nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 6, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0342.''

SUPPLEMENTARY INFORMATION:

Titles

a. Other On-the-Job Training and Apprenticeship Training Agreement and Standards, VA Form 22–8864 (Training Programs Offered Under Title 38 U.S. Code Section 3677 and 3678).

b. Employer's Application to Provide Training, VA Form 22–8865 (Under Title 38 U.S. Code Section 3677 or 3678).

OMB Control Number: 2900–0342.

Type of Review: Extension of a currently approved collection.

Abstract: VA uses the information on VA Form 22–8864 to ensure that a trainee is entering an approved training program. VA Form 22–8865 is used to ensure training programs and agreements meet statutory requirements for approval of an employer's job training program.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on March 8, 2001, at pages 14000 and 14001.

Affected Public: Business or other for-profit, Not-for-profit institutions, Farms, and State, Local or Tribal Government.

Estimated Annual Burden: 450 hours.

a. VA Form 22–8864—225 hours.

b. VA Form 22–8865—225 hours.

Estimated Average Burden Per Respondent: 120 minutes.

a. VA Form 22–8864—30 minutes.

b. VA Form 22–8865—90 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 600.

a. VA Form 22–8864—450.

b. VA Form 22–8865—150.

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0342'' in any correspondence.

Dated: June 20, 2001.

By direction of the Secretary.

Donald L. Neilson,

Director, Information Management Service.

[FR Doc. 01–16888 Filed 7–5–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW–IRIS]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATE: Comments must be submitted on or before August 6, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981 or e-mail to: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–NEW–IRIS'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Inquiry Routing and Information System (IRIS).

OMB Control Number: 2900–NEW–IRIS.

Type of Review: New collection.

Abstract: The World Wide Web is a powerful medium for the delivery of information and services to veterans, dependents, and active duty personnel worldwide. The proposed Inquiry Routing and Information System (IRIS) would allow a VA customer to be able to submit his or her questions at any time and receive answers more quickly than through standard mail. Because the system is automated, inquires would be directed to the appropriate individual/office automatically. The contact information being solicited will be used to identify the particular veteran. VA personnel will use the contact information to determine the location of a specific veteran's file, and to accomplish the action requested by the correspondent such as processing a benefit claim or filing material in the individual's claims folder.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on February 15, 2001, at page 10564.

Affected Public: Individuals or Households.

Estimated Annual Burden: 2,000 hours.

Estimated Average Burden Per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 12,000.

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, (202) 395–7316. Please refer to ''OMB Control No. 2900–NEW–IRIS'' in any correspondence.

Dated: June 20, 2001.

By direction of the Secretary.

Donald L. Neilson,

Director, Information Management Service.

[FR Doc. 01–16889 Filed 7–5–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Illnesses Not Associated With Service in the Gulf During the Gulf War

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) hereby gives notice that the Secretary of Veterans Affairs, under the authority granted by the Persian Gulf War Veterans Act of 1998, Pub. L. 105–277, 112 Stat. 2681–742 through 2681–749 (codified at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Pub. L. 105–368, 112 Stat. 3315, has determined that there is no basis to establish a presumption of service connection for any disease based on service in the Persian Gulf during the Persian Gulf War.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant or Bill Russo, Attorney-Advisor, Compensation and

Pension Service, Regulations Staff, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7213 and (202) 273–7211, respectively.

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements

Title 16 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, entitled the Persian Gulf War Veterans Act of 1998, Pub. L. 105–277, 112 Stat. 2681–742 through 2681–749 (codified at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Pub. L. 105–368, 112 Stat. 3315, directed the Secretary to seek to enter into an agreement with the National Academy of Sciences (NAS) to review and evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between exposure to the agent, hazard, or medicine or vaccine and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association; (2) the increased risk of illness among individuals exposed to the agent, hazard, or medicine or vaccine; and (3) whether a plausible biological mechanism or other evidence of a causal relationship exists between exposure to the agent, hazard, or medicine or vaccine and the illness. These laws also required that NAS submit reports on its activities every two years (as measured from the date of the first report) for a ten-year period.

Section 1602 of Pub. L. 105–277 provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) exists between exposure of humans or animals to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Southwest Asia theater of operations during the Persian Gulf War and the occurrence of a diagnosed or undiagnosed illness in humans or animals, the Secretary will publish regulations establishing presumptive service connection for that illness. If the Secretary determines that a presumption of service connection is not warranted, he is to publish a notice of that determination, including an explanation of the scientific basis for that determination. The Secretary's determination must be based on consideration of the NAS reports and all other sound medical and scientific information and analysis available to the Secretary.

Although Pub. L. 105–277 does not define ''credible evidence,'' it does instruct the Secretary to ''take into consideration whether the results (of any study) are statistically significant, are capable of replication, and withstand peer review.'' Simply comparing the number of studies which report a significantly increased relative risk to the number of studies which report a relative risk that is not significantly increased is not a valid method for determining whether the weight of evidence overall supports a finding that there is or is not a positive association between exposure to an agent, hazard, or medicine or vaccine and the subsequent development of the particular illness. Because of differences in statistical significance, confidence levels, control for confounding factors, and other pertinent characteristics, some studies are clearly more credible than others, and the Secretary has given the more credible studies more weight in evaluating the overall weight of the evidence concerning specific illnesses.

II. The National Academy of Sciences Report

Public Law 105–277 and 105–368 directed the Secretary of Veterans Affairs to obtain from the NAS an independent scientific review of the evidence regarding associations between diseases and exposure in military service to selected risk factors encountered or experienced during the Gulf War. Following acceptance of a contract with the Department for this purpose, the Institute of Medicine of the NAS made a determination to limit its initial review to an analysis of the health effects of depleted uranium (DU), the chemical warfare agent sarin, vaccinations against botulinum toxin and anthrax, and pyridostigmine bromide (PB), which was used in the Gulf War as a pretreatment for possible exposure to nerve agents. NAS issued its initial report, entitled ''Gulf War and Health, Volume 1. Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines,'' on September 7, 2000.

