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Fielding, Fred - General Files

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Office of Special Counsel Reports & Scott Bloch Issues [5]

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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
001	Report	Analysis of Disclosures, Agency Investigation and Reports...	6	N.D.	P6/b6; b7c;
002	Report	Analysis of Disclosures, Agency Investigation and Reports...	6	08/18/2008	P6/b6; b7c;
003	Letter	OSC File No. DI-07-3067 - To: POTUS - From: Scott Bloch	2	08/07/2008	P6/b6; b7c;
004	Letter	OSC File No. DI-07-3067 - To: POTUS - From: Scott Bloch	2	08/07/2008	P6/b6; b7c;
005	Letter	OSC File No. DI-07-3067 - To: Henry Paulson - From: Scott Bloch	3	11/27/2007	P6/b6; b7c;

COLLECTION TITLE:
Counsel's Office, White House

SERIES:
Fielding, Fred - General Files

FOLDER TITLE:
Office of Special Counsel Reports & Scott Bloch Issues [5]

FRC ID:
11293

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
006	Letter	OSC File No. DI-07-3067	1	N.D.	P6/b6; b7c;
007	Letter	[Letter]	4	07/09/2008	P6/b6; b7c;
008	Report	OSC Report on Analysis of Disclosure, Agency Report...	54	08/04/2008	P6/b6; b7c;

COLLECTION TITLE:
Counsel's Office, White House

SERIES:
Fielding, Fred - General Files

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Bakke, Mary Beth

From: Smith, John M.
Sent: Thursday, September 04, 2008 2:24 PM
To: Bossert, Thomas P.
Cc: Tysarczyk, Eric J.; Fielding, Fred F.; Bakke, Mary Beth
Subject: FW: pumping equipment in New Orleans

Attachments: Scann001.PDF

Scann001.PDF (206 KB)

NOT DOJ!

Tom,

Please see attached follow-up letter from DOJ's OSC to the President.

-----Original Message-----
From: Bakke, Mary Beth
Sent: Thursday, September 04, 2008 2:18 PM
To: Smith, John M.
Subject: OSC: pumping equipment in New Orleans

Please see attached.
MB

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

John Smith
9-4-08

August 28, 2008

The Honorable Fred F. Fielding
Counsel to the President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-2724

Dear Mr. Fielding:

I am transmitting the enclosed letter to the President concerning the above-referenced case regarding the pumping equipment in New Orleans. If I may provide more information concerning this matter, please do not hesitate to contact me.

Sincerely,

Scott J. Bloch

Enclosures

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

www.osc.gov

The Special Counsel

August 28, 2008

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-2724

Dear Mr. President:

On August 4, 2008, I informed you by letter that the report to me regarding the New Orleans flood protection system submitted by the Department of Defense (DoD) did not appear to be reasonable within the meaning of 5 U.S.C. § 1213(e)(3). In 2007, U.S. Army Corps of Engineers (USACE) civil engineer Maria E. Garzino disclosed serious allegations to my office concerning the pumping equipment manufactured and installed in New Orleans by a contractor, Moving Water Industries, and the related lack of proper government oversight and contract management.[1] In sum, Ms. Garzino alleged that the pumping equipment was defective and largely untested.

On May 14, 2008, in response to my September 21, 2007, referral, then DoD Inspector General Claude M. Kicklighter substantiated several of Ms. Garzino's allegations. However, the DoD report concluded that "... these deficiencies were performance-related shortcomings that did not rise to the level of a serious violation of law or regulation, abuse of authority or gross mismanagement. Nor did they result in a gross waste of funds or a danger to public health or safety."

As you know, after reviewing the report, I informed you, the Honorable Carl Levin, Chairman of the Senate Committee on the Armed Services, the Honorable Ike Skelton, Chairman of the House Armed Services Committee, and the Honorable Gordon S. Heddell, Acting DoD Inspector General, that the agency report appeared superficial and dismissive. In Ms. Garzino's substantial and detailed comments, she concluded that the DoD report was devoid of engineering and mathematical interpretation with severely flawed and erroneous conclusions representing, in her words, a "whitewash."

On August 8, 2008, shortly after receiving my letter, Acting Inspector General Heddell notified me that he strongly agreed "... that every effort must be made to assure the citizens of New Orleans that pumps designed for flood protection will perform as specified during hurricanes." Consequently, Acting Inspector General Heddell directed his office to determine

[1] Ms. Garzino has worked as a DoD employee for approximately 17 years, including ten years as a USACE engineer. From March 2006 to September 2006, Ms. Garzino was detailed to USACE New Orleans District, and served as Team Leader of Pumping Systems Installation.

whether the pumps were, in fact, adequately tested and to evaluate the likelihood that the pumps could be vulnerable to failure in the event of a hurricane. A copy of Acting Inspector General Heddell's letter is enclosed for your review.

I am encouraged by the prompt response of Acting Inspector General Heddell to engage his organization to ensure that the pumps will perform when needed in order to provide flood protection to the people of New Orleans. Given that Hurricane Gustav is presenting a threat to the Gulf Coast, it is imperative that DoD continue to take steps to ensure the public health and safety of the citizens of New Orleans. Therefore, as a result of DoD's encouraging response, I have reopened the above-referenced case. Acting Inspector General Heddell has pledged to keep me informed regarding his progress and to provide me with the results of his agency findings. In turn, I am determined to provide ongoing oversight of DoD's progress and findings, and will continue to keep you and members of Congress informed about these important safety and management issues.

Respectfully,

Scott J. Bloch

Enclosure

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

The Honorable Scott J. Bloch
Special Counsel, U.S. Office of Special Counsel
1730 M. Street, N.W., Suite 300
Washington, D.C. 20036-4505

AUG 8 2008

Re: OSC File No. DI-07-2724

Dear Mr. Bloch:

Thank you for sharing with me your letter of August 4, 2008, to the President in regard to the Department of Defense Inspector General (DoD IG) report of May 14, 2008. I strongly agree that every effort must be made to assure the citizens of New Orleans that pumps designed for flood protection will perform as specified during hurricanes.

Having recently been designated as the Acting Inspector General for the Department of Defense, I have carefully reviewed the history of this issue. Based upon my review, and the need for public confidence in New Orleans' flood protection system, I have concluded that an outside opinion is warranted.

Accordingly, I have directed that my office immediately begin the process to secure a contractual arrangement with a professional engineering company to determine whether the pumps in question were, in fact, adequately tested; and to evaluate the likelihood that the pumps could be vulnerable to failure in the event of a hurricane.

I will keep you advised regarding my progress and will provide you the results of the findings. If you have any questions, please contact me at (703) 604-8300.

Sincerely,

Gordon S. Heddell

Gordon H. Heddell
Acting

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 18, 2008

The Honorable Fred F. Fielding
Counsel to the President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-1725

Dear Mr. Fielding:

Pursuant to 5 U.S.C. § 1213(e)(3), I am transmitting the enclosed letter and reports to the President. If I may provide more information concerning this matter, please do not hesitate to contact me.

Sincerely,

Scott J. Bloch

Enclosure

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 18, 2008

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-1725

Dear Mr. President:

I received disclosures from a whistleblower employed at the Department of Veterans Affairs (VA), New Mexico VA Healthcare System (the Hospital), Albuquerque, New Mexico. The whistleblower alleged that a research physician directed researchers to cross the U.S. border into Mexico and Canada to obtain and smuggle blood products into the U.S. for use in research at the Hospital. In addition, the whistleblower alleged that researchers also obtained blood products for research from needles discarded in the blood draw lab.

I required the Honorable R. James Nicholson, then Secretary of Veterans Affairs, to conduct an investigation into the whistleblower's disclosures pursuant to 5 U.S.C. § 1213(c) and (d). The Secretary directed the VA Office of Inspector General (OIG) to investigate this matter. On December 12, 2007, the Honorable Gordon H. Mansfield, Acting Secretary of Veterans Affairs, forwarded to OSC a two-page report summarizing the OIG investigation and findings. Upon follow-up with the VA Office of General Counsel (OGC) and OIG, OSC was advised that a comprehensive, 18-page report detailing the investigation methodology, findings, recommendations, and agency comments had been published on the VA website. OSC obtained a copy of the comprehensive report from the agency's website.

As discussed in the attached Analysis of Disclosures, the agency investigation substantiated the allegation that researchers transported blood samples obtained in two research protocols across the Mexican border into the United States without the appropriate U.S. Customs declarations and without the approval of the VA's Institutional Review Board (IRB). The investigation did not substantiate the allegation that researchers obtained and transported blood samples to the U.S. from Canada. Further, the investigation did not substantiate the allegation that researchers obtained blood specimens from discarded needles in the Hospital lab.

Upon OSC's review of the published report, we requested additional information regarding the status of the agency's implementation of recommendations made by OIG, and whether the agency had taken or intended to take any administrative or disciplinary action against the research physician in charge of the two protocols. On June 3, 2008, OGC provided a supplemental "status update" regarding the implementation of the recommendations. The

supplemental report did not, however, provide any information in response to our inquiry regarding administrative or disciplinary action taken by the agency, and OGC has not responded to further inquiry from OSC regarding this issue. The whistleblower did not provide comments on the agency reports.[1] As required by law, 5 U.S.C. § 1213(e)(3), I am now transmitting the reports to you.

I have reviewed the original disclosures and the agency reports. Based on that review, I have determined that the agency reports contain all of the information required by statute. In addition, I have determined that the agency's findings and its response to the allegations appear to be reasonable, with the exception of disciplinary action, or the lack thereof, taken by the agency. OSC was unable to ascertain whether the agency has, in fact, taken any disciplinary action. In light of the serious nature of the agency's findings of non-compliance with federal and agency-wide requirements and ethical standards for research activities involving human subjects, we believe that disciplinary action is warranted in this case.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency reports to the Chairmen of the Senate and House Committees on Veterans' Affairs. In light of the referral to the U.S. Attorney's Office noted in the two-page summary initially provided to OSC, we will not include the agency reports in OSC's public file, in accordance with 5 U.S.C. § 1219(a). Accordingly, we have closed the matter.

Respectfully,

Scott J. Bloch

Enclosures

[1] The two-page summary forwarded to OSC by the Acting Secretary indicated that the OIG findings were presented to the U.S. Attorney's Office for a decision on whether the acts were criminal and prosecutable. The U. S. Attorney's Office declined prosecution. When a case is referred for possible criminal investigation or prosecution, OSC is not permitted to send the report to the whistleblower for comment. 5 U.S.C. § 1213(f). Thus, OSC did not provide a copy of the two-page summary to the whistleblower. However, the comprehensive report published by the agency on its website and the supplement to that report do not include any reference to potential criminal allegations or referral to the U.S. Attorney's Office. In light of the agency's publication of the report, OSC ensured that the whistleblower received a copy of the published and supplemental reports and was provided an opportunity to comment.

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Report	Analysis of Disclosures, Agency Investigation and Reports...	6	N.D.	P6/b6; b7c;

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COLLECTION:
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SERIES:
Fielding, Fred - General Files

FOLDER TITLE:
Office of Special Counsel Reports & Scott Bloch Issues [5]

FRC ID:
11293

OA Num.:
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NARA Num.:
10382

FOIA ID and Segment:
2014-0441-F
2014-0210-F

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THE SECRETARY OF VETERANS AFFAIRS

WASHINGTON

December 12, 2007

The Honorable Scott J. Bloch
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW - Suite 300
Washington, DC 20036-4505

Dear Mr. Bloch:

This is to advise you that the Department of Veterans Affairs' Office of the Inspector General has concluded its review of the Albuquerque, New Mexico, VA Healthcare System, your file number OSC DI-07-1725. A copy of the findings is enclosed for your convenience.

If you have any questions regarding this matter, please contact Mr. Ken Greenberg, Executive Secretary to the Department, at (202) 273-4869.

Sincerely yours,

Gordon H. Mansfield
Acting

Enclosure

Office of Special Counsel
Referral of Whistleblower Allegations
OSC File # DI-07-1725
OIG MCI # 2007-03025-HI-0366

1. **Summary of the information with respect to which the investigation was initiated.**

   The U. S. Office of Special Counsel (OSC) sent a letter to the Secretary of Veterans Affairs on August 7, 2007, referring a complaint. The Secretary referred the matter to the Office of Inspector General (OIG) on August 8, 2007. The allegations were that a principal investigator (PI) at the New Mexico VA Health Care System (the system) crossed the Mexican and Canadian borders to obtain blood samples for research. The complainant further alleged that researchers obtained blood samples from used needles from the system laboratories. The OIG conducted a review to evaluate the complaint.

2. **A description of the conduct of the investigation.**

   The OIG's Office of Investigations, along with the Office of Healthcare Inspections, conducted an investigation which included an onsite visit from August 27–31, 2007. While onsite, OIG officials inspected 80 rooms in three buildings housing research offices and laboratories, looking for refrigerators that contained blood products. Investigators photographed blood samples found in the PI's laboratory and obtained documents from the laboratory describing the type of testing performed. Nine individuals were interviewed including blood bank officials, phlebotomists, the Compliance Officer, the named PI, and other researchers working on the PI's protocols. Staff examined documentation pertaining to protocols involving the named PI including Institutional Research Board (IRB) files, grant submissions, position descriptions for researchers involved in the PI's studies, and documents pertaining to the PI's accounts at the affiliated nonprofit corporation. This included all source documents for expenditures and travel vouchers. OIG staff reviewed audits performed by nonprofit corporation personnel on protocol consent forms and obtained lists of all subjects enrolled in the PI's protocols. These were compared with documents submitted to the IRB listing the number of subjects recruited for each protocol involving the PI. Investigators conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

3. **A summary of any evidence obtained from the investigation.**

Although a person may ship a biological product into the United States for investigational *in vitro* diagnostic use only (21 C.F.R. § 312.60), these specimens must be declared to United States Customs officials and certain labeling is required. Investigators substantiated that researchers transported blood samples obtained in two protocols across the Mexican border into the United States without the appropriate Customs Declarations and without IRB approval. During interviews, OIG staff was told that on one occasion, United States Customs officials questioned the researchers about the containers of blood samples. Researchers were allowed to cross into the United States, but subsequently received a telephone call from the Food and Drug Administration (FDA) advising them to discontinue the practice. Information obtained from interviews varied as to whether this practice continued after the phone call from the FDA. Investigators were told that at some point, researchers began using international kits for shipping the blood which were accompanied by the appropriate Customs Declaration. The findings were presented to the U.S. Attorney's Office for a decision on whether the acts were criminal and prosecutable, and the Assistant United States Attorney declined prosecution of the case. OIG investigators did not substantiate the allegation that researchers obtained blood samples from Canada and transported the specimens across the border. Investigators also did not substantiate that researchers obtained blood specimens from used needles.

4. **A listing of any violation or apparent violation of any law, rule, or regulation.**

We found evidence of violations of (1) Veterans Health Administration (VHA) Handbook 1200.5 – *Requirements for the Protection of Human Subjects in Research*, (2) VHA Directive 2000-043 – *Banking of Human Research Subjects' Specimens*, and (3) 21 C.F.R. § 312.60.

5. **A description of any action taken or planned as a result of the investigation.**

VA OIG recommendations with respect to the allegations were that management:

- Suspend the two reviewed research protocols pending the implementation of corrective actions;
- Verify that subjects recruited for both protocols met criteria for the studies, make all verification documents available, and notify journals publishing any data from either protocol of this finding; and
- Ensure all research protocols that conduct activities internationally have IRB and Office of Research and Development approval, and comply with Federal regulations.

Veterans Health Administration officials concurred with the OIG recommendations and have taken action to implement them.

Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Importation of Blood Products for Research Purposes
New Mexico VA Health Care System
Albuquerque, New Mexico

Report No. 07-03025-32

November 30, 2007

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Call the OIG Hotline – (800) 488-8244

Executive Summary

The VA Office of Inspector General (OIG) reviewed allegations that a principal investigator (PI) at the New Mexico VA Health Care System (the system) crossed the Mexican and Canadian borders to obtain blood samples for research. Additionally, the complainant alleged that researchers obtained blood samples from used needles. The OIG conducted a review to determine the validity of the allegations.

