Occupational injuries and illnesses among emergency medical services (EMS) workers: A NEISS-Work telephone interview survey OMB No. 0920-0834

Request for Office of Management and Budget Review and Approval for Revision of Federally Sponsored Data Collection

Section A

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

A.1.1 Background

Emergency medical services (EMS) workers have one of the highest rates of non-fatal occupational injuries and illnesses. However, a minimum of information regarding occupational injuries to EMS workers is available, and it is often outdated and/or extracted from populations limited by region and/or work type (e.g., career versus volunteer) [Hogya and Ellis, 1990; Gershon et al., 1995; Maguire et al., 2005; Studnek et al., 2007]. Based on injury case reports from two urban EMS agencies from 1998 to 2002, Maguire et al. [2005] estimated a non-fatal injury and illness rate of 34.6 per 100 full time EMS personnel. During that same time period, the annual rate for non-fatal injuries and illnesses among private sector workers declined from 6.7 per 100 workers to 5.3 per 100 workers [USDOL, n.d.]. Studnek et al. [2007] estimated an annual non-fatal injury or illness rate of 8.1 per 100 EMS professionals based on voluntary survey results from a sample of EMS workers in the National Registry of Emergency Medical Technicians collected between the years of 1999 and 2005.

This OMB request is for a revision of an ongoing data collection project (OMB No. 0920-0834). When completed, this project will fill an existing information gap by collecting and reporting detailed information on non-fatal occupational injuries and illnesses¹ occurring to EMS workers. The project is based on an existing occupational supplement to a national surveillance system: National Electronic Injury Surveillance System (NEISS-Work), allowing for the reporting of weighted national estimates to describe work-related injuries to EMS workers who sought treatment in EDs. NEISS-Work data are abstracted from medical records of all workers treated in a nationally representative sample of hospital emergency departments and include both volunteer and career EMS workers. In addition to using the existing NEISS-Work data, data are collected via telephone interviews of EMS workers identified in the NEISS-work database. The interview survey collects additional details about the worker, the injury, and the circumstances of the injury from the injured worker. Many of these details have not been captured in other EMS worker studies but are necessary to focus and inform prevention efforts. In the initial OMB application we projected a need for four years of data collection. Having completed preliminary analyses on 1 ¹/₂ years of data, we continue to project that an additional 24 months of data collection are needed to enable reporting of detailed results, producing stable numbers that meet NEISS-Work reporting requirements. Results from our preliminary analysis indicate that EMS workers are completing the telephone interview in its entirety and we will be able to report detailed results describing the injury circumstances for common injury events among EMS workers. However, most of the data collected to-date cannot be shared with people who are not approved NEISS-Work users as the numbers do not meet established reporting and confidentiality requirements. Due to the need for additional data, we are requesting OMB approval for an additional 24 months. The revisions to the data collection are: (1) The estimated annual burden hours have decreased slightly based on our analysis of the annual number of respondents to-date and (2) the estimated respondent costs have decreased slightly due to a decrease in the average hourly wage of EMS workers. No other significant changes have been made to this proposal. This ICR is not related to the American Recovery and Reinvestment Act of 2009.

¹ The term "injuries" will be used throughout the remainder of the report in place of "injuries and illnesses" as it is estimated that greater than 90% of cases captured are injury-related.

This project is a collaborative effort between the Office of Emergency Medical Services (OEMS) within the National Highway Traffic Safety Administration (NHTSA) and the Division of Safety Research (DSR) within the National Institute for Occupational Safety and Health (NIOSH). NHTSA has been making efforts to be responsive to the need to collect improved data on EMS worker injuries. In May 2007 they published a report titled, "Feasibility for an EMS Workforce Safety and Health Surveillance System" based on the findings of an EMS steering committee and a consensus panel. Findings in that report indicated that there is no existing surveillance system that can provide comprehensive EMS injury data. However, the report does describe several possible surveillance systems that could contribute to producing a more complete picture of EMS injuries. NEISS-Work was one of the few surveillance systems described as "suitable" for this task. In April 2007, NHTSA chose to further explore the capabilities of NEISS-Work and gave DSR funds to conduct a NEISS-Work telephone interview survey specific to EMS workers. The telephone interview was developed collaboratively by NHTSA and NIOSH and pilot tested on nine workers. NIOSH analyzed the data and compiled a report describing the background, methodology, and results. Upon discussing the pilot test results with NIOSH and reviewing the pilot test report, NHTSA determined that using NEISS-Work telephone interview surveys is a feasible method to collect detailed data on injuries to EMS workers.

Under P.L. 91-596 Section 20 (Appendix A), NIOSH is tasked with conducting research involving innovative methods, techniques, and approaches for dealing with occupational safety and health problems. This project addresses this directive by using a routine surveillance system that captures occupational injuries and illnesses to workers, narrowing the scope down to EMS workers, and adding telephone interview methodology in an effort to capture more detailed data. As noted previously, NEISS-Work is one of a few surveillance systems capable of collecting this information, and it is the only surveillance system receiving funding in order to implement such an effort.

The National Occupational Research Agenda (NORA) effort lead by NIOSH established national research and activity goals for groups of industry sectors. These goals prioritize and direct much of the occupational research within the Centers for Disease Control and Prevention. One of the industry groups is the Public Safety Sub-Sector that is inclusive of EMS workers. The project described in this package will contribute to Public Safety Sub-Sector Strategic Goal 16, "Create an integrated occupational health and safety surveillance data system for Emergency Medical Services (EMS) personnel and evaluate risks for their exposures, illnesses, injuries and fatalities by 2013." More specifically, it will address Intermediate Goal 16.2, "Establish ongoing surveillance systems and evaluate trends, emerging issues, and intervention needs for EMS through collaboration with Federal and State agencies and professional agencies."

