

September 26, 2006

James Salsman
353 Aldean Avenue
Mountain View, California 94043

SUBJECT: July 12, 2006, Requests for Action Under 10 CFR 2.206

Dear Mr. Salsman:

Your petition, dated July 12, 2006, [Accession Number ML062140659 in the Agencywide Documents Access and Management System (ADAMS)], addressed to Luis A. Reyes, was referred to the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards, pursuant to 10 CFR 2.206 of the Commission's regulations. You supplemented your petition with the following:

Email or teleconference	Date	Time	ADAMS Accession Number
Email	08/05/06	07:21 p.m.	ML062480408
Teleconference	08/07/06	01:15 p.m.	ML062430614
Email	08/07/06	02:04 p.m.	ML062480420
Email	08/09/06	08:11 p.m.	ML062480426
Teleconference	08/10/06	01:00 p.m.	ML062430630
Email	08/11/06	08:44 p.m.	ML062480451
Email	08/15/06	04:52 p.m.	ML062490082
Email	08/15/06	05:05 p.m.	ML062490083
Email	08/17/06	05:28 p.m.	ML062490090
Email	08/17/06	05:35 p.m.	ML062490096

After considering the petition request, and information provided in your e-mails and the teleconferences, the Public Review Board (PRB) has determined that your July 12, 2006, request does not meet the criteria for acceptance as a 10 CFR 2.206 petition, and does meet the criteria for rejection as a 10 CFR 2.206 petition, as explained below.

In your petition, you named remedies a, b, c and d, asking for the following actions:

- (a) “. . . that all uranium munitions licenses be explicitly modified to require a good-faith effort to quantify the dates, times, locations, quantities, and types of pyrophoric uranium munitions use, along with an estimation of the kinds of targets involved, and also

provide any available information which might further specify the amounts, locations, times, and results of pyrophoric uranium munitions use;

(b) . . . that those licenses be explicitly modified to require the licensees to determine the amount of uranyl oxide gas produced in pyrophoric uranium munitions combustion in air under typical and observed use conditions;

(c) . . . that those licenses be explicitly modified to require the licensees to determine the extent of both reproductive and developmental toxicity from typical uranium combustion product inhalation in at least five diverse species of mammals (e.g., chimpanzee, pig, sheep, rabbit, mouse) using chromosome aberration analysis of lymphocytes and gonocytes in statistically significant numbers of exposed and control animals; and,

(d) . . . that those licenses be explicitly modified to require the licensees to publish their estimates and determinations from the license modifications specified in remedies (a), (b), and (c) above, and provide for the independent verification of all such studies' aspects, through the use of anonymous bidding of contracts for replication and auditing of data gathering and analysis, and also requiring that both initial and validating studies be published in the peer-reviewed medical or scientific literature."

You also asked, ". . . for any further corrective action as deemed by the Commission, such as financial penalties requested in my petition of 3 April, 2005, as amended."

As the basis for your request, you stated that, ". . . the gross negligence on the part of the licensees, in, among other things, failing to ever measure the gaseous products of uranium combustion and thereby failing to establish the correct toxicological profile of uranium combustion product exposure." In addition, you stated that ". . . empirical measurement of the amount of UO₃ gas produced by uranium combustion is necessary for determining the proper medical response to uranium combustion product exposure." Your letter states that this is because, ". . . urine isotope ratio studies which depend on detecting uranium from slowly dissolving uranium oxide particles do not necessarily indicate uranium combustion product inhalation exposure or the extent of uranyl poisoning . . ." while explaining that, in addition, ". . . karyotyping measurements of chromosome aberrations will proportionately reflect uranyl exposure, in addition to other genetic damage." Finally, you stated as a basis for remedy:

"Because of the substantial reproductive harm caused by uranyl poisoning, it is clear on the face of the allegations that a result materially different from the issuance of the existing licenses would have been likely had uranium trioxide vapor emission from uranium munitions been considered upon the initial applications for the licenses allowing them."

You discussed your petition with the PRB in a telephone conference on August 7, 2006. The PRB considered the information provided in the telephone conference in determining whether the petition meets the criteria for consideration under 10 CFR 2.206. The PRB's initial recommendation was to reject your requests for review under 10 CFR 2.206. After being informed of the PRB's initial recommendation, you were offered a second meeting with the PRB to provide any additional relevant information and explanation to support your request for the PRB's consideration before making its final recommendation on the treatment of your request. The second meeting with the PRB, via teleconference, was held on August 10, 2006.