We substantiated that researchers transported blood samples obtained in two protocols across the Mexican border into the United States without the appropriate Customs Declarations and without Institutional Review Board (IRB) approval. We did not substantiate the allegation that researchers obtained blood samples from Canada and transported the specimens across the border. We also did not substantiate that researchers obtained blood specimens from used needles.

During the review, we identified several compliance issues in both protocols. The concerns consisted of the use of an unlicensed physician to conduct certain diagnostic interviews and to draw blood without disclosing this to the IRB; irregularities in the de-identification of the informed consent documents; unavailability of medical records for some subjects to support pre-existing diagnoses qualifying the subjects for the study; failure to obtain approval from either the IRB or the Office of Research and Development (ORD) for conducting research activities internationally; and the use of a tissue bank not approved by the VA.

Therefore, we recommended that management suspend the two protocols pending the implementation of corrective actions which included verifying that subjects recruited for both protocols met criteria for the studies, making all verification documents available to the OIG, and notifying the journals publishing any data from either protocol of this finding; and auditing all active protocols of the named PI to ensure compliance with human subjects' protections policies and regulations.

We also recommended that management ensure all unlicensed physicians engaged in research activities have a scope of practice and are in compliance; ensure research protocols that conduct activities internationally have appropriate IRB and ORD approval, and comply with Federal regulations; comply with Veterans Health Administration Handbook 1200.1, *The Research and Development Committee Handbook*; and comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Veterans Integrated Service Network (10N18)

SUBJECT: Healthcare Inspection – Importation of Blood Products for Research Purposes, New Mexico VA Health Care System, Albuquerque, New Mexico

Purpose

The VA Office of Inspector General (OIG) received an anonymous complaint with allegations that a principal investigator (PI) at the New Mexico VA Health Care System (the system) crossed the Mexican and Canadian borders to obtain blood samples for research. The complainant further alleged that researchers obtained blood samples from used needles from the system laboratories. The OIG conducted a review to evaluate the complaint.

Background

The system is a Level 1 tertiary referral center, located in Albuquerque, NM, which is authorized to operate 310 beds. It is one of seven medical centers located in Veterans Integrated Service Network (VISN) 18. The system maintains an active research program involving human subjects, which conducts both biomedical research and social science research. Research studies follow specific plans for implementation known as protocols. Biomedical protocols focus on medical drugs or devices, health prevention or promotion, therapeutic interventions, Phase I oncology trials, and bench research. Social science research is more descriptive, frequently utilizing questionnaires and interviews. Each protocol may involve multiple researchers (known as investigators), but each must have one PI who maintains ultimate responsibility for the protection of human subjects enrolled in the protocol. In research protocols conducted at more than one site, each site must have a PI.

Research protocols conducted at VA medical centers or by VA investigators must be approved by both an Institutional Review Board (IRB) and by the Research and Development (R&D) Committee. In multi-center trials, the IRB and R&D Committee at

each involved site must separately approve the protocol. In this case, the system utilizes the affiliate IRB at the University of New Mexico, and in accordance with VA policy, maintains its own R&D Committee.

Special protections are in place for research involving the banking or collection of human research subjects' specimens, including genetic studies. Veterans Health Administration (VHA) Directive 2000-043, *Banking of Human Research Subjects' Specimens*, November 6, 2000, states: "It is imperative that human research subjects donating the specimens receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject." This directive also requires that any projects collecting or storing human biological tissue specimens utilize VA-sponsored tissue banks.

Further, while a person may ship a biological product for investigational *in vitro*[1] diagnostic use only (21 C.F.R. 312.60) into the United States, these specimens must be declared to customs officials and certain labeling is required. Human body fluid specimens of 7 to 15 milliliters require labeling with an appropriate descriptive name of the product, a statement of intended use, and a statement that the specimen is negative for human immunodeficiency or Hepatitis B or that it was not tested for these diseases by a Food and Drug Administration (FDA) approved test.

The OIG received an anonymous complaint that alleged that a PI directed researchers at the system to cross the border into Mexico to obtain blood and transport the blood back across the border. The complainant further alleged that researchers went to the laboratory at the system to obtain used needles containing small blood samples and used these samples in research.

Methodology

To investigate the allegations, we conducted a site visit from August 27–31, 2007, at the system. While onsite, we inspected 80 rooms in three buildings housing research offices and laboratories, looking for refrigerators that contained blood products. We photographed blood samples found in the PI's laboratory and obtained documents from the laboratory describing the type of testing performed. Nine individuals were interviewed, including blood bank officials, phlebotomists, the Compliance Officer, the named PI, and other researchers working on the PI's protocols.

We examined documentation pertaining to protocols involving the named PI, including IRB files, grant submissions, position descriptions for researchers involved in the PI's studies, and documents pertaining to the PI's accounts at the affiliated nonprofit corporation. This included all source documents for expenditures and travel vouchers.

[1] *In vitro*, is Latin for "in glass," meaning in an artificial environment such as a test tube; the opposite of *in vivo*, meaning inside the body.

We reviewed audits performed by nonprofit corporation personnel on protocol consent forms and obtained lists of all subjects enrolled in the PI's protocols. These were compared with documents submitted to the IRB listing the number of subjects recruited for each protocol involving the PI.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Results

We substantiated that blood samples obtained in two protocols (hereafter Protocol 1 and Protocol 2) were transported across the border into the United States from Mexico. However, we did not find that commercial blood products were imported for research purposes. Our inspection of 80 laboratories and offices revealed 35 refrigerators in research areas or offices. Two refrigerators contained blood products. One laboratory refrigerator contained tools for blood analysis, and one refrigerator contained five bags of plasma for a documented research study. The plasma did not originate from Mexico, nor did our inspection disclose the existence of any other commercial blood products which appeared to originate from Mexico.

Additionally, the complainant alleged that researchers obtained blood products and samples from Canada, which were transported across the border for use in research. We could not substantiate this allegation. Expense vouchers submitted to the nonprofit organization did not reveal trips to a Canadian location for research related purposes. No supplies for obtaining blood samples were purchased, and no receipts for international transportation of specimens or supplies from Canada were declared in expense reports reviewed by investigators. The complainant provided us with no documentation in support of this allegation. No one we interviewed admitted to traveling to or conducting research in Canada. Therefore, we did not substantiate this allegation.

However, we did find irregularities in the recruitment process, verification of inclusion criteria, informed consent de-identification, and the credentialing and privileging of research personnel involved in the two protocols reviewed. Finally, we note that both protocols involved the banking of tissue specimens from human subjects at an offsite tissue bank not approved by VA for use in these particular protocols.

Protocol 1

Protocol 1 involved the recruitment of Latino families for purposes of identifying genetic tendencies towards a certain illness. The study was Federally funded, with the system acting as a subcontractor to a designated non-VA site. As a multi-center trial, the study involved three other cities in the United States and two research centers in Mexico. The protocol required each human subject enrolled to give a blood sample and a licensed physician to conduct certain diagnostic interviews of the subjects. All of these activities

would be conducted over a 2 to 3 day period. The samples would then be stored in a tissue bank and used by other researchers to study certain disorders. VHA's Office of Research and Development (ORD) had not approved the importation of blood specimens from other countries for either protocol.

The protocol in no way referenced veterans, nor did it disclose system researchers would conduct any research activities outside the United States. VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research*, permits non-veterans to be enrolled in VA-approved research studies only when there are insufficient veterans to complete the study. While this protocol was designed to include family members, which would necessarily include non-veterans, families without any veteran members were also recruited.

The PI submitted an application to the IRB for full review of Protocol 1 on November 26, 2003. This application stated that researchers would recruit subjects through clinical referral, advertisement, and medical record review. It further indicated that "[a]ctivities associated with our portion of this study will be conducted at the Albuquerque VA. It is possible that some interviews and blood draws may have to be conducted at patient homes if they are unable to travel to Albuquerque." Subjects would be paid a total of $125 for two interviews and a blood draw. The application to the R&D Committee at the system stated that a specialist physician would perform the interviews. The IRB approved the protocol on January 5, 2004. The IRB's file contained no documentation that the PI or system investigators would be collecting blood samples outside the United States.

The PI requested that the IRB close the study on December 7, 2005. As of the date of study closure, system researchers had enrolled a total of 46 subjects. In reviewing the PI's files, we found 46 consent forms and data on 50 individuals. Eleven of the consent forms had the same date. On at least nine occasions, interview summary documents recorded the interviews occurred in Juarez, Mexico. A travel voucher dated January 16, 2005, was submitted for reimbursement to the nonprofit corporation "for taking the government car into Juarez . . . to see a subject for the Latino Genetics study."

The interviews were conducted by a social worker and an unlicensed physician, not by a specialist physician as was stated in submissions to both the IRB and R&D Committee. Further, the IRB was informed that only one individual, who was a Certified Laboratory Phlebotomist, would draw blood for the study. That individual did not accompany the researchers to Juarez, Mexico. The unlicensed physician drew blood samples for the research in Juarez. No IRB documents we reviewed disclosed that anyone other than the named phlebotomist would obtain blood specimens from the subjects.

In all nine cases in which documents recorded that interviews were conducted in Juarez, it was also noted that medical records were not available for the subjects. IRB submissions, however, stated that individuals with a previous diagnosis of a certain

disease would be recruited. We found no evidence in the PI's files that documented a previous diagnosis of any disease state for the enrolled individuals. Because medical records were unavailable for these patients, we do not know how the PI determined that these individuals had any medical diagnosis prior to enrollment in the study, nor were we able to independently verify that the subjects recruited met inclusion and exclusion criteria.

Research notes support that blood samples were obtained at the time of the subject interviews. Through our interviews with research personnel, we established that, on several occasions, the blood was transported back into the United States by placing it in a vehicle that was then driven across the border. Research personnel told us they did not declare the blood samples to United States Customs officials. Documents submitted to the IRB for this study did not disclose that blood specimens would be transported from Mexico into the United States by investigators under the authority of the system IRB. The IRB submissions we reviewed did not reference international subject recruitment by system researchers.

Protocol 2

The second protocol (Protocol 2) received IRB approval on June 20, 2005. It involved essentially the same process of interviewing subjects and obtaining blood samples for genetic analysis. The only difference was that it focused on a different disorder. The IRB initially approved recruitment of subjects through clinical referral, advertisement, and medical record review. Also, we were told that subjects were recruited by obtaining identifying information from an organization providing services for patients with a specific disorder. We found documentation that an employee of the an advocacy organization for that disorder received payments of around $600 per month for "discussing design, risks and potential benefits with area clergymen, medical staff and health care workers." Each family member participating in the study would receive a total of $125. The per capita income of Mexico is $7,870; in the United States, it is $26,036. A payment of $125 [in dollars] in Mexico is equivalent to roughly $413 in the United States, as a percentage of per capita income. VHA Handbook 1200.5 requires prospective investigators in their proposal to "substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the perspective research subjects . . . ."

On April 20, 2007, the PI submitted a progress report to the IRB, which stated that they recruited subjects through oral presentations at various advocacy and health institutions. There was no reference to individuals being recruited through their clergy. The progress report disclosed that 54 subjects had been recruited for the study. Under the number of subjects recruited at local sites excluding the system but under the authority of the institution's IRB, the PI entered not applicable. We were given no documents suggesting that the IRB knew of or approved the recruitment of subjects from Mexico by investigators under their authority.

We requested all informed consent documents signed by the subjects for this protocol. The study coordinator informed us that the principal site of the research required that copies of the informed consent documents be sent to them; the coordinator also said the site requested that the informed consent documents be de-identified. We examined 37 consent forms in detail, noting that 15 had the names obliterated to the point that identifying information could not be discerned from the consent form. Only one of the consent forms recorded the subject ID number on it; the others were located with documents that recorded subject ID numbers. The remaining 22 consent forms did have identifying information on them. The PI informed the IRB that researchers at other sites would not have access to personal identifiers of the subjects. Specifically, he stated that the "identifiers will be kept at the VA and will never be sent to . . . [the primary research site]." No one we interviewed could explain why some consent forms were de-identified and others were not. However, we were informed that copies of all consent forms had been sent to the primary site for the study.

IRB documents submitted by the PI for Protocol 2 stated that interviews could be conducted at subject's homes if they were unable to travel to the system. On January 14, 2007, one researcher listed Juarez, Mexico, as a destination with use of a Government vehicle. The researcher also submitted a travel voucher including a hotel stay in Juarez, Mexico, as recently as April 14, 2007. On May 19, 2007, and June 3, 2007, a researcher rented a car and obtained approval to take the car into Mexico. These expenses were submitted for reimbursement as part of two separate trips for the purposes of interviewing subjects for Protocol 2. During the trip on May 19, 2007, the researcher submitted a reimbursement request for supplies for obtaining blood samples.

We interviewed the individual submitting this travel voucher. He admitted that he and two other researchers involved in the protocol would go into Juarez to interview subjects at their homes. He estimated that a total of 20 such samples were obtained on different occasions. We received conflicting interview testimony from other individuals concerning the number of times this occurred. There was no dispute, however, that blood was collected in Mexico and subsequently transported in the researchers' vehicle across the border into El Paso. From El Paso, the blood samples were shipped to the institution testing and banking the specimens. This tissue bank was not approved by VA for use in this protocol.

During interviews, we were told that on one occasion, United States Customs officials questioned the researchers about the containers of blood samples. They were allowed to cross into the United States, but subsequently received a telephone call from the FDA advising them to discontinue the practice. Information obtained from interviews varied as to whether this practice continued after the phone call from the FDA. We were told that at some point, researchers began using international kits for shipping the blood; these kits were accompanied by an appropriate customs declaration. Documents submitted to the IRB did not disclose research activities would be conducted outside the United States.

Finally, the complainant also alleged that researchers obtained used laboratory supplies and blood samples from the system's laboratory after hours for use in research. We did not substantiate this allegation. Expense vouchers submitted to the nonprofit organization revealed researchers purchased supplies for obtaining blood samples and traveled to the subject location to obtain those samples. The complainant provided us with no documentation in support of this allegation. No one we interviewed admitted to utilizing any used laboratory materials for research purposes. We therefore did not substantiate this allegation.

Additional Deficiencies Identified in the Compliance Program

Because of the deficiencies identified in this report, we chose to examine the system's compliance program to determine whether the system identified problems prior to our site visit. Under system policy, the Research Compliance Officer (RCO) is a member of the R&D Committee and is responsible for developing and continually reviewing policies and procedures for the Human Research Protection Program to ensure compliance with current regulations. The RCO works in a dual capacity, which allows two-thirds of the position's time to the compliance and business integrity officer role and one-third of the position's time to the RCO role.

System policies state that audits of medical records, research protocols, consent forms and like documents will be conducted by the Research Service to evaluate the facility's compliance with National Committee for Quality Assurance Accreditation standards, in addition to all applicable Federal rules and regulations. The RCO, in conjunction with the Research Service must develop an audit plan and schedule. The policy further states that periodic compliance audits will be conducted to ensure adherence to Research Compliance Program requirements and to assist in the reduction of identified problem areas. Audit and monitoring results would be submitted to the system Compliance Steering Committee.

Despite this policy, we find that a dedicated RCO for Research Services did not exist at the time of our review. Without this position, the system could not ensure that research conducted met compliance standards. The system Compliance Officer had not audited any protocols during an 8-month tenure and did not believe that such audits were a responsibility of the current position or of the predecessor. Further, the system Monitoring & Auditing Plan for fiscal year 2007 did not include a plan for the Research Service. Without an annual plan for monitoring and auditing, Research Service compliance with regulations cannot be assured.

The nonprofit agency pays for a position (classified as without compensation on VA rolls) in Research Service that is utilized to conduct audits of research protocols. However, a review of all audits conducted in calendar year 2006–2007 revealed only one quarterly audit of two consent forms without deficiencies for Protocol 2 and none for

Protocol 1. Protocol 2 contained 54 subjects. We found no evidence that any other aspects of the study were reviewed. Based on the limitations of the audit for this protocol, investigators cannot be assured that quarterly audits conducted in Research Service accurately reflect a state of compliance with VHA and Federal regulations.

