

Supporting Statement for Collection of Information Follow-up Activities for Product-Related Injuries

A. Justification

1. Information to be collected and circumstances that make the collection of information necessary

Section 5(a) of the Consumer Product Safety Act (CPSA)(15 U.S.C. § 2054(a)) requires the Commission to collect information related to the cause and prevention of death, injury, and illness associated with consumer products. CPSC staff conducts continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from incidents involving consumer products. CPSC staff obtains information about product-related deaths, injuries, and illnesses from a variety of sources, including news outlets, death certificates, consumer complaints, and medical facilities.

CPSC staff also operates the National Electronic Injury Surveillance System (NEISS), which provides timely data on consumer product-related injuries treated in hospital emergency departments in the United States. CPSC staff also uses the NEISS system to collect information on childhood poisonings in accordance with the Poison Prevention Packaging Act of 1970.

From these sources, the CPSC staff selects cases of interest for further investigation by contacting persons who witnessed or were injured in incidents involving consumer products. These investigations are conducted on-site (face-to-face), by telephone, or by the Internet. On-site investigations are usually made in cases where the CPSC staff need photographs of the incident site, the product involved, or detailed information about the incident. This information can come from face-to-face interviews with persons who were injured or who witnessed the incident, as well as via contact with state and local officials, including police, coroners and fire investigators, and others with knowledge of the incident.

Through Interagency Agreements, the CPSC staff also use the NEISS system to collect information on injuries for the Centers for Disease Control and Prevention (NEISS All Injury Program (NEISS-AIP)). The NEISS-AIP is a sub-sample of approximately 2/3rds of the full NEISS sample. In addition to the standard data variables collected on all NEISS injuries, the NEISS-AIP collects additional variables on several studies for CDC (Adverse Drug Events, Assaults, Self-Inflicted Violence, and Work-Related Injuries) and one study on non-crash motor vehicle-related injuries for the National Highway and Transportation Safety Administration (NHTSA). Additional special study variables are collected for CDC in the full NEISS sample for firearm-related injuries.

2. Use and sharing of collected information

CPSC staff uses the information from this collection to support development and improvement of voluntary standards; proceedings for the development of mandatory standards and regulations; information and education campaigns; and administrative and judicial proceedings for enforcement of the statutes, standards, and regulations administered by the agency. The information informs the agency in its efforts to remove unsafe products from channels of distribution and consumers' homes, and it provides information to the public about the safety of consumer products.

No records released to the public contain personally identifiable information; geographic and personal identifiers have been masked.

3. Use of information technology (IT) in information collection

All NEISS data are reported electronically, and NEISS respondents directly submit data to CPSC through the Internet on laptops provided by CPSC. Information for follow-up investigations from NEISS and other sources are collected through traditional face-to-face, telephone, or Internet-based interviews with consumers, witnesses, and other knowledgeable parties, such as fire, police, and healthcare professionals.

4. Efforts to identify duplication

There is no other national surveillance system of product-related injuries, childhood poisonings, and other injuries treated in emergency departments. The detailed information obtained from hospital emergency records about incidents associated with consumer products is not available from any other source.

5. Impact on small business

This collection of information is voluntary and does not have a disproportionate impact on small businesses.

6a. Consequences to Federal program or policy activities if collection is not Conducted or is conducted less frequently

If this information were not collected or were collected less frequently, the CPSC and other agencies that rely on this data would lack timely and detailed information to identify new hazards and support rulemaking proceedings, assist in efforts to develop or improve voluntary standards; perform actions to obtain correction of products that present a substantial product hazard, and conduct informational campaigns.

6b. Consequences to Federal program or policy activities if collection is not used for statistical estimates

The current NEISS probability sample was drawn and recruited in 1995-1996 and implemented in 1997. Since then several of the selected hospitals have stopped participating for reasons such as closures and mergers with other hospitals, and were replaced with other purposively-selected hospitals. While hospital weights are adjusted to account for changes in the population of hospitals over time, the current sample of hospitals participating in NEISS is being reviewed to assess their representativeness. The selection process may be revised in future years in order to strengthen the quality and representativeness of the estimates generated by the NEISS-AIP.

An independent statistical assessment of the NEISS and NEISS-AIP samples is being conducted under CPSC contract 61320619F0134, with a period of performance of September 27, 2019 – September 26, 2020.

The contractor shall address the following in this independent, statistical assessment:

- A. A review of the current NEISS and NEISS-AIP samples, including
 1. The distribution of the hospital EDs and emergency room visits on the hospital frames (1997 vs. current frame) in relation to the NEISS and NEISS-AIP samples by major census regions,
 2. The CPSC methodology of selecting and recruiting replacement hospitals
 - i. The number of primary hospitals still participating in the NEISS and NEISS-AIP samples
 - ii. The number of replacement hospitals in the NEISS and NEISS-AIP samples and the time it takes to replace a hospital
 3. The weighting of the data to calculate national estimates
 4. Monthly adjustments to the weights for non-response
 5. Annual adjustments to the weights based on the purchase of an annual hospital frame.
- B. Pros/Cons of:
 1. Keeping the current NEISS sample
 2. Keeping the current NEISS-AIP sample
 3. Increasing the current NEISS-AIP sample to the full NEISS sample
 4. Resampling NEISS
 - i. Resampling methods to replace full sample
 - ii. Resampling methods to retain maximum number of current hospitals
 - iii. Resampling methods to retain current hospitals, taking into account if hospital is a primary or replacement hospital

