and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 1, 2002.

**A. Federal Reserve Bank of Kansas City** (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

*1. Citizens Bancshares, Inc., ESOP*, Edmond, Oklahoma; to become a bank holding company by acquiring up to 30 percent of the voting shares of Citizens Bancshares, Inc., Edmond, Oklahoma, and thereby indirectly acquire voting shares of Citizens Bank of Edmond, Edmond, Oklahoma.

**B. Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

*1. Pubco Bancshares, Inc.*, Slaton, Texas; to acquire 100 percent of the voting shares of Shamrock Bancshares, Inc., Shamrock, Texas, and thereby indirectly acquire voting shares of Shamrock Delaware Financial, Inc., Dover, Delaware, and First National Bank, Shamrock, Texas.

Board of Governors of the Federal Reserve System, January 3, 2002.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 02–473 Filed 1–7–02; 8:45 am]

**BILLING CODE 6210–01–S**

## GENERAL SERVICES ADMINISTRATION

**[OMB Control No. 3090–0262]**

### Submission for OMB Review; Comment Request Entitled Identification of Products With Environmental Attributes

**AGENCY:** Office of Acquisition Policy, GSA.

**ACTION:** Notice of request for extension to previously approved OMB Clearance (3090–0262).

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the General Services Administration (GSA), Office of Acquisition Policy has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning the Identification of Products with Environmental Attributes.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of contracts, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

A request for public comments was published at 66 FR October 29, 2001. No comments were received.

**DATES:** Comment Due Date: February 7, 2002.

**ADDRESSES:** Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: Ed Springer, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to Stephanie Morris, General Services Administration, Acquisition Policy Division, 1800 F Street, NW., Room 4035, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Beverly Cromer, Office of Acquisition Policy (202) 208–6750.

**SUPPLEMENTARY INFORMATION:**

### A. Purpose

The General Service Administration is requesting the Office of Management and Budget (OMB) to review and approve information collection, 3090–0262, concerning the Identification of Products with Environmental Attributes. The GSA requires contractors submitting Multiple Award Schedule Contracts to identify in their GSA price lists those products that they market commercially that have environmental attributes. The identification of these products will enable Federal agencies to maximize the use of these products to meet the responsibilities expressed in statutes and executive orders.

### B. Annual Reporting Burden

*Respondents:* 9,200.
*Annual Responses:* 9,200.
*Burden Hours:* 46,000.
*Obtaining Copies of Proposals:* Requester may obtain a copy of the proposal from the General Services Administration, Regulatory Secretariat (MVP), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 501–4744. Please cite OMB Control No. 3090–0262, Identification of Products with Environmental Attributes.

Dated: December 31, 2001.

**Al Matera,**

*Director, Acquisition Policy Division.*

[FR Doc. 02–441 Filed 1–7–02; 8:45 am]

**BILLING CODE 6820–61–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Airborne Exposure Limits for Chemical Warfare Agents GA (Tabun), GB (Sarin), and VX

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Notice of proposed revisions to CDC recommendations for protection of public health and safety during disposal or transport of chemical warfare agents GA (tabun), GB (sarin), and VX through revision of worker and general population airborne exposure limits.

### Purpose

CDC presents proposed recommendations for airborne exposure limits for the chemical warfare agents GA (tabun or ethyl N,N-dimethyl-phosphoramidocyanidate, CAS 77–81–6); GB (sarin or O-isopropyl-methylphosphonofluoridate, CAS 107–44–8); and VX (O-ethyl-S-(2-diisopropylaminoethyl)-

methylphosphonothiolate, CAS 50782–69–9).

Before these recommendations are finalized, CDC requests comments from the public, all interested parties, environmental and health regulators, the Department of Defense (DOD), and other organizations involved in handling, transporting, or demilitarizing chemical warfare agents. More specifically, CDC seeks scientifically and professionally defensible data or information that would persuade CDC to alter its recommendations to be more or less conservative.

**SUMMARY:** CDC's recommendations are based on comments by scientific experts at a public meeting convened by CDC on August 23–24, 2000, in Atlanta, Georgia; the latest available technical reviews; and the latest available risk assessment approach frequently used by regulatory agencies and other organizations (1). Airborne exposure limits for chemical warfare agents GA (tabun), GB (sarin), and VX were re-evaluated by using a conventional risk assessment methodology for developing airborne exposure limits described by the U.S. Environmental Protection Agency (EPA). This methodology is considered conservative; however, the calculated exposure limits are not numerically precise and do not define precise thresholds of potential human toxicity.

**Note:** There is no indication that the current exposure limits, as implemented by the U.S. Army Program Manager for Chemical Demilitarization, have been less than fully protective of human health. This may be due to rigorous exposure prevention efforts in recent years as well as the conservative implementation of the existing limits.

*Proposed Airborne Exposure Limits for GB:* CDC proposes a worker population limit (WPL) value of $3 \times 10^{-5}$ mg/m$^3$, expressed as an 8-hour time-weighted average (TWA). Additionally, CDC recommends a short-term excursion limit (STEL) of $1 \times 10^{-4}$ mg/m$^3$ to be used in conjunction with the WPL. Exposures above the WPL up to the STEL should not be longer than 15 minutes and should not occur more than 4 times per day, and there should be at least 60 minutes between successive exposures in this range. The STEL should not be exceeded during the work day, even if the cumulative exposure over the 8-hour TWA is not exceeded. CDC proposes a decrease in the general population limit (GPL) to $1 \times 10^{-6}$ mg/m$^3$. These WPL, STEL, and GPL values are approximately threefold lower than the values recently recommended by the U.S. Army. An immediately dangerous to life or health (IDLH) value of 0.1 mg/m$^3$ is proposed for GB.