Transcripts of the two teleconference meetings are located in ADAMS at Accession Numbers ML062430614 and ML062430630.

Rejection of your requests for review in the Section 2.206 process does not preclude consideration of your concerns by NRC. Your requests constitute a generic concern about the nature and magnitude of safety hazards associated with inhaled gaseous combustion byproducts of depleted uranium (DU) munitions. To the extent that your concerns pertain to adequacy of Commission regulations concerning licensed use of DU munitions, your concerns will be treated as part of the petition for rulemaking initiated by your request, PRM-20-26, 70 *Fed. Reg.* 34699-347001 (June 15, 2005), and will be addressed in the petition for rulemaking.

To the extent your concerns pertain to the safety of inhaled gaseous uranium trioxide (UO₃) combustion products of DU munitions in combat use, your requests are rejected for review under 10 CFR 2.206. Contrary to 10 CFR Section 2.206(a), you have not set forth facts that constitute a basis for the petition with respect to safety concerns about combat use of DU munitions. Specifically, to the extent that your requests pertain to combat or foreign use of DU munitions, the petition is rejected because NRC has no authority to regulate combat or foreign use of such radioactive materials. The scope of NRC's regulatory authority over radioactive materials is prescribed by statute. NRC has not been granted statutory authority to regulate all uses of all radioactive materials. NRC has no statutory authority to regulate combat or foreign use of DU munitions, just as NRC has no statutory authority to regulate combat or foreign uses of radioactive materials such as nuclear weapons and nuclear-powered submarines. In addition, this issue was subject to NRC staff review and evaluation, for which a resolution was achieved; it is located in the December 30, 2005, Director's Decision DD-05-08 (ML053460450), and can also be found in *In the Matter of Department of the Army, et al.* (DD-05-8), 62 NRC 866 (2005), 883-884. To the extent your current request is a request for reconsidering DD-05-08, it will not be treated as a 10 CFR 2.206 petition because it does not present significant new information, meaning that your current request provided no information that could change the conclusions of DD-05-08. However, the Department of Defense (DOD) Explosive Safety Board establishes policy for providing protection from damaging effects of DOD military munitions, and the Office of the Secretary of Defense, Health Affairs, addresses DU medical testing of the military during and after deployment and combat operations.

NRC does have statutory authority under the Atomic Energy Act of 1954, as amended, to regulate the manufacture, fabrication, receipt, possession, transfer, and testing of DU munitions, and has issued licenses to do so. Those NRC licenses require the licensee to conduct surveys and monitor DU munitions and to test DU munitions under controlled conditions, to protect individuals from exposure to the combustion byproducts of DU munitions, and to take measures to prevent exposures under accident conditions.

Requests (a) and (b):

With respect to your requests made in (a) and (b), to require licensees to quantify their pyrophoric uranium munitions use, to determine the amount of uranyl gases produced in licensed uses, and to describe their licensed use of pyrophoric munitions, the PRB has determined that requests (a) and (b) do not meet the criteria for acceptance and do meet the criteria for rejection for review as a Section 2.206 petition for the following reasons:

(1) Requests (a) and (b) do not meet the criteria for acceptance:

- You have not specified facts that constitute a basis for your requests or which are sufficient to warrant further inquiry. You set forth no facts to indicate that license conditions to prevent exposures are inadequate, nor to indicate that the licenses have violated NRC license conditions to prevent exposures to combustion byproducts, NRC limits, or other NRC requirements. Your stated basis that licensees have been grossly negligent in failing to measure uranyl oxide gas combustion products of DU munitions, and in failing to establish the correct toxicological profile of uranium combustion product exposures, presumes an NRC requirement to do so. However, there is no NRC requirement to measure uranyl oxide gas combustion products.
- Your concerns about the safety of licensed use and resulting release of UO_3 are being reviewed in an NRC petition for rulemaking, PRM-20-26. This proceeding is available in which you are a participant and through which your concerns about the adequacy of NRC limits for UO_3 , with respect to reproductive and developmental toxicity, and whether measurement of exposure by use of urine samples reveals the full extent of exposure to inhaled UO_3 , could be addressed.