In reporting its findings, NAS included one exposure in the category ''Sufficient Evidence of a Causal Relationship': Exposure to sarin and dose-dependent acute cholinergic syndrome that is evident promptly (seconds to hours) after sarin exposure and resolves in days to months. This category means:

> Evidence is sufficient to conclude that a causal relationship exists between the exposure to a specific agent and a health outcome in humans. The evidence fulfills the criteria for sufficient evidence of an association (below) and satisfies several of the criteria used to assess causality: strength of association, dose-dependent relationship, consistency of association, temporal relationship, specificity of association, and biological plausibility.

The NAS included three entries in the category ''Sufficient Evidence of an Association'': (1) PB and transient acute (that is, short-lasting, and immediately after exposure) cholinergic effects in doses normally used in treatment and for diagnostic purposes; (2) Anthrax vaccination and transient acute local and systemic effects; and (3) Botulinum toxoid vaccination and transient acute local and systemic effects. This category means:

> Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out with reasonable confidence.

The NAS placed one item in the category ''Limited/Suggestive Evidence of an Association'': exposure to sarin at doses sufficient to cause acute cholinergic signs and symptoms and subsequent long-term effects. This category means:

> Evidence is suggestive of an association between an exposure to a specific agent and a health outcome in humans, but is limited because chance, bias, and confounding could not be ruled out with confidence.

Roughly half of the NAS conclusions were in the category ''Inadequate/Insufficient Evidence to Determine Whether an Association Does or Does Not Exist.'' This category means:

> The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association between an exposure to a specific agent and a health outcome in humans.

The health effects in this category included: (1) Exposure to uranium and lung cancer at higher levels of cumulative exposure (greater than 200 mSv or 25 cGy); (2) Exposure to uranium and lymphatic cancer; bone cancer; nervous system disease; nonmalignant respiratory disease; or other health outcomes (gastrointestinal disease, immune-mediated disease, effects on hematological parameters,

reproductive or development dysfunction, genotoxic effects, cardiovascular effects, hepatic disease, dermal effects, ocular effects, or musculoskeletal effects); (3) PB and long-term adverse health effects; (4) Exposure to sarin at low doses insufficient to cause acute cholinergic signs and symptoms and subsequent long-term adverse health effects; (5) Anthrax vaccination and long-term adverse health effects; (6) Botulinum toxoid vaccination and long-term adverse health effects; and (7) Multiple vaccinations and long-term adverse health effects.

The NAS included two items in the final category ''Limited/Suggestive Evidence of *No* Association'': (1) Exposure to uranium and lung cancer at cumulative internal dose levels lower than 200 mSv or 25 cGy; and (2) Exposure to uranium and clinically significant renal dysfunction. This category means:

> There are several adequate studies, covering the full range of levels of exposure that humans are known to encounter, that are mutually consistent in not showing a positive association between exposure to a specific agent and a health outcome at any level of exposure. A conclusion of no association is inevitably limited to the conditions, levels of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded.

NAS noted that detecting adverse health effects as the result of a specific vaccination is a complex task due to a number of factors, including lack of long-term follow-up, small sample sizes, multiple vaccinations, multiple end points, lack of symptoms specific to that vaccination, passive reporting systems, high vaccination rates, restricted population, and progress in vaccine technology.

III. VA Response to the National Academy of Sciences Report

Following receipt of the NAS report, the VA formed a task force to review the report and pertinent studies and make recommendations to the Secretary to assist him in determining whether a positive association exists between exposure to an agent, hazard, or medicine or vaccine and any illness. This review involved a collaborative effort between representatives from the Veterans Health Administration, the Veterans Benefits Administration, the Office of General Counsel, and the Office of Policy and Planning. Reviewers included VA scientists, attorneys, medical care providers, and policy planners. That review was completed, and the task force's recommendations were submitted to the Secretary. The review provided the scientific and medical basis for the Secretary's determination regarding medical consequences of service in the Gulf War.

This notice, pursuant to Pub. L. 105–277, conveys the Secretary's determination that there is no positive association between: Lung cancer and exposure to uranium at higher levels of cumulative exposure (greater than 200 mSv or 25 cGy); lymphatic cancer, bone cancer, nervous system disease, nonmalignant respiratory disease, gastrointestinal disease, immune-mediated disease, effects on hematological parameters, reproductive or development dysfunction, genotoxic effects, cardiovascular effects, hepatic disease, dermal effects, ocular effects, or musculoskeletal effects and uranium exposure; long-term adverse health effects and pyridostigmine bromide (PB) treatment; long-term adverse health effects and exposure to sarin at doses insufficient to cause cholinergic signs and symptoms; long-term adverse health effects and anthrax vaccination; long-term adverse health effects and botulinum toxoid vaccination; long-term adverse health effects and multiple vaccinations; lung cancer and exposure to uranium at cumulative internal dose levels lower than 200 mSv or 25 cGy; and clinically significant renal dysfunction and uranium exposure. The Secretary's determination on these health outcomes is based on NAS' findings that there is inadequate/insufficient evidence to determine whether an association does or does not exist, regarding all but the last two of these health outcomes, and limited/suggestive evidence of no association as to the last two. Accordingly, regarding all the health outcomes listed above, the Secretary found that the credible evidence for association is not equal to or greater than the credible evidence against the association or that there is insufficient credible evidence of a positive association, and he determined that a positive association does not exist.