A.1.2 Privacy Impact Assessment

Overview of the Data Collection System

The population for this study involves two inter-related segments: (1) all EMS worker cases identified within the routinely collected NEISS-Work data and (2) EMS workers identified in NEISS-Work who complete the telephone interview survey. Data collection for both segments is being completed by the Consumer Product Safety Commission (CPSC). The NEISS-Work data are collected in an ongoing, supplemental effort of the National Electronic Injury Surveillance System (NEISS) used to capture and report product-related injuries. While the hospital samples overlap, the data captured for NEISS and NEISS-Work are mutually exclusive. Data obtained via

the telephone interviews have been collected since July 2010 and will enhance the information available through NEISS-Work.

In 1972, as authorized by statute (the Consumer Product Safety Act Sec. 5. [15 U.S.C. § 2054]), CPSC initiated the collection of consumer product-related injury and illness information through a surveillance system that uses a national probability-based sample of hospital emergency departments—the National Electronic Injury Surveillance System (NEISS). Although the CPSC maintains a Privacy Act System of Records CPSC-1

(http://www.cpsc.gov/BUSINFO/frnotices/fr99/repub.html) for its Injury Investigation Files the NEISS records are not retrievable by personal identifiers and hence are excluded from the CPSC system of records. These records may be provided to another Federal, State or local agency or authority engaged in activities relating to health, safety, or consumer protection in accordance with section 29(e) of the Consumer Product Safety Act. The NEISS data are abstractions of existing information from emergency department medical records as collected by contract hospitals and paid records abstractors. Informed consent of the injured/ill patient is not required and data sharing by the hospital with CPSC and other federal agencies is allowed under the Health Insurance Portability and Accountability Act of 1996. For the purposes of the OMB Paperwork Reduction Act, CPSC has previously deemed that because there is no patient respondent burden, data are abstracted from existing records by CPSC contract, and other factors that OMB information collection approval was not required for the basic NEISS data. However, CPSC also uses information attained through NEISS to conduct in depth follow-up investigations including by telephone. CPSC collects information through the follow-up investigations with the approval of OMB (OMB Control No: 3041-0029) based on information collection extension requests every three years.

Beginning in 1981, NIOSH began conducting research using NEISS data as authorized by the Occupational Safety and Health Act, Section 20, "Research and Related Activities" and Section 22(d), "Authority of Director, National Institute for Occupational Safety and Health" (29 U.S.C. 669, 671 (d)). The work-related injury data attained by NIOSH from CPSC through what is now referred to as NEISS-Work do not contain direct personal identifiers such as name, social security number, or contact information. Similarly this information is not provided to NIOSH in the ongoing study, but is obtained from the participating hospitals and retained by CPSC only for the purposes of conducting the follow-up interviews.

NIOSH used NEISS in 1981-1987 and again in 1991 through the present. In the 1990's NIOSH conducted several follow-up telephone interview studies in collaboration with CPSC under their approval to collect information. OMB was regularly informed of such. Beginning in approximately 2002, CPSC requested that all federal agencies using NEISS for follow-up investigations seek their own OMB approval for the specific follow-up study (as is being done herein). Two additional NEISS-Work follow-up telephone interview studies were approved by in June 2012:

- (1) Barriers to Occupational Injury Reporting by Workers: A NEISS Telephone Interview Survey (OMB No. 0920-0939, Expiration: 6/30/2014)
- (2) Underreporting of Occupational Injuries and Illnesses by Workers (OMB No. 0920-0938; Expiration: 6/30/2015)

Routinely collected NEISS-Work data are captured from a national stratified probability sample of 67 of the approximately 5,400 rural and urban hospitals in the U.S. and its territories. At each of these hospitals, a coder employed by CPSC abstracts standardized information from the

emergency department (ED) record. For NEISS-Work, this information is captured for all persons identified as having a work-related injury and meeting the following criteria:

(1) First visit for an injury treated in an emergency department;

(2) Civilian, non-institutionalized worker; and

(3) Performing an activity for pay or other compensation, or volunteering for an organized group such as an EMS squad or fire department.

Worker emergency department records are abstracted without restriction by age, type of employer or industry, or employer size. Work-relatedness is determined by the hospital abstractor based on the information provided in the ED-chart at the time of treatment. Indication or filing of a Workers' Compensation claim is not required. NEISS-Work guidelines for defining a work-related injury generally follow the Occupational Safety and Health Administration's (OSHA) requirements for recordable injuries. Commuting to or from work and non-professional sports or recreational-related injuries are normally excluded. However, because emergency responders may respond to urgent situations in personal vehicles, these cases are included. Because emergency responder jobs often have physical fitness requirements, cases involving injury during fitness activities are also included.

In addition, injuries are captured regardless of product involvement and regardless of intent as long as the injury occurred while working. Incidents resulting in a loss of consciousness are included as are heart attacks that occur at work, similar to the OSHA requirements. Common illnesses are not reportable within NEISS-Work unless a causal link to work activities can be established (e.g., TB exposure at work). Typical non-work-related illnesses, diseases, and chronic conditions include: cancer, diabetes, arthritis, kidney stones, epilepsy, infections, flu, sore throat, colds, urinary tract infections and sexually transmitted diseases. Routine visits for either screening or treatment referral for drug or alcohol use are also not reportable within NEISS-Work.

NHTSA and NIOSH project staff developed EMS worker case criteria (Appendix C) to identify EMS worker injuries from the routinely collected NEISS-Work data. The case identification criteria were based on various occupation or industry indicators that might be found in the ED chart to signify that the injured worker was highly likely to have been providing emergency medical services or conducting related work activities at the time of injury. For example, charts that indicated that the injured worker was an ambulance driver, EMT, or firefighter/EMS providing medical aid, would have met the case capture criteria. To identify appropriate EMS cases based on the established criteria, CPSC completed an automated keyword search for EMS indicators by using a customized program in SAS software program.

The routinely collected NEISS-Work data are the property of NIOSH and used for a variety of projects. They are maintained on password protected computers and in secure files in locked NIOSH offices. They are archived on a secure network drive accessible only by those persons who have completed required annual confidentiality training. The archived NEISS-Work files will be maintained for a minimum of 20 years after the study is completed or becomes inactive in accordance with the CDC Records Control Schedule.