(2) Requests (a) and (b) meet the criteria for rejection:

- Requests (a) and (b) of your July 12, 2006, e-mail are similar to the request made in your April 3, 2005, petition. The requests (a) and (b) are a combination and rephrasing of Item 1 of the petition summary [In the Matter of Department of the Army, et al. (DD -05-8), 62 NRC 866 (2005), 868] and your proposed first two amendments to the April 3, 2005, petition that you submitted on October 19, 2005, which provided comments on the proposed Director's Decision DD-05-08 [*In the Matter of Department of the Army, et al.* (DD -05-8), 62 NRC 866 (2005), 882]. To the extent that your requests (a) and (b) are the same as your previous requests, requests (a) and (b) have been subject to NRC staff review and evaluation for which a resolution has been achieved in Director's Decision DD-05-08. *In the Matter of Department of the Army, et al.*, (DD-05-8), 62 NRC 866 (2005), 874-875 and 882-883. To the extent this request is a request to reconsider Director's Decision DD-05-08, it will not be treated as a 10 CFR 2.206 petition because it does not present significant new information, meaning that your current request provided no information that could change the conclusions of DD-05-08.
- Requests (a) and (b) are based on claimed deficiencies in existing NRC rules. You assert that NRC limits on UO_3 exposure are inadequate in that they do not adequately consider developmental and reproductive toxicity, that measurement of exposure by use of urine samples does not reveal the full extent of exposure to inhaled UO_3 and whether exposure to inhaled UO_3 complies with NRC limits and that if NRC had considered reproductive harm caused by uranyl poisoning, NRC would have taken different action on DU munitions license applications. Your concerns about licensed use of DU munitions, resulting in release of gaseous uranium products, are being addressed in a proceeding to which you are a participant, an NRC petition for rulemaking, PRM-20-26.

Request (c):

- With respect to your request (c), that NRC modify DU munitions licenses to require a determination of the extent to which reproductive and developmental toxicity for uranium combustion product inhalation in five species of mammals, using chromosome aberration analysis of lymphocytes and gonocytes in statistically significant numbers, the PRB has determined that request (c) does not meet the criteria for acceptance and does meet the criteria for rejection for review as a 10 CFR 2.206 petition for the following reasons:

(1) Request (c) does not meet the criteria for acceptance:

- You have not specified facts that constitute a basis for your requests and which are sufficient to warrant further inquiry. You set forth no facts to indicate that license conditions to prevent exposures are inadequate, that the licensees have violated NRC license conditions to prevent exposures to combustion byproducts, or that licensees have violated NRC limits or other NRC requirements. Your stated basis, that the licensees' failure to measure UO_3 gaseous combustion products of DU munitions and failure to develop a correct toxicological profile of uranium combustion products is "gross negligence," presumes requirements to do so, but there are no NRC requirements to measure UO_3 gaseous combustion products or to develop a toxicological profile.
- Your concerns about the safety of licensed use resulting in release of gaseous UO_3 are being addressed in PRM-20-26. This proceeding is available in which you are a participant, and through which your concerns about the adequacy of NRC limits for UO_3 with respect to reproductive and developmental toxicity, and whether measurement of exposure by use of urine samples reveals the full extent of exposure to inhaled UO_3 , could be addressed.

(2) Request (c) meets the criteria for rejection:

- Request (c) of your July 12, 2006, letter is similar to the request made in your April 3, 2005, petition. Request (c) is a combination and rephrasing of Item 6 of the petition summary [In the Matter of Department of the Army, et al., (DD-05-8), 62 NRC 866 (2005), 869]] and your proposed second amendment to the April 3, 2005, petition that you submitted on October 19, 2005, which provided comments on the proposed Director's Decision DD-05-08 [In the Matter of Department of the Army, et al., (DD-05-8), 62 NRC 866 (2005), 882].
- To the extent request (c) is the same as your 2005 request, it has been the subject of NRC staff review and evaluation for which a resolution has been achieved in Director's Decision DD-05-08 [*In the Matter of Department of the Army, et al.*, (DD -05-8), 62 NRC 866, 880-881 and 882-883 (2005)]. To the extent request (c) is a request to reconsider DD-05-08, it will not be treated as a 10 CFR 2.206 petition because it does not present significant new information, meaning that no information was provided, which could change the conclusions of DD-05-08.
- Request (c) is based on claimed deficiencies in existing NRC rules. You assert that NRC limits on UO_3 exposure are inadequate in that they do not adequately consider developmental and reproductive toxicity, that measurement of exposure by use of urine samples does not reveal whether exposure to inhaled UO_3 complies with NRC limits, and that if NRC had considered reproductive harm caused by uranyl poisoning, NRC would have taken different action on DU munitions license applications.