*Proposed Airborne Exposure Limits for GA:* Although not as well-studied as GB, GA is approximately equal in potency to GB. Therefore, CDC proposes the same exposure limits for GA as for GB.

*Proposed Airborne Exposure Limits for VX:* CDC proposes that the VX WPL, expressed as an 8-hour time-weighted average, should be decreased to $1 \times 10^{-6}$ mg/m$^3$. Additionally, CDC proposes a VX STEL of $4 \times 10^{-6}$ mg/m$^3$. These proposed WPL and STEL exposure limits are a factor of 10 lower than the U.S. Army's recommendation. CDC proposes that the GPL for VX should be decreased to $6 \times 10^{-7}$ mg/m$^3$ (a factor of 2 higher than the Army's recommendation). An IDLH value of 0.003 mg/m$^3$ is proposed for VX. Acknowledging the gaps in the data base for this agent, CDC considers the proposed VX exposure limits subject to re-evaluation in 3 years. New VX toxicity studies, which are anticipated to be completed within 3 years, have been recommended recently by the EPA National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee). CDC agrees that new toxicity studies may be helpful in setting VX exposure limits.

**DATES:** Submit comments within 60 days following the date of this publication in the **Federal Register**.

**ADDRESSES:** Comments may be sent to the following:

1. By mail. Submit your comments to Dr. Paul Joe, CDC, 4770 Buford Highway, Mail Stop F–16, Atlanta, Georgia 30341.

2. In person or by courier. Deliver your comments to Dr. Paul Joe, CDC, 4770 Buford Highway, Mail Stop F–16, Atlanta, Georgia 30341.

3. Electronically. You may submit your comments electronically by e-mail to Dr. Paul Joe at *pbj4@cdc.gov,* or you can submit a computer disk to Dr. Paul Joe, CDC, 4770 Buford Highway, Mail Stop F–16, Atlanta, Georgia 30341. Electronic documents will be accepted in WordPerfect or Microsoft Word.

**FOR FURTHER INFORMATION CONTACT:** Dr. Paul Joe, Centers for Disease Control and Prevention, 4770 Buford Highway, Mail Stop F–16, Atlanta, Georgia 30341, Telephone number: 770–488–7091, E-mail address: *pbj4@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The nerve agents GA, GB, and VX are organophosphate esters that were designed specifically to cause incapacitation or death in military use. These agents are among the most potent of all chemical warfare agents and have extraordinarily high levels of acute toxicity. In vapor or aerosol form, the nerve agents can be inhaled or absorbed through the skin or the eyes. As a liquid, they can be absorbed through the skin, conjunctiva, and upper gastrointestinal tract. The agents' toxicity is related primarily to their ability to inhibit acetylcholinesterase, which is a critical enzyme needed for nerve function (2). Health symptoms can include runny nose, tightness in the chest, dimness of vision and pinpointing of eye pupils, difficulty in breathing, drooling and excessive sweating, nausea, vomiting, cramps, involuntary defecation and urination, twitching, staggering, headache, confusion, drowsiness, coma, and convulsions. The signs and symptoms can be followed by cessation of breathing and death (3). At superlethal doses, GB caused delayed neuropathy in antidote-protected chickens. VX has not been shown to cause delayed neuropathy in animals or humans. The health effects from low-dose chronic (long-term) exposure have not been demonstrated clearly.

Studies of genotoxicity, carcinogenicity, developmental, and reproductive toxicity associated with GB and VX have been primarily negative (2,4).

GA, GB, and VX no longer are manufactured in the United States; however, they are stored currently at eight locations in the continental United States by the DOD. Section 1412 of Public Law 99–145 [50 U.S.C. 1521] mandates that the present stockpile of chemical warfare agents be destroyed. Public Law 91–121 and Public Law 91–441 [50 U.S.C. 1512] mandate that the Department of Health and Human Services (DHHS) review DOD plans for transporting and/or disposing of chemical warfare agents and make recommendations for protecting human health and safety. DHHS delegated this authority to CDC.

In 1987, CDC requested public comments on recommendations for protecting human health and the environment from potential adverse effects of long-term exposure to low-airborne doses of agents GA, GB, VX, mustard, and lewisite (L). CDC incorporated public comments, including comments from scientific experts outside CDC, and in 1988 recommended worker and general population airborne exposure limits for GA, GB, VX, mustard (H, HD, HT), and L. (See Table 1.) The U.S. Army adopted these airborne exposure limits in 1990.

TABLE 1.—CURRENT CDC-RECOMMENDED AIRBORNE EXPOSURE LIMITS*

[All values expressed as milligrams per cubic meter air [mg/m$^3$]]

| Agent | General population limit (GPL) | Worker population limit (WPL) |
|---|---|---|
| GA, GB | 0.000003 ($3 \times 10^{-6}$) | 0.0001 ($1 \times 10^{-4}$). |
| VX | 0.000003 ($3 \times 10^{-6}$) | 0.00001 ($1 \times 10^{-5}$). |
| H, HD, HT | 0.0001 ($1 \times 10^{-4}$) | 0.003 ($3 \times 10^{-3}$). |
| L | 0.003 ($3 \times 10^{-3}$) | 0.003 ($3 \times 10^{-3}$). |
| Averaging Time | 72 hours | 8 hours. |

*Referred to as ''Control Limits'' in Federal Register, Volume 53, No. 50, March 15, 1988, pp. 8504–07.