IV. Depleted Uranium

Although depleted uranium is the form of uranium that was present in the Gulf War, there are few studies of the health effects of this form of uranium. Consequently, NAS studied the health effects of natural and processed uranium in workers at plants that processed uranium for use in weapons and nuclear reactors. The NAS noted that the chemical toxicity of DU is virtually identical to that of natural uranium. NAS also noted that natural uranium is a low-level radioactive element, and DU emits radioactivity that is 40% lower than natural uranium. Lung cancer mortality has been the focus of many studies of workers employed in the uranium processing industry. In a large study of employees at Oak Ridge, Tennessee uranium processing and research facilities NAS found that the employees experienced a small increase in lung cancer mortality. NAS stated that analysis showed that uranium exposure was not associated with lung cancer mortality, and that other factors related to socioeconomic status could account for the lung cancer deaths. (Frome EL, Cragle DL, McLain RW. 1990. Poisson regression analysis of the mortality among a cohort of World War II nuclear industry workers. Radiat Res 123(2):138–152).

Another study combined data from four separate studies. (Dupree EA, Watkins JP, Ingle JN, Wallace PW, West CM, Tankersley WG. 1995. Uranium dust exposure and lung cancer risk in four uranium processing operations, Epidemiology 6(4):370–375). NAS stated that this study found that the dose-response did not suggest any lung cancer risk up to 25 cGy exposure. Above that level, there were too few cases to draw any conclusions. A dose-response relationship refers to the finding of a greater health effect (response) with higher exposure to an agent. The gray (Gy), formerly the rad, is the unit that describes the amount or exposure to absorbed radiation in terms of energy deposited on a tissue.

NAS found that a significant association with lung cancer appeared in a recent study in which significant increases in lung cancer mortality occurred in the small group of workers with a cumulative internal dose of 200 mSv or more. (Ritz B. 1999. Radiation exposure and cancer mortality in uranium processing workers. Epidemiology 10(5):531–538). The sievert (Sv) is the International System unit of radiation absorbed equivalent, defined as that producing the same biologic effect in a specific tissue as 1Gy of high-energy x-rays. NAS viewed this finding with caution, however, because the subgroup with the elevated risk had only three cases of lung cancer and because the study did not consider the confounding factor of cigarette smoking. NAS also noted that after controlling for external dose in this study, internal doses up to 200 mSv are not associated with excess risk of lung cancer. Accordingly, the Secretary has determined that the credible evidence against an association between lung cancer and uranium exposure outweighs

the credible evidence for such an association, and he determined that a positive association does not exist.

NAS found that the number of cases was too small and the confidence intervals for standardized mortality ratios (SMRs) too wide to draw any conclusions about an association between uranium and lymphatic cancer. NAS noted that the largest study included the period early in the nuclear industry in which workers were exposed to relatively high amounts of inhaled uranium. (Polednak AP, Frome EL. 1981. Mortality among men employed between 1943 and 1947 at a uranium processing plant. J Occup Med 23(3):169–178). In that study, NAS stated that there were fewer deaths (37) from lymphatic cancer than the expected (SMR=61). Accordingly, the Secretary has determined that the credible evidence against an association between lymphatic cancer and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS noted that bone cancer is rare; thus, the number of cases in all studies is small. NAS concluded that studies to date have not found an increase in bone cancers due to uranium exposure. As one example, NAS noted that the large size of the Oak Ridge cohort provides some evidence that exposure to uranium is not associated with a large excess risk of bone cancer (i.e., a relative risk of 3.0 or greater) (Polednak and Frome, 1981). Accordingly, the Secretary has determined that the credible evidence against an association between bone cancer and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS noted that the preponderance of evidence indicates little or no clinically important renal effects from exposure to uranium. The strongest evidence is the absence of kidney damage in workers exposed to high levels of soluble uranium compounds (Kathren RL, Moore RH. 1986. Acute accidental inhalation of U: A 28 year follow-up. Health Phys 51(5):609–619) and in veterans exposed to depleted uranium from embedded shrapnel. Kidney function was normal in Gulf War veterans with embedded depleted uranium fragments years after exposure, despite high urinary uranium concentrations in some of the subjects (McDiarmid MA, Keogh JP, Hooper FJ, McPhaul K, Squibb K, Kane R, DiPino R, Kabat M, Kaup B, Anderson L, Hoover D, Brown L, Hamilton M, Jacobson-Kram D, Burrows B, Walsh M. 2000. Health effects of depleted uranium on exposed Gulf War veterans. Environ Res 82(2):168–180). Accordingly, the Secretary has determined that the credible evidence against an association between clinically significant renal dysfunction and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS found that the evidence regarding exposure to uranium and diseases of the nervous system is not strong enough to form a firm conclusion. In a study of Gulf War veterans, results from a battery of computer-based neurocognitive tests suggest a statistical relationship between elevated urinary uranium levels and ''problematic performance on automated tests assessing performance efficiency and accuracy'' (McDiarmid et al., 2000). NAS found that the authors of this study did not adequately define their testing methods or the method for deciding the expected level of performance. Traditional tests of neurocognitive function did not show any statistical differences in performance between the veteran cohort and a control group. Accordingly, the Secretary has determined that the credible evidence against an association between diseases of the nervous system and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Several studies found a significant excess risk of nonmalignant respiratory disease. (Dupre EA, Cragle DL, McLain RW, Crawford-Brown DJ, Teta MJ. 1987. Mortality among workers at a uranium processing facility, the Linde Air Products Company Ceramics Plant, 1943–1949. Scand J Work Environ Health 13(2):100–107; Frome et al., 1990). NAS noted, however, other, larger studies which showed SMRs insufficient credible evidence to conclude that there is a positive association of less than or close to 100 (unity), do not confirm those findings. (Checkoway H, Pearce N, Crawford-Brown DJ, Cragle DL. 1988. Radiation doses and cause-specific mortality among workers at a nuclear materials fabrication plant. Am J Epidemiol 127(2):255–266; Polednak and Frome, 1981; Ritz, 1999). NAS noted that none of the above studies was able to control for smoking. Accordingly, the Secretary has determined that the credible evidence against an association between nonmalignant respiratory disease and uranium exposure outweighs the credible evidence for an association, and he has determined that a positive association does not exist.