Request (d):

- With respect to your request (d), to modify DU munitions licenses, to require licensees to publish, in the peer-reviewed literature, information collected pursuant to requests (a) through (c), independent verification of studies, and validating studies, the PRB has determined that request (d) cannot be accepted for review as a 10 CFR 2.206 petition because requests (a) through (c) were not accepted and were rejected for review as 10 CFR 2.206 petition.
- Your claim that Margaret Ryan of the United States Navy made a deliberate inaccurate statement in the peer-reviewed scientific literature, in violation of NRC requirements and 18 USC 1001, does not constitute a basis for requests (a) through (d) or your request for civil penalties. Margaret Ryan wrote, along with coauthors Patricia Doyle and Noreen Maconochie:

“Two surveys stand out as being particularly large: one from the USA (Kang et al. 2001) and the other from the UK (Doyle et al. 2004). Both reported some evidence of a modest increase in risk of birth defect for male veterans’ offspring born after the war, although cautious interpretations were offered because of concern about reporting bias.”

This statement appeared in a journal article, titled, “Reproductive Health of Gulf War Veterans,” in the Philosophical Transactions of the Royal Society B.¹ You contend that the use of the term “moderate increase” is imprecise and is usually not used with a doubling of effects mentioned in a 2001 article by Dr. Kang et al.² No violation of NRC rules or of Section 186 of the Atomic Energy Act was identified for several reasons. The statement was not made to NRC. The statement is an opinion on a technical matter and not a statement of fact. The statement is not material in that Margaret Ryan’s mere opinion that the risk is “moderate” is not capable of influencing an agency decision. In addition, no violation of 18 USC 1001 was identified. Even if Margaret Ryan’s statement was “within the jurisdiction of . . . the Government of the United States,” within the meaning of 18 USC 1001, the statement is an opinion on a technical matter and not a statement of fact, and is not material in that Margaret Ryan’s mere opinion that the risk is “moderate” is not capable of influencing an agency decision.

The PRB has determined that your request for civil penalties against DU munitions licensees does not meet the criteria for acceptance for review as a Section 2.206 petition because you have not specified facts that constitute a basis for your request for civil penalties. NRC authority under Section 234 of the AEA is limited to issuance of civil penalties for violations of NRC requirements, but you have identified no violations of NRC requirements, as explained above.

¹Philosophical Transactions of the Royal Society B (2006) 361, 571-584, doi:10.1098/rstb.2006.1817, published online 24 March 2006

²“2001 Pregnancy Outcomes among US Gulf War Veterans: a Population-based Survey fo 30,000 Veterans,” Annals of Epidemiology, 11, 504-511. [doi:10.1016/S1047-2797(01)00245-9]

For all the reasons herein above, the NRC PRB has determined that your July 12, 2006, request does not meet the criteria for acceptance and does meet the criteria for rejection for review as a 10 CFR 2.206 petition.

Currently, staff is reviewing generic issues raised by your 10 CFR 2.206 petition, in your related 10 CFR 2.802 petition for rulemaking, PRM-20-26, which concerns the adequacy of existing NRC regulations pertaining to limits for ingestion and inhalation occupational values, effluent concentrations, and releases to the environment, for all heavy-metal radionuclides with non-radiological chemical toxicity hazards -- particularly for uranium oxides.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Thank you for bringing these issues to NRC's attention.

Sincerely,

/RA/

Charles L. Miller, Director
Division of Industrial
and Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: Departments of the Army,
Navy, and Air Force
ATK Tactical Systems Co., LLC

For all the reasons herein above, the NRC PRB has determined that your July 12, 2006, request does not meet the criteria for acceptance and does meet the criteria for rejection for review as a 10 CFR 2.206 petition.

Currently, staff is reviewing generic issues raised by your 10 CFR 2.206 petition, in your related 10 CFR 2.802 petition for rulemaking, PRM-20-26, which concerns the adequacy of existing NRC regulations pertaining to limits for ingestion and inhalation occupational values, effluent concentrations, and releases to the environment, for all heavy-metal radionuclides with non-radiological chemical toxicity hazards -- particularly for uranium oxides.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Thank you for bringing these issues to NRC's attention.

Sincerely,

/RA/

Charles L. Miller, Director
Division of Industrial
and Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: Departments of the Army,
Navy, and Air Force
ATK Tactical Systems Co., LLC

Distribution: G20060666
IMNS r/f NMSS r/f MRodger NMSSOd

ML062640210

OFC	MSIB	Editor	MSIB	MSIB	INMS
NAME	JDeCicco	Ekraus _{fax}	T Harris	T Essig	C Miller
DATE	09/15/06	09/18/06	09/21/06	09/ 22 /06	09/ 26 /06

OFFICIAL RECORD COPY