

Supporting Statement A

EVALUATING THE EFFECTIVENESS OF
OCCUPATIONAL SAFETY AND HEALTH PROGRAM ELEMENTS IN THE
WHOLESALE RETAIL SECTOR
(0920-0949, Expiration 10/31/2015)

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

Steve Wurzelbacher, Ph.D.
Research Industrial Hygienist
Project Officer
swurzelbacher@cdc.gov

National Institute for Occupational Safety and Health
Division of Surveillance, Hazard Evaluations, and Field Studies
1090 Tusculum Avenue, Mail Stop R14
Cincinnati, Ohio 45226

513-841-4322 (phone)
513-841-4486 (fax)

ICRO Desk Officer Review September 16, 2015

Table of Contents

Section Title	Page Number
A. JUSTIFICATION	
A1. Circumstances Making the Collection of Information Necessary.....	3
A2. Purpose and Use of Information Collection.....	7
A3. Use of Improved Information Technology and Burden Reduction.....	10
A4. Efforts to Identify Duplication and Use of Similar Information.....	11
A5. Impact on Small Businesses or Other Small Entities.....	11
A6. Consequences of Collecting the Information Less Frequently.....	11
A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	12
A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	12
A9. Explanation of Any Payment or Gift to Respondents.....	15
A10. Assurance of Confidentiality Provided to Respondents.....	15
A11. Justification for Sensitive Questions.....	18
A12. Estimates of Annualized Burden Hours and Costs.....	18
A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	20
A14. Annualized Cost to the Government.....	20
A15. Explanation for Program Changes or Adjustments.....	20
A16. Plans for Tabulation and Publication and Project Time Schedule.....	21
A17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	22
A18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	22

LIST OF ATTACHMENTS

Attachment A: Occupational Safety and Health Act [29CFR § 671]
Attachment B: 60-Day Federal Register Notice
Attachment C: NIOSH Strategic Goals and Activities
Attachment D-1: Relation of Project to Broader CDC Research Agenda
Attachment D-2: Prior OSH Program Effectiveness Studies
Attachment E-1: OBWC - NIOSH Letter of Agreement.
Attachment E-2: Letter of Support from OBWC
Attachment E-3: Comparison of US and Ohio NAICS Codes
Attachment F: Information Security Plan
Attachment G: Informed Consent
Attachment H-1: OSH Program Evaluation Survey, Year 1
Attachment H-2: OSH Program Evaluation Survey, Year 2
Attachment I: IRB submission for Data Collection
Attachment J: OSH Program Survey Sampling Strategy
Attachment K: OSH Program Survey Sample Size Requirements
Attachment L: Non-Respondent Follow-Up Interview

SECTION A. JUSTIFICATION

- Goal of the study: Examine the association between survey-assessed occupational safety/health program elements (organizational policies, procedures, practices) and workers compensation outcomes in wholesale/retail trade firms.
- Intended use of the resulting data: Provide wholesale/retail trade firms a summary of evidence-based safety/health program elements to prevent injury/illness and a validated tool to assess their own program
- Methods to be used to collect: Prospective survey where a stratified sample of wholesale/ retail trade firms self-assess programs.
- The subpopulation to be studied: Wholesale/retail trade firms insured by the Ohio Bureau of Workers' Compensation
- How data will be analyzed: Linear, logistic, and Poisson regression

A1. Circumstances Making the Collection of Information Necessary

Background

This is an extension of the information collection request (ICR) number 0920-0949 (expiration date is 10/31/2015) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The extension is being requested for an additional 3 years.