The GPL is the maximum concentration to which members of the general population may be continually exposed 24 hours per day, 7 days per week. The GPL is intended for application to the entire general population, including all ages and medical conditions (e.g., infants, elderly, infirm, and healthy). Historically, the GPL for VX did not reflect a tenfold reduction from GB GPL as was the case for the WPLs. The primary reason for the difference was the technical inability to conduct VX air monitoring at such low concentrations. The analytical limitations are reflected further in the 72-hour averaging period rather than a more conventional 24-hour period.

The WPL is intended to be assessed as a time-weighted average for a conventional 8-hour workday and a 40-hour week. This WPL represents a concentration to which it is believed that virtually all workers may be repeatedly exposed, day after day, without adverse effect. CDC recommends that the WPLs be implemented in conjunction with the medical surveillance provisions and other requirements defined in Department of Army Pamphlets 40–173 and 40–8 or successive documents (5,6).

**Note:** The proposed risk assessment methodology derives exposure limits below concentrations where any acute or chronic effects would be expected to occur. The existing and proposed exposure limits are intended to protect workers and the public from potentially adverse effects from short-term or long-term exposure to GA, GB, and VX. The existence of potential adverse health effects resulting from long-term, low-dose exposure to these agents has not been demonstrated clearly.

Now, 13 years later, CDC is re-evaluating the limits for GA, GB, VX, and mustard based on the latest risk assessment models and any updated scientific data. On August 23–24, 2000, CDC convened a public meeting in Atlanta, Georgia, where outside scientists joined CDC scientists to discuss the exposure limits for GA, GB, and VX. The re-evaluation consisted of lengthy review of all available information about the agents, including some information previously classified by allied nations, and therefore, are unavailable for the open review process used by CDC in the past. A public meeting to discuss the exposure limits for mustard was held on September 11–12, 2001. The proposed mustard exposure limits will be presented in a separate **Federal Register** announcement. The L stockpile is relatively small and located at only one storage site; therefore, revisions to the exposure limits for L are not being considered at the present time.

## II. Approach and Methodology

### *A. Purpose of the Public Meeting*

The purpose of the public meeting was to discuss the airborne exposure limits for GA, GB, and VX recently proposed by the US Army. Attendees at the August 23–24, 2000, public meeting convened by CDC included risk assessors, toxicologists, physicians, a veterinarian, and several chemists. These experts were from universities, state environmental agencies, and non-CDC federal agencies. The scientific experts were asked whether or not there was a need to modify exposure limits to reflect current risk assessment methodologies and any newly available data. The meeting agenda included the following:

- Presentations on risk assessment models and scientific data and recommended modifications to existing exposure limits based on comments from individual scientific experts,
- Panel discussions by scientific experts, and
- Discussions of the technical feasibility to monitor at proposed modified exposure limits by air monitoring experts.

The meeting was not held as a federal advisory committee; therefore, CDC did not seek unanimity or consensus; take votes; or rely solely on the attendees to formulate federal policy. Statements by members of the working group, which are included in this **Federal Register** notice, represent only one part of the information considered by CDC. The experts attended the meeting solely to provide their individual expert advice to CDC and the public for consideration.

### *B. Method for Deriving Exposure Limit Criteria*

The EPA risk assessment approach, which was used in this assessment, is used to extrapolate potential biological effects in humans at low-level exposures where such epidemiologic or toxicologic data are not directly available. This method for deriving exposure criteria has evolved over 30 years. This evaluation's approach was based on guidance described in an EPA publication (7). The derivation of a non-cancer exposure criteria involve the following:

- Defining the critical adverse effect (which is assumed protective for all other, often more serious, effects);
- Selecting the most appropriate animal or human study or studies, if more than one yields the same end point, to serve as the basis for a limit;
- Establishing a threshold dose below which adverse health effects are not expected to occur or are extremely unlikely; and
- Defining appropriate uncertainty factors (UFs) to apply to the threshold dose.

In selecting a study, a no-observed-effect-level (NOEL)—a product of concentration and time (Ct) at which subjects showed no detectable effects-or a no-observed-adverse-effect-level (NOAEL)—a Ct at which subjects showed no detectable harmful effects—is preferred over a lowest-observed-effect-level (LOEL) or a lowest-observed-adverse-effect-level (LOAEL)—the lowest Ct at which an effect or adverse effect was seen. Studies of human responses generally are preferred over studies on laboratory animals. Such preferences are not rigid; the number of subjects and technical aspects of how the study was conducted play an important role.

As many as five uncertainty factors and one modifying factor may be applied to the selected exposure dose, which is usually a NOAEL or LOAEL (7,8). They are $UF_H$ (heterogeneity of susceptibility within human

populations), $UF_A$ (animal to human extrapolation), $UF_S$ (subchronic to chronic exposure extrapolation), $UF_L$ (LOAEL to NOAEL extrapolation), $UF_D$ (database incomplete), and MF (modifying factors). By convention, these factors assume values of 1, 3, or 10 and are multiplied together to yield an overall uncertainty factor. The observed Ct product (LOAEL or NOAEL) is divided by the overall UF and then adjusted for duration of exposure (40 hours per week for workers and 168 hours per week for the general population). This basic method was applied by EPA to many common toxicants to establish chronic reference doses for human exposure. In summary, the general equation for deriving the WPL would be as follows:

$$WPL = \frac{LOAEL_{inhal} \times Resp_{exptl} \times Exp_{exptl}}{Resp_{occup} \times Exp_{occup}} \times \frac{1}{UFs \times MF}$$

WPL = Worker population limit
$LOAEL_{inhal}$= Lowest observed adverse effect level (if available, use no observed adverse effect level)
$Resp_{exptl}$ = Experimental subject minute volume
$Resp_{occup}$ = Occupational minute volume
$Exp_{occup}$ = Occupational exposure time (480 minutes/day x 5 days)
$Exp_{exptl}$ = Experimental exposure time
UFs = Uncertainty factors
MF = Modifying factor

The GPL would be derived in an analogous manner, adjusting for continuous exposure, differences in assumed respiratory rates, and possible differences in application of certain UFs.