5. Resampling the NEISS-AIP as a two-thirds subset of a new NEISS sample
6. Resample NEISS-AIP to a full new NEISS sample.
- C. Alternative methods to adjust for replacement hospitals that cause significant changes to annual national estimates for high profile products/groups and disrupt trend analysis.
- D. Alternative methods to estimate injuries for incidents with high variability or that are geographical in nature (3-year moving averages, 5-year estimates, small area estimation).
- E. Uniform suppression criteria for unstable/small estimates.
- F. Basic structure of the resampling of the NEISS/NEISS-AIP with alternative criteria (number of participating hospitals, total estimated cases, minimum variances, maximum retention of existing hospitals).

7. Special circumstances requiring respondents to report information more often than quarterly or to prepare responses in fewer than 30 days

Timely reporting of consumer product-related injuries and childhood poisonings treated in emergency departments is necessary to identify, investigate, and respond to new or changing hazards. In CY2018, 50% of the NEISS records were received within 5 days of treatment and 90% within 38 days.

8. Agency's Federal Register Notice and related information

A notice in the *Federal Register* was published [MONTH XX, 2019. (XX FR XXXXX)].

9. Decision to provide payment or gift

NEISS respondents enter into contracts with CPSC and are compensated for their efforts. See Section 12(a) for details of the estimated burden and costs. A number of persons are contacted through a face-to-face, telephone, or Internet interview to provide additional information about selected injuries or incidents associated with consumer products of special interest to CPSC. See Section 12(b) for details of the estimated burden and costs. In general, respondents are not compensated for participating in an interview.

10. Assurance of confidentiality

If a person who is asked to provide information about a product-related injury or incident claims that any information submitted to the CPSC is trade secret or confidential business information, that information is subject to the agency's procedures for withholding confidential information from public disclosure codified at 16 CFR part 1015, subpart B. If such information is requested under provisions of the Freedom of Information Act, the person who provided the information is

notified and given the opportunity to respond and seek judicial relief before the CPSC's release of the information. In addition, any accident or investigation report made under the CPSA by an officer or employee of the CPSC shall be made available to the public in a manner that will not identify any injured person or any person treating him or her, without the consent of the person so identified.

11. Questions of a sensitive nature

The CPSC's staff takes care to design interview guides so that persons who witness or are injured in incidents associated with consumer products are not requested to provide any information of a sensitive nature.

12 (a). Estimate of hour burden to NEISS respondents

The NEISS system collects information on consumer product-related incidents and other injuries from a statistical sample of 96 hospitals in the United States. Respondents to NEISS include hospitals that directly report information to NEISS, and hospitals that allow access to a CPSC contractor who collects the data. Collecting emergency department records for review, correcting error messages, and other tasks takes about 36 minutes per day. Each record takes about 30 seconds to review. Coding and reporting records that involve consumer products or other injuries takes about 2 minutes per record. Coding and reporting on additional special study information (Adverse Drug Effects) takes about 2 minutes and 90 seconds per record for other special studies. Respondents also spend about 36 hours per year in related activities (training, evaluations, and communicating with other hospital staff).

In CY 2018, there were 130 NEISS respondents (total hospitals and CPSC contractors). These NEISS respondents reviewed an estimated 5.53 million emergency department records and reported 727,544 total cases (363,221 consumer product-related injuries for CPSC, and 364,323 other injuries for the NEISS-AIP). The table below lists the number of reported cases, and the number of reported cases with additional special study information.

Total NEISS Cases Reported	727,544
Consumer Product-Related Injuries	363,221
CDC NEISS-AIP	364,323
Special Studies Reported (subset of above)	
Child Poisoning (CPSC)	4,734
Adverse Drug Events (CDC)	36,858
Assaults (CDC)	32,990
Firearm-Related Injuries (CDC)	6,159
Self-Inflicted Violence (CDC)	9,106
Work-Related Injuries (CDC)	38,132
Motor Vehicle Non-Crash Injuries (NHTSA)	12,813

The total burden hours for all NEISS respondents are estimated to be 100,781 for CY 2018. The average burden hours per respondent is 775 hours. However, the total burden hours on each respondent varies, due to differences in the sizes of the hospitals (*e.g.*, small rural hospitals versus large metropolitan hospitals). The smallest hospital reported 82 cases with a burden of about 258 hours, while the largest hospital reported 47,801 cases with a burden of about 4,125 hours.

The total costs to NEISS respondents for CY 2018 was approximately \$3,391,000. NEISS respondents enter into contracts with CPSC and are compensated for these costs. The average cost per respondent is estimated to be about \$26,000. The average cost per burden hour is estimated to be \$33.65 per hour (including wages and overhead). However, the actual cost to each respondent varies, due to the type of respondent (hospital versus CPSC contractor), size of hospital, and regional differences in wages and overhead. Therefore, the actual annual cost for any given respondent may vary between \$3,048 at a small rural hospital, and \$329,690 at the largest metropolitan hospital.

