Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–02984 Filed 2–8–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–12PZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Proficiency Testing in US Clinical Laboratories: Perception, Practices and Potential for Expanded Utility—NEW—The Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The primary focus of this project is to conduct a systematic analysis in order to understand which types of laboratories follow Proficiency Testing (PT) and Good Laboratory Practices (GLPs), to identify ways that PT and GLPs could be better promoted, and to identify populations that would benefit from receiving information on PT GLPs. The Association of Public Health Laboratories (APHL) and Centers for Disease Control and Prevention (CDC) hope to learn more about the perceived benefits and burden of performing PT. This information may be helpful to the CDC as the Clinical Laboratory Improvement Amendments (CLIA) regulations for PT are revised. Our survey population frame is 20,500 Certificate of Compliance laboratories and 16,800 Certificate of Accreditation laboratories. All of these laboratories are required to perform PT in accordance with CLIA. Many of these laboratories also use their PT results internally to further improve laboratory quality at no additional cost.

The first phase of this project was conducted by the APHL through focus group research in 2011. The research explored how clinical and public health laboratories perceived commercial PT programs and explored the ways in which the laboratories used PT to assure and improve the quality of their testing. This second phase of the project will be administration of a survey to build on the preliminary findings from the focus group research and help identify the types of laboratories that would benefit from learning about additional uses for PT. This information will be helpful to disseminate PT and GLPs to laboratories in a strategic and targeted way based on findings from this survey.

The goal is to achieve an 80% response rate (29,840 out of 37,300 laboratories). APHL and CDC will strive to ensure a high response rate by promoting the survey through advertisements in laboratory trade publications, at professional meetings, and possibly through programs and laboratory accreditation organizations.

The cohort of laboratories surveyed will be all Certificate of Compliance and Certificate of Accreditation laboratories listed in the Centers for Medicare and Medicaid Services (CMS) Online Survey, Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information and relevant characteristics including laboratory specialty and laboratory type for each laboratory.

The survey will be administered through a web-based survey system, specifically Survey Monkey. APHL will send each laboratory a postmarked letter explaining the survey and provide them with a link to log in to the survey with a unique identifier on their address label. Two weeks afterwards, APHL will follow-up with a postcard reminder which will also include that unique identifier.

There are no costs to respondents other than their time.

The annualized estimated burden is 9,947 hours.

Estimated Annualized Burden Hours:

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Laboratorians	Laboratory Practices	29,840	1	20/60

Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–12PE]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Interventions to Reduce Shoulder MSDs in Overhead Assembly—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health

at work for all people through research and prevention. Under Public Law 91–596, sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH proposes to conduct a study to assess the effectiveness and cost-benefit of occupational safety and health (OSH) interventions to prevent musculoskeletal disorders among workers in the Manufacturing sector.

Musculoskeletal disorders (MSDs) represent a major proportion of injury/illness incidence and cost in the U.S. Manufacturing (MNF) sector. In 2008, 29% of non-fatal injuries and illnesses involving days away from work (DAW) in the MNF sector involved MSDs and the MNF sector had some of the highest rates of MSD DAW cases. The rate for the motor vehicle manufacturing sub-sector (NAICS 3361) was among the highest of MNF sub sectors, with MSD DAW rates that were higher than the general manufacturing MSD DAW rates from 2003–2007. In automotive manufacturing overhead conveyance of the vehicle chassis requires assembly line employees to use tools in working postures with the arms elevated. These postures are believed to be associated with symptoms of upper limb discomfort, fatigue, and impingement syndromes (Fischer et al., 2007). Overhead working posture, independent of the force or load exerted with the hands, may play a role in the development in these conditions. However, recent studies suggest a more significant role of localized shoulder muscle fatigue in contributing to these disorders. Fatigue of the shoulder muscles may result in changes in normal shoulder kinematics (motion) that affect risk for shoulder impingement disorders (Ebaugh et. al., 2006; Chopp et al., 2010).

The U.S. Manufacturing sector has faced a number of challenges including an overall decline in jobs, an aging workforce, and changes in organizational management systems. Studies have indicated that the average age of industrial workers is increasing and that older workers may differ from younger workers in work capacity, injury risk, severity of injuries, and speed of recovery (Kenny et al., 2008; Gall et al., 2004; Restrepo et al., 2006). As the average age of the industrial population increases and newer systems of work organization (such as lean manufacturing) are changing the nature of labor-intensive work, prevention of MSDs will be more critical to protecting older workers and maintaining productivity.

This study will evaluate the efficacy of two intervention strategies for reducing musculoskeletal symptoms and pain in the shoulder attributable to overhead assembly work in automotive manufacturing. These interventions are, (1) an articulating spring-tensioned tool support device that unloads from the worker the weight of the tool that would otherwise be manually supported, and, (2) a targeted exercise program intended to increase individual employees' strength and endurance in the shoulder and upper arm stabilizing muscle group. As a primary prevention strategy, the tool support engineering control approach is preferred; however, a cost-efficient opportunity exists to concurrently evaluate the efficacy of a preventive exercise program intervention. Both of these intervention approaches have been used in the Manufacturing sector, and preliminary evidence suggests that both approaches may have merit. However, high quality evidence demonstrating their effectiveness, by way of controlled trials, is lacking. This project will be conducted as a partnership between NIOSH and Toyota Motors Engineering & Manufacturing North America, Inc. (TEMA), with the intervention evaluation study taking place at the Toyota Motor Manufacturing Kentucky, Inc. (TMMK) manufacturing facility in Georgetown, Kentucky. The prospective intervention evaluation study will be conducted using a group-randomized controlled trial multi-time series design. Four groups of 25–30 employees will be established to test the two intervention treatment conditions (tool support, exercise program), a combined intervention treatment condition, and a control condition. The four groups will be comprised of employees working on two vehicle assembly lines in different parts of the facility, on two work shifts (first and second shift). Individual randomization to treatment condition is not feasible, so a group-randomization (by work unit) will be used to assign the four groups to treatment and control conditions. Observations will be made over the 10-month study period and questionnaires will include the Shoulder Rating Questionnaire (SRQ), Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, a Standardized Nordic Questionnaire for body part discomfort, and a Work Organization Questionnaire. In addition to the questionnaires a shoulder-specific functional capacity evaluation test battery will be administered at 90 and 210 days, immediately pre- and post-intervention, to confirm the efficacy of the targeted exercise program in improving shoulder capacity.