This data collection is authorized by Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C. 669) (**Attachment A**). The 60-day Notice for this collection was published in the Federal Register on February 21, 2012, as required by 5 CFR 1320.8(d) (**Attachment B**). The data collection has also been approved and renewed by the NIOSH Institutional Review Board (study number HSRB-11-DSHEFS-03XP; expiration date 07/09/2016). Accomplishments from the previous approval period include the collection of the 1st year survey of a planned two year survey collection. There have been no resulting publications to date. The request for renewal is being made because there was a substantial delay in receiving security clearance to operate. To illustrate, this project received clearance from the Office of Management and Budget (OMB) on 10/23/2012. A full certification and accreditation (C&A) data security package was submitted to the Office of the Chief Information Security Officer (OCISO) on 4/30/13 and the Certification Agent signed the Authority to Operate on 01/08/2014. This substantial delay for security clearance was unexpected. As of 8/31/15, approximately 1,856 firms indicated they were willing to complete the 1st year survey, but only 255 completed it. The C&A delay may have been a factor in this low response rate. The small business nature of wholesale/retail trade firms in the sample may have also made this particular

participant group very difficult to engage in survey research. The proposed extension of the information collection will address the need to assess the effectiveness of occupational safety and health (OSH) programs among wholesale/ retail trade (WRT) sector firms. This need is expressed in a number of NIOSH Strategic Goals and CDC's broader research agenda (**Attachments C and D1**). For example, there is some evidence that OSH prevention programs built on key elements (management leadership, employee participation, hazard identification and control, medical management, training, and program evaluation) reduce losses. However, there is little evidence on the relative effectiveness of program elements compared to each other. This project aims to develop reliable OSH program metrics and to determine which elements have the greatest impact on injuries, illnesses and work disability. A renewed partnership between NIOSH and the Ohio Bureau of Workers Compensation (OBWC) provides a timely opportunity to conduct such research in a relevant, efficient, and impactful manner. OBWC has many strengths as a potential research partner, including its size (approximately 250,000 insured establishments), diversity of industry that is largely representative of the larger US in both industry classification (**Attachment E-3**), and their active engagement in intervention research.

For the current study, NIOSH and the OBWC are collaborating to examine the association between survey-assessed OSH program elements (organizational policies, procedures, practices) and workers compensation (WC) outcomes in a stratified sample of OBWC-insured wholesale/ retail trade (WRT) firms. Crucial OSH program elements with particularly high impact on WC losses will be identified in this study and disseminated to the WRT sector. There are expected to be up to 4,104 participant firms and surveys are being administered twice to the same firms in successive years (e.g. the 1st survey was already collected and the 2nd survey is being collected now). A nested study at 60 firms is asking multiple respondents at each firm to participate.

A2. Purpose and Use of Information Collection

To date, the 1st year survey has been collected and the 2nd year survey collection is underway. All information collected is being used to determine whether a significant relationship exists between self-reported firm OSH elements and firm WC outcomes while controlling for covariates. Some preliminary analyses have been conducted on the 1st year data, but the 2nd year survey collection is needed to finalize analyses. Results of the study (in de-identified and aggregated form) will be disseminated in the scientific literature and in educational materials through NIOSH and OBWC channels (website, publications). The privacy of all data collected is being protected to the extent legally possible, as covered by the Privacy Act of 1974, Title 5, United States Code, Section 522 (a). Individual participant personal information is not being published in any identifiable form.

The data collection for the OSH program study is part of a multi-phase project between NIOSH and OBWC that is fully funded. The project was awarded federal funds through the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. The contracted funds have been obligated to complete this project.

The 2nd year data collection is justified because two years of data are needed to assess changes over time and the 1st year survey was much smaller than anticipated. The overall project is justified because very few studies for the effectiveness of OSH program elements have been conducted. Clearly there is a need to conduct rigorous research to define further the effectiveness of OSH programs. This will enable evidence based practices to be shared with the greatest audience possible. Such data has practical utility to the federal government, state government, and private stakeholders.

For example, the federal Occupational and Safety and Health Administration (OSHA) has proposed a regulation for an injury/illness prevention program (US Federal Register, 2010b). OSHA is in the process of soliciting input for this potential standard. On January 6, 2012, OSHA took the first step toward rulemaking and notified the Small Business Administration (SBA) that it intends to convene a small business review panel. OSHA is also required to submit justification for the implementation of proposed regulations. Without rigorous studies on the effectiveness of OSH program elements, such analyses can be difficult.