Conclusions and Recommendations

While not substantiating that researchers used blood specimens obtained improperly from used needles for research purposes, we did find that researchers at the system transported blood specimens across the border between the United States and Mexico without the appropriate Customs Declarations and without IRB approval. We further identified numerous compliance issues in the two protocols reviewed, including the use of an unlicensed physician to conduct certain diagnostic interviews and to draw blood without disclosing this to the IRB; irregularities in the de-identification of the informed consent documents; unavailability of medical records for some subjects to support pre-existing diagnoses qualifying the subjects for the study; and failure to obtain approval from either the IRB or the ORD for conducting research activities internationally. Finally, the use of a tissue bank not approved by the VA for this protocol did not comport with VHA policies and procedures. Weaknesses identified in the compliance program prevented the system from identifying many of these issues prior to our review.

In addition to violations of regulations, policies and procedures, we further found payments made to subjects in Juarez and the use of clergy to assist in recruitment of subjects raised significant ethical questions in the conduct of these two protocols. The IRB had approved a sum of money for subject participation on the understanding that system researchers were conducting their activities, including subject recruitment, within the United States. The IRB had not determined whether $125, equivalent to $413 in the United States as a percentage of per capita income, might be viewed as a coercive sum of money in Juarez, Mexico. Further, given the special influence clergy may have over parishioners and the fact that this particular recruitment method was not disclosed to the IRB, we believe that the ethics of such an arrangement may be questionable.

We therefore made the following recommendations:

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications

resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook.*

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Comments

The VISN and System Directors agreed with the findings and recommendations and generally provided acceptable improvement plans. (See Appendixes A and B, pages 11–18, for the full text of comments.) With regard to Recommendation 7, while they did not provide a research audit plan, along with a timeline for conducting regular audits and reporting findings as required by local policy, we will follow up on all planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 15, 2007

From: VISN Director (10N18)

Subject: **Review of Research Activities, New Mexico VA Health Care System, Albuquerque, New Mexico**

To: Director, Dallas Healthcare Inspections Division (54DA)

Thru: Director, Management Review Office (10B5)

I concur with the findings from the OIG review of research activities and with the actions plans developed by the New Mexico VAHCS. If you have any questions, please contact my Executive Assistant, Joan Funckes, at 602-222-2692.

Patricia A. McKlem

VISN Director's Comments to Office of Inspector General's Report

The following VISN Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Concur **Target Completion Date:** Completed

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Concur **Target Completion Date:** 11/30/2007

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Concur **Target Completion Date:** Completed

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Concur **Target Completion Date:** Completed

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Concur **Target Completion Date:** 2/15/2008

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook.*

Concur **Target Completion Date:** 1/31/2008

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Concur **Target Completion Date:** 1/31/2008

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 11, 2007

From: Director, New Mexico VA Health Care System (501/00)

Subject: **Review of Research Activities, New Mexico VA Health Care System, Albuquerque, New Mexico**

To:

I concur with the findings from the OIG research activities review. Attached are responses with action plans as appropriate for each recommendation.

GEORGE MARNELL

System Director's Comments to Office of Inspector General's Report

The following System Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Concur **Target Completion Date:** Completed

Protocol 2 has been suspended by the IRB (Human Research Protection Committee-HRRC). After an extensive audit of Protocol 2, the IRB withdrew approval for Protocol 2 and required that all research activities for this study cease on September 18, 2007. In a letter to the investigator dated September 19, 2007 - "Notification of Termination of HRRC Approval" referring to Protocol 2, the IRB determined that the violations discovered during the IRB audit of Protocol 2 met the definition of continuing non-compliance and were therefore to be reported to the Office of Human Research Protections (OHRP) and the sponsor NIH (which has already occurred). The IRB also determined that, due to multiple violations and the inability to distinguish which subjects may have been recruited inappropriately, all data collected by the VA Albuquerque site, including blood specimens sent to the NIH repository, could not be used and were to be destroyed immediately. Verification that this has occurred is pending within 60 days of the termination letter.

Protocol 1 was closed December 8, 2005 with no activity on this study after this date. An IRB audit of this study was recently completed and will be presented to the same IRB subcommittee which reviewed the audit and made the recommendations for termination of Protocol 2. This will occur on October 16, 2007.

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Concur **Target Completion Date:** 11/30/2007

The IRB audit of Protocol 2 could not clearly identify whether inclusion or exclusion criteria were met for all subjects. This was one reason why the IRB terminated Protocol 2 and has requested that all data and blood specimens be destroyed immediately along with notification of the OHRP and the NIH. An extensive IRB audit of Protocol 1 has already been completed and will be presented to the IRB on October 16, 2007. Similar concerns regarding inclusion and exclusion criteria for subjects in Protocol 1 exist. Speaking to the PI, and performing a Medline search has not identified any published reports from these studies to date. As mentioned, the IRB has requested that all data and blood samples from Protocol 2 be destroyed. This study is ongoing so it is likely that the research data from our site can be removed prior to publication of results from the larger study. The NMVAHCS research office in conjunction with the IRB will request assistance from the NIH identifying any pending publications which may include data from Protocols 1 and 2 acquired from our site. If such publications are identified, the NMVAHCS research office in conjunction with the IRB will notify the appropriate journals of the findings.

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Concur **Target Completion Date:** Completed

There are currently no unlicensed physicians performing research in the NMVAHCS. Effective September 4, 2007 the Associate Chief of Staff, Research Service for the NMVAHCS began reviewing and initialing off on the position descriptions for all facility personnel engaged in research activities to ensure that they meet current requirements for scopes of practice of unlicensed research personnel. In the case of an unlicensed physician, a scope of practice will be written, reviewed, and approved by the ACOS for Research, the Chief of Staff and the Director.

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Concur **Target Completion Date:** Completed

A review of current active protocols completed by 10/5/07 shows that there are currently no international research projects. Any future projects involving international research will have ORD and IRB approval, and comply with Federal regulations. As noted in the OIG report and our IRB audits, Protocol 1 and Protocol 2 were not approved for international research. The development of a more rigorous research audit plan as outlined in the response to Recommendation 7 below should help insure that future non-compliance in the conduct of international studies will be avoided.

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Concur **Target Completion Date:** 2/15/2008

The research program of the named PI is undergoing review by our IRB. Audits are currently underway on selected studies of the PI at the direction of the IRB. Additionally the PI has been required by the IRB to conduct self audits on all studies prior to receiving continuing approval to conduct research. Selected results of these self audits will be spot checked by the IRB. This investigator has 20 active studies. Audits on all of the investigator's studies will need additional time to complete so a deadline of 2/15/2008 is set to meet this recommendation.

Status? Admin action on PI?

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook.*

Concur **Target Completion Date:** 1/31/2008

The R&D Committee adopted the guidelines in the revised VHA Handbook 1200.1 at the April 12, 2007 meeting of the R&D Committee. A site visit by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is scheduled for November 19, 2007, as part of the VA Research accreditation process, and our facility will receive feedback concerning our program. At our R&D Committee meeting scheduled for October 11, 2007, a subcommittee was appointed to review the issues of research non-compliance in Protocols 1 and 2. It is expected that recommendations from this subcommittee will serve to strengthen research quality assurance at our facility and help to ensure compliance with VHA Handbook 1200.1.

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Concur **Target Completion Date:** 1/30/2008

Audits will be performed that are in compliance with Medical Center Memorandum 151-9 and appropriately documented.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Andrea Buck, M.D., J.D., Medical Consultant (202) 565-8496
Acknowledgments	Linda DeLong, Director Karen Moore, Associate Director Richard Cady, Investigator Roxanna Osegueda, Program Analyst

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DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

In Reply Refer To:

June 3, 2008

U.S. Office of the Special Counsel
Ms. Jennifer Pennington
1730 M Street, NW
Suite 300
Washington, D.C. 20036

Dear Ms. Pennington:

Attached is the Status Report on the Inspector General's recommendations regarding certain research programs in the New Mexico VA Healthcare System (Report No. 07-03025-32). Should you have any questions, please contact Susan Blauert at 202.461.4910.

Sincerely,

Walter A. Hall

HEALTHCARE INSPECTION, IMPORTATION OF BLOOD PRODUCTS FOR RESEARCH PURPOSES NEW MEXICO VA HEATH CARE SYSTEM, ALBUQUERQUE, NM –Report No. 07-03025-32

STATUS UPDATE

1. Following an anonymous tip, VA's Office of Inspector General (OIG) reviewed allegations that a principal investigator (PI) with the New Mexico VA Health Care System (NMVAHCS) improperly imported of blood products for research purposes. OIG substantiated that researchers transported blood samples obtained in two protocols across the Mexican border into the United States without the appropriate Customs Declarations and without Institutional Review Board (IRB) approval. In addition, OIG identified several other compliance issues in both protocols. These findings were published on November 30, 2007. The report also made seven recommendations to the VISN Director regarding these protocols. Below is an update on the status of the recommendations.

2. Recommendation 2: OIG recommended that the VISN verify that subjects recruited for both protocols identified in the report met the inclusion and exclusion criteria for the studies. The studies in question were reviewed by the NMVAHCS IRB Human Research Review Committee (HRRC) at the University of New Mexico. The HRRC terminated the study "Genetics of Bipolar Disorder in Latino populations" due to continuing non-compliance and directed the specimens and data resulting from the study be destroyed. The study "Genetics of Schizophrenia in Latino populations" had already been closed but the HRRC concluded that it met the definition of serious non-compliance and ordered the subject data and records de-identified. In addition, HRRC directed that all blood samples that were collected and sent to the NIH repository be withdrawn and destroyed. The PI appealed these HRRC decisions. With respect to the 'Bipolar' study, HRRC ultimately allowed use of data and specimens from subjects appropriately recruited in NM. The remaining data fell under the initial ruling. HRRC upheld its earlier ruling regarding the 'Schizophrenia' study. That data was de-identified. The destruction of samples from both studies is currently being implemented. No publications have resulted from the data or specimens collected.

3. Recommendation 5: OIG recommended an audit of all of the named PI's active protocols to ensure compliance with applicable human subjects protections policies and regulations. Audits of the PI's active protocols are complete. There was no evidence of serious non-compliance. Some relatively minor issues were identified and corrective action was taken.

4. Recommendation 6: OIG recommended that the VISN require that research quality assurance comply with VHA Handbook 1200.1. The system's Research Compliance Officer developed an audit template to address compliance with the handbook policies. A subsequent audit of Research Services found that they were

in compliance with Handbook 1200.1. On March 14, 2008, the NMVAHSC Human Subjects Research Protection Program received full accreditation from the Association for Accreditation of Human Research Programs (AAHRP).

5. Recommendation 7: OIG recommended that the VISN comply with Medical Center Memorandum 151-9 in establishing a research audit plan. A comprehensive standard operating procedure for audits was developed by the NMVAHCS's Research and Development Committee and Research Compliance Officer.

6. Other recommendations: Recommendations 1, 3, and 4 were closed on February 29, 2008.

Coffman
Farrew

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

FACSIMILE COVER SHEET

TO:

Name: The Honorable Fred Fielding	
Title: Counsel to the President	
Organization: The White House	
Office / Location: Washington, D.C.	
Telephone: (202) 456-2632	**Fax:** (202) 456-6279

FROM:

Name: Scott J. Bloch	
Organization: Office of Special Counsel	
Office / Location: Washington, D.C.	
Telephone: (202) 254-3601	**Fax:** (202) 653-5151

Date: August 18, 2008	**Number of pages, including this cover sheet: 9**

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U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 18, 2008

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-1725

Dear Mr. President:

I received disclosures from a whistleblower employed at the Department of Veterans Affairs (VA), New Mexico VA Healthcare System (the Hospital), Albuquerque, New Mexico. The whistleblower alleged that a research physician directed researchers to cross the U.S. border into Mexico and Canada to obtain and smuggle blood products into the U.S. for use in research at the Hospital. In addition, the whistleblower alleged that researchers also obtained blood products for research from needles discarded in the blood draw lab.

I required the Honorable R. James Nicholson, then Secretary of Veterans Affairs, to conduct an investigation into the whistleblower's disclosures pursuant to 5 U.S.C. § 1213(c) and (d). The Secretary directed the VA Office of Inspector General (OIG) to investigate this matter. On December 12, 2007, the Honorable Gordon H. Mansfield, Acting Secretary of Veterans Affairs, forwarded to OSC a two-page report summarizing the OIG investigation and findings. Upon follow-up with the VA Office of General Counsel (OGC) and OIG, OSC was advised that a comprehensive, 18-page report detailing the investigation methodology, findings, recommendations, and agency comments had been published on the VA website. OSC obtained a copy of the comprehensive report from the agency's website.

As discussed in the attached Analysis of Disclosures, the agency investigation substantiated the allegation that researchers transported blood samples obtained in two research protocols across the Mexican border into the United States without the appropriate U.S. Customs declarations and without the approval of the VA's Institutional Review Board (IRB). The investigation did not substantiate the allegation that researchers obtained and transported blood samples to the U.S. from Canada. Further, the investigation did not substantiate the allegation that researchers obtained blood specimens from discarded needles in the Hospital lab.

Upon OSC's review of the published report, we requested additional information regarding the status of the agency's implementation of recommendations made by OIG, and whether the agency had taken or intended to take any administrative or disciplinary action against the research physician in charge of the two protocols. On June 3, 2008, OGC provided a supplemental "status update" regarding the implementation of the recommendations. The

supplemental report did not, however, provide any information in response to our inquiry regarding administrative or disciplinary action taken by the agency, and OGC has not responded to further inquiry from OSC regarding this issue. The whistleblower did not provide comments on the agency reports.[1] As required by law, 5 U.S.C. § 1213(e)(3), I am now transmitting the reports to you.

I have reviewed the original disclosures and the agency reports. Based on that review, I have determined that the agency reports contain all of the information required by statute. In addition, I have determined that the agency's findings and its response to the allegations appear to be reasonable, with the exception of disciplinary action, or the lack thereof, taken by the agency. OSC was unable to ascertain whether the agency has, in fact, taken any disciplinary action. In light of the serious nature of the agency's findings of non-compliance with federal and agency-wide requirements and ethical standards for research activities involving human subjects, we believe that disciplinary action is warranted in this case.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency reports to the Chairmen of the Senate and House Committees on Veterans' Affairs. In light of the referral to the U.S. Attorney's Office noted in the two-page summary initially provided to OSC, we will not include the agency reports in OSC's public file, in accordance with 5 U.S.C. § 1219(a). Accordingly, we have closed the matter.

Respectfully,

Scott J. Bloch

Enclosures

[1] The two-page summary forwarded to OSC by the Acting Secretary indicated that the OIG findings were presented to the U.S. Attorney's Office for a decision on whether the acts were criminal and prosecutable. The U. S. Attorney's Office declined prosecution. When a case is referred for possible criminal investigation or prosecution, OSC is not permitted to send the report to the whistleblower for comment. 5 U.S.C. § 1213(f). Thus, OSC did not provide a copy of the two-page summary to the whistleblower. However, the comprehensive report published by the agency on its website and the supplement to that report do not include any reference to potential criminal allegations or referral to the U.S. Attorney's Office. In light of the agency's publication of the report, OSC ensured that the whistleblower received a copy of the published and supplemental reports and was provided an opportunity to comment.

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Report	Analysis of Disclosures, Agency Investigation and Reports...	6	08/18/2008	P6/b6; b7c;

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COLLECTION:
Counsel's Office, White House

SERIES:
Fielding, Fred - General Files

FOLDER TITLE:
Office of Special Counsel Reports & Scott Bloch Issues [5]

FRC ID:
11293

OA Num.:
10820

NARA Num.:
10382

FOIA ID and Segment:
2014-0441-F
2014-0210-F

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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Document Originally
Attached to
Following Page

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

FACSIMILE COVER SHEET

TO:

Name: The Honorable Fred F. Fielding	
Title: Counsel to the President	
Organization: The White House	
Telephone:	**Fax:** (202) 456-6279

FROM:

Name: The Honorable Scott J. Bloch	
Organization: U.S. Office of Special Counsel	
Office / Location:	
Telephone:	**Fax:**

Date: August 7, 2008	**Number of pages, including this cover sheet:** 4

Message: If you have problems with this transmission, please contact Ed Flood at (202) 254-3622.