CPSC has previously used telephone interview survey methods to collect data related to injury incidents, including occupational injury incidents. CPSC maintains OMB approval "for a collection of information obtained from persons who have been involved in or have witnessed incidents associated with consumer products" (OMB control number 3041-0029). While the

cases in this EMS worker study are mutually exclusive of the product-related cases captured by CPSC, the study practices follow those used by CPSC in their follow-up activities for consumer product-related activities.

In order to complete interviews in this telephone interview study, CPSC attempts to obtain contact information for every NEISS-Work EMS case identified from the treating hospital that has a recorded age of 18 years-old or over at the time of treatment. While hospitals are generally cooperative in releasing this information, a few hospitals decline to participate owing to individual hospital privacy rules or require that a letter be sent to the patient providing them the option of having their contact information withheld. Usually in the latter instance, if no response is received from the patient within approximately 10 days, the hospital releases the information to CPSC. There are also instances where the contact information released by the hospital is incorrect or out-of-date. Once contact information is obtained by CPSC, potential respondents are sent a letter describing the study, informing them of their rights as a participant, and giving them the opportunity to opt out of participating by calling a toll-free number. The contact information is then given to telephone interviewers under contract to CPSC to complete the interviews. The telephone interviewers are required to make at least ten attempts to contact the EMS workers. The contact attempts are made at varying, but reasonable, hours of the day and on varying days of the week. When no personal contact is made after a number of attempts, the interview is set aside and contact attempts are made at a later date as time permits to maximize the response rate while minimizing recall bias issues. Interviewers are trained to be considerate of respondents and their families, leaving a minimal number of messages or speaking with the respondent or another individual of the residence to arrange a convenient interview time. Messages include a toll-free response number so that the respondent may call at their convenience. When no personal contact is made, no message system is available, or there is no indicator of an incorrect number, the interviewer typically spreads their call attempts over a longer time period and commonly makes more than 10 contact attempts over the initial contact attempt period and the subsequent missed interview follow-ups. The interviewers comply with CPSC contract requirements as approved by OMB. If contact is made with a potential respondent, they are offered the options to participate in the survey at the time of contact, participate in the survey at a later time, or refuse participation. The current response rate for CPSC telephone interviews is approximately 40-45%. As of January 2012, the overall interview response rate was 41%. However, of those EMS workers who could be contacted, the response rate was 80%.

Because of the inherent cost of the telephone interview data and their intrinsic value to researchers, upon completion of this research study, the data will be maintained by the DSR as "active" files for a period of up to five years. Subsequently, the data will be maintained as archived protected data files for a period of up to 20 years in accordance with the CDC Records Control Schedule.

Items of Information to be Collected

NEISS-Work routine data collection includes: demographics (age, sex, race, ethnicity, job title, business type, and employer name); medical characteristics (treatment date, diagnosis, body part affected, and disposition (e.g., treated and released or hospitalized)), and incident characteristics (locale, fire or motor vehicle involvement, and a brief narrative description). NIOSH staff review all cases for work-relatedness, recode selected variables, and add standardized Occupational Injury and Illness Classification System codes for the event or exposure and the source and secondary source of injury. The job title, business type, and employer name variables are

collected as free form literal text. Currently, NIOSH does not routinely code these variables to standardized industry or occupation classification systems. However, NIOSH does use the information to identify and subset selected worker populations such as EMS workers for special studies.

The data collected via the telephone interviews (Appendix D) captures valuable, detailed information to supplement the routine data collected in NEISS-Work. Specifically, the aggregated results of the telephone interview will describe and quantify:

- Nature, causes, and contributing factors of occupational injuries to EMS workers;
- EMS worker injury events and factors related to those events (including use of personal protective equipment);
- Characteristics and work backgrounds of injured EMS workers; and
- Outcomes and impacts of EMS worker injuries.

While contact information, including name, address and phone number, is collected by CPSC from the case medical records, this information is only used to mail the initial study letter and to contact the individual for the telephone interview. This information is never released to NIOSH or NHTSA. Please refer to section A.10 (Assurance of Confidentiality Provided to Respondents) for further details as to how individual contact information is collected, used, and then removed prior to data transmission to NIOSH and NHTSA and how information in identifiable form is protected.

<u>Identification of Website(s) and Website Content directed at Children Under 13 Years of Age</u> The project does not involve any web-based data collection methods nor is it associated with any websites with content directed at children under 13 years of age.

A.2 Purpose and Use of Information Collection

The data for this project are being collected to provide national estimates of non-fatal injuries among EMS workers. Results will describe characteristics of the EMS workers being injured, the types of injuries incurred, the circumstances surrounding the injuries, and the impacts of the injuries on the workers.

There are several reasons the data collected for this project fulfill a positive need:

- 1. NIOSH and NHTSA are invested in improving the health and safety of EMS workers. In order to address this task, they must understand the injuries occurring to EMS workers and the surrounding circumstances.
- 2. One of the primary duties of the EMS workforce is to protect and address the health of the public. Thus, to continue to meet the health needs of the public, it follows that it is necessary to take steps to reduce injuries among EMS workers, enabling them to continue to perform their duties. Following a public health model, these steps begin with surveillance and risk factor identification, both of which are addressed in this project.
- 3. Existing data describing EMS worker non-fatal injuries are limited. Thus, the data from this project will fill a data gap that needs to be understood in order to effectively prevent non-fatal injuries among this high risk population. The data will justify the focus of additional funds and efforts on this issue.
- 4. As addressed in the NHTSA publication titled "Feasibility for an EMS Workforce Safety and Health Surveillance System," there are very few existing surveillance systems that

provide an opportunity to collect data on EMS worker injuries. NEISS-Work not only provides this opportunity, but has the unique ability to collect extensive detail on a national sample of EMS workers, collected regardless of the EMS worker's type of employment (i.e., career versus volunteer).