The exposure criteria resulting from this risk assessment approach should be evaluated in context with the uncertainties and default assumptions used in the risk assessment approach. One of the uncertainties that needs to be considered is the ''order-of-magnitude'' imprecision associated with the exposure criteria estimate (8). From a purely mathematical standpoint, this refers to a $\log_{10}$ interval around the exposure criteria estimate (i.e., approximately threefold above and below). It is important to recognize that this imprecision includes only the statistical uncertainty in interpreting the underlying data. Uncertainties inherent in the choice of the model to conduct the extrapolation are potentially far larger and cannot be quantified easily. Research into specific areas of uncertainty associated with the EPA methodology has been reported. Most studies support the belief that the uncertainty factors described above provide estimates that are protective or err toward lower limits (9). That is, the composite uncertainty factor tends to result in an estimate of the dose (or exposure limit) that is likely not to cause adverse health effects.

## III. Presentations at the Public Meeting

### *A. U.S. Army Proposal*

The U.S. Army completed reviews of exposure limits for G-agents and VX and suggested lowering the GPL for one of the agents (10,11). (See Table 2.) The Army's proposals decreased the GPL for VX by one order of magnitude, from $3 \times 10^{-6}$ milligrams per cubic meter air ($mg/m^3$) to $3 \times 10^{-7}$ $mg/m^3$, and decreased the averaging time from 72 hours to 24 hours.

TABLE 2.—U.S. ARMY-PROPOSED EXPOSURE LIMITS

[All values expressed as milligrams per cubic meter air [$mg/m^3$]]

| Agent | | General population limit (GPL) | Worker population limit (WPL) | Short-term exposure limit (STEL) ‡ | Immediately dangerous to life and Health (IDLH) ‡ |
|---|---|---|---|---|---|
| GA, GB | Proposed ..... | 0.000003 (3x10 $^{-6}$) † ... | 0.0001 (1x10 $^{-4}$) ..... | 0.0004 (4x10 $^{-4}$)** ..... | 0.1 (1x10 $^{-1}$). |
| VX | Proposed ..... | 0.0000003 (3x10 $^{-7}$)† .. | 0.00001 (1x10 $^{-5}$) ..... | 0.00004 (4x10 $^{-5}$) ..... | 0.01 (1x10 $^{-2}$). |
| GD | Proposed ..... | 0.000001 (1x10 $^{-6}$)† .... | 0.00003 (3x10 $^{-5}$) ..... | 0.001 (1x10 $^{-3}$)** ..... | 0.05 (5x10 $^{-2}$). |
| GF | Proposed ..... | 0.000001 (1x10 $^{-6}$)† .... | 0.00003 (3x10 $^{-5}$) ..... | 0.001 (1x10 $^{-3}$)** ..... | 0.05 (5x10 $^{-2}$). |
| Averaging time | 24 hours ..... | 8 hours ..... | 15 min, 4x/day ..... | 30 miyn.. | |

†24-hour time-weighted average.
** 8-hour time-weighted average worker limit may not be exceeded.

The U.S. Army proposed exposure limits for agents GD (Soman, O-pinacolyl-methylphosphonofluoridate, CAS 96–64–0) and GF (O-cyclohexyl-methylphosphonofluoridate, CAS 329–99–7). These agents are not part of the U.S. stockpile, and neither transportation nor open-air testing is being considered for these agents. Therefore, they fall outside the scope of the DHHS/CDC mandate and were not considered in this process.

The U.S. Army-proposed WPL for GB, expressed as an 8-hour time-weighted average, is identical to the existing WPL but was derived from a different source. The proposed WPL was based on a human study conducted in 1949 by McKee and Woolcott, which yielded a LOAEL of 0.06 $mg/m^3$, 20 minutes/day for 4 days per week (12). Proposed uncertainty factors were $UF_H = 1$, $UF_A = 1$, $UF_S = 10$, $UF_L = 3$, $UF_D = 1$, MF = 1 for an overall uncertainty factor of 30. Adjusting for differences in breathing rates and exposure durations yielded $3.3 \times 10^{-5}$ $mg/m^3$, expressed as an 8-hour time-weighted average. This differs from the existing limit, $1 \times 10^{-4}$ $mg/m^3$ by a factor of 3. The U.S. Army authors concluded that the methodology was not sufficiently precise to warrant a change from the existing limit to the newly calculated limit and proposed leaving the current limit unchanged. The same study was used as a basis for a GPL of $1.1 \times 10^{-6}$ $mg/m^3$, which differed from the present GPL ($3 \times 10^{-6}$ $mg/m^3$) by a factor of 3 and was deemed within an acceptable uncertainty range.

The Army proposed a STEL of 0.0004 $mg/m^3$ for GB. The STEL is defined as a 15-minute time-weighted average exposure that should not be exceeded during the workday, even if the 8-hour WPL is not exceeded. Exposures up to the STEL should not be longer than 15 minutes and should not occur more than 4 times a day, and there should be at least 60 minutes between successive exposures in this range. The proposed STEL would have the effect of permitting four, 15-minute exposures per day up to 0.0004 $mg/m^3$ of GB or GA

with the added requirement that the 8-hour WPL may not be exceeded.

