

**REQUEST FOR OMB REVIEW AND APPROVAL  
UNDER THE PAPERWORK REDUCTION ACT AND 5 CFR 1320**

**Long-Term Efficacy of a Program to Prevent Beryllium Disease**

**Part A**

Principal Investigator:

Christine R. Schuler, PhD  
NIOSH  
Division of Respiratory Disease Studies  
1095 Willowdale Road, MS H2800  
Morgantown, WV 26505  
304-285-6072  
CSchuler@cdc.gov

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Table of Contents

A. JUSTIFICATION.....4

- 1. Circumstances Making the Collection of Information Necessary .....4
- 2. Purpose and Use of Information Collection .....8
- 3. Use of Improved Information Technology and Burden Reduction .....9
- 4. Efforts to Identify Duplication and Use of Similar Information....10
- 5. Impact on Small Businesses or Other Small Entities .....10
- 6. Consequences of Collecting the Information Less Frequently ..... 10
- 7. Special Circumstances Relating to the Guidelines of 5CFR 1320.5 .....10
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....10
- 9. Explanation of Any Payment or Gift to Respondents.....10
- 10. Assurance of Confidentiality Provided to Respondents.....10
- 11. Justification for Sensitive Questions.....11
- 12. Estimates of Annualized Burden Hours and Costs.....11
  - a. Hour Burden to Respondents.....11
  - b. Annualized Cost to Respondents.....12
- 13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers.....12
- 14. Annualized Cost to the Government.....12
- 15. Explanation for Program Changes or Adjustments.....12

16. Plans for Tabulation and Publication and Project Time Schedule.....13

17. Reason(s) Display of OMB Expiration Date is Inappropriate.....13  
.....

18. Exceptions to Certification for Paperwork Reduction Act  
Submissions.....13

## A. JUSTIFICATION

### 1. Circumstances Making the Collection of Information Necessary

The Occupational Safety and Health Act, Public Law 91-596 (section 20[a][1]) authorizes The National Institute for Occupational Safety and Health (NIOSH) to conduct research to advance the health and safety of workers (Appendix A).

Beryllium is a lightweight metal with many applications. Exposed workers may be found in the primary production, nuclear power and weapons, aerospace, scrap metal reclamation, specialty ceramics, and electronics industries, among others. The size of the United States (US) workforce at risk for chronic beryllium disease (CBD) may be as high as one million. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed.

Exposure to beryllium can lead to sensitization and cause an immunologic granulomatous lung disease. Sensitization is a cell-mediated allergic-type response that may be detected in the peripheral blood with the beryllium lymphocyte proliferation test (BeLPT). Sensitized workers often have or develop CBD, which can be diagnosed with tests including bronchoalveolar lavage and transbronchial biopsy. However, it is not presently known what percent of sensitized workers will eventually develop disease. Symptoms of CBD include shortness of breath, cough, and fatigue, with typical treatment aimed at modulating the immune response, usually with corticosteroids. Treatment is generally delayed until impairment is apparent; CBD is not curable. Industry screening programs have enabled the early identification of CBD in persons without apparent symptoms, known as subclinical disease (sCBD). Progression from sensitization to sCBD to clinical impairment is not uncommon. One recent study followed 55 sensitized workers without CBD; 1/3 developed CBD within an average period of less than four years and pulmonary function declined during an average follow-up of less than five years (Newman et al, 2005). Despite increased knowledge gained by the ability to detect subclinical disease, many questions remain about exposure-related risks, disease mechanisms, and the natural history of sensitization and disease.

Researchers have studied various exposed populations, including those working in the primary beryllium industry (Kreiss et al, 1996, 1997; Henneberger et al, 2001; Rosenman et al, 2005; Schuler et al, 2005), service and distribution centers (Stanton et al, 2006), nuclear weapons (Kreiss et al, 1993a; Stange et al, 2001, 2004), ceramics (Kreiss et al, 1993b), mining and milling ores (Deubner et al, 2001), precision machining (Newman et al, 2001), decontamination and decommissioning of beryllium-contaminated buildings (Sackett et al, 2004), and construction trades workers (Welch et al, 2004). Workers in these studies are currently or were formerly exposed to different forms of beryllium. Sensitization has been found in 1 - 14% of worker groups studied, with CBD diagnosed in 10 - 100% of the sensitized. Failure to prevent CBD has been documented in every assessed group in facilities using traditional compliance-based approaches to prevention (see Table 1).