5. Data dissemination will occur via publications (both peer reviewed and non-peer reviewed), presentations, and fact sheets. These various methods will reach people concerned with EMS health and safety, enabling them to develop informed and targeted prevention methods. Dissemination of the results will also be targeted to EMS workers to raise their awareness of non-fatal injury risks on the job.

There are several negative consequences to not collecting and disseminating detailed EMS worker data:

- 1. Non-fatal injuries among EMS workers continue to be poorly understood, providing weak support to targeting additional resources, research, and prevention efforts towards this issue.
- 2. Prevention efforts to reduce EMS worker injuries lack the data to be effectively targeted. Consequently, these efforts may have little impact on reducing and/or eliminating the circumstances leading to the greatest number of injuries.
- 3. Being unable to use data to develop targeted and needed prevention interventions could result in minimal to no reduction in EMS worker injuries. This, in turn, could result in a loss of EMS workers from the workforce and a decrease in the staff available to protect and address the health of the public.

This project has much practical utility in that it will produce and disseminate products that alert EMS workers and others vested in EMS worker health and safety to the greatest EMS worker injury problems and risk factors. Consequently, it will provide the essential groundwork for developing effective prevention programs that will reduce EMS worker injuries. Ultimately, a reduction in EMS worker injuries is necessary to maintain and grow the EMS workforce. A loss of EMS workers due to injuries poses a threat to serving the day-to-day health and emergency response needs of the public. In addition, recognizing that EMS workforce would be a great risk to the success of emergency preparedness and response needs.

Collecting detailed data that will lead to effectively reducing injuries to EMS workers has direct benefit to NIOSH, addressing one of the agencies primary objectives to "conduct research to reduce work-related illnesses and injuries." Specifically, this project will contribute to the mission of the NIOSH research program for the Public Safety Sub Sector "to eliminate occupational injuries, illnesses, and fatalities among workers in law enforcement, fire fighting, corrections, and emergency medical services through a focused program of research and prevention." In addition, this project addresses the mission of the NIOSH Emergency Preparedness and Response Program "to advance research and collaborations to protect the health and safety of emergency response providers and recovery workers by preventing diseases, injuries, and fatalities in anticipation of and during responses to natural man-made disasters and novel emergent events."

This project directly supports a NHTSA OEMS goal to promote and ensure a prepared, credentialed, and safe EMS workforce. The project will aid in better understanding the nature and types of injuries occurring to the EMS workforce, along with understanding the specific tasks and/or prevailing circumstances associated with injury events. Thus, enabling appropriate

intervention and prevention strategies to be developed and distributed among all EMS stakeholders. In the long-term, this will help insure the health, safety, and overall wellness of EMS workers, which is essential for ensuring the capable and robust workforce that the NHTSA OEMS desires to achieve and maintain.

The primary funding for this project is being provided by NHTSA who funded the pilot project and the development of the protocol, including this OMB package. NIOSH provided them with an estimated cost for the project, based on a recommended four years of data collection which is estimated to meet NEISS-Work data reporting requirements, allowing for the reporting of detailed and stable results. The cost estimate included time for analysis of data and the production of products. After reviewing the pilot test results and discussing the estimated budget, NHTSA has verbally committed to funding this project for the duration. To date they have provided the full amount of funding requested annually. As NIOSH has routinely funded collection of the NEISS-Work data collection effort since 1998, there will be no additional charge to NHTSA for the collection of these data.

While this project collects data from a national sample and provides weighted estimates and confidence intervals representative of national numbers, it is limited in that it only provides numbers based on emergency department treated injuries. Consequently, the injuries captured are those that need immediate medical care. These injuries do not frequently result in hospitalization. However, at the present time, this surveillance system offers the best potential for capturing details regarding EMS worker injuries from a national perspective and from a source that is inclusive of both career and volunteer EMS workers. All products from this project will explicitly acknowledge that the scope is limited to ED-treated injuries. An occupational supplement to the 1988 National Health Interview Survey indicated that work-related ED treated injuries are representative of approximately one-third of all work-related injuries incurred.

A.2.1 Privacy Impact Assessment Information

The purpose of this project is to describe non-fatal injuries occurring to EMS workers and disseminate that information in multiple forms to reach a variety of EMS stakeholders. Specific objectives are as follows:

- 1. Describe the magnitude and the types of occupational injuries occurring to EMS workers to define injuries of greatest concern based on frequency and severity.
- 2. Describe characteristics of injured EMS workers to better define the population of EMS workers incurring injuries.
- 3. Describe events, sources, surrounding circumstances, and exposure to risk to better target injury prevention efforts.
- 4. Describe injury outcomes so that long-term outcomes and impacts on the worker and consequently, the workforce, can be better understood.

The data will be used to produce publications (both peer reviewed and non-peer reviewed), presentations, and fact sheets for dissemination among EMS stakeholders, including the EMS workers themselves, EMS employers, and persons tasked with protecting the health and safety of EMS workers. Dissemination of this information is expected to alert EMS stakeholders of the primary injury-related issues and provide data to guide the design of prevention programs. Successful dissemination is dependent on reaching the correct target audience. Through previous work and collaborative efforts, the NHTSA OEMS has established an extensive network of EMS stakeholders who are vested in improving the health and safety of EMS workers. This existing

network will be a key component to effectively disseminating the findings from this study and translating them into practice.

The name, phone number, and address of potential telephone interview study respondents is collected by CPSC contracted medical records coders and given to CPSC contracted telephone interviewers. This information is destroyed upon completion of the telephone interview or a declaration by the telephone interviewer that the potential respondent is not reachable or does not meet the EMS worker case criteria defined within this study (Appendix C). This information is never released to NIOSH or NHTSA.