In one study, after the accidental inhalation exposure to high levels of uranium, one individual experienced transient gastrointestinal distress. (Lu S, Zhao F–Y. 1990. Nephrotoxic limit and annual limit of intake for natural uranium. Health Phys 58(5):619–623). In that same study, however, NAS found that a case of accidental dermal exposure to uranium produced no reported gastrointestinal effects. Accordingly, the Secretary has determined that the credible evidence against an association between gastrointestinal disease and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS noted that the available scientific literature lacks documentation on adverse immunological effects of uranium. Two studies found that quartz dust-exposed uranium miners had a higher risk for the development of systemic autoimmune disease (Conrad K, Mehlhorn J, Luthke K, Dorner T, Frank K–H. 1996. Systemic lupus erythematosus after heavy exposure to quartz dust in uranium mines: Clinical and serological characteristics. Lupus 5(1):62–69; Conrad K, Levy Y, Blank M, Mehlhorn J, Frank K–H, Roch B, Shoenfeld Y. 1998. The pathogenic 16/6 idiotype in patients with silica associated systemic lupus erythematosus (SLE) and uranium miners with increased risk for development of SLE. JRheumatol 25(4):660–666). Another study reported that uranium miners were more likely to develop scleroderma. NAS stated that it is important to note that exposure to silica in quartz dust may be associated with both SLE and scleroderma. (Baur X, Rihs HP, Altmeyer P, Degens P, Conrad K, Mehlhorn J, Weber K, Wiebe V. 1996. Systemic sclerosis in German uranium miners under special consideration of autoantibody subsets and HLA class II alleles. Respiration 63:368–375). Accordingly, the Secretary has determined that there is insufficient credible evidence to conclude that there is a positive association between adverse immunological effects and uranium exposure.

NAS found that only a few studies have examined the effects of uranium on human reproduction and development. In a subgroup of Gulf War veterans with embedded depleted uranium fragments in soft tissues and muscles, semen contained uranium (McDiarmid et al., 2000). However, the semen characteristics were the same in Gulf War veterans with high urinary uranium excretion as in veterans with low excretion. Accordingly, the

Secretary has determined that the credible evidence against an association between human reproduction abnormalities and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS found that, in the study of Gulf War veterans with retained fragments of depleted uranium, changes in peripheral blood lymphocytes were identical to those of nonexposed Gulf War veterans (McDiarmid et al., 2000). Accordingly, the Secretary has determined that the credible evidence against an association between changes in peripheral blood lymphocytes and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS noted that there was no elevated risk for cardiovascular disease in a study of uranium workers (Lu and Zhao, 1990). Accordingly, the Secretary has determined that the credible evidence against an association between cardiovascular disease and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS found that, in a three-year follow up of an individual accidentally exposed to uranium tetrafluoride (Lu and Zhao, 1990), serum hepatic enzyme levels and liver function tests were within normal limits. Accordingly, the Secretary has determined that the credible evidence against an association between hepatic disease and uranium exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS found that dermal, ocular, and musculoskeletal effects of uranium have not been reported in the literature. Accordingly, the Secretary has determined that there is insufficient credible evidence to conclude that there is a positive association between adverse effects on these body systems and uranium exposure.

V. Sarin

Sarin is a highly toxic nerve agent produced for chemical warfare. In its report, NAS noted that exposure to sarin can be fatal within minutes to hours. In vapor or liquid form, sarin can be inhaled or absorbed, respectively, through the skin, eyes, or mucous membranes.

Possible Sarin Exposure During the Gulf War

According to Department of Defense (DoD) investigators, during the Gulf War no U.S. service members were exposed to chemical warfare nerve agents, including sarin, at levels sufficient to cause acute cholinergic poisoning signs and symptoms. In November 1996 DoD established the Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses (OSAGWI) to coordinate DoD's investigations into incidents that may have involved exposure to chemical warfare agents. OSAGWI's activities have been overseen by external independent groups, initially by the Presidential Advisory Committee on Gulf War Veterans Illnesses, and since February 1998 by the Presidential Special Oversight Board.

Khamisiyah was the site of a large ammunition storage area located in southern Iraq. In March 1991, shortly after the cease-fire, U.S. forces used explosives to destroy unmarked chemical warfare munitions at this site. The September 4, 1997, OSAGWI report ''Modeling the Chemical Warfare Agent Release at the Khamisiyah Pit,'' describes joint efforts by DoD and the Central Intelligence Agency to model the release of chemical warfare nerve agents, including sarin, from demolition of chemical warfare munitions at Khamisiyah. This effort involved interviews with U.S. servicemembers present at the demolitions, investigations of amounts and purity of chemical munitions and the agent they contained, meteorological reconstruction studies to evaluate wind directions and atmospheric movement of chemical agents following release, and experimental demolitions of similar chemical warfare munitions.