**Table 1. Beryllium sensitization (BeS) and CBD in beryllium-exposed workplaces**

Industry or Job/Study	Population	BeS (%)	CBD (%)
Current beryllia ceramics workers; Henneberger et al, 2001 <sup>1,3</sup>	151	9.9	3.3
Current machining facility workers, followed up to 4 yrs; Newman et al, 2001	235	9.4	5.5
Current metal, oxide & alloy production workers; Kreiss et al, 1997 <sup>3</sup>	627	6.9	3.3
Current beryllia ceramics workers; Kreiss et al, 1996 <sup>1,3</sup>	136	5.9	4.4
Current copper-beryllium alloy plant workers; Schuler et al, 2005 <sup>4</sup>	152	5.9	3.3
Current, former nuclear weapons workers, followed for 3 yrs; Stange et al, 2001 <sup>2,4</sup>	5173	4.5	1.6
Current mining/extraction workers; Deubner et al, 2001 <sup>3</sup>	75	4.0	1.3
Current, former nuclear weapons workers, followed 1-3 yrs; Stange et al, 1996 <sup>2,4</sup>	4397	2.4	0.4
Current nuclear weapons workers; Kreiss et al, 1993a <sup>2</sup>	890	2.0	1.7
Current, former beryllia ceramics workers; Kreiss et al, 1993b	505	1.8	1.8
Current, former construction trades workers; Welch et al, 2004	3842	1.4	0.1
Current copper-beryllium distribution center workers; Stanton et al, 2006 <sup>3</sup>	88	1.1	1.1
Current nuclear weapons facility decontam./decomm. workers; Sackett et al, 2004	2221	0.9	0.1

<sup>1</sup> Same facility; <sup>2</sup> Same facility; <sup>3</sup> Brush Wellman Inc. facilities; <sup>4</sup> 2001 study includes some of 1996 results.

The burden of CBD in manufacturing workers whose jobs supported Cold War efforts led to the Energy Employees Occupational Illness Compensation Program (EEOICP) Act in 2001 (Department of Energy (DOE), 2001), which provides compensation to eligible current and former workers who developed disease due to exposure to radiation, silica, or beryllium. Brush Wellman Inc. (BWI) workers are covered by the EEOICP and may benefit from involvement in the proposed research through determination of EEOICP eligibility.

Since 1998, NIOSH and BWI, the primary producer of beryllium and beryllium-containing materials in the US, have collaborated on a series of workplace surveys: a 1992 survey conducted at the Tucson, Arizona beryllium oxide ceramics facility (Kreiss et al, 1996), followed-up in 1998 (Henneberger et al, 2001); a 1993-94 survey at the Elmore, Ohio metal, oxides, alloys, and ceramics production facility (Kreiss et al, 1997), followed-up in 1999 (Schuler et al, 2003); a cross-sectional survey in 2000 at the Reading, Pennsylvania copper-beryllium alloy finishing facility (Schuler et al, 2005); and a cross-sectional survey in 2000-01 at three copper-beryllium alloy distribution centers (Stanton et al, 2006). In addition, NIOSH independently surveyed former workers who had participated in the 1992 Tucson and 1993-94 Elmore studies (Kitt et al, 2003).

One of our major findings from this series of epidemiologic studies was that engineering controls designed to reduce airborne beryllium exposure at higher-risk work processes were not sufficient to reduce development of sensitization and CBD. Subsequent to the 1992 Tucson survey (Kreiss et al, 1996), BWI implemented new engineering controls targeted at high-risk processes, such as machining. The 1998 Tucson survey was conducted to determine whether the prevalence of sensitization and CBD had declined

(Henneberger et al, 2001); 1998 sensitization rates were slightly higher than 1992 rates. The targeted engineering controls did not reduce sensitization among all workers hired after their implementation, but did reduce sensitization among more recently hired machinists. The prevalence of sensitization among all machinists remained high, but was lower among those hired after the 1992 survey, most of whom were hired in 1996-98. Subsequent to the 1993-94 Elmore survey (Kreiss et al, 1997), engineering controls designed to reduce airborne exposure to beryllium particles were also implemented. The prevalence of sensitization and CBD found in the 1999 follow-up survey were not reduced compared to 1993-94 (Schuler et al, 2003). Thus, the engineering controls did not reduce sensitization among workers hired after their implementation.