The Army proposed a value of 0.1 mg/m$^3$ as the immediately dangerous to life or health (IDLH) concentration for GB. The GB IDLH was based on an acute human toxicity study, and the value was calculated in accordance with National Institute for Occupational Safety and Health (NIOSH) guidance (10). The Army adjusted the IDLH down by a factor of 2 to address the female occupational worker population, which is potentially more sensitive than the male occupational worker population to GB vapor.

There are limited data on VX compared to some of the other G-agents, but the WPL recommendation was based on a relative potency estimate of 10 for pupillary constriction; so the Army-proposed WPL for VX is 1/10 of the corresponding value for GB or $1 \times 10^{-5}$ mg/m$^3$, and the Army-proposed GPL is $3 \times 10^{-7}$ mg/m$^3$. A STEL of $4 \times 10^{-5}$ mg/m$^3$ for VX was proposed. The value was based ultimately on the WPL, such that four exposures per day at the STEL would not cause the WPL to be exceeded. The Army-proposed VX IDLH of 0.01 mg/m$^3$ was also determined using a relative potency estimate of 10.

*B. Airborne Exposure Limits for GB*

1. WPL for GB

The U.S. Army document served as the starting point for discussion at the public meeting (10). The expert panel members differed in their assessment of how best to derive limits from the available data. Most of the members thought that limits for GB should be based on the McKee and Woolcott study, which yielded a LOAEL of 0.06 mg/m$^3$ (12). However, one member was concerned about deriving long-term exposure limits from short-term experimental data, particularly when little long-term toxicity data are available.

One member noted that application of an interspecies uncertainty factor greater than 1 is unjustified when evidence suggests that the species studied is as sensitive or more sensitive than man. A calculation based on the Weimer animal data using an interspecies uncertainty factor of 1 would yield a GB WPL of $5 \times 10^{-5}$ mg/m$^3$ (13). However, this member also thought that human studies should be given more weight and joined others in recommending a limit based on the McKee and Woolcott report (12). Another member argued for a limit of $4 \times 10^{-6}$ mg/m$^3$ based on uncertainty factors of 10 for short-term to long-term extrapolation and 3 for interindividual variability. Yet another member argued that studies by Harvey and Johns would be better critical studies to utilize (14, 15). Working from these data would yield a 15-minute STEL of 0.008 mg/m$^3$ and a WPL for GB of $2.5 \times 10^{-6}$ mg/m$^3$ after an eightfold adjustment for time of exposure and a tenfold adjustment for cumulative effect.

Four members recommended that if the U.S. Army-proposed derivation were used, CDC should accept the calculated exposure limit value ($3.3 \times 10^{-5}$ mg/m$^3$) rather than utilizing the rounded-up value $1 \times 10^{-4}$ mg/m$^3$ that was recommended by the Army.

Several members speculated that information concerning human exposures during manufacture and disposal of GB could be more relevant than the studies cited. Unfortunately, records of environmental conditions from the time period GB was manufactured are not adequate to support such analysis. Conversely, worker and environmental monitoring records for recent GB demilitarization activities are well documented. However, engineering controls to prevent exposure have been rigorous; therefore, GB exposures have been very rare, have occurred primarily during maintenance operations, and have been minimal. Consequently, these data are not useful for developing exposure limits.

2. STEL for GB

The U.S. Army-proposed STEL was based on the WPL, such that four exposures per day at the STEL would not result in the WPL being exceeded. At the public meeting, the proposed STEL elicited considerable discussion. Several members of the expert panel thought that the Army-proposed STEL was too low numerically because of the method used to calculate it. Using the critical effect LOAEL, several experts recalculated a new value—a Temporary Excursion Limit (TEL). The TEL for GB was calculated to be 0.01 mg/m$^3$ for a 5-minute exposure not more than once per day.

3. General Population Limit for GB

The Army-proposed GPL for GB was based on the same study and the same method used for deriving the WPL. The GPL was calculated by adjusting for the longer time of exposure and greater population variability. The uncertainty factors were as follows: 10 for short-term to long-term extrapolation, 10 for variability among individuals, and 3 for low-effect to no-effect extrapolation. Three members of the working group thought the Army-proposed GPL was adequate. One thought that the proposed limits were probably at least tenfold lower than needed to protect public health. That is, the GPL could be at least tenfold greater and still be protective. The member who proposed a WPL of $2.5 \times 10^{-5}$ mg/m$^3$ advised adding an uncertainty factor of 3 for variation within the population and an uncertainty factor of 3 for extrapolating from low-effect to no-effect yielding the proposed value $3 \times 10^{-6}$ mg/m$^3$ but by a different line of reasoning. One member argued for a GPL of $1 \times 10^{-6}$ mg/m$^3$, noting that using the lower value incorporated an uncertainty factor of 3 for variability within population. It was noted that the Johns data indicate that doses causing a given degree of pupillary constriction generally range over a factor of less than 2.0 from the geometric mean (that is, from about half the geometric mean to about twice the geometric mean), providing at least some evidence for small variability within human populations to this particular low-dose effect (15).

*C. Airborne Exposure Limits for VX*

Exposure limits for VX were more difficult for the experts to address because the experimental VX data were considered inadequate and do not form a good basis for VX exposure limits. Nonetheless, one of the working group members noted that the VX studies by Bramwell and Crook argue for a VX WPL of $4 \times 10^{-7}$ mg/m$^3$ and $3 \times 10^{-9}$ mg/m$^3$, respectively (16, 17). However, several panel members had scientific concerns about these studies. Regarding the Bramwell study, some panel members were concerned that benzene, which was used as a solvent in the VX generation, could alter the exposure characteristic of VX. As for the Crook study, the accuracy of the VX vapor concentrations was questioned.