The data collected for this study capture "employment status" and a few demographic characteristics (sex and month and year of birth). Specifically, the telephone interview portion of the study asks the respondent for details regarding their employment at the time of their injury. These details include whether they were employed as an EMS worker at the time of injury and whether they were on duty as an EMS worker at the time of injury. This information is used to determine whether they meet the case criteria for participation in the study. Additional employment status information collected includes: (1) the level at which the respondent practices as an EMS worker (i.e., this refers to the level of certification); (2) number of years the respondent has worked as an EMS worker; (3) the type of EMS worker the respondent was functioning as at the time of injury (e.g., full-time employee, part-time employee, volunteer, etc.); (4) whether or not the respondent has been trained as a fire fighter and if so, what amount of their job involves EMS duties; and (5) whether or not the respondent has returned to work following their injury. These employment and demographic details are necessary to define the population of EMS workers being injured so that prevention programs can be focused on specific EMS worker populations as warranted by the data results. This information is accessible to NIOSH and NHTSA project staff. When the project is completed, the data will be disseminated to EMS stakeholders and the general public in aggregate form only, following NIOSH DSR reporting requirements that were established to insure confidentiality protection and the reporting of stable estimates.

The collection of IIF and other data included in the NIOSH/NHTSA accessible database for this project will have little to no effect on the respondent's privacy. CPSC, NIOSH, and NHTSA all take extensive safeguards to protect against any release of individual level data. Aggregated data is required to be screened by NIOSH DSR staff who are intimately familiar with NEISS-Work data. This ensures adherence to data reporting requirements prior to release, preventing a recipient of the data results from being able to tease apart identifiable individual level data from aggregate results. The largest potential for an adverse event would be related to a breach in confidentiality from either NIOSH or NHTSA project staff or CPSC contracted telephone interviewers. The NIOSH project staff will notify CPSC immediately upon: (1) discovering any breach or suspected breach of security, (2) discovering any unauthorized disclosure of the confidential information or (3) receipt of any legal, investigatory, or other demand for access to the confidential information in any form. Should any of these issues occur, project progress will be halted until approval is received from CPSC to resume project activities. In addition, the Human Subjects Review Board (HSRB) will be informally notified of any potential breach of confidentiality within two working days of an incident and formally notified within two weeks of an incident. Proven violation of confidential information related to or obtained from the data is cause for immediate termination of access to any data. The method of the violation will be examined and additional safeguarding procedures implemented to decrease the likelihood of a similar incident happening during the remainder of the project.

A.3 Use of Improved Information Technology and Burden Reduction

Routine NEISS-Work data are collected by hospital coders via abstraction of the information found in ED records. Computerized systems are used for the collection and transmission of these surveillance data. Thus, there is no burden on the injured workers.

All follow-back studies performed by CPSC, collecting data directly from the injured person, are done via telephone interview surveys. The data collection process is guided by and entered into a Computer Assisted Telephone Interview (CATI) system. This CATI system is used by CPSC for other follow-back studies and is required for new follow-back studies. Use of the CATI facilitates administration of the questionnaire as skip patterns are automated, lessening the time the respondent needs to wait for the interviewer to find the correct question and eliminating concerns with inaccuracy due to incorrectly following skip patterns.

The telephone interview survey was developed collaboratively by NIOSH staff, NHTSA staff, and other EMS stakeholders to insure capture of the most useful information. The survey questions were carefully chosen in consideration of what information is needed to inform prevention efforts. Previous years of NEISS-Work data specific to EMS workers were analyzed to determine whether or not it is likely that enough data will be collected to meet reporting requirements. In addition to prioritizing the information of greatest potential use, questionnaire developers went to great lengths to evaluate and consequently eliminate questions if they felt the information provided would have little utility and/or have a strong likelihood of not meeting reporting requirements.

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

This project was developed based on findings from an EMS steering committee and a consensus panel that were created to discuss possibilities for surveillance of injuries to EMS workers. Experts in both groups identified and reviewed a variety of surveillance systems that potentially offered a means for collecting injury related data on EMS workers. The findings were published by NHTSA in a report titled "Feasibility for an EMS Workforce Safety and Health Surveillance System." Concluding that it was cost prohibitive to develop a new surveillance system, this report identified a few existing surveillance systems that have the potential to contribute additional knowledge to the current understanding of EMS worker injuries. NEISS-Work was one of four non-fatal surveillance systems ranked as having "medium suitability" for contributing to the surveillance of non-fatal injuries to EMS workers. No surveillance system was given a "high suitability" rating.

NEISS-Work is unique from other surveillance systems in that it has the option to collect data directly from the worker using telephone interviews, providing greater details and insight than can be obtained from abstracting data from written records (e.g. medical records or worker's compensation records) alone. Consequently, much of the data collected for this project is available only via NEISS-Work. In addition, the method of identifying cases via a sample of ED records provides a national sample of both career and volunteer EMS workers, something that other datasets cannot provide when analyzed individually.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses are involved in this data collection.

A.6 Consequences of Collecting the Information Less Frequently

Without collection of these data, NIOSH and NHTSA will not meet their goal of better understanding EMS worker injuries so as to raise awareness of contributing injury factors and enable the development of targeted and effective interventions. These agencies, as well as others concerned with improving EMS worker health and safety, will be resigned to relying on broad level data collected from limited samples of EMS workers. Consequently, EMS stakeholders will continue to lack the data needed to inform and justify effective injury prevention efforts.

Each respondent will be asked to complete the questionnaire one time for a designated ED treated injury. There are no legal obstacles to reduce the burden.

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

Having reviewed all special circumstances related to the guidelines of 5 CFR 1320.5, we believe that this request fully complies with the regulation 5 CFR 1320.5.

There is a small possibility that an EMS worker could incur two work-related injuries and be treated in an ED within the NEISS-Work sample on two separate dates within one quarter of the year. Should this happen, they would be offered the chance to complete the telephone interview for each of the separate injuries, but they would not be required to do so as the respondent will always maintain the right to refuse participation. We suspect that the likelihood of a respondent participating twice, especially within the same quarter of a year, is small given that NEISS-Work does not capture cases seen in the ED that are deemed to be re-injuries or follow-up related to the original injury.

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

A.8.A 60-Day Federal Register Notice Information

A 60-Day Federal Register Notice for approval of a revision was published in the *Federal Register* on May 21, 2012, vol.77, No. 98, pp. 30014-30015 (see Appendix B). One public comment was received in response to this notice (see Appendix H). The comment focused on changing the administration and practices of the Centers for Disease Control and Prevention, which is beyond the scope of this project. The sender was acknowledged for their comment, but no changes were made to the project.