A second major finding was that beryllium sensitization and CBD can occur in conditions of low beryllium exposure. In the 1992 Tucson survey, none of the sensitized workers, including those with CBD, had an average beryllium exposure above  $1.1 \mu\text{g}/\text{m}^3$ , and three of those with CBD had average exposures of  $0.3 \mu\text{g}/\text{m}^3$  or less (Kreiss et al, 1996). In the 1998 Tucson survey, only four participants had average exposure levels that exceeded the  $2.0 \mu\text{g}/\text{m}^3$  Occupational Safety and Health Administration (OSHA) permissible exposure limit, one of whom was sensitized; among the sensitized workers hired after the 1992 survey, two had average estimated exposure levels  $\leq 0.06 \mu\text{g}/\text{m}^3$  (Henneberger et al, 2001). In the 1993-94 Elmore survey, the median average exposure among those with CBD was  $1.3 \mu\text{g}/\text{m}^3$  (Kreiss et al, 1997). The 2000 Reading survey showed levels of sensitization and CBD similar to those found at other facilities with much higher air levels of beryllium (Schuler et al, 2005).

A third major finding was that risk of sensitization and CBD is very likely underestimated by prevalence data from cross-sectional surveys. The original participants in the 1992 Tucson survey were followed for up to 11 years. By 2003, through a series of surveys of current and former workers, we were able to follow-up 83% of the surveyed workers who had a normal BeLPT in 1992. Among all not sensitized in 1992, 11% had become sensitized and 7% had developed CBD by 2003 (Kitt et al, 2003), compared to 6% and 4%, respectively, in 1992 (Kreiss et al, 1996). Among only those who had at least one follow-up test, 13% had become sensitized and 9% now had CBD. Thus, the total burden of disease among the original 1992 cohort was at least 16% sensitized and 11% with CBD. These findings suggest that the longitudinal burden of disease is higher than is implied by cross-sectional studies and that risk of disease continues after employment ceases.

In response to these findings, especially those showing that targeted engineering controls failed to reduce beryllium sensitization and CBD rates, BWI implemented a comprehensive preventive program (the "Program") at its three main plants. The Program included additional engineering controls, including enclosing machines and work processes that produced high concentrations of particles, restricting access to zones placed under negative atmospheric pressure to contain generated particles, redesigning locker rooms to segregate "dirty" and "clean" areas, transition zones between production and non-production areas, and installation of tacky mats and/or air showers at production area exits. The Program also included administrative controls emphasizing the control of particle migration. The company established new rules about clothing, requiring long

sleeves in production areas, aprons for wet processes, required clothing be kept visibly free of beryllium contamination, made end-of-shift showering and changing of clothing at two facilities mandatory, and later introduced transition shoes to be worn between production and locker areas. BWI placed new emphasis on cleanliness, scheduling regular wipe-downs in production areas and locker rooms. They expanded the use of personal protective equipment (PPE), requiring half-face negative pressure respirators and powered air-purifying respirators in production and/or process areas at two facilities. Finally, BWI included measures to address non-respiratory routes of exposure, such as the dermal route, by mandating full-time glove use in production areas. Later, when results of under-glove monitoring at one facility showed that skin was not fully protected, the company modified the glove use policy to include donning gloves prior to handling any other PPE.

Following the design and initiation of the Program, a system of mandatory medical surveillance using the BeLPT was also established, which focused on newly hired workers, as previously hired workers may have had past exposures conferring long-term risk of CBD (Henneberger et al, 2001). Sensitization had previously been identified at high levels early in employment (Henneberger et al, 2001; Schuler et al, 2005), but in the first cross-sectional surveys at each facility, the wide range of employment tenure made it difficult to determine the onset of sensitization or CBD for longer-term workers (Kreiss et al, 1996, 1997; Schuler et al, 2005). Thus, frequent testing in the first years of employment was designed to provide rapid feedback on the effectiveness of the Program, allowing for refinements and modifications. BeLPTs were done at hire, and at intervals of 3, 6, 12, 24, and 48 months of employment, after which workers were provided testing at three-year intervals.