State organizations such as the OBWC that sponsor prevention programs are seeking to evaluate the effectiveness of their various programs using the most scientifically rigorous methods possible. For this reason, OBWC is eager to collaborate with NIOSH on this project. The goal is to identify evidence based practices and programs that can be shared with the greatest audience possible. In this way, OBWC can efficiently allocate their resources among program alternatives that range widely from primary prevention to disability management. OBWC and NIOSH have also formalized an agreement (**Attachment E-1**) to outline a collaborative research partnership and specify a data sharing agreement to ensure data security. This OSH program effectiveness study represents one of the key steps towards addressing many of the partnership goals and OBWC is committed to supporting these projects, starting with the WRT sector (see the letter of support from OBWC in **Attachment E-2**).

The results of the current study are also relevant for private companies (such as WRT companies, workers compensation or health insurance carriers) that may sponsor prevention programs. Premium discount programs for developing OSH programs are currently rare among private insurance companies. If a rigorous study can determine the level of effectiveness of such a program, other insurance and WRT companies may utilize this data to determine whether such a program should be implemented or expanded.

The findings from this project will also be transferred to private stakeholders and OSH practitioners using several main channels:

- OBWC (website, publications, annual safety conference, and personnel)
 - o The OBWC has a developed infrastructure to reach companies within the state of Ohio. NIOSH and OBWC just signed a formal agreement and this project will leverage this collaboration to encourage participation in the studies, solicit input from WRT companies, and provide results as they become

available. As well, OBWC offers a free yearly safety conference (with an average attendance of ~6,000) where presentations and workshops about the studies will be conducted.

NIOSH (website, publications, and personnel)

- Links to the same dissemination products outlined in the OBWC section above will also be cross promoted on the WRT portion of the NIOSH website.

WRT trade organizations (website, publications, and personnel)

- Links to the same dissemination products will also be provided directly to several trade organizations. Additional outreach is already being conducted with other WRT trade organizations within the state of Ohio to raise awareness of NIOSH in general, and the specific studies with OBWC and to solicit input and participation in the research. Aspects of the studies will also be submitted for publication in trade journals.

Peer reviewed journals

- For this study, at least one manuscript will be submitted for publication in a peer reviewed journal. Main audiences for these types of journals are fellow researchers, but also OSH practitioners.

Overview of the Data Collection System

Questionnaires are being administered using several options (self-administered secure web portal, self-administered hard copy forms, and telephonic interviews). The respondent is strongly encouraged to use the self-administered web-based format of the survey. It is estimated that the vast majority (95%) is being collected via the online system. For those respondents lacking internet connections or those who do not wish to complete a web-based survey, a hard copy format is next offered. An interview option is offered as a last resort for those respondents who do not find the web-based or hard copy formats acceptable. Survey data are collected for this study primarily using an online secure website that complies with applicable 508 requirements to accommodate individuals with disabilities (<http://www.hhs.gov/od/508policy>). NIOSH contractors are primarily conducting the data collection and data management. Information will be maintained until 2017, two years after the conclusion of the study.

Items of Information to be Collected

No information in identifiable form (IIF) is being collected as part of the actual survey or the informed consent process. The names and job titles of respondents at each firm are being collected from the study partner OBWC and from publicly available resources (such as www.manta.com) which provide contact information for commercial firms.

Information collected via the surveys is described below. Collected information are being used to determine whether a significant relationship exists between self-reported firm OSH elements and firm WC outcomes while controlling for covariates. Individual participant personal information is not being published in any identifiable form and is being protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). The questionnaire data are standard tools used to assess OSH programs. The study is designed to determine the effectiveness of particular OSH program elements in reducing workers compensation (WC) injury/ illness outcomes. The survey is provided in **Attachments H-1 and H-2** and described below.

