personnel and NIOSH for the semi-quantitative assessment tool

We will evaluate the agreement between NIOSH observations and the school facility managements' observations in the semi-quantitative assessment tool by computing and testing kappa statistics for each factor and location combination. If the estimated kappa between NIOSH and school personnel observations is greater than or equal to 0.4, we will consider the agreement to be acceptable (Landis and Koch 1977).

3. Analyzing respiratory health outcomes with environmental indices

We will analyze lung function, symptom outcomes, lower and upper respiratory medication use, quality of life scores, and sick leave with dampness/mold indices and quantitative measures of contaminants in dust using generalized linear model methods for repeated measurements. For dichotomous dependent variables we will specify a binomial distribution and logit link function, while for continuous outcomes we will specify a

normal distribution and the identity link function. The models will allow for correlation between the three measures on each participant or on each room, and for time-varying explanatory variables. We will use the SAS® GENMOD (SAS Institute, 2003) procedure to apply these models.

4. *Analyzing intervention effectiveness*

For models on health outcomes that look for changes over time between the three schools, the explanatory variables will include school (three levels: A, B and C), survey round (three levels, 2008, 2009, 2010), the interaction between school and survey round (9 levels), demographics for each participants (age, sex, history of atopy, smoking category), home water damage in the past 12 months, home mold odor in the past 12 months, and job stress factors. We will look for significant differences in health outcomes between schools and an interaction effect of survey round and school. We will look at the trends over the study rounds within schools. We will also run models on health outcomes that investigate associations with the semi-quantitative and quantitative objective environmental measures.

For the models with exposure measures (both semi-quantitative and quantitative) in each room as outcomes, the explanatory variables will include school (three levels: A, B and C), survey year (three levels: 2008, 2009, and 2010), the interaction between school and survey round (9 levels). We will look for significant difference in exposure outcomes among schools and an interaction effect of survey round and school. We will look at the trends over the study rounds within schools.

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

We are not requesting an expiration date display exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.