We assessed the initial effectiveness of the Program in preventing beryllium sensitization by analyzing the BeLPT results of workers from the Tucson ceramics facility who were hired during the Program's first five years (2000 to 2004) (Cummings et al, 2006). Our comparison group was workers who had been hired within 60 months of, and participated in, the 1998 survey (late 1993 to 1998). Both groups were similar with respect to age, work tenure, and production area vs. non-production jobs. In the 2000-04 group, 93 workers contributed 1480 person-months of employment and one worker was determined to be sensitized, for an incidence rate of 0.7 cases of sensitization per 1000 person-months. In the 1993-98 group, 69 workers contributed 1081 person-months of employment and six workers were found to be sensitized, for an analogous "incidence rate" of 5.6 cases per 1000 person-months. The "incidence rate ratio" comparing the 1993-98 group to the 2000-04 group was 8.2 (95% CI, 1.2-188.8). It was not known whether any of the 1998 survey participants would have demonstrated abnormal BeLPT results on hire, since pre-work testing was not done at that time. The 2000-04 incidence rate was thus recalculated to include four workers who had positive tests on hire and were excluded from the initial incidence estimate. This resulted in a 2000-04 incidence rate of 2.7 cases per 1000 person-months; the 1993-98 results were still 2.1 times greater (95% CI, 0.6-8.4). A second analysis approach was to treat the 2000-04 results as though they had been collected cross-sectionally, similarly to the 1998 survey data. The sensitization prevalence was 1.0% (1/97) for the 2000-04 population and 8.7% (6/69) for the 1993-98 population, which was 8.4 (95% CI, 1.04-68.5) times higher than the 2000-04 group. Despite limitations, such as comparing incidence rates to prevalence-derived data and

unknown sensitization status at hire among the 1993-98 group, these results are promising.

These results demonstrating primary prevention of beryllium sensitization in an industrial setting, while encouraging, are preliminary and necessitate further investigation. The above study addressed workers at just one of BWI's three main facilities. Most 2000-04 workers in that study had a length of employment of less than two years, with an overall mean of 16 months. Thus, longer-term follow-up at all three facilities is needed to determine if the reduction in sensitization is maintained with time, or merely delayed, as well as assess the effectiveness of programmatic components, which were not all introduced at the same time. Another limitation to these findings is that they included only workers who were employed at the facility at the time of testing. Including former workers, who have past, but not ongoing, exposure to beryllium will provide a more complete description of the program's effectiveness and provide valuable information to current workers concerned about their risk of developing sensitization (and ultimately CBD) after leaving employment. Including former workers who were tested at hire but left prior to the first test interval should also help provide a more complete picture of risk associated with employment after Program implementation.

## **2. Purpose and Use of Information Collection**

This follow-up study is designed to evaluate the effectiveness of a comprehensive protection program at three BWI beryllium plants. Workers hired after implementation of the Program, defined as January 1, 2000 for the Tucson plant, February 20, 2000 for the Elmore plant, and January 1, 2001 for the Reading plant, are required to participate in medical surveillance for beryllium sensitization as a mandatory condition of employment. BWI does not provide routine testing to former workers. For purposes of this study, we will conduct an additional single round of follow-up testing using the BeLPT to identify sensitization among all current and former workers hired between each plant's implementation date and 2008. Review of informed consent will be obtained from the NIOSH Human Subjects Review Board for the proposed follow-up testing; the consent will permit NIOSH to gain access to each participant's existing medical surveillance records from BWI. To the current medical and work history questionnaire that we have used in other studies at these facilities, we added a module of questions on the effectiveness of the Program. Questionnaires will be administered when blood is drawn for the proposed BeLPTs. BWI will continue to refer incident cases of sensitization to the EEOICP for clinical evaluation for CBD, and NIOSH will also refer former workers found to be sensitized.

We will document the history of each facility's Program from date of implementation through 2008, with a description of the type of control effort (engineering, administrative or personal protective equipment [PPE]) and its effective year. A "sentinel improvement" at each facility, defined as the change or improvement most likely to have reduced exposure, will be determined.