Because the available experimental VX data were considered inadequate, the derivation of the exposure limit was based on the relative potency of VX as compared to GB. The exposure limits proposed by the Army are based on a tenfold difference (relative potency) in the ability of VX to cause miosis compared to GB. This tenfold potency difference was questioned because some publications stated that the potency difference may be twelvefold to thirty-threefold or higher, especially at low concentrations (18,19).

The Army's publication proposing VX exposure limits included little detail used in deriving the tenfold potency factor (11). However, discussion in a previous U.S. Army study indicated that recovery from the miosis effects of VX is about four times as fast as recovery from the effects of GB (19). According to

this publication, if VX potency is about twenty-five times greater than GB but the effective recovery is four times greater, the relative VX potency for continuous exposure would be approximately 25/4 that of GB. The overall factor of 10 is a approximation (rounding) of 25/4. Compared to GB, VX does not undergo a second, irreversible, reaction known as aging as quickly when it reacts with acetylcholinesterase; this may be one reason that the biological effects of VX exposure recover more quickly when compared to GB.

CDC notes that the EPA NAC/AEGL committee for VX recently proposed a relative potency of 12 with application of a modification factor of 3 for the incomplete VX data set. The potency factor of 12 was based on a 1971 British study that measured the ability of VX to cause 90% pupil constriction in rabbits (18). The application of a relative potency of 12 with a modifying factor of 3 for the inadequate VX data base effectively resulted in a relative potency of 36 (3×12) (20).

All experts would have preferred better, VX-specific data and would have preferred avoiding the use of relative potency, but four of the experts concurred with the use of an overall tenfold difference in relative potency for extrapolating from GB to VX. Given the preference of several experts for a GB WPL of $3\times10^{-5}$ mg/m$^3$, that would call for a WPL of $3\times10^{-6}$ mg/m$^3$ for VX rather than the $1\times10^{-5}$ mg/m$^3$ that was proposed by the Army. Accordingly, preference by several experts for a GB GPL of $1\times10^{-6}$ mg/m$^3$ would suggest a VX GPL of $1\times10^{-7}$ mg/m$^3$.

*D. CDC's Proposed Recommendations*

1. Airborne Exposure Limits for GB

Noting the opinions of the experts at the public meeting, CDC proposes a change from the present exposure limit to the lower exposure limit derived from the McKee and Woolcott studies (12). CDC believes that the calculated WPL value of $3\times10^{-5}$ mg/m$^3$, expressed as an 8-hour time weighted average, will protect workers from short-term or long-term health effect exposures for a working lifetime. The CDC-proposed WPL value, consistent with the calculation from this risk assessment, is approximately threefold lower than the Army-recommended value of $1\times10^{-4}$ mg/m$^3$. CDC recognizes that the risk assessment methodology is imprecise, and quantitative differences in risk between exposure concentrations of less than an order of magnitude generally are not discernable. However, CDC could not identify relevant examples from other risk assessments where such rounding-up had been conducted. Additionally, since the ''calculated'' WPL was thought to be technically feasible and four experts at the public meeting recommended using the ''calculated'' values from the risk assessment, CDC proposes the $3\times10^{-5}$ mg/m$^3$ as the WPL for GB.

In addition to the WPL, CDC recommends a STEL of $1\times10^{-4}$ mg/m$^3$ to be used in conjunction with the WPL. The STEL is defined as a 15-minute time-weighted average exposure that should not be exceeded during the workday, even if the 8-hour WPL is not exceeded. Exposures up to the STEL should not be longer than 15 minutes and should not occur more than 4 times a day, and there should be at least 60 minutes between successive exposures in this range. The purpose of this value is to provide a reasonable limit to excursions over the WPL. The value associated with the STEL is numerically identical to the existing 8-hour time-weighted worker exposure limit.

CDC proposes $1\times10^{-6}$ mg/m$^3$ as the GB GPL, expressed as a 24-hour time-weighted average. This GPL value, which is consistent with the calculation from the risk assessment, is threefold lower than the Army-recommended value and the current GPL. CDC believes current analytical methods can be modified to monitor at this new concentration.

The expert panel members did not focus on, or object to, the Army-proposed immediately dangerous to life or health (IDLH) value of 0.1 mg/m$^3$ for GB (10). Accordingly, CDC proposes an IDLH of 0.1 mg/m$^3$.

2. Airborne Exposure Limits for GA

Although not as well-studied, GA is approximately equal in potency to GB. The Army proposed, and members of the expert groups agreed, that it would be reasonable to use the same exposure limits for both. CDC proposes the same exposure limits (WPL, STEL, GPL, and IDLH) for GA as those recommended for GB.

3. Airborne Exposure Limits for VX

Since the toxicity data for VX are inadequate, CDC proposes derivation of the VX WPL, STEL, and GPL from the calculated exposure limits for GB, using a relative potency of 12 compared to GB and application of a modifying factor of 3 for the incomplete VX data set. This approach, which effectively results in a relative potency of 36, is the same as that recently proposed by the EPA NAC/AEGL committee (20). CDC proposes that the WPL for VX should be decreased to $1\times10^{-6}$ mg/m$^3$ (a factor of 10 lower compared to the current value and the U.S. Army's recommendation). Additionally, CDC proposes VX STEL of $4\times10^{-6}$ mg/m$^3$.