These results were put together to model an exposure plume showing a geographical area in which any U.S. servicemember present would be exposed to chemical warfare nerve agents, including sarin, at a level sufficient to cause first noticeable effects, i.e., minimum acute cholinergic signs and symptoms. DoD also mailed nearly 20,000 surveys to U.S. servicemembers who had been within 50 km of Khamisiyah at the time of the demolition. Of 7,400 responses received, ''* * * over 99 percent show[ed] no physical effects that could be correlated with exposure to the chemical warfare agent sarin.'' The report concluded, ''No military units were located under the first-effects portion of the plume, which is consistent with the lack of reported effects and with DoD's survey results, which had over 99 percent of the respondents showing no signs of physical effects that could be correlated with exposure to sarin. The troops that performed the demolition had evacuated the area.''

On December 5, 2000, OSAGWI announced the results of its revised modeling of possible sarin exposure from the Khamisiyah demolition. Based on this modeling, OSAGWI revised its estimate of the numbers of U.S. troops who may have been exposed to very low levels of chemical agent for a brief period of time (less than 3 days) after the demolition. As part of that announcement, OSAGWI stated that medical personnel and others who were near Khamisiyah in March 1991 have been interviewed and reported no evidence of health problems related to chemical agent exposure at the time of the demolitions. In addition, OSAGWI stated that its analysis continued to show that the exposure levels would have been too low to activate chemical alarms or to cause any acute or long-term health effects among U.S. troops.

In summary, OSAGWI's investigations of possible exposure or injury of U.S. servicemembers by chemical warfare nerve agents during the Gulf War have found only a single incident—demolition activities at Khamisiyah, Iraq—where exposure was found to be likely. In all other incidents investigated, OSAGWI found that exposure was unlikely, indeterminate or had definitely not occurred. OSAGWI includes a notice in all reports that additional information could change their conclusions. OSAGWI found no other instance where exposure to sarin or other chemical warfare agents was likely.

Acute Effects of Sarin

NAS reported that, in humans, exposure to high doses of sarin produces a well-characterized acute (i.e., immediate) cholinergic syndrome featuring a variety of signs and symptoms affecting the peripheral and central nervous systems (Gunderson CH, Lehmann CR, Sidell FR, Jabbari B. 1992. Nerve agents: A review. Neurology 42(5):946–950). This syndrome, as well as cholinergic signs and symptoms, is evident seconds to hours after exposure and usually resolves in days to months. At high doses, convulsions and death can occur. The peripheral effects are categorized as either muscarinic or nicotinic, in reference to the type of receptor stimulated by acetylcholine. The muscarinic signs and symptoms usually appear first (Lotti M. 2000. Organophosphorous compounds. In:

Spencer P, Schaumburg H, Ludolph A, eds. Experimental and Clinical Neurotoxicology. 2nd edition. New York: Oxford University Press. Pp. 897–925), although the sequence of effects may vary according to the route of sarin's absorption (Stewart CE, Sullivan J Jr. 1992. Military munitions and antipersonnel agents. In: Sullivan JB Jr, Krieger G, eds. Hazardous Materials Toxicology: Clinical Principles of Environmental Health. Baltimore: Williams & Wilkins. Pp. 986–1014). If the dose of sarin is sufficiently high, death results after convulsions and respiratory failure (Lotti, 2000).

NAS reported that the acute health effects of sarin are highly dependent on dose. Because the actual doses to humans under battlefield or terrorist circumstances cannot be measured, and may be difficult to reconstruct, they can be inferred on the basis of their acute clinical effects. A high level of sarin exposure of humans (after single or multiple exposures) is presumed to have occurred when the acute cholinergic syndrome is manifest. An intermediate-level exposure is presumed to have occurred when the acute cholinergic effect is limited to miosis (contraction of the pupil), rhinorrhea (an extreme type of runny nose), and depressed cholinesterase levels in the blood. Finally, low-level exposure may have occurred even though there are no immediately detectable cholinergic signs and symptoms (Brown MA, Brix KA. 1998. Review of health consequences from high-, intermediate- and low-level exposure to organophosphorous nerve agents. J Appl Toxicol 18(6): 393–408). NAS reported that U.S. troops did not report acute cholinergic symptoms at the time, but the possibility of low-level, asymptomatic exposures cannot be discounted. In a series of studies on members of a naval battalion (n = 249) called to active duty for the Gulf War, Haley and Kurt (1997) found that veterans who believed themselves to have been exposed to chemical weapons [1] were more likely to be classified as having one of six postulated syndromes (Haley RW, Kurt TL. 1997. Self-reported exposure to neurotoxic chemical combinations in the Gulf War. A cross-sectional epidemiologic study. JAMA 277(3):231–237). Specifically, this syndrome—labeled by the investigators as ''confusion—ataxia'' or ''syndrome 2'' features problems with thinking, disorientation, balance disturbances, vertigo, and impotence. This was the only syndrome of the six to have been associated with self-reported chemical weapons exposure. There is no evidence of sarin exposure among the veterans in the two studies summarized above.

A follow-up study of vestibular function (sense of balance) was performed on a subset of those veterans (n = 23) who had the highest factor scores on three of the syndromes postulated in 1997 by Haley and Kurt (Roland et al., 2000). The study was designed to probe the nature of veterans' vestibular symptoms, rather than to examine the relationship between vestibular performance and exposure in the Gulf War. Of the 23 veterans in this study, 13 exhibited syndrome 2, whereas the others exhibited syndromes 1 (impaired cognition) and 3 (arthromyoneuropathy). Based on a new questionnaire, veterans with syndrome 2 reported dizzy spells with greater frequency and longer duration than veterans with the other two syndromes. Veterans with syndrome 3, but not syndrome 2, performed significantly differently from controls on dynamic platform posturography (a test similar to that used by Japanese researchers to identify impairment in sarin-exposed females). (Yokoyama K, Araki S, Murata K, Nishikitani M, Okumura T, Ishimatsu S, Takasu N. 1998a. A preliminary study on vestibulo-cerebellar effects of Tokyo subway sarin poisoning in relation to gender difference: Frequency analysis of postural sway. J Occup Med 40(1):17–21). Veterans with other syndromes also had performance decrements on some of the measures of vestibular function. The study concluded that there was both subjective and objective evidence of injury to the vestibular system in this group of Gulf War veterans with newly postulated syndromes. Haley and Kurt (1997) hypothesized that these newfound chronic syndromes represent variants of organophosphorous induced delayed neuropathy (OPIDN) caused by exposure to various combinations of organophosphates (pesticides and nerve agents) and carbamate pesticides that inhibit certain enzymes.