In summary, this study will evaluate the effectiveness of two interventions to reduce musculoskeletal symptoms and pain in the shoulder associated with repetitive overhead work in the manufacturing industry and will disseminate the results of evidence-based prevention practices to the greatest audience possible. NIOSH expects to complete data collection in 2014. There are no costs to respondents other than their time. The total estimated annual burden hours are 472.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Employees	Informed Consent Form	125	1	5/60
	Consent of Photographic Image Release	125	1	2/60
	PAR–Q (Physical Activity Readiness)	125	1	2/60
	Shoulder Rating Questionnaire (SRQ)	125	10	4/60
	Disabilities of the Arm Shoulder and Hand (DASH)	125	10	6/60
	Standardized Nordic Questionnaire for Musculoskeletal Symptoms Instrument.	125	10	4/60
	Work Org Questionnaire	125	3	26/60

Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1182]

Draft Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.'' This draft Quantitative Risk Assessment (the draft QRA) includes an Interpretative Summary, a Technical Report, with Appendixes, and a risk assessment model. The purpose of the draft QRA is to evaluate the effect of factors such as the microbiological status of milk, the impact of cheese manufacturing steps, and conditions during distribution and storage on the overall risk of invasive listeriosis to the consumer in the United States or Canada of soft-ripened cheese. The draft QRA makes it possible to evaluate the effectiveness of some process changes and intervention strategies in reducing the risk of listeriosis. We are making the draft QRA available for public comment.

DATES: Submit either electronic or written comments on the draft QRA by April 29, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

Listeria monocytogenes (*L. monocytogenes*) is a widely occurring pathogen that can be found in agricultural and food processing environments. Ingestion of *L. monocytogenes* can lead to the development of listeriosis, with consequences that may include septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Epidemiological data show that listeriosis has one of the highest hospitalization rates and one of the highest case fatality rates among foodborne diseases in the United States (Ref. 1). Serious illness may occur in people considered to be more susceptible, such as the elderly, individuals who have a preexisting illness that reduces the effectiveness of their immune system, and pregnant women (Ref. 2).

The United States and Canada have experienced sporadic illnesses and outbreaks of listeriosis associated with the consumption of soft cheese. Both FDA and Health Canada—Santé Canada continue to evaluate the safety of soft cheese, particularly soft cheese made from unpasteurized milk.

II. Quantitative Risk Assessment

The draft QRA (Refs. 3 to 6) provides a science-based analytical approach to collate and incorporate available data into a mathematical model. It provides risk managers with a decision-support tool to evaluate the effectiveness of current and future interventions to reduce or prevent listeriosis from consumption of soft-ripened cheeses. The draft QRA also may be used to target risk communication messages, identify and prioritize research needs, and provide a framework for coordinating efforts with stakeholders. The draft QRA has undergone an independent external peer review consistent with the requirements in the Office of Management and Budget's ''Final Information Quality Bulletin for Peer Review.'' FDA's response to the peer-review is available electronically on the FDA Web site (Ref. 7).

The draft QRA focuses on the sources of *L. monocytogenes* contamination, the effects of individual manufacturing and/or processing steps, and the effectiveness of various intervention strategies on the levels of *L. monocytogenes* in the product as consumed and the associated risk of invasive listeriosis. The draft QRA's scope is:

- Pathogen of concern: *L. monocytogenes;*
- Food(s) of concern: Camembert, as an example of soft-ripened cheese;
- Populations of interest: The general populations of the United States and Canada, and subpopulations identified as at-risk in both countries (i.e., pregnant women, immunocompromised individuals, and the elderly population);
- Endpoint of concern: Invasive listeriosis; and
- Risk metric: The probability of invasive listeriosis per soft-ripened cheese serving.

The draft QRA uses a quantitative approach, using mathematical and probabilistic modeling, to estimate the risk per serving of soft-ripened cheese (using Camembert cheese as an example) in both countries. The draft QRA tests the effects of some alternatives on those risks. The draft QRA uses data from the literature, from government nutrition surveys, from a specific survey on home storage time and temperature practices, and from specific expert elicitations. FDA invites comments that can help FDA and Health Canada—Santé Canada improve:

- The approach used;
- The assumptions made;
- The modeling techniques;
- The data used; and
- The clarity and the transparency of the draft QRA documentation.

When finalized, FDA intends to use this risk assessment (which is limited to one pathogen in one type of cheese), along with other information and scientific assessments that more comprehensively consider the different pathogens that can be present in all types of cheeses made from raw milk, in its reevaluation of the existing 60-day aging requirements for cheeses made with raw milk (e.g., 21 CFR 133.182(a)).

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

The draft QRA is available electronically on the FDA Web site *http://www.fda.gov/food/scienceresearch/researchareas/*