CDC proposes a VX GPL of $6\times10^{-7}$ mg/m$^3$, expressed as a 24-hour time-weighted average. The VX GPL, derived from the GB GPL to which the relative potency of 12 and a modifying factor of 3 was applied, was initially calculated as $3\times10^{-8}$ mg/m$^3$. However, currently available monitoring methods are unable to reliably detect VX at this concentration. CDC believes that reliable monitoring is a crucial aspect for implementing the exposure limits and therefore proposes to increase the GPL to a concentration that can reliably be monitored. The CDC proposes $6\times10^{-7}$ mg/m$^3$ for the VX GPL, a value that is both protective and technically feasible to monitor.

The proposed VX GPL of $6\times10^{-7}$ mg/m$^3$, used in conjunction with the existing perimeter montoring programs, will be protective because long-term releases of VX are unlikely. Routine maintenance and monitoring procedures implemented for worker safety near the potential sources of releases (where concentrations potentially would be higher than at the perimeter) prevent long-term releases. At demilitarization sites, perimeter monitoring results for 12-hour samples are typically available within 72 hours. Detections of chemical agent above the action level result in (1) an investigation to determine the source of the vapor and (2) corrective action to eliminate the source. In the derivation of the GPL in accordance with EPA methodology, the exposure period of the critical study is adjusted for a continuous 7-day exposure for the general population. The perimeter monitoring results at demilitarization sites are obtained within 72 hours (3 days) following sampling. To correct the assumption of continuous exposure for 7 days, a factor of 3 days potential exposure per 7 days was applied to the calculated VX GPL of $3\times10^{-8}$ mg/m$^3$. Additionally, in the derivation of the GPL, an uncertainty factor of 10 was applied to extrapolate from sub-chronic to chronic exposures. Since a chronic exposure is unlikely, this extrapolation would not be needed. These calculations result in adjusting the initially calculated VX GPL of $3\times10^{-10}$ mg/m$^3$ to $6\times10^{-7}$ and support the conclusion that the proposed GPL of $6\times10^{-7}$ is protective of human health. This adjustment of the VX GPL was made in acknowledgment of the technical limitations of current air monitoring methods, while assuring that the GPL would be protective of public health.

The expert group members did not object to the Army-proposed IDLH values for VX (0.01 mg/m$^3$), although there was little specific discussion among the panel. In accordance with relative potency approach used for WPL and GPL (potency factor of 12 with a modifying factor of 3), CDC proposes a VX IDLH of 0.003 mg/m$^3$.

4. Proposed Implementation of the VX GPL

Current data suggest that air monitoring at the proposed VX GPL concentration is on the fringe of technical feasibility for current methods. CDC investigated this issue with representatives from NIOSH, the U.S. Army, and other independent consultants. CDC representatives heard compelling evidence that current VX air monitoring methods may need further development. At the proposed VX GPL, the mass of other ambient organic materials normally found in the air (background chemicals) will greatly exceed the mass of VX to be measured. These background materials cause analytical problems in discerning and quantifying VX.

Halting disposal until improved monitoring methodology can be developed presents at least three grave problems:

a. There is greater cumulative risk from continued storage compared to continued disposal under the existing exposure limits.

b. The desired level of sensitivity and selectivity may not be easily attainable.

c. The United States has treaty obligations to complete the disposal within a specified time.

Inasmuch as delay in disposal presents an unacceptable risk to public health and safety, CDC proposes the following interim measures regarding monitoring at the proposed VX GPL:

a. CDC proposes a multifaceted research program to look at commercially available systems that have the potential to improve air monitoring at the proposed VX GPL. Further, CDC recommends that the Army use one or more Ph.D.-level analytical chemist(s) who have air monitoring experience to direct this program.

b. CDC proposes suspension of the 20% action level for the VX GPL until the monitoring methodology can be improved.

c. For all demilitarization sites handling VX, CDC proposes that all qualitative responses above a 3:1 signal-to-noise ratio for VX from perimeter stations be evaluated (i.e., those that are below the limit of quantification for VX). When VX is qualitatively detected, action should be taken to investigate the possible sources of these responses.

*E. Summary of Proposed Recommendations*

CDC's foremost concern is protecting human health and safety. This concern requires a carefully considered balance of utilizing best possible risk analysis while considering technical feasibility and avoiding unintended consequences of recommendations that could increase total risk. CDC's recommendations are made with this balance in mind.

CDC proposes adjustments to the exposure limits for GA, GB, and VX to the values shown in Table 3.

TABLE 3.—DC CURRENT AND PROPOSED AIRBORNE EXPOSURE LIMITS

[All values expressed as milligrams per cubic meter air [mg/m$^3$]

| Agent | General population limit* (GPL) | | Worker population limit** (WPL) | Worker short-term exposure limit*** (STEL) | Immediately dangerous to life or health*** (IDLH) |
|---|---|---|---|---|---|
| GA, GB | Current | $3\times10^{-6}$ | $1\times10^{-4}$ | | |
| | proposed | $1\times10^{-6}$ | †$3\times10^{-5}$ | $1\times10^{-4}$ | 0.1 |
| VX | Current | $3\times10^{-6}$ | $1\times10^{-5}$ | | |
| | proposed | $6\times10^{-7}$ | ‡$1\times10^{-6}$ | $4\times10^{-6}$ | 0.003 |

* 24-hour time-weighted average. For the VX GPL, analyses of sample results within 72 hours is required.
** 8-hour time-weighted average.
† To be implemented in conjunction with the GB STEL.
‡ To be implemented in conjunction with a VX STEL.
*** Not previously considered by CDC.

Acknowledging the gaps in the database for VX, CDC considers the proposed VX exposure limits subject to re-evaluation in 3 years. New VX toxicity studies, which are anticipated to be completed within 3 years, have been recommended recently by the EPA NAC/AEGL Committee. CDC agrees that additional toxicity studies could be helpful in the derivation of exposure limits for VX.