According to NAS, four human populations have been studied following exposure to sarin: military volunteers who were exposed several decades ago to nonlethal doses of sarin and other chemical warfare agents (National Research Council. 1982. Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Vol. 1: Anticholinesterases and Anticholinergics. Washington, DC: National Academy Press. National Research Council. 1985; Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Vol. 3. Final Report. Current Health Status of Test Subjects. Washington, DC: National Academy Press); industrial workers with documented accidental acute exposure to sarin (Duffy FH, Burchfiel JL, Bartels PH, Gaon M, Sim VM. 1979. Long-term effects of an organophosphate upon the human electroencephalogram. Toxicol Appl Pharmacol 47(1):161–176); and victims of the sarin terrorist attacks in Matsumoto City in 1994 and Tokyo in 1995 (Morita H, Yanagisawa N, Nakajima T, Shimizu M, Hirabayashi H, Okudera H, Nohara M, Midorikawa Y, Mimura S. 1995. Sarin poisoning in Matsumoto, Japan. Lancet 346(8970):290–293).

NAS noted that major limitation of most human studies of either long- or short-term health effects is the inability to document actual exposure levels. Most studies of sarin were undertaken in the aftermath of occupational accidents or terrorist attacks. In such cases, the exposure levels were inferred from clinical effects. NAS further noted that high-level exposure is inferred from the acute cholinergic syndrome with outcomes including miosis, rhinorrhea, apnea, convulsions, and possibly death. NAS noted that high-level exposure requires hospitalization or emergency treatment. Intermediate-level exposure is inferred from minimal or threshold cholinergic effects such as miosis or rhinorrhea and limited decline in cholinesterase activity measured in the blood (<20 percent). Low-level exposure can be inferred from proximity to a documented exposure with no clinically detectable cholinergic signs or symptoms or detectable change in blood cholinesterase activity (Brown and Brix, 1998).

Long-Term Health Effects of Sarin

According to NAS, there have been relatively few human studies of sarin's long-term health effects. NAS noted that, in the literature on the survivors of the Japanese terrorist attacks, many health effects were reported to persist after sarin exposure: Fatigue, headache, visual disturbances (asthenopia, blurred vision, and narrowing of the visual field), asthenia, shoulder stiffness, and symptoms of post-traumatic stress disorder; fear of subways; and abnormal test results of unknown clinical significance on the digit symbol test of psychomotor performance, EEG records of sleep, event-related potential, visual evoked potential, and computerized posturography. However, given the mixed exposure not only to sarin, but

[1] Based on self-reports about their perceptions of CW exposure, rather than any evidence of symptomatology. Their geographical and temporal location in relation to the Khamisiyah demolition site was not reported. The questionnaire was sent to participants in 1994, before DoD reported that chemical weapons exposure could have occurred.

also to the trauma of the terrorist attack, it is unclear which of these effects are specifically associated with sarin exposure.

NAS' conclusions were based on retrospective studies of three different exposed populations in which the acute cholinergic signs and symptoms were documented as an acute effect of exposure. The findings from those studies are based on comparisons with control populations. One population consisted of industrial workers accidentally exposed to sarin in the United States; the other two populations were civilians exposed during terrorism episodes in Japan. The health effects listed above were documented at least 6 months after sarin exposure, and some persisted up to a maximum of 3 years, depending on the study. Whether the health effects noted above persist beyond the 3 years has not been studied. There are no well-controlled human studies expressly of sarin's long-term health effects at doses that do not produce acute signs and symptoms.

VA Determination on Sarin

The NAS report concluded that there is ''sufficient evidence of a causal relationship between exposure to sarin and a dose-dependent acute cholinergic syndrome that is evident seconds to hours subsequent to sarin exposure and resolves in days to months.'' The NAS report also found ''limited/suggestive evidence of an association'' between ''exposure to sarin at doses sufficient to cause acute cholinergic signs and symptoms and subsequent long-term health effects.'' Finally, the NAS found ''inadequate/insufficient evidence to determine whether an association does or does not exist'' between ''exposure to sarin at low doses insufficient to cause acute cholinergic signs and symptoms and subsequent long-term adverse health effects.''

The Secretary determined that the decision whether to establish presumptions of service-connection based on sarin exposure properly should be based on certain factual determinations and policy considerations. The Secretary determined, as a factual matter, that (1) no U.S. Armed Forces personnel were exposed to sarin in the Gulf War theatre in amounts sufficient to cause severe, acute effects; and, (2) even if personnel were so exposed, their symptoms would have been such that VA would undoubtedly compensate them anyway for chronic effects under existing law. Given the high level of confidence of the DoD, as evinced by its reports and studies, that no service-members were exposed to sarin at a level producing any acute symptoms or signs of exposure, the Secretary has concluded that it is extremely unlikely that any United States military personnel were exposed to sarin to a degree that would trigger such a presumption during the Gulf War. Based on these factual findings, the Secretary has concluded that such presumptions would be very unlikely to benefit any veterans. Under these circumstances, creation of presumptions of service connection could lead to confusion among potential claimants and have a negative impact on the claims adjudication process. In addition, the Secretary has concluded that the law does not require creation of a presumption in this situation.