The incidence rate for beryllium sensitization will be calculated for the period of time from the implementation date through this study's proposed round of testing. As we will have at least two data points on each person (at hire and the proposed testing, either during employment or afterward), we will calculate incidence as number of cases per

1000 months of person-time. To determine whether the Program at each plant has been effective in reducing sensitization, each plant's incidence rate will be calculated separately and compared to analogous data derived from cross-sectional plant surveys conducted shortly before Program implementation. To determine whether the Program's implementation at each plant has improved over time, participants will then be subdivided into early hires (those hired between Program implementation and the above-mentioned "sentinel improvement") and later hires (those hired after the "sentinel improvement"). Incidence rates among early hires will then be compared to incidence rates among later hires. Ultimately, data from all three plants will be combined for an overall Poisson (rate) regression analysis for sensitization that will include relevant covariates such as work processes, genetic marker status (for those participating), and indices of the effectiveness of the preventive program collected via questionnaire interview. We will also conduct a similar rate regression analysis for CBD.

This information will be collected by NIOSH research staff and contractors. The information collected in this study will provide a more complete description of the program's effectiveness in reducing the development of sensitization.

### **3. Use of Improved Information Technology and Burden Reduction**

This survey will utilize a computer-assisted personal interview work and medical history questionnaire (Appendix B) developed to automate this aspect of the data collection. The medical portion will cover the period from date of hire to the present, comprising questions about respiratory symptoms and diseases from the 1978 ATS/DLD respiratory questionnaire (Ferris, 1978), dermatological problems, and cigarette smoking behavior. The work history portion will cover the period from date of hire to the present (for current workers) or date of termination (for former workers) and will obtain information on jobs or processes performed; duration of a typical workweek; other BWI facilities a worker has worked at or visited; and beryllium exposure outside of BWI employment. The work history will include a module containing a series of questions that address the effectiveness of the preventive program. The module will have an open-ended question to allow for comments that the participant would like to make regarding possible improvements in the Program or its implementation. Demographic information will also be collected. As data are entered, programming within the instrument will skip to the next appropriate question and check for out-of-range responses and answers that are inconsistent with previously entered data. The instrument will also calculate totals where required in the work history to ensure that all time periods between date of hire or last survey and date of interview are covered. The worker will have the opportunity to correct his or her current response immediately. This realtime editing process will shorten the time between the collection of data and the availability of those data to be analyzed and interpreted. This method of questionnaire collection greatly reduces the burden on the participants.

We conducted focus groups with groups of 6 – 8 employees at each of the three facilities to discuss the questions developed for the questionnaire module addressing the effectiveness of the preventive program. The employees provided suggestions for better ways to word the questions and provided information specific to their facilities that

enabled us to use the correct terminology and response categories when designing the questions.

**4. Efforts to Identify Duplication and Use of Similar Information**

BWI is the only US company producing beryllium and beryllium-containing materials from ore to product, and knows of no customers involved in similar research.

**5. Impact on Small Businesses or Other Small Entities**

No entries into small businesses or other small entities will take place during this project.

**6. Consequences of Collecting the Information Less Frequently**

We cannot answer the public health research questions proposed in this study without interviewing workers and obtaining their medical and work history information. There are no legal obstacles to reduce the burden.

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

There are no special circumstances.

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

Public Comment, as required by 5 CFR 1320.8(d), was solicited in the Federal Register, Number 81, Volume 72, page 21022 on April 27, 2007. A copy of the notice can be found in Appendix C. No comments were received.

This proposal was reviewed and approved by the Human Subjects Review Board (HSRB) at NIOSH on March 23, 2007. HSRB final approval can be found in Appendix D.

**9. Explanation of Any Payment or Gift to Respondents**

No payments will be made to the respondents.

**10 Assurance of Confidentiality Provided to Respondents**

This submission has been reviewed for Privacy Act applicability and it has been determined that the Privacy Act is applicable. The medical history and work history information that will be collected as part of this study will be retained at NIOSH. NIOSH will continue to use standard methods to ensure the data is protected and treated in a secure manner. These practices include: the removal of all personal identifiers from data files being analyzed and coding laboratory samples with unique numbers. Access to personally identifiable information is restricted to staff who need to know, for example staff who contact participants to inform them of their results. All data records, files, and logs linking unique study identification numbers with identifiers are maintained in secure files and rooms. Electronic files with personal identifiers will be kept in password-protected computer accounts.