OSH Program Survey: This survey is being administered twice to the same firms in successive year. The first year survey has been collected and the second year survey is in process. A nested study at 60 firms is asking multiple respondents at each firm to participate. Based on pilot-testing, it is estimated it requires on average 12 minutes (up to a maximum of 20 minutes) per data collection.

Year 1 (see **Attachment H1**):

Safety Training- 5 questions

Safety Diligence- 11 questions

Hazard Detection and Control- 7 questions

Health and Safety Leadership- 9 questions

Ergonomics Practices- 5 questions

Disability Case Management- 7 questions

Proactive Return to Work- 8 questions

Wellness- 4 questions

People Oriented Culture- 8 questions

Firm Background Information- 6 questions

Respondent Background Information- 6 questions

Year 2 (see **Attachment H2**):

The Year 2 survey is the same as Year 1, except the Respondent Background section is reduced if the same respondent at the firm answers the survey, and the Firm Background section includes requested safety and health changes in last 12 months.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

As described, the proposed research involves the collection of information through a secure website. The research does not direct any website content at children under 13 years of age. All data collection and records management practices and systems (including the online survey system) adhere to all applicable federal, Health and Human Services (HHS), Centers for Disease Control (CDC), and NIOSH IT security policies and procedures [Security Requirements for Federal Information Technology Resources, January 2010; Health and Human Services Acquisition Regulation (HHSAR), Clause 352.239-72]. See the Information Security Plan in Attachment F for more information.

No information in identifiable form (IIF) is being collected as part of the actual survey or the informed consent process. The names and job titles of respondents at each firm are being collected from the study partner OBWC and from publicly available resources (such as www.manta.com) which provide contact information for commercial firms. This individual participant personal information is being maintained in a separate secure database to coordinate contacts at each firm.

Actual surveys are identified only using a unique identifier (created by NIOSH contractors) to track each survey completed at the firm. Individual participant information is not being published in any identifiable form and is protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). Information will be maintained until 2017, two years after the conclusion of the study. The IIF data will only be used by NIOSH researchers for the purposes outlined below.

IIF Being Collected	Purposes
First and last name of the individual participant	The first and last name of the individual participant is not being collected in the actual surveys, but is maintained in a separate secure database to coordinate contacts at each firm. The first and last name of the individual participant is being used for recruitment and to send the participant hard copy questionnaires if the participant requests paper versions for their mode of data collection. The first and last name of the individual participant is also used to send a hard copy of aggregated study results if requested by the individual.
Street address of the participating firm	The street address of the participating firm is not collected in the actual surveys, but is maintained in a separate secure database to coordinate contacts at each firm. The street address of the participating firm is used for recruitment and to send the

	participant hard copy questionnaires if the participant requests paper versions for their mode of data collection. The street address of the participating firm is also used to send a hard copy of aggregated study results if requested by the individual.
Firm phone number of the individual participant	The firm phone number of the individual participant is not collected in the actual surveys, but is maintained in a separate secure database to coordinate contacts at each firm. The firm phone number of the individual participant is used for recruitment and to prompt participants to submit the data collection.
Firm email address of the individual participant	The firm email address of the individual participant is not collected in the actual surveys, but is maintained in a separate secure database to coordinate contacts at each firm. The work email address of the individual participant is used for recruitment and to prompt participants to submit the data collection. The firm email address of the individual participant is also used to send an electronic copy of aggregated study results if requested by the individual.

The proposed survey contains questions that rate a firm’s OSH program, but none that should be considered sensitive on a personal basis. The impact on the privacy of the individual is considered to be minimal if there were a breach of security.