A.8.B Consultation with Persons Outside the Agency

Prior to the development of this study, NHTSA convened an EMS steering committee and a consensus panel to examine the feasibility of creating an EMS workforce injury surveillance system. These groups specified the important characteristics and elements of an EMS surveillance system and reviewed multiple existing surveillance systems to determine their capability to collect EMS worker data. They noted a few existing surveillance systems, including NEISS-Work, that "already contribute to, or show potential in, increasing our understanding of EMS workforce illness and injury."

In 2008 the study protocol was reviewed by three external peer reviewers and two internal peer reviewers who are knowledgeable about EMS worker safety and health and have previously conducted research studies in this area. The comments of the external reviewers and our responses to those comments can be found in Appendix E. The external peer reviewers were:

- Robyn Gershon, DrPH, Professor/Researcher, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University; Phone: (212)305-1186; E-mail: rg405@columbia.edu
- Rebecca Heick, PhD, EMT-P, MS, Adjunct Faculty Member, Trinity College of Nursing and Health Sciences-Rock Island, IL; Phone: (563)355-1010; E-mail: <u>epidemiologist2006@msn.com</u>
- Gordon Smith, MD, MPH, Professor of Epidemiology, National Study Center for Trauma and EMS, School of Medicine, University of Maryland; Phone: (410)328-3847; E-mail: <u>gssmith@som.umaryland.edu</u>

In addition to the listed external reviewers, the protocol has been reviewed by NHTSA staff as well as NIOSH staff who are not directly involved in the project but have worked in the area of EMS safety and health or closely related areas. In addition to soliciting reviews of the entire protocol NIOSH and NHTSA also solicited comments specifically related to the questionnaire from EMS stakeholders external to both agencies.

Prior to initiating this study, NIOSH met with telephone interviewers participating in this project to explain this study and provide training on administration of the questionnaire. Collection of the telephone interview data is monitored by both CPSC and NIOSH. If any concerns arise during the data collection process, CPSC addresses the issues with the telephone interviewers. CPSC maintains regular contact with the medical records coders that abstract NEISS-Work surveillance data from medical records and with the contracted telephone interviewers. In turn, NIOSH maintains regular contact with the CPSC staff responsible for these activities. This includes, but is not limited to, attendance at annual coding meetings hosted by CPSC, periodic face-to-face meetings with CPSC staff, weekly e-mail communications, and periodic phone calls.

A.9 Explanation of Any Payment or Gift to Respondents

This study does not provide a payment or gift to the respondents.

A.10 Assurance of Confidentiality Provided to Respondents

In order to contact respondents for participation in the telephone interview survey, the names, addresses, and telephone numbers of EMS workers identified in the NEISS-Work data are collected from their medical records by the CPSC supervised hospital coders who abstract routine NEISS-Work data. CPSC attempts to obtain contact information for every NEISS-Work EMS case identified from the treating hospital. While hospitals are generally cooperative in releasing this information, a few hospitals decline to participate owing to individual hospital privacy rules or require that a letter be sent to the patient providing them the option of having their contact information withheld. Usually in the latter instance, if no response is received from the patient within approximately 10 days, the hospital releases the information to CPSC. Once contact information is obtained by CPSC, the contact information is then given to telephone interviewers under contract to CPSC to complete the interviews.

At least five business days prior to calling an EMS worker identified in the NEISS-Work data, the worker is sent a letter describing the study and the measures that are taken to protect their privacy should they choose to participate in the study (Appendix F). The letter being mailed to potential participants has been written to provide them with the information required in an informed consent. A waiver of written informed consent has been granted by the HSRB as collecting written informed consent would likely be detrimental to the response rate of the study. It would also increase the study cost and the time lapse between the treatment date and interview date.

The letter being sent prior to the interview and the script read at the beginning of the telephone interview (included in Appendix D) emphasize that EMS worker participation is voluntary and the confidentiality protections that will apply should they choose to participate. The letter gives the workers an opportunity to opt out of the telephone interview study by calling a toll-free number. If they do not opt out, the telephone script confirms their willingness to participate by asking, "Would you please help us by answering some questions?" A positive response to this question is deemed to be the subject's verbal consent to participate.

Completion of contact with a subject is determined by a potential respondent declining to participate, the inability to contact a potential respondent, the decision that the potential respondent does not meet the study eligibility criteria, or a respondent completing the telephone interview survey. Once contact is completed, the subject's name, phone, and address information is stripped from the database. CPSC completes quality assurance checks on all data submitted and takes precautions to insure that contact information is never transmitted to NIOSH or NHTSA. Contact information is destroyed following removal from the database as there is no need to maintain this information.

Routinely collected NEISS-Work surveillance data include identifiable information containing demographic data (not including birth date), employment status data, and a short narrative describing the injury incident. Analyses of these data will be used to provide a general overview of injuries to all EMS workers in the surveillance system and to compare telephone interview respondents with non-respondents to determine any potential response biases. The surveillance data will be linked to the individual case data captured via telephone interviews for purposes of validating the information received and assessing nonresponse bias.

The collected during the telephone interview survey (Appendix D) also contain identifiable information, including information on employment status and demographics (sex, month of birth, and year of birth). This information is necessary to define the target population of greatest need when focusing prevention plans. All data collected for this project will only be presented in aggregate form. Even in aggregate form, the data will need to meet NIOSH NEISS-Work reporting requirements, designed to insure data stability and help protect worker privacy, prior to release. NIOSH has three criteria for determining reportability of NEISS-Work data results:

- 1. Number of cases treated within the hospital sample must exceed a specified value;
- 2. The extrapolated national estimates must exceed a specified value; and
- 3. The coefficient of variation must be less than or equal to 33%.

Because of confidentiality restrictions, NIOSH does not publicly release the minimum sample case or national estimate requirements. Variance requirements are released.