CDC does not specifically recommend the use of these airborne exposure limits for uses other than transportation, demilitarization, or general population protection. For example, the 8-hour WPL value historically has been used for the Army-designated 3X decontamination, surveillance activities of leakers in storage, and charcoal unit mid-beds. CDC believes that the WPL is not necessarily applicable to all these activities, and the specific technical and safety requirements for each activity need to be considered individually.

The allowable limits for stack emissions were not discussed at the meeting. The allowable stack concentration (ASC) is a ceiling value that serves as a source emission limit and not as a health standard. It is used for monitoring the furnace ducts and common stack. The ASC provides an early indication of an upset condition and must be measurable in a timely manner. Modeling of worst-case credible events and conditions at each installation should confirm that the GPL monitoring level is not exceeded at the installation boundary as a consequence of a release at or below the ASC. Lowering the GPL might have the effect of lowering the stack concentration limit; therefore, modeling will need to be conducted to determine if the existing ASCs continue to be appropriate.

Dated: January 2, 2002.

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**References**

1. 65 FR 120, June 21, 2000, pp. 38559–60.

2. Munro NB, Ambrose KR, Watson AP. Toxicity of the organophosphate chemical warfare agents GA, GB, and VX: implications for public protection. Environ Health Perspect 1994;102:18–38.

3. U.S. Army. Detailed and general facts about chemical agents—TB 218. Aberdeen Proving Ground, MD: U.S. Army Center for

Health Promotion and Preventive Medicine, October 1996.

4. Perrotta DM. Long-term health effects associated with subclinical exposures to GB and mustard. Armed Forces Epidemiological Board, Environmental Board. July 18, 1996.

5. U.S. Army. Occupational health guidelines for the evaluation and control of occupational exposure to mustard agents H, HD, and HT. Washington, DC: Headquarters, Department of the Army, August 1991; pamphlet 40–173.

6. U.S. Army. Occupational health guidelines for the evaluation and control of occupational exposure to nerve agents GA, GB, GD, and VX. Washington, DC: Headquarters, Department of the Army, December 1990; pamphlet 40–8.

7. U.S. Environmental Protection Agency. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. Washington, DC: U.S. Environmental Protection Agency, October 1994; Report No. EPA/600/6–90/066F.

8. U.S. Environmental Protection Agency. Risk assessment guidelines for Superfund. Washington, DC: U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Human Health Evaluation Manual, Vol 1, Part A, Interim Final, 1989. Publication No. EPA/540/1–89/002.

9. Dourson ML, Felter SP, Robinson D. Evolution of science-based uncertainty factors in non-cancer risk assessment. Regul Toxicol Pharmacol 1996;24:108–20.

10. Mioduszewski RJ, Reutter SA, Miller LL, Olajos EJ, Thomson SA. Evaluation of airborne exposure limits for G-agents: occupational and general population exposure criteria. Aberdeen Proving Ground, MD: Edgewood Research, Development, and Engineering Center, U.S. Army Chemical and Biological Defense Command, April 1998; Publication No. ERDEC–TR–489.

11. Reutter SA, Mioduszewski RJ, Thomson SA. Evaluation of airborne exposure limits for VX: worker and general population exposure criteria. Aberdeen Proving Ground, MD: Edgewood Research, Development, and Engineering Center, U.S. Army Chemical and Biological Defense Command, February 2000; Publication No. ECBC–TR–074.

12. McKee WHE, Woolcott R. Report on exposures of unprotected men and rabbits to low concentrations of nerve gas vapour. PRP–143. Porton Down, 1949.

13. Weimer JT, McNamara BP, Owens EJ, Cooper JG, van der Wal A. Proposed revision of limits for human exposure to GB vapor in nonmilitary operations based on one-year exposures of laboratory animals to low airborne concentrations. Aberdeen Proving Ground, MD: Edgewood Arsenal Technical Report, Project 728012.21, February 1972—July 1979. U.S. Army 1979.

14. Harvey JC. Clinical observations on volunteers exposed to concentrations of GB. MLRR 114. 1952.

15. Johns RJ. Effect of low concentrations of GB on the human eye. MLRR 100. 1952.

16. Bramwell ECB, Ladell WSS, Shepard RJ. Human exposure to VX vapour, PTP 830. Ministry of Defense, Chemical and Biological Defense Establishment, Salisbury, Wiltshire. January 1963. Report AD335612L.

17. Crook JW, Hott P, Owens EJ, Cummings EG, Farrand RL, Cooper AE. The effects of subacute exposures of the mouse, guinea pig, and rabbit to low-level VX Concentrations. ARCSL–TR–82038. Aberdeen Proving Ground, MD: Chemical Systems Laboratory, June 1983. Report AD29615.

18. Callaway S, Dirnhuber P. Estimation of the concentrations of nerve agent vapour required to produce measured degrees of miosis in rabbit and human eyes. Chemical Defense Establishment, Porton Down, Salisbury, Wiltshire. July 1971. Technical Paper No. 65.

19. McNamara BP, Leitnaker FC, Vocci FJ. Proposed limits for human exposure to VX vapor in nonmilitary operations. Edgewood Arsenal, Aberdeen Proving Ground, MD: Headquarters, Department of the Army, July 1973; Edgewood Arsenal Special Publication EASP 1100–1 (R–1).

20. 66 FR 85, May 2, 2001, pp. 21940–21964.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS–10001]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

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Dated: December 20, 2001.

**Julie E. Brown,**

*Acting Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS–P–0015SPA, CMS–250 through 254, CMS–10008, and CMS–287]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the