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U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 7, 2008

The Honorable Fred F. Fielding
Counsel to the President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-3067

Dear Mr. Fielding:

Pursuant to 5 U.S.C. § 1213(e)(3), I am transmitting the enclosed letter, report and whistleblower's comments to the President. If I may provide more information concerning this matter, please do not hesitate to contact me.

Sincerely,

Scott J. Bloch

Enclosures

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Washington, D.C. 20036-4505

The Special Counsel

August 7, 2008

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Counsel to the President
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Washington, D.C. 20500

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Scott J. Bloch

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DEPARTMENT OF THE TREASURY
WASHINGTON, D.C.

ASSISTANT SECRETARY

JUN - 2 2008

The Honorable Scott J. Bloch
The Special Counsel
U.S. Office of Special Counsel
1730 M St, N.W., Suite 300
Washington, DC 20036-4505

Dear Mr. Bloch:

In response to your letter dated November 27, 2007, attached is the completed Report of Investigation for OSC File DI-07-3067.

The Environment, Safety, and Health Division at the Headquarters of the Department of Treasury conducted an investigation into the allegations referred to us by your office. Based on the evidence discovered during the investigation at the Bureau of Engraving and Printing, these allegations have been found to be unsubstantiated.

Pursuant to Treasury Order 101-05, I have the authority to sign on behalf of the Department regarding this matter. My point of contact for this matter is Stephen Wallace, Environment, Safety, and Health Director at (202) 622-1712 or Stephen.Wallace@do.treas.gov, please contact him if you have any questions.

Sincerely,

Peter B. McCarthy
Assistant Secretary for Management
and Chief Financial Officer
Department of the Treasury

REPORT ON INVESTIGATION OF

OSC File No. DI-07-3067

Executive Summary

By letter dated November 27, 2007, the Office of Special Counsel (OSC) referred allegations of safety violations at the Bureau of Engraving and Printing to the Secretary of the Treasury and requested an investigation and report to the OSC. Specifically the allegations are:

(1) BEP supervisors instruct employees to improperly use manlifts without ground support in violation of safety regulations, and
(2) BEP employees and/or contractors store and mix various toxic chemicals and cleaning supplies in an unventilated room.

The Environment, Safety, and Health Division in the Headquarters Operations at the Department of the Treasury conducted an investigation by interviewing witnesses, touring the facility, researching and reviewing regulatory and best practice documents, and reviewing emails and other internal communications.

An analysis of the data collected resulted in a conclusion that both allegations were unsubstantiated.

Table of Contents

SECTION I: INTRODUCTION

A. Description of Allegations

By letter, dated November 27, 2007 (Attachment 1), the Office of Special Counsel (OSC) referred allegations of safety violations to the Secretary of Treasury that the OSC determined required an investigation and the submission of a report. The allegations were brought forth by a Bureau of Engraving and Printing (BEP) employee, (hereafter referred to as the "complainant"), and claim that safety violations involving the use of rolling scaffolds, (hereafter referred to as "manlifts"), and the storage and mixing of chemicals at the BEP, a bureau of the Department of the Treasury.

Specifically the two allegations are:

> (1) BEP supervisors instruct employees to improperly use the manlifts without ground support.
> (2) BEP employees and/or contractors store and mix various toxic chemicals and cleaning supplies in an unventilated room.

B. Scope of Authority

By letter dated November 27, 2007, Special Counsel Scott Bloch referred to Treasury Secretary Paulson allegations of unsafe work practices at the Bureau of Engraving and Printing. Pursuant to 5 U.S.C. § 1213, Mr. Bloch requested that Treasury investigate the allegations and submit a report to the OSC on the findings. The matter was initially referred to the BEP. After consultation with Treasury Headquarters, the matter was then referred to the Office of the Inspector General (OIG). The OIG analyzed the allegations, researched the applicable laws, and concluded that the Department's Environment, Safety, and Health Division in Departmental Offices Operations (hereafter referred to as the ESHD) should conduct the investigation. Following the OIG's recommendation, the matter was subsequently assigned to the Office of the Assistant Secretary of Management/CFO, and tasked to the ESHD. Stephen Wallace, Director of ESHD and Judith Reilly, ESHD Manager, conducted the investigation.

C. Background

Mission at the BEP

The BEP manufactures United States currency, which includes ink making, engraving, plate making, offset printing, intaglio printing, product inspection, packaging, currency storage shipping, and an array of support staff and trades. A small number of specialty documents, such as portions of U.S. passports, immigration and naturalization documents, and Medal of Honor Certificates are also produced at the BEP.

The BEP produces and recycles inks in their in-plant Ink Mill. The BEP maintains a full range of highly skilled trades including Machinists, Plumbers, Painters, Metal Workers,

Electro-machinists and other Allied Crafts that maintain and repair production equipment, as well as perform facility renovations and repair.

Environment, Safety, and Health at the BEP

The Office of Environment, Health, and Safety (OESH) at the BEP develops policy and assists with its implementation. The OESH Chief reports to the Associate Director (Management), who reports to the Director of the BEP. This organizational structure allows objectivity in addressing sensitive issues, access to the Director, and effective implementation innovations. The OESH is staffed with 41 full-time equivalents (17 government employees and 24 contract employees). The Chief serves as the DASHO (Designated Agency Safety, and Health Officer), and BEQO (Bureau Environmental Quality Officer).

Employee involvement in the continuous health and safety improvement process is a valued practice at the BEP. The artisans, craftsmen, and trade employees are critical in developing initiatives to reduce health and safety risks, and to achieving the BEP's strategic goals. The BEP has implemented a number of management systems designed specifically to increase employee involvement including:

- The Joint Occupational Safety, Health, and Environment Committee (JOSHEC): The JOSHEC is comprised equally of labor and management representatives. The group is co-chaired by the DASHO and Vice President of the Joint Labor Council (JLC) and represents 17 unions at the BEP. Subcommittees are formed to address specific issues such as training and management of injuries and illnesses.

- Environmental Management System (EMS): The EMS includes health and safety matters, and complies with ISO 14001 standards. The EMS includes an Executive Team, Implementation Team, and Technical Work Groups (TWGs). With the exception of the Executive Team, all teams include labor representation. Worker involvement is critical to the success of the EMS TWGs. TWGs comprised of employees considered to be subject matter experts include the following:

    - Lead solder elimination.
    - Chromium replacement.
    - Lockout–Tag out.
    - Job Safety Analysis.

SECTION II: INVESTIGATIONAL METHODOLOGY

ESHD conducted its investigation over a five-month period. The investigation included the following:

(1)Interviewing eyewitnesses and knowledgeable personnel to gain insight on the specific allegations and general safety practices.

(2) Touring the facility to observe the mobile manlifts (which the complainant referred to as scaffolds), and the room where employees were allegedly mixing chemicals with improper ventilation.

(3) Extensively researching and reviewing several documents to determine regulatory requirements and best practices, as well as policies and practices at the BEP, and

(4) Reviewing emails and other internal communication that had occurred regarding the allegations.

(1) Interviewing employees

Staff from the ESHD conducted interviews with several BEP employees. Based on the historical documents reviewed, ESHD decided to interview safety staff, the complainant, his supervisor, other employees who do similar work to the complainant so their perspectives could be evaluated, and the BEP staff responsible for the cleaning crew. The Deputy Director of the BEP was also interviewed since she was specifically referenced by the complainant in the OSC letter as a person with knowledge of the allegations. Specific names of interviewees are available upon request from the Office of General Counsel, Department of the Treasury. Interviews were conducted by Stephen Wallace PE, CSP and Judith Reilly CIH, CSP. Interviewees (by position) included:

January 17, 2008	Safety Manager Supervisor, plumbing shop supervisor Safety Specialist
March 4, 2008	Plumber, complainant Plumber # 1 Plumber # 2 Deputy Director of the BEP
March 12, 2008	Contracting Officer's Technical Representative COTR) on the janitorial contract and liaison to the cleaning crew Plumber # 3

(2) Touring the facilities

A walk-through was conducted of the room where the "mixing" of cleaning materials occurs to observe and evaluate the area.

Both models of mobile manlifts were observed and inspected.

(3) Researching and reviewing documents, regulations, and best practices

A. Manufacturer's Recommendations

The Owners Manuals for two different mobile manlifts were reviewed to determine manufacturer's recommendations for using them in conjunction with Allegation #1.

Material Safety Data Sheets (MSDS) for the materials referred to in Allegation #2 were received from the BEP staff and examined for toxicity, as well as personal protective equipment and ventilation requirements and recommendations.

B. Applicable Regulations and Standards

The Department of Treasury is required through the Code of Federal Regulations (CFR) 29 CFR 1960 to comply with the OSHA regulations as they relate to general industry and construction. These are located in 29 CFR 1910 and 1926. The following regulations were reviewed to determine applicability to the allegations:

29CFR 1910.1200 Hazard Communications
29CFR 1910.29 Manually propelled mobile ladder stands and towers
29CFR 1910.178 Powered Industrial Trucks
29CFR 1926.452 Additional requirements applicable to specific types of scaffolds
29CFR 1926.453 Aerial lifts

Both OSHA and the Manufacturers refer to the American National Standards Institute (ANSI) standards and the following ANSI standard was reviewed:

ANSI/SIA A92.3-1990

(4) Reviewing emails

A review of emails dating back to 2004 was conducted. The BEP safety manual which contains policy and procedures was reviewed to determine its applicability to these allegations. Training, inspection, incident records, and shift activity logs dating back to 2004 were also analyzed. The safety video that was shown in 2005 and referenced by the complainant was requested, but could not be located. The ESHD investigation team interviewed personnel who had viewed the safety video to gather their recollections of the information presented.

SECTION III: DATA COLLECTION

INVESTIGATIONAL FINDINGS - ALLEGATION 1:

Allegation: BEP supervisors instruct employees to improperly use manlifts without ground support.

(1) Interviewing employees

January 17, 2008, conducted by Stephen Wallace PE, CSP and Judith Reilly CSP, CIH

Safety Manager, BEP

The Safety Manager gave a historical account of the allegations and safety concerns originating in 2004 over the need for ground support when working at heights. He indicated that there is no regulatory requirement for a second person to be in attendance, but on a case-by-case basis the nature of the work could require assistance and needs to be discussed with the supervisors as the situation arises. He indicated the procedures were discussed and felt that the procedures were fully understood by the plumbers. He also provided a list of names of the personnel most closely involved in this issue.

Supervisor, plumbing shop

The Supervisor indicated that the "manlifts" in question are actually mobile operator lifts, commonly referred to as "manlifts." All models of lifts used at the BEP can be locked down using outriggers so the lift does not move when an operator is performing work from the elevated platform (Figure 1). One of the lifts has a safety switch that prevents the lift from being operated unless the outriggers are down; the older model relies on the operator to put the outriggers down but will operate if they are not engaged. Because of the railing, additional fall protection is not required on this equipment. In general, work is done at about 12 to 15 feet although the equipment will rise to 20 feet. The Supervisor remembers that a safety video was shown, but does not recall if it specified the need for two people. He understands that it is not an OSHA requirement and has communicated that to his staff. He recalls that there was time for questions after the safety video was shown. He has asked his staff to make him aware when additional help is needed or if there is any fear of heights. The Supervisor indicated that he tries to accommodate all requests for additional help.

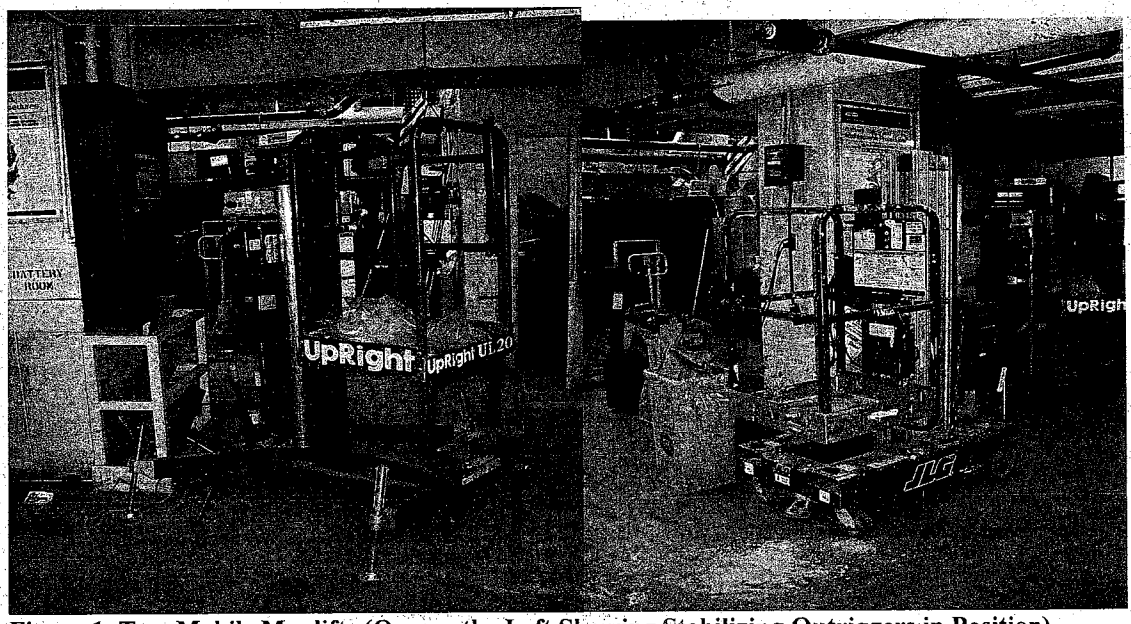

Figure 1. Two Mobile Manlifts (One on the Left Showing Stabilizing Outriggers in Position)

Safety Specialist

The Safety Specialist described how he arranged and showed the safety video. He indicated he remembers two workers in the safety video are shown carrying an extension ladder but indicated that the safety video never said it was a requirement to have a second person at the base. The Safety Specialist indicated that the message was that it may require two people to carry a ladder, but it did not explicitly state or imply that two people are required when the ladder is in use. When questions continued to be raised, the Safety Specialist said he contacted the Occupational Safety and Health Administration (OSHA) for clarification on this issue and was informed that two people are not necessary unless there is some other hazard like a confined space, uneven surface, or inability to secure the equipment. He also communicated to all plumbers the need to communicate with supervisors if there are special circumstances that warrant additional help or if anyone is afraid of heights. Communication during work is usually via radio or phone.

March 4, 2008, conducted by Stephen Wallace PE, CSP and Judith Reilly CSP, CIH

Plumber, Complainant

The complainant noted a concern about employees working at heights without someone on the ground as backup. He used the word "scaffold" and indicated that this term refers to the rolling manlifts used by the plumbers to reach and work at elevated locations. He believes that the safety video applied to ladders and rolling manlifts and did indicate a requirement for two people to be present. He further believes he heard the BEP safety specialist say there was a requirement for two people but that the safety specialist later changed his statement to indicate there was not a need for two people. The complainant believes the ground support would help prevent an accident involving someone passing

by and would assist the worker above in the event of an emergency. He indicated radios are not always used and that no communication exists. He is concerned that the controls in the manlift are in the cage and if something happens to operator, the ground support could use the emergency release to bring him down. The complainant said he does have a problem with heights if working outside, but generally heights are not a problem to him. He believes other plumbers have the same concerns about working at elevations without ground support. After getting no satisfaction in 2004 and 2005, the complainant indicated he went up the chain of command to the Facilities Director. (BEP Safety reported to the Facilities Director in 2006.)

The complainant also said that he remembered training had been conducted on how to safely set up the new mobile manlifts.

Plumber # 1

Plumber # 1 does the same type of work as the complainant. He frequently uses the manlifts and is aware that they must be secured by using the outriggers. He also indicated that sometimes two people are needed to carry a ladder for certain big jobs. He believes two people are preferable but recognizes that this is not needed or required in most cases. He also indicated that whenever he has asked for additional help, the supervisor accommodates the request based on the nature of the hazard and the need.