No genetic information is obtained through this questionnaire (Appendix B). The survey component of this study (and the questionnaire for which this OMB request for approval addresses) and the genetic component are completely separate. Workers may elect to

participate in the survey without participating in the genetic research. The consent form (Appendix E) states that all workers who agree to participate in this study will be protected as part of the CDC Privacy Act system 09-20-0154, Medical and Laboratory Studies. They are also informed that their information (other than the personally identifiable genetic information obtained from blood analyses which is protected by a 308(d) Assurance of Confidentiality (Appendix F), and is separate from this OMB request) may be given to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct research investigations regarding occupational health effects; to one or more potential sources of vital statistics, for example, to make a determination of death; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records (Appendix E - Use of Information and Confidentiality).

### 11. Justification for Sensitive Questions

There are no questions of a sensitive nature with the exception of the Social Security number (SSN). The collection of the SSN is done for identification purposes only, and will only be used as such. NIOSH is authorized to collect SSN information based on the Public Health Service Act, Section 301 (42 U.S.C. 241) and the Occupational Safety and Health Act, Section 20 (29 U.S.C. 669). The consent form states that we are requesting the participant's SSN and that we are authorized to do so (Appendix E). It also states that furnishing their SSN is voluntary.

### 12. Estimates of Annualized Burden Hours and Costs

#### 12.A Estimated Annualized Burden Hours

Type of Respondents	No. of Respondents	No. Responses per Respondent	Average Burden/Response (in hours)	Total Burden Hours
Former workers*	113	1	45/60	85
Current workers**	80	1	45/60	60
Participant Consent and Authorization for Release of Information	193	1	15/60	48
Total	386	-----	-----	193/yr.***

\* Former workers will participate during their own time.

\*\* Current workers will participate during work hours and will thus be compensated for their time by their employer.

\*\*\* Data collection planned over a 3 year period.

These hour burden estimates include the time for reviewing the instructions as well as completing and reviewing the questionnaire. Additionally, because the consent form is lengthy (nine pages) an additional 15 minutes has been added to complete the form and an entry has been added to reflect this.

**12.B Estimated Annualized Burden Cost**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Former Worker	85	\$19.53*	\$1660
Current Worker	60	\$19.53	\$1,172
Workers completing consent and authorization form	48	\$19.53	\$ 937
Total Annual Cost \$/yr**			\$3769

\* The average hourly wage of the former workers is difficult to estimate, given that we do not know what their current occupations are. Therefore, we have utilized the average hourly wage that these individuals would be paid if they were currently working at Brush Wellman Inc.

\*\*Burden of cost over a three year period.

**13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There are none.

**14. Annualized Cost to the Government**

Item	Cost
Equipment and supplies	\$15,000
Personnel	\$1,058,025
Contract services*	\$272,170
Travel	\$55,627
Remuneration to respondents	\$0
Annualized estimate of federal costs	\$350,205.50/yr

\* In the event that contract services are used.

**15. Explanation for Program Changes or Adjustments**

Not applicable. This is a new data collection. Therefore, we are not requesting a revision or extension.

## 16. Plans for Tabulation and Publication and Project Time Schedule

<i>Calendar Year</i>	<i>2007</i>				<i>2008</i>				<i>2009</i>				<i>2010</i>			
<i>Fiscal Year</i>	<i>FY2007</i>				<i>FY2008</i>				<i>FY2009</i>				<i>FY2010</i>			
	<i>Q1</i>	<i>Q2</i>	<i>Q3</i>	<i>Q4</i>												
Dev Program effectiveness module	X	X														
HSRB approval		X	X													
OMB approval		X	X	X												
Contact Tucson CW & FW				X	X											
Presentations to Tucson CW & FW					X											
Tucson CW & FW data collection						X					X					
Contact Elmore CW & FW							X	X								
Presentations to Elmore CW & FW								X								
Elmore CW & FW data collection									X	X	X					
Contact Reading CW & FW										X						
Presentations to Reading CW & FW										X						
Reading CW & FW data collection											X					
Data preparation						X	X	X	X	X	X	X				
Manuscript preparation								X	X	X	X	X	X	X	X	X

### ***Statistical analysis.***

All statistical procedures will be performed by using program modules provided by the SAS Institute, Inc. Statistical differences will be considered to be achieved if the p-value, the probability of obtaining a difference by chance, is less than 0.05, and the null hypothesis is rejected.

### **17. Reason(s) Display of OMB Expiration Date 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 certification.