A3. Use of Improved Information Technology and Burden Reduction

In order to maximize efficiency and reduce burden, a web-based survey is proposed for the majority (estimated 95%) of all data collection. At a secure web site, the survey is be constructed for easy respondent use, allowing the automatic administration of skip patterns, while maintaining a simple, seamless navigation. Web-based surveys have gained increasing acceptance as a research tool as they offer many advantages, including:

- On-line surveys create cost efficiencies because respondents complete them during a much shorter window of time than other survey modes, and at a substantially reduced cost (i.e., less labor is involved than telephone or in-person surveys; postage is required for mail-based surveys);
- On-line surveys create time efficiencies (i.e., less time to complete the survey because it can be programmed to efficiently guide respondents through skip patterns so that they are not asked questions that do not apply to them or have to spend time navigating through complex instructions);
- All responses are automatically recorded, allowing for minimal data cleaning, and rapid tabulation and analysis of findings;

- Respondents potentially have the option of answering questions in a private setting where they feel comfortable and at ease (e.g., at home);
- Respondents can complete the survey within their own time schedule, and can exit the survey at any time and resume the survey where they ended;
- Previous research [Catalano et al 2006] suggests that workers in some industries prefer completing an online survey when given a choice between a web survey and a paper survey.

The respondent is strongly encouraged to use the self-administered web-based format of the survey. For those respondents lacking internet connections or those who do not wish to complete a web-based survey, a hard copy format is next be offered. It is estimated approximately 5% of respondents require hard copy formats. An interview option is offered as a last resort for those respondents who do not find the web-based or hard copy formats acceptable. It is estimated approximately less than 1% of respondents require personal interview formats.

A4. Efforts to Identify Duplication and Use of Similar Information

NIOSH has searched the scientific literature, contacted colleagues at NIOSH and OSHA, contacted professional, labor and industry organizations representing WRT workers. To date, NIOSH is unaware of any prospective OSH program effectiveness study being conducted in the WRT sector with such a design as the proposed research. As evidenced by the letters of support (**Attachment E-2**), the OBWC agrees that there is a need for such a rigorous study to determine the effectiveness of OSH programs and identify evidence based practices.

A5. Impact on Small Businesses or Other Small Entities

Small OBWC-insured WRT businesses are included in this study. To reduce burden for all respondents, a web-based survey is used for the majority of data collection. All participants are asked to complete the entire survey, but questions have been held to the minimum required for the intended use of the data.

A6. Consequences of Information Collected Less Frequently

Surveys are administered in the second year to the same sampled firms in the first year. The data being collected includes an OSH program assessment survey (**Attachments H-1 and H-2**). The frequency of this data collection is justified because OSH program attributes can vary over time and less frequent measures would not be sensitive to business climate variation or to changing work exposures. The planned frequency of data collection is already at a minimum level to reduce burden on respondents while also retaining sensitivity for a valid intervention effectiveness study. There are no legal obstacles to reduce the burden.

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

There are no special circumstances associated with this data collection activity. This request fully complies with regulation 5 CFR 1320.5.

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

A: In accordance with 5 CFR 1320.8(d), a review of the proposed study was sought through a 60-day publication period in the Federal Register /Vol. 80, No. 132 / Friday, July 10, 2015 / (**Attachment B**). No comments were received in response to the Federal Register notice.

B: NIOSH has consulted with numerous individuals and organizations outside the agency regarding the availability and usefulness of the proposed data collection. The following chronology documents these contacts:

NIOSH researchers met several times with OBWC representatives from 2009-2015 to establish a long term and sustainable research partnership and discuss research goals and projects. A formal agreement (**Attachment E-1**) was then developed outline a collaborative research partnership and specify a data sharing agreement to ensure data security. An early stated goal was to evaluate the effectiveness of the OBWC sponsored prevention programs. NIOSH and OBWC co-developed the current OSH program study as a way to determine which program elements most impact losses. As indicated in the background literature review, very few studies have been designed in such a rigorous way and conducted for this purpose. Some highlights of external contacts regarding the study are summarized below.

In 2010, the OSH program study was peer-reviewed in 2010 as part of a multi-phase project between NIOSH and OBWC and rated based on project approach, potential impact, innovation, and significance through the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. The project received favorable scores and was chosen for funding by NIOSH from Fiscal Year 2011 through Fiscal Year 2014.