Plumber # 2

Plumber # 2 is a plumber and does the same type of work as the complainant. He frequently uses the manlifts and is aware that they must be secured by using the outriggers. He indicated that if people work alone, they must be more watchful of their surroundings, but he believes that this is an acceptable risk and that he often works alone. Plumber # 2 indicated that he does get help on a case-by-case basis when the work necessitates a second person but height alone does not warrant that help.

Current Deputy Director of the BEP (formerly the Associate Director for Management - responsible for the Office of Environment, Health, and Safety)

While she was in her role as Facilities Director in December of 2006, the current Deputy Director spoke with the complainant about this issue. The complainant had not been satisfied with the responses he was receiving from the Chief of OEHS and continued up the chain of command to the Director of Facilities. She explained that the complainant mentioned ladders and manlifts and the need for a second person. She further explained that the complainant believed the issue was not being addressed. She contacted the OEHS Chief who assured her that the issue had been addressed many times over the years.

March 12, 2008, conducted by Stephen Wallace PE, CSP

Plumber # 3

Plumber # 3 was sent to the equipment distributor for a train-the-trainer class on the mobile manlifts. He gave a demonstration of this equipment when the equipment was purchased. Everyone was given instructions and a key and told to consult the manufacturer's owner manual for more information. He indicated that there is no manufacturer requirement to have a second person. The manual is kept on the lifts for quick reference. He also indicated that these lifts are meant to be used alone and there is an emergency button to enable the equipment to be lowered if there is a problem. Plumber #3 believes that there is almost always someone in the nearby area. He remembers the safety video that was shown but believes it did not say that two workers were needed.

(2) Touring the facility

A walk-through was done by Mr. Wallace to observe the mobile scaffold (manlifts) in question.

(3) Researching and reviewing documents, regulations, and best practices

A. BEP documents review

In the BEP safety manual, ladders and manlifts are covered in Chapter 17, General Safety and Health practices. In Section 17-3 Walking and Working Surfaces it indicates ladders and manlifts must be secured. There is no requirement for ground support.

A system of construction permits is in place at BEP. A permit is required for "any project involving demolition, major equipment installation or removal, construction, modification, facelifts, or major repair". Permits are signed by the shop representative and a safety representative. In the General Requirements Checklist there is a line item that states, "Scaffolding and ladders must meet OSHA requirements". The checklist requires "yes" or "no" answers.

Training records in the form of sign-in sheets are kept to document shop training.

B. Review of Regulations and guidelines

1. Several OSHA regulations were reviewed for applicability and content and are summarized below:

29CFR 1910.29 Manually propelled mobile ladder stands and towers

This section states "...is intended to prescribe rules and requirements for the design, construction and use of mobile work platforms (including ladder stands but not including aerial ladders) and rolling (mobile) scaffolds (towers)".

There is no reference to the need for a second person or ground support.

29CFR 1910.178 Powered Industrial Trucks

This section states "...contains safety requirements relating to ...use of fork trucks, motorized hand trucks, and other specialized industrial trucks powered by electric motors or internal combustion engines".

This standard does not specifically apply to the mobile manlifts or scaffolds.

29CFR 1926.452 Additional requirements applicable to specific types of scaffolds

Section (w) of this standard covers mobile scaffolds, including construction requirements, power systems, casters and brackets, securing manlifts, and other general use requirements. The standard requires that mobile scaffolds be stabilized to prevent tipping during movement and that platforms not extend beyond the base supports.

There is no requirement in this section for a second person to provide ground support.

29CFR 1926.453 Aerial lifts

Applies to elevating and rotating work platforms and therefore does not apply to the mobile scaffolds.

Discussion with the Occupational Safety and Health Administration

Judith Reilly, ESHD Manager from the Departmental Offices, contacted the local OSHA office for an interpretation and spoke to Mr. David Miller, DC Area Office. Mr. Miller indicated that these manual lifts are not "aerial lifts" although many employees mistakenly categorize them as such. He indicated that that only 29 CFR1910.29 and 1926.452 will apply. He also responded that none of the regulations contain a requirement for ground support or that a second person to be in attendance based solely on the fact that employees are working at heights.

2. The Manufacturer's Owner's Manual

The following Owner's manuals were reviewed:

"Traveler", Model # TV-15/20/25 Snorkel Economy, Inc
UL 20 Series Numbers 17745 to current, Upright, Inc

The lifts have hydraulic motors and controls at the platform level. The owner's manual for the UL 20 states that in the event of an emergency where the lift fails to lower, the

operator is to "ask a person on the ground to open the Emergency Lowering Valve to lower the platform". This same procedure is described for the "Traveler" model but is not as detailed, simply noting to "locate emergency lowering valve on the top of the motor/pump assembly" located at ground level. However, neither manual contains a requirement to have a person in constant attendance at the ground level.

3. ANSI standards

ANSI/SIA A92.3-1990 applies to Manually Propelled Elevating Aerial Platforms. In the standard, ANSI defines "aerial platform" as a manually propelled device that has an adjustable position platform supported from ground level by a structure".

According to Mr. David Miller of OSHA, this ANSI standard applies only to manual platforms that have an articulating arm and move in directions other than simply up and down. The BEP mobile manlifts only moves in a vertical position.

However, though this standard was deemed not applicable to these specific mobile "manlifts", ESHD staff still reviewed it and found that there is no requirement in the ANSI standard to have a second person as ground support.

(4) Reviewing emails

Emails were reviewed from BEP safety staff and the complainant. Below is a summary of the emails reviewed:

Initially the complainant raised a question concerning the general policy at the BEP as it relates to working at elevations on ladders and manlifts, and the policy on allowing for people to work alone at elevations. Over the next few weeks, the complainant and the BEP safety office had an Email dialogue about the manlifts. It was explained to the complainant that the regulations do not require ground support in all instances of elevated work. The complainant asked if BEP could go beyond the regulations and implement a policy that would require support personnel when people were working at elevations. It was explained that policies are in place and listed on the construction permits and in the BEP safety manual and that each task is evaluated on a case-by-case basis to determine if additional assistance is necessary.

INVESTIGATIONAL FINDINGS - ALLEGATION 2

Allegation: BEP employees and/or contractors store and mix various toxic chemicals and cleaning supplies in an unventilated room.

(1) Interviewing employees

Safety Manager, BEP

The Safety Manager indicated that the "chemicals" in question are all cleaning materials and the only "mixing" that takes place is dilution with water. He also stated that the Material Safety Data Sheets (MSDS) and ventilation in the room was reviewed and found to be adequate for the following reasons:

(1) The materials are diluted in a room approximately 25 feet wide, 47 feet long and 12.5 feet high with a volume of approximately 15,000 cubic feet.

(2) There is a garage-size door leading into the room which is always open. (see Figure 2)

(3) In response to a complaint, an assessment of the area was done and indicated that natural ventilation in this room allows fresh air to flow from the adjacent hallway through this entranceway into the area where the cleaning materials are diluted. Measurements taken on January 23, 2008 indicated the air flow into the room to be 1,710 cubic feet per minute (cfm) or 102,600 cf per hour. Given the volume of the room (15,000 ft^3) and the air flow (1,710 cfm), the number of room exchanges is determined to be 6.8 room exchanges/hour.

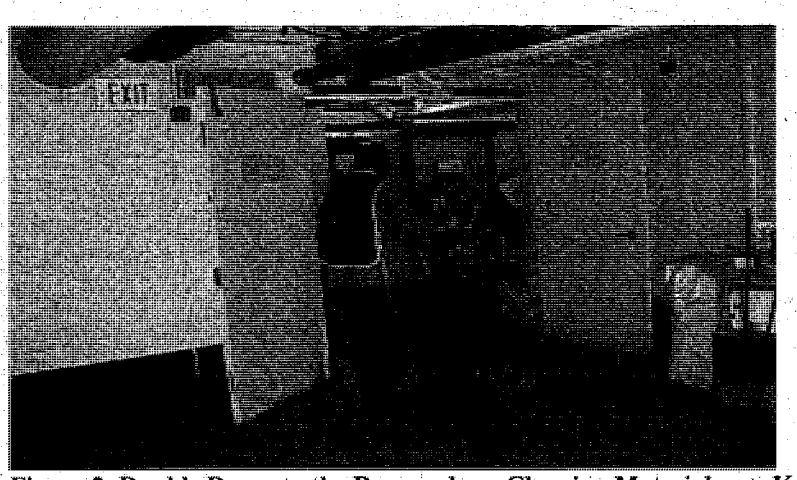

Figure 2. Double Doors to the Room where Cleaning Materials are Kept (Doors are Always Kept Open)

Plumber, complainant

The complainant alleges that he suffered a headache while working in this area putting in a drain line. He does not believe there is adequate room ventilation and on the day in question, he said that he secured fans and put them around the room to move the air. He did not go to the Health Unit, but reported the incident to his supervisor. He stated that the other Plumber with him (Plumber # 2) also got a headache.

Supervisor, plumbing shop

The Supervisor indicated that the materials are cleaning solutions. When the complainant mentioned the incident to him, he directed it to the safety office to do an assessment. (Refer to Safety Manager's interview above for the results of this assessment) No other employees have complained to him about the chemicals.

Plumber # 2

Plumber # 2 was working with the complainant putting in the drain line. He states that there was an odor but he did not get a headache and has no concerns about working in the room.

Plumber # 3

Plumber # 3 indicated that he occasionally works in the area and has smelled the cleaning materials, but they do not bother him.

Contractor's Technical Representative (COTR) for cleaning contract

The COTR for cleaning oversees the contractor who works with the cleaning materials. He has never received any complaints from the Goodwill Industries employees (i.e., the cleaning crew) or any BEP employees. All the materials used are listed as trouble-free low odor. He visits this area frequently and has not smelled any strong odors other than smells associated with cleaning materials. He also felt that the safety office has been responsive to any concerns he has raised.

(2) Touring the facility

A walk-through was done by Mr. Wallace to observe the area where the cleaning materials are diluted. (Figure 3)

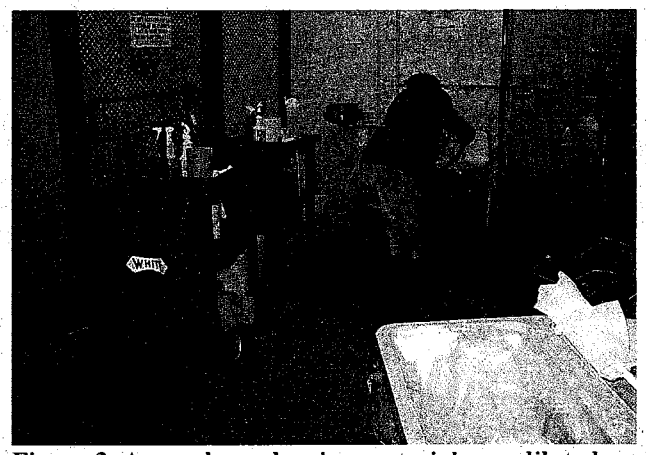

Figure 3. Area where cleaning materials are diluted

(3) Researching and reviewing documents, regulations, and best practices

A. Evening Shift Log

An evening shift log dated July 31, 2006 indicates "there had been an employee complaint regarding irritating vapors inside room 23-3-A". The entry also states that the Recommended Corrective Action was further investigation.

In response to this complaint, the Office of Environment, Health, and Safety (OESH) at BEP evaluated the situation in the room. They determined that the materials were used in accordance with manufacturer instructions and there was enough measured airflow through the room to provide adequate ventilation.

B. Review of Material Safety Data Sheets

The Material Safety Data Sheets were reviewed for the following cleaning materials:

Ajax Disinfectant Crème Cleanser - Lime
Bubblegum Deodorizer
Clorox Bleach Toilet Bowl Cleaner
CI – 153 Carpet Care Products
CI – 128 Carpet Care Products
CI – 211/212 Carpet Care Products
CI – 150 Carpet Care Products
Crystal Simple Green
Elky Pro Water Soluble Deodorant
Elky Pro Defoamer
Elky Pro Hi-Gloss Restorer
Elky Pro Maximum Orange
Elky Pro Kwik Kleen
Elky Pro Super Stripper
Elky Pro Water Soluble Deodorant – Lemon
Elky Pro Water Soluble Deodorant – Herbal
Elky Pro Sea breeze
Gentle Clean
HealthCare Disinfectant
Hesco Cinnamon Dry Air
Mint Surge
Value Plus Mint Surge
Vanish Non-acid bowl and Bathroom Cleaner
Windex Multi-surface Cleaner with Vinegar

The following precautions were observed in the ventilation section on the different MSDS:

- no special precautions
- use in open areas
- use with adequate room ventilation
- general mechanical ventilation.

None of the MSDS required local exhaust ventilation or use in a hood.

C. Review of Regulations

OSHA 29 CFR 1910.1200 Hazard Communication was reviewed. This standard sets requirements for the use of hazardous materials in the workplace. It requires labels and Material Safety Data Sheets which describe the proper storage of chemicals.

(4) Reviewing emails

No emails were identified pertaining to this allegation.

SECTION IV: ANALYSIS

ALLEGATION # 1 ANALYSIS

An email chain in late 2004 addressed the concern for ground support although the complainant did not appear to accept the interpretation of the safety standards as defined by BEP safety management. The BEP Safety Manual requires that employees must secure manlifts with outriggers when they are working on them. When specific circumstances indicate that attendants should be present, the other plumbers said that help is provided. (One instance discussed with the investigation team was a person with diabetes who does not work alone for long periods of time.) The complainant does not accept BEP management's interpretation of the OSHA standards and continues to feel the need for a second person or ground support in all instances.

The equipment in question is covered by OSHA 29 CFR 1910.29 when working in general industry and 29 CFR 1926.452 (w) when working large projects that meet the definition of construction. There is no requirement for ground support or a second person in OSHA regulations. This was covered in an OSHA Standards Interpretation dated 2/23/2000 and discussed with a specialist in OSHA in March 2008.

The manufacturer's owners manual indicates someone on the ground needs to activate the emergency lowering mechanisms if the operator controls fail to lower the device. There is no requirement for a specific ground support person to be a "standby" for this emergency function. A passerby or anyone on the ground working in the area could perform this function. In the interviews conducted it was noted that there are usually other BEP employees working in or around the area where the plumbers work.

The documents reviewed require manlifts to be secured, and this is accomplished. The mobile manlifts are secured through the use of the outriggers in case the scaffold is bumped or rolls out of place while someone is working on the elevated platform.

ALLEGATION # 2 ANALYSES

Commercial cleaning materials are often supplied as concentrates that must be diluted before use. At the BEP, this dilution is referred to as "mixing" by some employees but all mixing of these cleaning materials simply involves the dilution of the concentrate with

water. Many of these concentrates contain a scent to make the cleaning product more appealing. In the concentrated form the scent may be less appealing to some individuals but, based on the Material Safety Data Sheets (MSDS) for the cleaning materials, this does not pose a health hazard.

The MSDS for the cleaning materials indicate "use with adequate ventilation". None of the MSDS required local exhaust ventilation or use in a hood. Based on the low inherent safety and health hazards of these materials reflected in the MSDS and the number of room air exchanges per hour, it was determined that adequate ventilation is in place in the subject area.

SECTION V: CONCLUSION

ALLEGATION # 1

Based on the investigation, the complainant's allegation is not substantiated.

There is no statutory requirement for a second person to be in attendance on the ground level while personnel are working in the mobile manlifts. However, when circumstances indicate that a second person is necessary for a particular job, the BEP will continue to ensure that assistance is available.

ALLEGATION # 2

Based on the investigation, the complainant's allegation is not substantiated.

Based on the assessment of the ventilation requirements listed in the MSDS and on the number of air exchanges in the room per hour, there is adequate ventilation in the area.