12 (b). Estimate of hour burden to other respondents

CPSC staff conducts field interviews of about 375 persons each year. On average, an on-site interview takes about 4.5 hours. Staff also conducts about 175 in-depth investigations (IDIs) by telephone. Each telephone IDI requires about 20 minutes. CPSC staff plan to conduct about 50 internet-based questionnaires per year that require about 20 minutes each.

CPSC staff estimates 1,763 annual burden hours on these respondents: 1,688 hours for face-to-face interviews; 58 hours for in-depth telephone interviews, and 17 hours for Internet-based questionnaires.

CPSC's staff estimates the value of the time required for reporting is \$36.77 an hour (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2019: <https://www.bls.gov/new.release/ecec.toc.htm>). At this valuation, the estimated annual cost to the public is about \$64,826.

13. Estimate of other total annual cost burden to respondents or record keepers

The only costs to respondents from this collection of information are those described in item 12, above.

14. Estimate of annualized costs to the Federal government

The cost to the government of the collection of the NEISS information is estimated to be about \$5.4 million a year. This estimate includes \$3.4 million in compensation to NEISS respondents described in section 12(a) above. This estimate also includes \$1.984 million for about 172 professional staff months each year. The estimate of

professional staff months includes the time required to: oversee NEISS operations (e.g., administration, training, quality control); prepare questionnaires, interviewer guidelines, and other instruments and instructions used to collect the information; conduct face-to-face and telephone interviews; and evaluate responses obtained from interviews and completed forms. Each month of professional staff time costs the agency about \$11,532. This is based on a GS-12 mid-level salaried employee. The average yearly wage rate for a mid-level salaried GS-12 employee in the Washington, DC metropolitan area (effective as of January 2016) is \$94,520 (GS-12, step 5). This represents 68.3 percent of total compensation (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2019, Table 1, percentage of wages and salaries for all civilian management, professional, and related employees: <http://www.bls.gov/ncs/>). Adding an additional 31.7 percent for benefits brings average yearly compensation for a mid-level salaried GS-12 employee to \$138,389.

15. Program changes or adjustments

This request for the approval of an estimated 102,544 (100,781 NEISS and 1,763 other) burden hours per year is an increase of 21,334 hours, due to an increase in the number of emergency department charts being reviewed and coded since this collection of information was last approved by OMB in 2017.

This information collection request excludes the burden associated with other publicly available Consumer Product Safety Information Databases, such as Internet complaints, Hotline, and MECAP reports, which is accounted for under OMB control number 3041-0146. This information-collection request also excludes the burden associated with follow-up investigations conducted by other federal agencies.

16. Plans for tabulation and publication

The agency provides yearly reports of NEISS data to the public on its website. NEISS data are also available for public use through the CPSC website. The CPSC publishes results from some of its investigations of product-related injuries and incidents in *Federal Register* notices during rulemaking proceedings, and in safety alerts, news releases, and other informational materials that are disseminated to the general public, voluntary standards groups, firms, and trade associations. The agency has no specific plan to publish all of the data obtained from this collection of information.

17. Rationale for not displaying the expiration date for OMB approval

Not applicable.

18. Exception to the certification statement

Not applicable.

B. Collection of Information Employing Statistical Methods

1. The potential respondent universe includes patients treated in statistically selected hospitals participating in NEISS to report emergency department-treated, product-related injuries and other injuries. The affiliated NEISS hospitals report about 728,000 emergency department visits annually using existing information extracted from hospital records. Of those reported visits, about 363,000 are consumer product-related cases. Since hospital record data are limited, further information is frequently necessary, and about 550 of these cases are selected for further investigation.

The potential respondent universe also includes individuals involved with incidents recorded in newspaper articles, consumer complaints, death certificates, coroner's reports and any other injury sources that may be reported to the CPSC. These other data sources contribute more than 89,000 cases annually, of which about 1,700 are selected for further investigation.

2. Cases associated with categories of interest are selected daily from the hundreds of incident reports received each day by the CPSC. CPSC investigators call to interview or to arrange to visit the victim or others to determine specific details about the accident sequence. Information collected from the victim, family member, witness, or others is reported on an investigation form designed for this purpose.

When less than 100 percent of the surveillance cases are selected for investigation, the universe of cases is stratified by relevant factors, such as type of injury or consumer product involved and a simple random sample of cases is selected.

The estimation procedure for probability surveys involves multiplying the original surveillance case weight by the case weight appropriate for the follow-back investigation. Normally, the latter is the reciprocal of the probability of selection, adjusted, where needed, for non-response and an annual ratio adjustment to take into account hospitals that open and close and/or change in size.

3. About 77 percent of the victims involved in the selected incidents are successfully contacted. Of those contacted, about 95 percent agree to provide information voluntarily on the circumstances of the incident. For probability surveys, responses are weighted to account for non-responses. The results from probability surveys can be generalized to the universe studied.

4. No tests of procedures or methods will be undertaken.

5. Contact for collection and analysis of NEISS data:

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