In 2011, NIOSH and OBWC contacted trade associations (Ohio Association of Wholesaler – Distributors, Ohio Council of Retail Merchants, Ohio Wholesale Marketers Association, Wholesale Beer & Wine of Ohio) to advertise the study and solicit feedback .

In 2011, NIOSH awarded the competitively-bid contract to the University of Texas (UT) for survey development, data collection and analysis. NIOSH, UT and OBWC worked together to develop the OSH program composite survey from pre-existing instruments. Those involved are listed below. OSH program Survey was pilot-tested using 9 contacts from OBWC-insured WRT firms.

In 2012, NIOSH and UT forwarded the survey to several private industry members of the NIOSH NORA WRT sector council. Telephone interviews were conducted to solicit feedback about ways to improve survey. Since 2012, NIOSH, OBWC and UT have held regular conference calls to discuss progress.

A9. Explanation of Any Payment or Gift to Respondents

This project received clearance from the Office of Management and Budget (OMB) on 10/23/2012. A full certification and accreditation (C&A) data security package was submitted to the Office of the Chief Information Security Officer (OCISO) on 4/30/13 and the Certification Agent signed the Authority to Operate on 01/08/2014. This substantial delay for security clearance was unexpected.

As of 8/31/15, approximately 1,856 firms indicated they were willing to complete the 1st year survey, but only 255 completed it. The C&A delay may have been a factor in this low response rate. The small business nature of wholesale/retail trade firms in the sample may have also made this particular participant group very difficult to engage in survey research. The UTSPH contractors remarked that they had successfully conducted similar research in other industries (such as manufacturing) but never encountered similar problems with survey completion.

It has been demonstrated that incentives increase participation and reduce non-response bias among study participants [Dillman 1996, as reported by Shettle and Mooney 1999]. Belman et al. [2005] offered a monetary incentive of \$20 for participation in their study, achieving a 70% participation rate.

The OBWC, NIOSH, and UTSPH agreed that the best way to encourage participants to complete 2nd year surveys would be to provide an incentive for completion. Therefore, as an additional method to encourage participants to complete surveys, an incentive (a lottery where each respondent can win a \$75 prize) is being proposed. All participants who complete the 2nd year data collection will be eligible to win.

A10. Assurance of Confidentiality Provided to Respondents

A. The CDC's Information Collection Review Office has reviewed this application and has determined that the Privacy Act is applicable.

The survey collects data about firms (self-reported ratings of a firm's OSH programs, firm demographics) and collect limited data about individual respondent demographics (job title/ tenure and gender). The study also maintains personal identifiers (respondent name, firm address, respondent phone number at the firm, and respondent email address at the firm) in a separate secure database to coordinate contacts at each firm. Although the Privacy Act does not apply to organizations, some of these firms may still view some data as sensitive. The method of handling the information complies with the Freedom of Information Act and the Privacy Act of 1974. Disclosure under the Privacy Act System is

permitted: to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records. All data collection and records management practices and systems (including the online survey) adhere to all applicable federal, Health and Human Services (HHS), Centers for Disease Control (CDC), and NIOSH IT security policies and procedures [Security Requirements for Federal Information Technology Resources, January 2010; Health and Human Services Acquisition Regulation (HHSAR), Clause 352.239-72]. For example, data are stored on encrypted CDs, flash drives, and/or file transfer protocol (ftp) sites according to applicable Federal Information Processing Standards Publications (FIPS PUBS, see <http://www.itl.nist.gov/fipspubs>). See the Information Security Plan in **Attachment F** for more information.

Questionnaires are administered primarily using a self-administered secure web portal. The survey is on a secure web site that is accessible by sampled members of the participating establishments. The hyperlink and internet address to the survey is only made available to members of participating establishments and researchers conducting the study. The information is not be directed at children under the age of thirteen years. Aggregated survey results will be made available on the NIOSH public internet site. Please see below for additional information related to the Privacy Impact Assessment.