NIOSH pays CPSC for collection of the routine NEISS-Work data and they will provide payment for collection of the EMS worker telephone interview data using money allocated to them through an interagency agreement with NHTSA. Both datasets are transmitted to NIOSH from CPSC. NIOSH then shares the EMS worker data with NHTSA. Because NIOSH requires a high level of protection and oversight for NEISS-Work surveillance data and associated datasets, they will retain ownership of the data to insure these protections are followed. However, NHTSA will be allowed access to the data as long as they continue to meet the NIOSH confidentiality requirements, including adherence to safe storage procedures and completion of annual confidentiality refresher training for every staff member with access to the data.

The protocol for this study was reviewed and approved by the NIOSH HSRB under an expedited review in January 2010. See Appendix G for a copy of the HSRB approval. Subsequently, the project officer has applied for and received annual renewal of this protocol. Neither CPSC nor NHTSA has their own IRB, thus both institutions linked an organizational FWA to NIOSH to enable them to defer to the NIOSH HSRB.

Privacy Impact Assessment

A.10.A Subject to the Privacy Act

This submission has been reviewed by ICRO and it was determined that the Privacy Act is applicable. The applicable Systems of Records Notice is 09-20-0136, "Epidemiologic Studies of Surveillance of Disease Problems." The data are also protected by the Consumer Product Safety Act.

A.10.B Securing information

Unless otherwise specified the information on access controls described below apply to all three collaborating agencies: NIOSH, NHTSA, and CPSC.

Technical Controls: CPSC telephone interview contractors use individual access and firewall protected laptop computers. For added safety, the laptops are also encrypted and password protected. The contractors adhere to the privacy protections proscribed in the CPSC interview contracts. Personal identifiers are provided to the interviewers to complete the interviews. Once the interview is completed the personal identifiers are removed from the data by CPSC and only de-identified data are provided to NIOSH and NHTSA.

Once collected, all data are stored on access-controlled agency computers. User authentication and robust passwords are required for data access within the agency firewalls. Data access from outside the firewall or offsite locations is not permitted. Within the firewall on agency servers, data files are located in access-controlled directories so that only individuals specifically authorized to access the project data may have read and/or write privileges.

Physical Controls: Each agency maintains a secure, guarded facility requiring employee identification badges and individual key cards. Visitors are restricted and require on-site escort. Security monitoring including closed circuit TV is in use.

Administrative Controls: CPSC has standard security protocols for acquiring the personal identifiers and providing the identifiers to the contract telephone interviewers. Similarly, NIOSH and NHTSA have in place standard processes for securing NEISS-Work confidential data. Thus,

no project specific data security plan is required. NIOSH adheres to division data security requirements that address data confidentiality and standard data security practices. All project data users (NIOSH and NHTSA) have confidential data training; sign data use agreements; and have role-based data access as described below.

The routine NEISS-Work surveillance data and the interview data are protected under the U.S. Consumer Product Safety Act and the Privacy Act. Once the personal identifiers are removed by CPSC prior to NIOSH or NHTSA receiving the data, the data are considered low to moderate sensitivity. NIOSH maintains an interagency agreement with CPSC ensuring protection of the NEISS-Work data per applicable law with additional stipulations to enhance the overall data protection. Similarly, NHTSA maintains an interagency agreement with NIOSH to have data access that focuses on data security requirements. In addition, NIOSH requires that all NIOSH and NHTSA staff and/or contractors sign NEISS-Work data use agreements, comply with specific confidential data practices, and take annual confidential data stewardship training. Moreover, NIOSH requires that all contracts led by NIOSH or NHTSA staff that involve access to NEISS-Work data include confidentiality provisions in the contract language including the requirements for individual data use agreements, training, and so on. Quarterly, NIOSH reviews individual data access needs. On an as needed basis, NIOSH removes access and conducts a data clearance process for departing employees and/or contractors or individuals who no longer have a demonstrated need for data access. These processes also occur for other agencies who acquire NEISS-Work data through NIOSH (i.e., NHTSA).

As the primary data steward for the NEISS-Work data including interview results, NIOSH follows CDC-wide backup protocols and maintains these data on a protected server that is backed up nightly. For this project the NIOSH staff directly involved in the data collection and analyses have full data access. All other NIOSH staff will have access to aggregated data only in a review capacity. In general NHTSA staff will have similar aggregated data access. Selected NHTSA individuals who have completed the data use agreements and who are playing an analysis role in this project will have full data access via files stored on the secure NHTSA server if they request this. NHTSA's data protection and backup processes are similar to the NIOSH processes.

NIOSH will maintain the files for a minimum of 20 years to allow for re-analyses and comparison with potential future surveys. In compliance with Federal Records Retention regulations, at the end of the retention period all individual interview data files will be destroyed. Because of the remote possibility for indirect identification of an individual respondent, no individual records will be transmitted to the National Archives.

A.10.C Obtaining respondent consent

Prior to receiving a telephone call, respondents are sent a letter inviting them to participate in the study (Appendix F). This letter explains the study to them and covers the required items found in an informed consent, including the purpose of the project and the protection of their individual responses during the release of the information. In addition to the letter, a written script is read to potential respondents when they are called for the telephone interview. This script also explains the purpose of the study and the privacy protections that are taken. Following these verbal explanations, the potential respondent is asked whether they are willing to participate. A positive response to this question is deemed to be the verbal consent of the respondent. The written script is included as part of Appendix D.

A.10.D Informing respondents of the voluntary nature of the survey

The introductory letter sent to respondents and the script read prior to initiation of the telephone call inform respondents that participation in this study is voluntary. Potential respondents are given the option to not participate by calling a toll-free number printed on the introductory letter prior to the telephone interview or by verbally declining participation at the time of the phone call.