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Letter	OSC File No. DI-07-3067 - To: Henry Paulson - From: Scott Bloch	3	11/27/2007	P6/b6; b7c;

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COLLECTION:
Counsel's Office, White House

SERIES:
Fielding, Fred - General Files

FOLDER TITLE:
Office of Special Counsel Reports & Scott Bloch Issues [5]

FRC ID:
11293

OA Num.:
10820

NARA Num.:
10382

FOIA ID and Segment:
2014-0441-F
2014-0210-F

RESTRICTION CODES

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Enclosure

Requirements of 5 U.S.C. § 1213(d)

Any report required under subsection (c) shall be reviewed and signed by the head of the agency[1] and shall include:

(1) a summary of the information with respect to which the investigation was initiated;

(2) a description of the conduct of the investigation;

(3) a summary of any evidence obtained from the investigation;

(4) a listing of any violation or apparent violation of law, rule or regulation; and

(5) a description of any action taken or planned as a result of the investigation, such as:

(A) changes in agency rules, regulations or practices;

(B) the restoration of any aggrieved employee;

(C) disciplinary action against any employee; and

(D) referral to the Attorney General of any evidence of criminal violation.

In addition, we are interested in learning of any dollar savings, or projected savings, and any management initiatives that may result from this review.

[1] Should you decide to delegate authority to another official to review and sign the report, your delegation must be specifically stated.

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Letter	OSC File No. DI-07-3067	1	N.D.	P6/b6; b7c;

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SERIES:
Fielding, Fred - General Files

FOLDER TITLE:
Office of Special Counsel Reports & Scott Bloch Issues [5]

FRC ID:
11293

OA Num.:
10820

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10382

FOIA ID and Segment:
2014-0441-F
2014-0210-F

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Letter	[Letter]	4	07/09/2008	P6/b6; b7c;

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Mr. Fielding cpy

Document Originally
Attached to
Following Page

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

FACSIMILE COVER SHEET

TO:

Name: The Honorable Fred Fielding	
Title: Counsel to the President	
Organization: The White House	
Office / Location: Washington, D.C.	
Telephone: (202) 456-2632	**Fax:** (202) 456-6279

FROM:

Name: Scott J. Bloch	
Organization: Office of Special Counsel	
Office / Location: Washington, D.C.	
Telephone: (202) 254-3601	**Fax:** (202) 653-5151

Date: August 4, 2008	**Number of pages, including this cover sheet:** 59
Message: Original and enclosures to follow by Federal Express delivery	

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1 OF 3

U.S. OFF CE OF SPECIAL COUNSEL
173) M Street, N.W., Suite 300
Wa: hington, D.C. 20036-4505

The Special Counsel

August 4, 2008

The Honorable Fred F. Fielding
Counsel to the President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-07-2724

Dear Mr. Fielding:

Pursuant to 5 U.S.C. § 1213(e)(3), I am transmitting the enclosed letter, report, and comments to the President. If I may provide more information concerning this matter, please do not hesitate to contact me.

Sincerely,

Scott J. Bloch

Enclosures

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 4, 2008

The President
The White House
Washington, DC 20500

Re: OSC File No. DI-07-2724

Dear Mr. President:

The United States Army Corps of Engineers (USACE) serves the Armed Forces and the nation by providing vital engineering services in support of national interests. As part of its mission, USACE has been tasked with providing critical hurricane and flood protection to the recently-devastated city of New Orleans. Maria E. Garzino, USACE Civil Engineer, alleged that USACE employees and Moving Water Industries (MWI) personnel installed defective pumps in New Orleans and circumvented contract requirements related to contract modifications and notifications at the expense of public safety and proper contract oversight.

I required the Honorable Robert Gates, Secretary of Defense, to conduct an investigation into Ms. Garzino's disclosure pursuant to 5 U.S.C. § 1213(c) and (d). Secretary Gates delegated responsibility for investigating Ms. Garzino's allegations to his Inspector General, the Honorable Claude M. Kicklighter, who submitted a report to me. Ms. Garzino also provided comments to the agency report. As required by law, 5 U.S.C. § 1213(e)(3), I am now transmitting the report and the whistleblower's comments to you.

Specifically, Ms. Garzino, who consented to the release of her name, stated that costly pumping equipment at three "outfall gated canal closure structures," which is part of the flood protection design to protect New Orleans, was inherently flawed due to poor pumping and hydraulic system designs; pumping equipment that had previously malfunctioned under favorable contractor testing conditions, and subsequently shown to be defective, was knowingly installed by USACE employees and MWI personnel; and that USACE and MWI employees were responsible for not providing proper oversight of the pumping equipment project which created a substantial and specific danger to public health and safety.

On May 14, 2008, the agency submitted a report in response to Ms. Garzino's disclosures. The report substantiated several of Ms. Garzino's allegations, but ultimately concluded that "... these deficiencies [were] performance related short-comings that did not rise to the level of a serious violation of law or regulation, abuse of authority, or gross mismanagement. Nor did they result in a gross waste of funds or a danger to public health or safety."

Ms. Garzino, however, vigorously disputed the agency's findings and provided OSC with extensive documentary evidence to support her account of events surrounding the design, testing, installation, operational capabilities, and contract irregularities. She stated that the agency's conclusions were severely flawed and erroneous, and represent a "whitewash," according to the available evidence and documentation. Ms. Garzino states that the agency report is devoid of engineering and mathematical interpretation, upon which the engineering profession is based. Merely transcribing without question and adequate scrutiny what others put forth, no matter how illogical, unsubstantiated, or void of fact, is unsuitable in any investigatory effort. Ms. Garzino believes that it is imperative that there be a vehicle in place that can provide a truthful, competent, and fair investigation of the evidence and documentation that exists in this matter. As required by law, 5 U.S.C. § 1213(c)(3), I am now transmitting the agency report along with Ms. Garzino's comments to you.

Having reviewed the agency's submissions and Ms. Garzino's comments, I have determined that the agency's report, taken together, contain all of the information required by statute, but, as explained in the enclosed Analysis of Disclosure, I must conclude that findings in the agency report do not appear reasonable within the meaning of 5 U.S.C. § 1213(e)(2). Ordinarily, in cases where I have found the report unreasonable, I would afford the agency head an opportunity to correct the deficiencies and submit a supplemental report. In this case, because of the exigencies of hurricane season, I have elected to forgo this option, and I am forwarding the reports, together with my comments and recommendations, to you.

The documentation and comprehensive explanation provided by Ms. Garzino in contrast with the agency's superficial and dismissive findings also suggest that, although Ms. Garzino regularly and persistently made USACE aware of serious flaws in the design, testing, installation, capabilities and contract issues that arose with the New Orleans pumps, USACE employees failed to act in a manner that was consistent with providing accountability to the process. Instead of taking Ms. Garzino's concerns seriously, USACE employees appeared to have taken a band-aid approach at the expense of good government and public health and safety. As explained in the Analysis of Disclosure, the agency report appears to make excuses on behalf of the USACE employees instead of holding employees and contractors accountable for their actions and assuring the citizens of New Orleans that the pumps, a critical pillar of the flood protection systems, would actually perform without catastrophic failure during the mildest of hurricanes. I am left to conclude that a thorough and impartial investigation conducted by independent professional engineers into these matters is warranted. Moreover, it appears that the pumps remain inadequately untested and vulnerable to failure in the event of a hurricane.

As required by § 1213(e)(3), I have sent a copy of the agency report and Ms. Garzino's comments to the Chairmen of the Senate and House Committees on the Armed Forces. We have also filed a copy of the agency report and Ms. Garzino's comments in our public file and closed the matter.

Respectfully,

Scott J. Bloch

Enclosures

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FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Report	OSC Report on Analysis of Disclosure, Agency Report...	54	08/04/2008	P6/b6; b7c;

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U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

FAC SIMILE COVER SHEET

TO:

Name: The Honorable Fred Fielding	
Title: Counsel to the President	
Organization: The White House	
Office / Location: Washington, D.C.	
Telephone: (202) 456-2632	**Fax:** (202) 456-6279

FROM:

Name: Scott J. Bloch	
Organization: Office of Special Counsel	
Office / Location: Washington, D.C.	
Telephone: (202) 254-3601	**Fax:** (202) 653-5151

Date: August 4, 2008	**Number of pages, including this cover sheet:** 29

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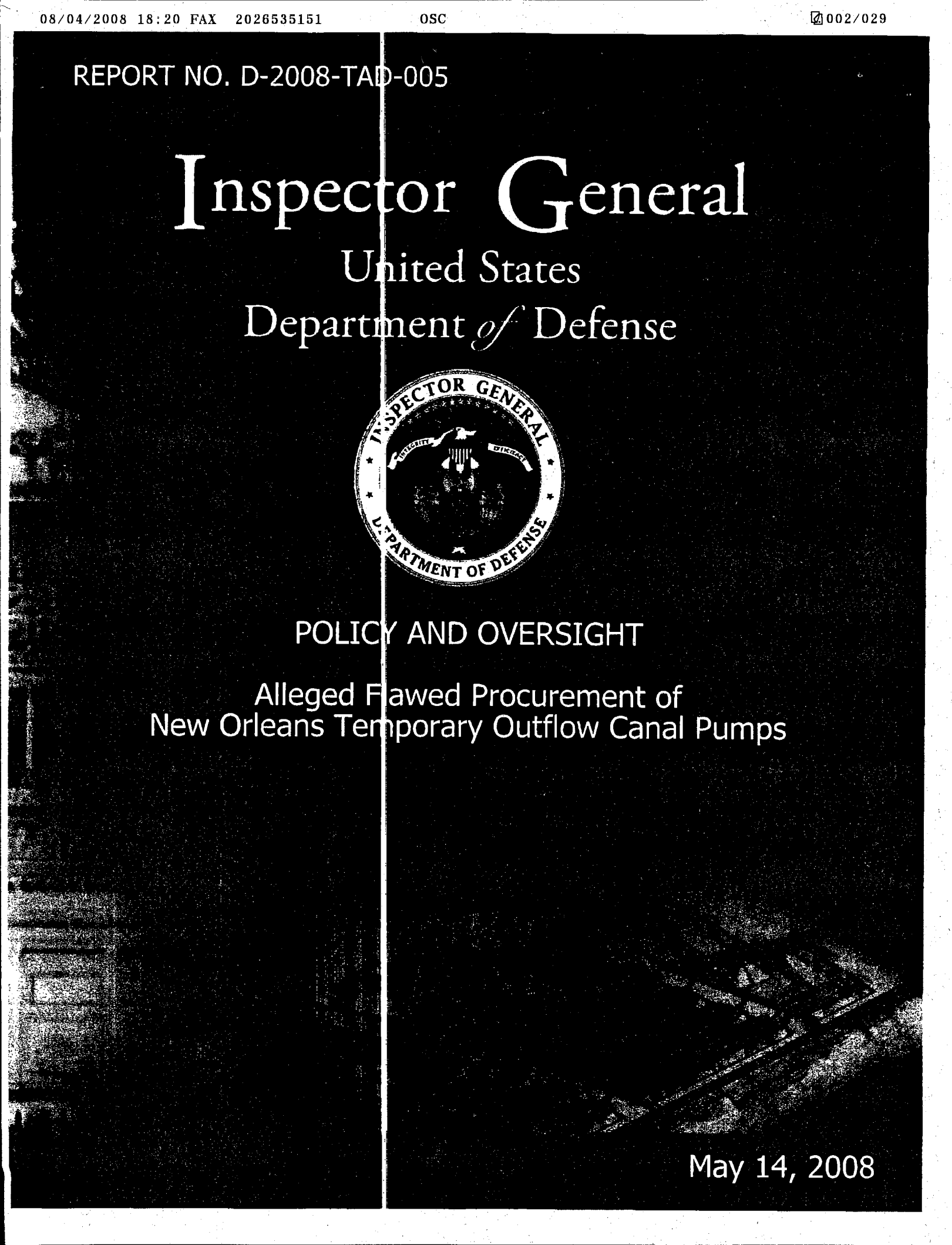
2 OF 3

REPORT NO. D-2008-TAD-005

Inspector General
United States Department of Defense

POLICY AND OVERSIGHT

Alleged Flawed Procurement of New Orleans Temporary Outflow Canal Pumps



May 14, 2008

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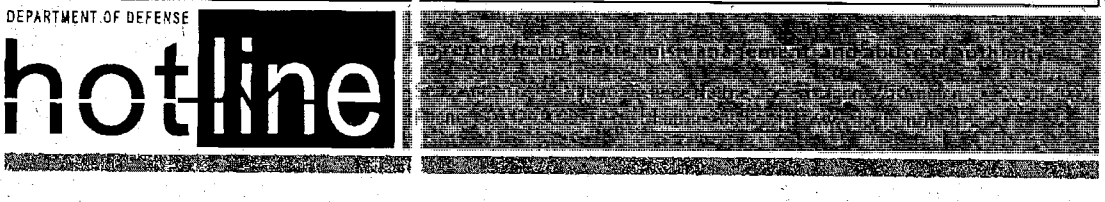

Acronyms

ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CO	Contracting Officer
COR	Contracting Officer's Representative
DOD	Department of Defense
ERDC	Engineer Research and Development Center
FAR	Federal Acquisition Regulation
GAO	Government Accountability Office
HI	Hydraulic Institute
HPU	Hydraulic Power Unit
IG	Inspector General
ITR	Independent Team Report
MFR	Memorandum for Record
MIPR	Military Interagency Procurement Request
NOAA	National Oceanic and Atmospheric Administration
OIG	Office of the Inspector General
OSC	Office of Special Counsel
QA	Quality Assurance
QARs	Quality Assurance Reports
QC	Quality Control
RFP	Request for Proposal
USACE	United States Army Corps of Engineers

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

MAY 14 2008

The Honorable Scott J. Bloch
Special Counsel, U.S. Office of Special Counsel
1730 M. Street, N.W.
Suite 300
Washington, D.C. 20036-4505

Re: OSC File No. DI-07-2724

Dear Mr. Bloch:

This is in response to your September 21, 2007, letter to the Secretary of Defense regarding "serious allegations which cast doubt on the integrity of costly pumping equipment installed in three main structures by USACE and its ability to protect New Orleans from further flooding," pursuant to 5 U.S.C. § 1213.

We have reviewed the allegations, prior reviews, and project documentation and interviewed the complainant and U. S. Army Corps of Engineers' project personnel. Our review did not find reasonable grounds to believe that there were criminal violations or deficiencies in the pump acquisition that constituted a danger to public health or safety.

Our report of investigation is enclosed. By memorandum from the Secretary of Defense dated February 9, 1998 (copy enclosed), the DoD Inspector General has been delegated authority to respond to requests for investigations under 5 U.S.C. § 1213.

If you have any additional questions regarding this matter please contact Mr. John R. Crane at (703) 604-8234.

Sincerely,

Claude M. Kicklighter

Enclosures: As stated

cc: Chief of Engineers, U.S. Army Corps of Engineers
Inspector General, Department of the Army

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THE SECRETARY OF DEFENSE
WASHINGTON, DC 20301

IG
C/brief

FEB 9 1998

MEMORANDUM FOR INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

SUBJECT: Delegation of Authority to the Inspector General

In accordance with the authority contained in Title 10, United States Code (U.S.C.), Section 113, I hereby delegate to the Inspector General, Department of Defense, full power and authority to act for the Secretary of Defense to respond to requests for investigations under Title 5, U.S.C. Section 1213 from the Special Counsel, Office of Special Counsel, relating to allegations of violations of law, gross mismanagement and certain other matters.

The authority delegated herein may not be redelegated.

William S. Cohen

Department of Defense Office of the Inspector General

Report No. D-2008-TAD-005 **May 14, 2008**

Alleged Flawed Procurement of New Orleans Temporary Outfall Canal Pumps

Introduction and Background

On September 21, 2007, the U.S. Office of Special Counsel (OSC) referred allegations to the Secretary of Defense concerning the United States Army Corps of Engineers (USACE) installation of pumping equipment in three main structures to protect New Orleans from further flooding. The OSC is authorized by 5 U.S.C. § 1213(a) and (b) to receive disclosures of information from Federal employees alleging violations of law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority, or a substantial and specific danger to public health or safety. When the Special Counsel finds that there is a substantial likelihood that one of these conditions exists, he is required to advise the appropriate agency head, and the agency head is required to conduct an investigation of the allegations and prepare a report, pursuant to 5 U.S.C. § 1213(c) and (g).