Furthermore, the Secretary has concluded that if any veteran had experienced severe, acute sarin-exposure symptoms (such as the cholinergic reactions discussed in the NAS report), those symptoms would have been observed and reported and any disability resulting therefrom could be compensated on a direct-service-connection basis, without the need of a presumption. Also, it is very likely that the existing presumption of service-connection codified at 38 CFR 3.317 regarding undiagnosed illnesses suffered by Gulf War veterans would provide a basis for service connection in the case of veterans suffering from long-term effects suspected of being residuals of sarin exposure. Under section 3.317, if a veteran suffers from a chronic disability resulting from an undiagnosed illness (or combination of undiagnosed illnesses) that became manifest during service or that becomes manifest to a degree of 10 percent or more before December 31, 2001, the disability shall be presumed to be service connected.

For the foregoing reasons, the Secretary has concluded that neither the acute and transient symptoms resulting from possible sarin exposure, nor any long-term health consequences associated with possible sarin exposure, warrant a presumption of service-connection.

VI. Pyridostigmine Bromide

Pyridostigmine bromide (PB) is a drug used during the Gulf War as a pretreatment to protect troops from the harmful effects of chemical warfare nerve agents. NAS noted that a large number of clinical studies have reported that PB causes acute transient cholinergic effects in normal volunteers, patients given PB as a diagnostic test of hypothalamic pituitary function, and myasthenia gravis patients treated with the drug for extended periods.

NAS found that the epidemiologic data do not provide evidence of a link between PB and chronic illness in Gulf War veterans, noting that there is a paucity of epidemiologic studies on PB and long-term adverse health effects in the peer-reviewed literature. Only two epidemiologic studies investigated the possible association of PB and chronic symptoms among Gulf War veterans. (Haley RW, Kurt TL. 1997. Self-reported exposure to neurotoxic chemical combinations in the Gulf War. A cross-sectional epidemiologic study. JAMA 277(3):231–237; Unwin C, Blatchley N, Coker W, Ferry S, Hotopf M, Hull L, Ismail K, Palmer I, David A, Wessely S. 1999. Health of UK servicemen who served in Persian Gulf War. Lancet 353(9148):169–178). NAS noted that the study by Haley and Kurt, 1997, is limited by the small, selected population studied. NAS also found that this study suffers from reporting bias for adverse health syndromes, and provides an inadequate basis for concluding that an association exists. NAS noted that the other epidemiologic study (Unwin et al., 1999) showed a similar association with adverse symptoms; however, NAS felt that recall and reporting bias may also explain this finding. NAS concluded that neither of these studies provides a basis for holding that a specific association between PB and chronic adverse health effects exists.

VA Determination on PB

Although the NAS report provided evidence of an association between PB and transient, acute cholinergic effects, the report indicated that such effects resolved in a matter of hours following exposure. For this reason, the Secretary has concluded that these acute effects were not in the nature of an illness within the contemplation of the governing statute. Accordingly, the Secretary has concluded that such effects failed to meet the standards for establishment of presumptive service connection based on exposure to PB.

NAS indicated that there are no reliable reports of chronic toxicity related to human PB exposure in clinical or military populations. NAS concluded that there was inadequate/insufficient evidence to determine whether an association does or does not exist between PB and long-term adverse health effects. We are not aware of any other reports of chronic toxicity related to human pyridostigmine bromide exposure in clinical or military populations. For these reasons, the Secretary has determined that the credible evidence against an association between long-term adverse health effects and PB outweighs the credible evidence for such an association, and he

has determined that a positive association does not exist.

VII. Vaccinations

Anthrax Vaccination

Concerns prior to the Gulf War regarding Iraq's offensive biological warfare capabilities led to decisions that available vaccines should be utilized as preventive measures against biological warfare agents. NAS used only the peer-reviewed literature to form its conclusions on the weight of the evidence for associations of the anthrax vaccine with adverse health effects. Only a few published peer-reviewed studies have examined potential adverse effects of the anthrax vaccine when administered to humans.

NAS located only one peer-reviewed study of the type of anthrax vaccine used in the United States (Brachman PS, Gold H, Plotkin S, Fekety FR, Werrin M, Ingraham NR. 1962. Field evaluation of a human anthrax vaccine. Am J Public Health 52:632–645). The Brachman study (and other early experimental studies) found transient local and systemic effects (primarily erythema, edema, induration) from the anthrax vaccine. However, this study did not assess adverse effects beyond 48 hours after vaccination. (NAS found that other published studies (limited to a few short-term studies) reported no significant long-term adverse effects of the vaccine.)

During the development of the anthrax vaccine, several early studies examined adverse reactions in humans but did not provide detailed information on the nature of the monitoring for adverse effects. These studies used early versions of the culture filtrate (protective antigen) vaccine. Wright and colleagues (Wright GG, Green TW, Kanode RG Jr. 1954. Studies on Immunity in Anthrax. V. Immunizing activity of alum-precipitated protective antigen. J. Immunol 73:387–391) described the reactions of 660 persons at Camp Detrick who received a total of 1,936 injections. They found that 0.7 percent of vaccinated subjects reported systemic reactions—typically consisting of mild muscle aches, headaches, and mild-to-moderate malaise lasting 1 to 2 days. Significant local reactions—typically swelling (5–10 cm in diameter) and local pruritus (itching)—occurred in 2.4 percent of the subjects. The incidence of local reactions increased with the number of injections.