B. Access to individual data is limited to authorized NIOSH researchers and contractors. Physical controls: NIOSH facilities have 24-hour security guards, and key card ID badges must be used to enter the buildings. Data in hardcopy form is stored in locked rooms or cabinets. Technical controls: all electronic data are stored on secure servers that are protected with firewalls and passwords. Any contractor charged with data collection, preparation, or management tasks to be performed away from a NIOSH facility is required to follow equivalent procedures.

The process for handling security incidents is defined in the system's Information Security Plan (**Attachment F**). Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate

C. This study uses an informed consent form to describe how respondents are informed about the intended uses of the information collection and plans for sharing the information. To minimize the collection of personal information, researchers have requested a waiver of documentation of informed consent. For online surveys, the respondent is asked to read the consent form (**Attachment G**) and acknowledges consent by clicking a button online. For hard copy surveys, the respondent is provided a hard copy of the informed consent form and asked to read the form prior to completing the survey. A returned completed form acknowledges consent. For phone interviews, the respondent is read the informed consent form and verbally acknowledges consent.

D. Respondents are informed that their participation is voluntary, and that they may discontinue the survey at any time. They are also advised that they do not lose any benefits to which they are otherwise entitled if they chose not to participate. The Privacy Act does apply and the informed consent form (**Attachment G**) address the effect on the respondent of not responding to the data collection request, the intended uses of the data, with whom information will be shared, and the legal authority for the data collection.

The interview collects potentially sensitive information about OSH program effectiveness at the participant’s firm. Risks to participants are low since the only information in identifiable form (IIF) is not being collected as part of the survey, but rather is maintained in a separate secure database to coordinate contacts at each firm. Each participant that enrolls in the study is subsequently identified only with a code on all other information collection forms. IRB approval for this data collection is pending (**Attachment I**).

Several controls (safeguards) are in place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected. Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule (see <http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy449.htm>). Controls are summarized in the table below.

Control Descriptions	Control Type
<ul style="list-style-type: none"> • User Identification • Passwords • Firewall • Virtual Private Network (VPN) • Encryption • Intrusion Detection System (IDS) • Common Access Cards (CAC) • Smart Cards 	Technical
<ul style="list-style-type: none"> • Guards • Identification Badges • Key Cards • Closed Circuit TV (CCTV) 	Physical

<p>1. Security Plan: The system security plan for this information collection is detailed in Attachment F.</p> <p>2. Contingency Plan: Files be backed up are backed-up weekly using an offsite Microsoft SQL server based in Atlanta, GA CDC offices.</p> <p>3: User Manuals: Created for this information collection.</p> <p>4. Personnel Training: All CDC and contract personnel (principal investigator, managers, operators, contractors and/or program staff) will receive yearly training using the system and made aware of their responsibilities for protecting the information being collected and maintained.</p> <p>5. Contractor Adherence: Contracts for staff that operate or use the system includes clauses ensuring adherence to privacy provisions and practices.</p> <p>6. Access Levels: Methods are put into place to ensure the least privilege possible (e.g., access is “role based” on a “need to know” basis). Accountability is ensured through yearly security reviews.</p> <p>7. IIF Policy: There are CDC policies or guidelines in place with regard to the retention and destruction of IIF.</p>	<p>Administrative</p>
---	-----------------------

A11. Justification for Sensitive Questions

The proposed survey contains no questions that may be considered personally sensitive. Answering any questions poses little risk to the individual respondent since all questionnaires are coded with a survey ID and only linked to data of individually identifiable form (IIF) that is being collected in a separate secure database to coordinate contacts at each firm. The data collection has also been approved and renewed by the NIOSH Institutional Review Board (study number HSRB-11-DSHEFS-03XP; expiration date 07/09/2016).