A.11 Justification for Sensitive Questions

The telephone interview survey asks for the respondent's primary diagnosis resultant from their injury. It also asks for any additional diagnoses resultant from the same injury. This information is necessary for understanding the nature of the injuries occurring to EMS workers. Other questions that may be considered sensitive are those pertaining to use of personal protective equipment (PPE) at the time of the injury incident. This information is needed to assess whether there are potential problems with EMS workers not using PPE and/or PPE not being effective in preventing injuries. As the survey is voluntary, respondents may refuse to answer any questions. Respondents are informed of their right to refuse participation and their right to refuse to answer individual questions in the introductory letter (Appendix F) and in the script that is read to them at the beginning of the telephone interview. Consent for completion of the telephone interview survey is described in the introductory letter and then confirmed in the written script at the beginning of the telephone interview.

A.12 Estimates of Annualized Burden Hours and Costs

A.12.A Estimates of Annualized Burden Hours

Based on the first year and a half of data collection (July 2010 – January 2012), the sample size for the telephone interview survey is estimated to be approximately 150 EMS workers annually for the remainder of this study. This is a reduction from the original estimate of 175 cases per year and consequently, a reduction in annualized burden. We expect to have approximately 600 completed interviews at the conclusion of four years of data collection (June 30, 2014).

All EMS workers who are identified in the routinely collected NEISS-Work data and for whom correct contact information is available will be offered the opportunity to participate in the study. As of January 2012, the response rate was 41% for all cases identified in the routine NEISS-Work data and 80% for all cases that could be contacted.

We recognize the importance of identifying data biases related to the characteristics of the respondent group. Using the routine NEISS-Work data, an analysis of all identified EMS workers will be performed to determine if there are any differences between the telephone interview respondent and non-respondent groups.

The telephone interview survey is a one time response survey with each telephone interview taking approximately 20 minutes to complete, resulting in an annualized burden estimate of 50 hours. A pilot test of the questionnaire was completed with nine EMS workers to assess the length of time needed to complete the questionnaire in addition to assessing the appropriateness

and the content of the questions being asked. Data collection is expected to span a time period of four years.

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	1	Total Burden (in hours)
EMS workers	150	1	20	0/60	50
Total		-			50

Estimated Annualized Burden Costs

A.12.B Estimates of Annualized Burden Costs

Based on the U.S. Department of Labor's Occupational Employment Statistics survey, the annual average wage for paid EMS workers is \$34,030 and their mean hourly wage is \$14.36. In addition to the paid EMS workers, there are a large number of EMS volunteers. There is no accurate way to determine the denominator of the EMS workforce. The Current Population Survey (CPS) estimated that there were 170,000 paid EMS workers. Certification numbers have provided a broad estimate of the entire EMS workforce, including volunteers, at 721,000, but these numbers have several flaws. When using certification numbers to enumerate the population, it is important to remember that numbers could be under- or over- estimated because certification does not reflect active work, certification requirements vary from state-to-state, and EMS workers can be certified in more than one state. Using the numbers from the CPS and from certification, the volunteer EMS workers could be projected to account for up to three-quarters of the EMS workforce. To simplify the estimation of annual burden hours, we assumed the burden for paid and volunteer EMS workers is equivalent in terms of the value of their time.

Estimated Annualized Burden Hours

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
EMS workers	50	\$14.36	\$718.00
Total		-	\$718.00

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

There are no additional cost burdens for respondents. All record keepers are contractors of the federal government. Thus, estimated cost burden to them is included in section A.14 describing the annualized cost to the government.

A.14 Annualized Cost to the Government

The annualized cost to the government for this project is estimated to be \$75,000. The table below summarizes a breakdown of the estimated costs. In order to arrive at this estimate, the project costs for each year were estimated in a detailed budget and then totaled and divided by the seven year life of the project, including four years of data collection. This estimate includes the 9% overhead costs involved in NIOSH performing the work for NHTSA. Labor costs were computed using comprehensive staff salary and benefit costs, and they accounted for promotions

and cost of living increases. The cost of interviews is inclusive of all money given to CPSC to hire contracted telephone interviewers, perform the telephone interviews, input the data, and submit the data to CPSC.

All funds are transferred to NIOSH from NHTSA. The annualized cost includes the cost of capturing the telephone interview data, the costs of analyzing NEISS-Work data and the telephone interview data, and the cost of preparing both peer reviewed and non-peer reviewed products. The cost of collecting NEISS-Work data is not included as those data are not collected exclusively for this project. They are historically collected and maintained under their own project allocation within NIOSH.

	Annual cost
Labor	\$57,400
Interviews	\$15,000
Travel and	
miscellaneous	\$2,600
Total cost	\$75,000

Budget for FY2010-FY2014

A.15 Explanation for Program Changes or Adjustments

For this revision request, the data collected to-date were used to produce an updated estimate of the number of completed interviews to be obtained each year. The data collected thus far indicate we will collect approximately 150 interviews annually. This is a reduction from the previous estimate of 175 that was extrapolated based on routine NEISS-Work surveillance data from earlier years. This reduction resulted in a decrease in the respondent burden hours from 58.3 to 50.

Also, the mean hourly wage was adjusted to reflect the wage reported by the Occupational Employment Statistics for 2011. The hourly wage decreased from the original report of \$14.84 to the current estimate of \$14.36. This resulted in a decrease of total respondent costs.

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

We plan to publish project results in both peer reviewed and non-peer reviewed journals. It is estimated that four years of data collection will be needed to produce large enough numbers to allow detailed reporting of results. However, if reportability criteria are met prior to the end of four years, data collection will be discontinued early. Our timeline, including future projections, is detailed in the Table A.16.1 below.

Project Time Schedule	
Activity	Time Schedule
Telephone interviewer training	March 2010
Begin data collection	July 2010
Begin regular monitoring/quality assurance of	September 2010
incoming data	
Provide annual project summary to NHTSA,	September 2011
including analysis of data collected to date.	

This annual summary will be provided after completion of every 12 month cycle of data collection.	
Renew OMB package	Process begun May 2012
Finalize dataset	October-November 2014
Analyses	April-May 2015
Publication ready for submission to peer-	October-November 2015
review journal	
Product ready for dissemination to EMS occupational health and safety organizations	January-February 2016

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

The OMB expiration date is displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.