In another study at Fort Detrick (Puziss M, Wright GC, 1963. Studies on immunity in anthrax. X. Gel absorbed protective antigen for immunization of man. J Bacteriology 85:230–236), 0.5-ml injections of protective antigen led to similar results. The study reported low rates of erythema, edema, or pruritus at the site of injection (no details were provided) and no systemic reactions. Darlow and colleagues (Darlow, HM, Belton FC, Camb BA. 1956. The use of anthrax antigen to immunize man and monkey. Lancet. 2:476–479) reported on the administration of 1,057 injections of the anthrax vaccine to 373 individuals (369 persons received two or more injections) over a period of 4 years. Most of the reactions were mild and brief (local tenderness and swelling). There was an increase in the number of persons experiencing pain after the second dose, and local reactions increased with successive booster injections. The study reported that three people had brief and mild fever.

Botulinum Toxoid Vaccination

NAS found only a few published peer-reviewed studies that examined the potential adverse health effects of the botulinum toxoid vaccine when administered to humans. One study (Fiock MA, Devine LF, Gearinger NF, Duff JT, Wright GG, Kadull PJ. 1962. Studies on immunity to toxins of Clostridium botulinum. VIII. Immunological response of man to purified bivalent AB botulinum toxoid. J Immunol 88:277–283) reported on tests of bivalent toxoid preparations by Parke, Davis, and Company. NAS noted that the study reported that after 800 injections, no systemic or severe local reactions occurred. NAS also noted that the report did not discuss the surveillance methods for monitoring adverse health effects. A subsequent study (Fiock MA, Cardella MA, Gearinger NF. 1963. Studies on immunity to toxins of Clostridium botulinum. X. Immunologic response of man to purified pentavalent ABCDE botulinum toxoid. J Immunol 90:697–702) examined four different pentavalent toxoid lots prepared by Parke, Davis, and Company. NAS noted that the only statement about adverse reactions made by the investigators in their report was that 400 individuals received the pentavalent toxoid with ''no marked local or marked systemic reactions.'' NAS stated that the studies have noted transient local and systemic effects of the botulinum toxoid vaccine; however, these studies have not used active surveillance to systematically evaluate long-term health outcomes.

Multiple Vaccinations

Military personnel often receive several vaccinations as they prepare for service in an environment with many endemic diseases. Several studies of Gulf War veterans have tried to discover an association between health outcomes and exposure to vaccinations. Unwin et al., 1999, reported the results of a large cross-sectional postal survey on a random sample of U.K. Gulf War, Gulf War era, and Bosnia conflict veterans. The Gulf War and Bosnia troops were vaccinated against hepatitis A and B, yellow fever, typhoid, poliomyelitis, cholera, and tetanus, as well as against biological warfare agents. NAS found that this study provided some limited evidence of an association between multiple vaccinations and long-term multisymptom outcomes. NAS also noted that this study was conducted through questionnaire and relied primarily on self-reports.

A recently released study (Hotopf M, David A, Hull L, Ismail K, Unwin C, Wessely S. 2000. Role of vaccinations as risk factors for ill health in veterans of the Gulf War: Cross sectional study. BMJ 320:1363–1367) reported on a further analysis of the United Kingdom data. This study focused on U.K. Gulf War veterans who reported that they had copies of their vaccine records. The study examined the vaccines received, the timing of vaccinations, and six health outcomes (multisymptom outcome, psychological distress, post-traumatic stress reaction, fatigue, health perception, and physical functioning). NAS found that this study is consistent with the hypothesis that receiving multiple vaccinations within a narrow window of time, during a period of presumed stress, could be associated with the development of multiple symptoms and impaired functional status. NAS noted, however, that this study was limited by its cross-sectional nature and the fact that it relied on vaccine records that had been retained by only 28 percent of the study respondents. NAS noted that there were limiting and confounding factors in both studies (Unwin et al., 1999; Hotopf et al., 2000) and NAS pointed out the need for further research. NAS found that certain multiple vaccination programs can lead to antibody responses, but there is little evidence of other adverse consequences beyond transient local and systemic effects seen frequently with any vaccination.

VA Determinations on Anthrax Vaccination, Botulinum Toxoid Vaccination and Multiple Vaccination

Although the NAS report provided evidence of an association between anthrax vaccination, botulinum toxoid vaccination and multiple vaccinations and transient acute local and systemic effects as are typically associated with vaccinations, these effects represent the

body's normal, short-term reaction to introduction of the beneficial vaccines. For this reason, the Secretary has concluded that these acute effects were not in the nature of an illness within the contemplation of the governing statute. Accordingly, the Secretary has concluded that such effects failed to meet the standards for establishment of presumptive service-connection based on anthrax vaccination, botulinum toxoid vaccination or multiple vaccinations.

NAS indicated that there are no reliable reports of chronic toxicity related to anthrax vaccination, botulinum toxoid vaccination or multiple vaccinations in clinical or military populations. NAS concluded that there was inadequate/insufficient evidence to determine whether an association does or does not exist between these vaccinations and long-term adverse health effects. We are not aware of any other reports of chronic toxicity related to these vaccinations in clinical or military populations. For these reasons, the Secretary has determined that the credible evidence against an association between long-term adverse health effects and these vaccinations outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

VIII. Conclusion

NAS reviewed published scientific and medical articles published, and issued the report entitled ''Gulf War and Health, Volume 1. Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines.'' In the judgment of the Secretary, the comprehensive review and evaluation of the available literature which NAS conducted in conjunction with its report permitted VA to determine whether a presumption of service connection should be established for any illness suffered by Gulf War veterans based on exposure to depleted uranium, sarin, PB, and certain vaccines. For the foregoing reasons, the Secretary has concluded that the establishment of a presumption of service connection is not warranted.

Approved: June 12, 2001.

Anthony J. Principi,

Secretary of Veterans Affairs.

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