In this case, the Special Counsel concluded that there was a substantial likelihood that the information provided by a Federal employee disclosed allegations covered by 5 U.S.C. § 1213, and referred the matter to the Secretary of Defense for investigation. The Special Counsel summarized the whistleblower allegations as follows:

> (1) the costly pumping equipment at three "outfall gated canal closure structures," which is part of the flood protection design to protect New Orleans, was inherently flawed due to poor pumping and hydraulic systems designs;
>
> (2) pumping equipment that had previously malfunctioned under favorable contractor testing conditions, and subsequently shown to be defective, was knowingly installed by USACE employees and . . . [the contractor] personnel; and
>
> (3) USACE employees and . . . [the contractor] personnel circumvented contract requirements related to contract modification and notifications at the expense of public safety and proper contract oversight.

Prior to Hurricane Katrina, the New Orleans Sewerage and Water Board pumped rainwater from the city into three drainage canals at 17th Street, London Avenue, and Orleans Avenue. These three canals flowed into Lake Pontchartrain unrestricted and while they were sufficient to prevent some, but not all, flooding from rainfall events, they were vulnerable to storm surges during a hurricane. The floodwalls lining both sides of the canals were designed to protect residents

from surges in Lake Pontchartrain driven by storms up to the "Standard Project Hurricane," roughly equivalent to a fast-moving category 3 hurricane. During Hurricane Katrina in August 2005, however, several breaches occurred in the floodwalls. This allowed a significant amount of water from Lake Pontchartrain to enter the city of New Orleans.

The United States Army Corps of Engineers (USACE) took action to restore New Orleans' flood protection to a pre-Katrina level by June 1, 2006, the beginning of the next hurricane season. The USACE considered strengthening the drainage canal floodwalls but decided to postpone this effort due to cost and time constraints. Instead, USACE decided to install three interim closure structures at the points where the canals meet Lake Pontchartrain. These closure structures, which remain open during normal weather periods, would be closed during major storm events to prevent a Lake Pontchartrain storm surge from entering the canals, breaching the floodwalls, and overflowing into the city. However, the closures would also prevent rainwater in the canals from flowing into the lake. Because the gates remained closed during a storm surge, large capacity pumping systems were needed to pump water out of the canals and into the lake.

The National Oceanic and Atmospheric Administration (NOAA) created storm event rainfall models for 10, 50, and 100-year storm events for the New Orleans canal system. The storm model used historical data to determine the average of the worst storms that have occurred every 10, 50, and 100 years. The statistical data was then used to predict an event that has a 1% probability of being equaled or exceeded in any year.

The Interim Closure Structure's Temporary Pumping System was designed to pump water for a 10-year rainfall event; not a 50-year or 100-year rainfall event like Katrina. A permanent pump system is planned to be completed by 2012 and will be designed to handle a 100-year storm event.

The USACE initiated the procurement of 34 large capacity hydraulic pumping systems to provide pumping capacity by June 1, 2006. Six additional pumps were procured to supplement the pumping capacity at the 17th Street Canal, the largest canal. The USACE stated that additional analysis in mid 2006, determined that a significant additional pumping capacity would be required at the 17th and London Avenue Canals to meet the 10-year rainfall event. Therefore contracts were let in 2007 for 19 direct-drive pumps to meet the 10-year rainfall event.

Each pumping unit consists of two major mechanical components; the hydraulic power unit (HPU), which is located on an elevated equipment platform, and the water pump, located in the canal on the protected side of the closure structures. The two components are connected by hydraulic lines. The water discharge piping runs from the water pump around the closure structure and then discharges into Lake Pontchartrain. The following terms are used in this report to distinguish components of the New Orleans Outflow Canal Pumps:

Hydraulic Pumping System
1. Pumping Unit
   a. Hydraulic Power Unit (HPU)
   b. Water Pump
2. Hydraulic Lines
3. Water Discharge Piping

Each pumping unit underwent testing at the factory and in the field. Problems were continuously encountered and corrected throughout the acquisition process. Final contractual acceptance testing was completed on September 15, 2007.

Conduct of the Investigation

We began the investigation on October 26, 2007, based on information provided by the Office of Special Counsel, which included the "Whistleblower Disclosure Affidavit" dated August 13, 2007; a Memorandum for Record (MFR) dated May 3, 2006, entitled "Defective Pumping Equipment," a "Declaration of ... [the complainant]," dated October 13, 2006, and a "Declaration of ... [the complainant]," dated April 23, 2007.

Based on the information described above, as well as a subsequent interview with the complainant, we categorized the specific allegations into the following five areas in order to cover the full range of concerns: Design, Testing, Installation, Operational Capabilities, and Contract Issues. Specific allegations in each category were then addressed during our fieldwork.

The interview with the complainant included the USACE, Los Angeles District counsel, who participated as an observer at the request of the complainant. During our interview, the complainant provided shop inspection reports, the contractor Quality Control (QC) reports, the complainant's testing documentation detailing test results of most pumps, and a MFR dated May 29, 2006, entitled "Implementation of New Corrective Measures to Correct Pumping Equipment Deficiencies."

We also interviewed personnel serving with the New Orleans District USACE, including the Project Manager, the Assistant Project Manager, the Contracting Officer (CO), and the Resident Engineer / Contracting Officer's Representative (COR). They provided contract documentation including the contractor proposal and the 33 contract modifications, New Orleans Military Interagency Procurement Request (MIPR) to the Jacksonville district for QC services,[1] USACE and Hydraulic Institute (HI) standards, storm event studies, operational test procedures, test logs, USACE's Engineer Research and Development Center

[1] The USACE New Orleans office issued a MIPR to the Jacksonville district office to obtain quality control services at the contractor's production facility in Deerfield, Florida.

(ERDC) capacity test reports, USACE's Quality Assurance Reports (QARs) at the installation sites, and pump maintenance logs. Meetings were held with USACE Headquarters and Government Accountability Office (GAO) Headquarters.

As part of our work, we examined other studies and evaluations of matters concerning post-Katrina flood control in New Orleans. Some of these studies specifically addressed the allegations made by complainant and will be referenced in this report when appropriate. Those studies included the following:

- U.S. Army Audit Agency, "Contracts of the Hurricane Protection System in New Orleans," (A-2006-0198-FFD) August 22, 2006

- U.S. Army Corps of Engineers, "Final Report MVN [Mississippi Valley, New Orleans] Outfall Canal Pumps," *Independent Team Report (ITR)*, May 11, 2007

- Government Accountability Office, "U.S. Army Corps of Engineers' Procurement of Pumping Systems for the New Orleans Drainage Canals," (GAO-07-908R) May 23, 2007

- U.S. Army Corps of Engineers, "MVN Outfall Canal Pump Report," *Memorandum for Record (MFR)*, June 4, 2007

- U.S. Army Audit Agency, "Contracts to Restore and Enhance the Southern Louisiana Hurricane Protection System," (A-2007-0216-FFD) September 11, 2007

- Government Accountability Office, "Army Corps of Engineers Known Performance Issues with New Orleans Drainage Canal Pumps Have Been Addressed, but Guidance on Future Contracts Is Needed," (GAO-08-288) December 31, 2007

Summary of Evidence and Analysis

As discussed above, we categorized allegations concerning the Interim Closure Structure, Pumping Station Project, into five issue areas: Design, Testing, Installation, Operational Capabilities, and Contract Issues. We assigned numbers to the allegations for ease of reference.

Design Allegations

Allegation #1: Flawed design allowed air to enter into Denison hydraulic pumps on the HPUs causing damage and subsequent failure of the pumps.

Facts: The contract states

> The work under this section shall consist of providing all pumping equipment including the hydraulically driven pumps, diesel drive units, and all piping, appurtenances, mechanical and electrical system as shown on the drawings and as specified herein.

It goes on to state:

> The supplier of the pumping equipment mentioned above shall assume responsibility for the proper functioning of the hydraulic motors, pumps, and hydraulic drive units as a complete system

The clause concerning the Contractor's obligation under Warranty of Supplies of a Noncomplex Nature, states:

> All supplies furnished under this contract will be free from defects in material and workmanship and will conform with all requirements of this contract...

The USACE stated that the Denison hydraulic pump design used in this acquisition was a standard design. The December 31, 2007, GAO report stated:

> ...according to the Lake Borgne Levee District official, this pump has been successfully used for about 20 years without having to prime the pumps prior to start-up.

The design required a prescribed start-up procedure for the HPU. The operating procedure required the operator to start-up the HPU at a slow speed and gradually increase it to the normal operating speed. Doing so would properly dissipate air that entered the hydraulic pipe whenever the suction pipe was opened for repairs and maintenance. If operators did not follow prescribed procedures for the initial start-up of the hydraulic power unit (i.e., conducted a rapid run-up), trapped air would cause a "dry run" and tear up the hydraulic pump.

The problem was addressed in the December 31, 2007, GAO report as follows:

> Corps officials from the New Orleans District emphasized to us that the redesign was requested to more adequately meet their needs, not because of concerns about the pumping systems operating as intended. ...[the contractor] subsequently agreed to modify the design of the hydraulic intake line at the request of the Corps. According to Corps officials, by the end of July 2007 and at its own expense...[the contractor] had redesigned and reinstalled the new flooded suction design on all 40 pumping systems.

The June 4, 2007, MFR and May 11, 2007, ITR also addressed this issue and made recommendations that have since been implemented.

This air intake problem first occurred during factory testing and surfaced again in June-July 2006 after the water pump systems were installed at sites. The contractor provided a temporary solution by first installing a safety valve on the hydraulic intake pipe to bleed the trapped air. The problem was resolved permanently when suction pipes were submerged in oil and moved to a "gravity feed" position in the hydraulic tank. On July 12, 2006, a no cost contract modification was issued that required the contractor to modify all existing hydraulic tanks to a flooded intake for the hydraulic pumps. After the implementation of the modification, each of the hydraulic pumps was tested prior to acceptance.

Analysis: The allegation was not substantiated. The hydraulic pump design was a standard design that required a prescribed start-up procedure. The air intake problem arose when the operator did not follow the prescribed hydraulic power unit start-up procedure subsequent to suction pipe flange repairs. The possibility of damage from improper start-up was eliminated by implementing a no cost modification that required that the suction pipes be moved to a "gravity feed" position in the hydraulic tanks that submerged intake pipes in the hydraulic oil tank thus preventing the air from entering into the pump. We concluded that this was a reasonable approach to eliminate the risk of damage and was accomplished at no additional contract cost to the Government.

Allegation #2: The complainant alleged:

> While trying to meet the contractually required testing requirements the pumping equipment experienced voluminous severe hydraulic system component failures, and ultimately, catastrophic pump assembly failures.

The complainant went on to state that failure occurred because the HPU components, including cams, hoses and piping were not designed to operate at 3000 pound/square-inch (psi) hydraulic pressure as required.

Facts: The contract explicitly states:

> All reinforced supply hose ... shall have a minimum safe working pressure of 3,000 psi.

During April 2006, HPUs and the water pumps were tested together at the contractor facility. The tests were observed by the USACE representatives from the Jacksonville District quality assurance team including the complainant. A number of test failures were attributed to improper functioning of Denison hydraulic pump units. The problems identified with the hydraulic pump components were: inappropriate cam and hydraulic hose sizes, seals, o-ring failures, and excessively hot hydraulic oil. These discrepancies were reported by the complainant and were acknowledged and addressed in the ITR as follows:

> b. 12 April first initial wet test and within 95 minutes there is a failure of pumping components.
>
> c. 13 April determined cam rings in hydraulic oil pump were wrong size causing failures. Originally the hydraulic oil pumps had cams of type no. 66 & 42;...[the contractor] replaced the 42 with a 50 to increase oil flow to the Rineer motor [water pump motors]. Corps personnel discovered that the 50 cam could not handle a continuous running pressure above 3000 psi. The cams were then at Denison's request to replace all hydraulic oil pumps with type 72 & 45, which Denison later indicated will run satisfactorily at a continuous running pressure of 3200 psi...

The ITR discussed the cam size issue further and stated:

> Also, sometime in July 2006, it was also found that...[the contractor] had installed cams that would not operate at pressures >3000 psi, the current system pressure being developed ranges from 3000 to 3200 psi. They had to replace the cams in the hydraulic system that would work for pressures >3000 psi. The current hydraulic systems now have the proper cams in place according to the manufacturer...

The ITR also addressed the flexible hose problem; it stated that the hydraulic oil high pressure hoses failed and the flexible hydraulic hoses that were below the water line were replaced with rigid piping. This corrected corrosion issues with the galvanized quick connects under water.

USACE representatives told us that some of the 4-inch diameter intake hoses attached to hydraulic pumps were rated for water use but were not rated for hydraulic oil. The contractor replaced the water hoses when the problem was brought to their attention. Some of the hyper extended o-rings/seals and improperly installed seals on the water pump motors were also replaced at installation sites. All Denison pumps were 100

percent inspected at the sites for defective parts. All inappropriately sized cams were replaced at the factory as well as at installation sites. No underrated components were allowed to remain on the HPUs.

Analysis: The allegation was substantiated. HPUs initially failed factory tests due to pump component failures. The cams, hoses, o-rings and seals failed because they were under rated and did not meet the 3000 psi requirement, were of inappropriate size, were incorrectly installed, or had manufacturing defects. We concluded that reasonable corrective actions were taken when problems were detected during factory tests, during 100 percent field inspection of the HPUs, and during acceptance tests conducted in the field. Corrective actions for the above items were accomplished at no additional cost to the Government.

Testing Allegations

Allegation #3: Factory testing for the hydraulic pump, and water pump was incomplete and defective equipment was shipped to the sites.

Facts: The original contract called for a performance test that measured pumping capacity. USACE representatives stated that they had problems performing these tests and obtained the services of an outside consultant to investigate these issues. The consultant reported that it was not a normal practice to test the capacity of every pump in the same production run. Variation in performance between identical pumps is expected to be slight based on manufacturing tolerances. Based on that assessment, USACE decided to replace the performance test with a 5-hour endurance test, which focused on the HPU. Each HPU was connected to a water pump for the test. Accordingly, the contract modification backup documentation stated:

> The prior testing required a 1 hour run test per pump and drive unit which was being conducted simultaneously, as well as two full size, seven point tests on two pumps, the new procedures requires 5 hours per drive unit as well as a 24 hour run test on one drive unit and pump combination.

The 5-hour test was later reduced to 3-hours based on the recommendations from USACE engineers and the consultant who stated that there would be no benefit to conducting the test for longer than 3 hours.

The contract modification deleted the requirement for testing each hydraulic pumping system. However, because there were numerous problems with the HPU during the factory test, the USACE decided to test every HPU, but test only a sample of water pumps. Ultimately, 9 water pumps were not tested.

The contractor's quality control forms documented that each of the HPUs completed the 3-hour factory test before being shipped. However, our review of the complainants' documentation and the Jacksonville shop inspection reports revealed that the Government identified one unit as not accepted. The Jacksonville shop inspection states:

> This DU was previously tested on 4/29/06 at 1955 Hrs. The unit shut down during the test for no apparent reason. CAT personnel troubleshot the unit and found a burned fuse and replaced it. When the engine was turned on it went through the automatic throttle, but could not hold the 1800 RPM. Also, the auto accumulator solenoid valve was not holding the pressure due to a possible internal leak. The pumps have to be engaged manually. Therefore, this engine is not acceptable.

Despite the failed test, the HPU was shipped to the installation site. When the USACE found out that the pump was shipped without the Government's approval of the testing, the project manager reviewed the issues found during factory tests and decided to correct the problems with the unit at the installation site rather than sending it back to the factory. After repairs were made, that pump completed the acceptance test in the field and accumulated a total of 25 hours as of March 2008.