A12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs are accrued to respondents other than their time to complete the survey. It is estimated that a maximum of 4,404 individuals will complete the surveys in year two. This includes 4,104 individuals from the sampling frame (incorporating a 10% uncertainty factor for second-year replacement firms/individuals) and 300 individuals from a nested study at 60 firms (where multiple respondents at each firm will be asked to

participate). A five-minute non-responder interview will be conducted with up to 792 individuals (10% of the sampling frame). The hour-burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All hour-burden estimates were derived from formal pilot testing.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Safety and Health Managers in Wholesale/ Retail Trade (WRT) Firms in Ohio	Occupational Safety and Health Program Survey	4,404	1	20/60	1468
	Informed Consent Form	4,404	1	2/60	147
	Non Responder Interview	792	1	5/60	66
Total Hours					1,681

B. Annualized Cost to Respondents

The total estimated annualized cost to respondents is \$46,793, as summarized in Table A.12-2. The mean hourly wage rate for Business Operations in the wholesale/ retail trade industry is \$27.80 (Bureau of Labor Statistics - Table 3. Hourly mean wage rates by industry and occupational group, May 2009).

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden (in hours)	Average Hourly Wage Rate	Total Respondent Costs
--------------------	-----------	-------------------------	--------------------------	------------------------

Safety and Health Managers in Wholesale/Retail Trade (WRT) Firms in Ohio	Occupational Safety and Health Program Survey	1468	\$27.80	\$40,811
	Informed Consent Form	147	\$27.80	\$4,081
	Non Responder Interview	66	\$27.80	\$1,901
Total				\$46,793

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

There are no capital or maintenance costs to respondents.

A14. Annualized Cost to the Government

Total costs include work performed over the course of four years by CDC research personnel (1 industrial hygienist, 1 epidemiologist, and 1 statistician) and contracted personnel, including tasks such as: (1) development of survey materials; (2) development of sampling frame and sample selection; (3) survey conduct; (4) sample tracking; (5) data receipt and processing; and (6) data entry and delivery. Estimated annualized costs to the Federal Government for the survey period are presented in Table A.14-1 below.

Table A.14-1. Estimated Annualized Cost to the Federal Government

	FY2011	FY2012	FY2013	FY2014	PROJECT	Annualized Cost
Personnel Salaries and Benefits	\$13,182	\$13,841	\$14,533	\$15,259	\$56,814	\$14,204
R&D Contract	\$141,000	\$141,000	\$137,000	\$134,000	\$553,000	\$138,250
				TOTAL	\$609,814	\$152,454

^a Includes a 3% personnel cost of living salary increase per year

The annualized cost to the Federal Government is \$152,454.

A15. Explanation for Program Changes or Adjustments

This is an extension of a data collection. The burden has not changed from the burden shown in the current inventory.

A16. Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis of the Data

Data collection will be completed over two years, followed by statistical analysis and dissemination of data. A full description of the statistical protocol is provided in Part B1 and B2 of this ICR. Results will be made available through publication in scientific journals and notices in trade publications, and through digital media such as the Internet.

Project Time Schedule

Table A.16-1. Project Time Schedule

Activity	Time Schedule (Months After OMB Approval)
All survey data collection systems (e.g. online systems, materials) were finalized.	Within 3 months after 1 st OMB approval
Individual participants were recruited from firms who have been identified as part of the sample. Informed consent forms (Attachment G) will be completed by participants.	Within 6 months after 1 st OMB approval
First annual survey data were collected (OSH program evaluation), Attachment H-1).	Within 15 months after 1 st OMB approval
Individual participants will be recruited from firms who have been identified as part of the sample. Informed consent forms (Attachment G) will be completed by participants.	Within 3 months after 2 nd OMB approval (current renewal)
Second annual survey data will be collected (OSH program evaluation), Attachment H2).	Within 6 months after 2 nd OMB approval (current renewal)

The analysis of study data will be completed to determine the effectiveness of OSH program elements at OBWC WRT firms.	Within 9 months after 2 nd OMB approval (current renewal)
--	--

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 Submissions

There are no exceptions to the certification.