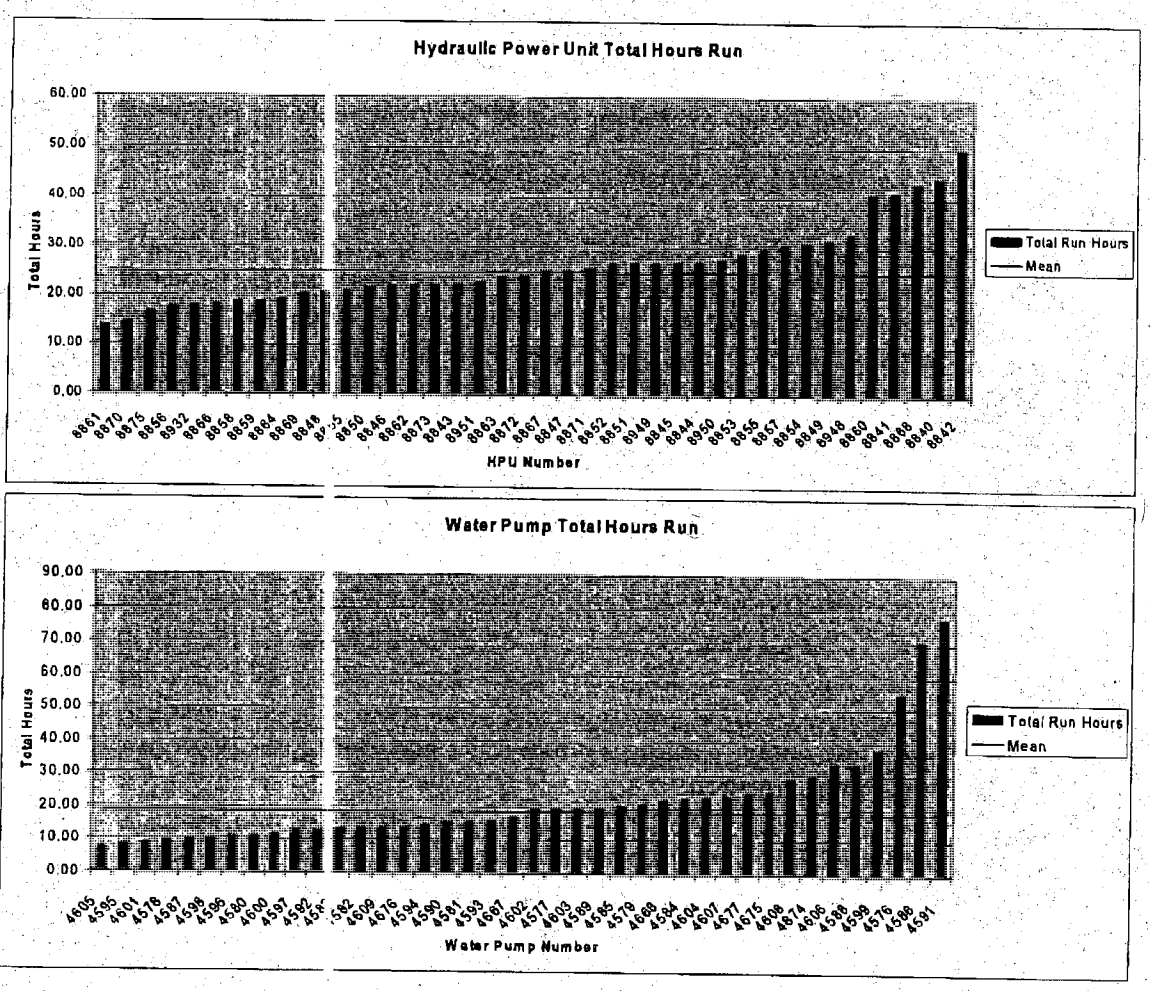
Analysis: The allegation was partially substantiated. The Jacksonville shop inspection reports show that one HPU did not pass the 3-hour factory test. We believe that the project manager's decision not to return the unit back to the factory and to correct all the problems with this pump at the site was reasonable, under the circumstances, because repairs could be accomplished in the field without incurring the delay and expense of returning the unit to the factory. Ultimately, this HPU passed the acceptance test at the site and logged more than 25 running hours. Testing of other units was accomplished as specified by the contract modification.

Allegation #4: The complainant alleged:

> New Orleans TFG pump team personnel were fully aware of the voluminous pumping equipment failures at the contractor testing facility, and were also fully aware that the more the pumping equipment was run the more it experienced catastrophic failures of the pump assemblies and the hydraulic systems components.

Facts: Although the factory and installation testing of the hydraulic pumping systems revealed numerous problems, the USACE and the contractor took corrective actions by performing inspections and fixing the problems as they found them. Confidence in the reliability of the hydraulic pumping systems has grown with the number of hours that have been accumulated from the 3-hour factory tests, the on site operational tests, the 2-hour on site acceptance tests, and subsequent maintenance runs.

As of the end of March 2008, the HPUs have run from 13 to 50 hours, with an average of 24 hours, and the water pumps have run from 7 to 77 hours, with an average of 18 hours. Beside the vigorous 3-hour factory tests, 2-hours acceptance test, and accumulated total running hours, the USACE also ran continuous 12-hour tests on two hydraulic pumping units at 1000 psi at the factory and a continuous 36-hour test on one HPU at 3000 psi at the site. See charts below.



The hydraulic pumping systems are now operational and managed by the New Orleans District Operation Division. The systems exercised periodically to ensure their readiness. Logs are kept with problems each pump encounters. Confidence in the reliability of the hydraulic pumping systems is also supported by the low number of problems encountered by the New Orleans District Operation Division as documented in their maintenance log files. We reviewed these files and only found routine maintenance items.

Analysis: The allegation was not substantiated. Although the factory testing of the HPU revealed several problems with specific components of the hydraulic pumping system, the USACE and the contractor took appropriated actions to correct known performance problems. Additionally, the average total running hours of each hydraulic pumping system up to March, 2008, gives us additional confidence that the system will reliably operate when needed.

Allegation #5: The complainant alleged:

> Appropriate and sufficient field testing requires delineating specific and befitting operating parameters with suitable engineering testing formulation, field engineering oversight, and record keeping - to date, to my knowledge, this has not occurred. Simply turning one, a couple, or a few pumps on for 15 to 45 minutes, under unknown conditions, with minimal oversight, and with no record keeping of the conditions, parameters, or oversight is not sufficient. The pumping equipment failures I witnessed most often became evident after hours of run time under normal operational speeds and pressures. At a minimum, real event operating conditions (as in a hurricane, i.e., full operating speeds and pressures) and run times (12 to 24 hours or more) should be applied for any field testing to ensure the pumping equipment operates as intended, and design defects have been mitigated properly.

Facts: The USACE prepared a test plan for the final acceptance of the hydraulic pumping systems in the field. The plan included the requirement to run for a minimum of 2 hours continuously with engine speeds of 1800 rpm and hydraulic pressure of 3,200 psi. The testing monitor was to verify a steady state condition with engine rpm, hydraulic system pressure, hydraulic oil temperature, engine jacket water temperature, canal level, ambient conditions, and no leaks from hydraulic and fuel systems.

The final acceptance tests for each hydraulic pumping system were conducted in the field by the contractor with oversight by USACE. USACE documented the tests with quality assurance reports (QARs) which recorded the testing parameters including pump speeds, run times, temperature, and deviations from test procedures. The 40 systems were accepted by the Government. The QARs documented that 4 of the hydraulic pumping systems were accepted with only 1.5 hours of testing and 6 systems were accepted with reduced speeds for the last half hour of the 2-hour tests, 1400 rpms instead of the required 1800. The reduced run times and speeds for the acceptance tests were caused by the canals running out of water, rather than an actual or anticipated equipment failure. USACE personnel stated that they accepted the systems with reduced hours and speeds because performance was demonstrated in the first 45 minutes by reaching steady state conditions.

In addition to the acceptance test for the hydraulic pumping systems, the USACE also performed a 36-hour test to prove that the HPU would function for that period of time. This test was performed with a HPU connected to a rented water pump in the canal.

Analysis: The allegation was partially substantiated, in that test runs were shorter than the 12 to 24 hours recommended by the complainant. However, the USACE did develop a test plan and recorded in QARs the extent to which each pumping system met the test requirements. Due to the limitation of the water level in the canal, the test procedures performed by the USACE and contractor were adjusted, but sufficient to demonstrate that the hydraulic pumping systems will function as designed. The 36-hour test on the HPU and the additional run hours on the hydraulic pumping systems provide additional evidence that these hydraulic pumping systems will meet endurance requirements.

Installation Allegation

Allegation #6: Defective and untested pumping equipment was installed.

Facts: As discussed above, 9 water pumps were not factory tested prior to installation and one HPU was received at the site without Government approval of the 3 hour factory testing. Problems identified at the factory testing included undersized gear oil circulation motors, hydraulic motor vibrations, suspect pipe welds, and lower than expected pumping capacity. Under the contract, final acceptance of the hydraulic pumping systems was not at the factory. It occurred in the field after, final acceptance testing.

Additional hydraulic pumping system issues were identified and corrected in the field, including hydraulic oil with foreign contamination (metal shavings and a jello like substance). We found that the problems were solved and that the systems are now fully operational.

The December 31, 2007 GAO Report addressed the issue as follows:

> Each pumping system has been successfully tested on site ... providing greater assurance that they perform as designed during future hurricane seasons...the Corps stated that all of the outstanding repairs have been completed and on-site testing indicates that the Hydraulic pumping systems are fully operational. Final acceptance of the pumping systems is expected to be completed early in calendar year 2008.

Analysis: The allegation was partially substantiated. All HPUs were tested at the factory before shipping. However, as noted above, one HPU failed factory test but was shipped to the site and 9 water pumps were not tested at the factory. However, all defects related to these problems were fixed at the installation sites. Indeed, the USACE has taken extensive corrective actions to fix the problems at the sites from April 2006 until May 2007. All 40 HPUs are in place and have been successfully installed and tested. We consider this approach reasonable in view of the urgency of achieving an immediate improvement to New Orleans' flood control protection and the unprecedented capacity of these individual pumping units.

Operational Capability Allegation

Allegation #7: USACE allowed less than full designed capacity performance as called out in the contract.

Facts: The contract stated that the pump shall be able to operable through the entire range and within a tolerance of 0 to plus 5% of capacity in gallons/minute (gpm) at a given Total Dynamic Head in feet of water. The required capacity in this operable range is specified in the following chart from the contract:

Design Condition Design Point	Max Head	Operating Point	Low Head Design Point
Flow	85,000 gpm	98,000 gpm	105,000 gpm
Total Dynamic Head (TDH)	16.8 FT.	12.1 FT.	8.5 FT.
%efficiency	80%	81%	80%
Max. Speed	400 RPM	400 RPM	400 RPM
Max. Horse Power (HP)	720	690	640

The Request for Proposal (RFP) required and the contractor provided a certified pump curve based on model studies identifying that the pumps proposed met contract requirements. The original contract required a full scale capacity test on each pump. Following the initial full size factory tests, USACE's pump testing consultant traveled to the contractor's facility to assess testing issues and production delays. The consultant's report stated:

> I recommended dropping the pump performance tests and adding an endurance test for three main reasons. First, there was expected to be only slight variations in pump performance considering they were all manufactured to be identical. Secondly, I had a low confidence level in the validity of the current performance tests and third we needed endurance testing to weed out mechanical problems before the pumps are shipped to New Orleans.

The USACE initiated a contract modification to implement these recommendations and replace the full scale capacity test with a model test.

In order to validate the contractor's original model test results, a full scale factory test was performed by the contractor in conjunction with ERDC in December 2006. The test results indicated that at the specified operating total dynamic head conditions, the measured discharge capacity was less than required as shown in the following chart:

TDH	Required Capacity	Actual Capacity	% Reduction
16.8 ft	85,000 gpm	82,960 gpm	6.5%
12.1 ft	98,000 gpm	93,982 gpm	4.1%
8.5 ft	105,000 gpm	98,280 gpm	2.4%

USACE stated that the accuracy of the instrumentation for this test was +/- 5%.

Because the original model test was not witnessed by the Government, the USACE and the contractor agreed to perform an additional model test to ensure the accuracy of the measured capacity of the pumping systems. The model test was conducted by the contractor in cooperation with USACE's ERDC in September 2007. The model test revealed that the hydraulic pumping systems' capacity was 1.4 percent less than required by the contract. The USACE stated that the deficit did not have significant impact because the 1.4 percent was within the testing equipment margin of error and the interim system comprised of both the hydraulic and direct drive pumping systems still exceeded the 10-year event system design criteria.

Model testing was considered more accurate for pumping capacity. The use of a model test is standard practice for a pump of this size according to both the USACE Engineering Manual 1110-2-3105 and the HI Standard, ANSI/HI 2.6-2000.

Analysis: The allegation was substantiated. The model testing did show that the hydraulic pumping systems' capacity was 1.4 percent less than required by the contract. However, the USACE stated that the deficit did not have significant impact because the 1.4 percent was within the testing equipment margin of error and the interim system comprised of both the hydraulic and direct drive pumping systems still exceeded the 10-year event system design criteria. Because the total system is capable of meeting the 10-year event design criteria, we find no basis to recommend equipment redesign or upgrade.

Contract Issues Allegations

Allegation #8: The complainant alleged:

> The Task Force Guardian ACE [USACE] team violated Federal procurement regulations with numerous and consequential unauthorized commitments, acted with implied authority without the knowledge or consent of the Contracting Officer, failed to take corrective action when knowledge of contracting improprieties were made evident, and refused to implement contract administration actions ordered by Contracting Officer to mitigate pumping design deficiencies.

Facts: The USACE contracting officer stated that she was in constant contact with the USACE team. We reviewed numerous emails, memorandums, records

of daily phone calls, and documentation of meetings with the USACE project manager that confirmed continual contact throughout the entire process of the testing and delivery of the hydraulic pump system to the three sites. We found evidence that the USACE team addressed each of the problems identified in those records, both at the factory and on site. As a result, of the continuous involvement of the contracting officer, 33 modifications were made to the contract from February 15, 2006 to November 13, 2007. For example the modifications involving funds included specification changes to hydraulic piping and hose. Additionally, revisions of testing procedures were made at no cost to the Government.

The December 31, 2007 GAO report stated:

> We found much of the documentation that the ITR specifically cited as missing - including request for proposals, independent government estimates, certified cost or pricing data, technical analyses, and price negotiation memorandums - was not required, because documentation was not relevant to the contract modifications in question...our review found that, for the most of the contract modifications, there was evidence of some analysis by the Corps and extensive back and forth discussion, usually by e-mail, between officials form the Corps and ... [the contractor].

Analysis: We found insufficient evidence to support the allegation. Documentation confirmed continual interaction between the contracting officer and other members of the USACE team throughout the acquisition process. The contracting officer stated that she was in daily contact with the project manager throughout the duration of the project. The Jacksonville quality control team provided technical support for the USACE team by providing oversight of the factory testing.

Allegation #9: USACE team personnel did not engage in usual and customary Corps of Engineers contract administration practices or conduct project oversight and documentation that would ensure even minimum requirements could be met to protect the Government's interests.

Facts: The contract stated:

> The field test shall be witnessed by the Government . . . Start-up tests and demonstration shall be performed by the pump manufacturer's representative and the Contractor, and witnessed by the Government...

The contract also required full size factory testing witnessed by the Government prior to shipment of the pumps. However, we found that the process for Government sign-off on the factory testing and designation of who had the authority to approve that the equipment was ready for shipment was not formalized.

The contract administration and documentation issue was extensively addressed by the MFR, ITR and the GAO reports. These reports found numerous deficiencies in contract documentation.

The June 4, 2007, MFR has addressed documentation, contract administration and oversight issues partially. It stated:

> My expectation is that the team should document their ongoing contract procurement actions even while working under crisis conditions. I will form a team to help them bring the documentation file up to date. An improvement in future operations would be to deploy a contract administration team to work along side the project delivery team, with the sole focus of performing and assuring correct and complete contract actions and documentation." It further stated: "Meanwhile our team of engineers worked with the manufacturer in the factory to adjust/retrofit/improve the pumps in actual field conditions daily to assure that the pumps reached the required level of reliability.

The ITR found certain key elements of the solicitation documents missing from the contract files. The ITR also noted several change orders (contract modifications) with apparent missing documentation.

The December 31, 2007 GAO report also stated:

> Contract files for the pumping systems, although incomplete at the time of the ITR review, now contain the required documentation for the type of contract and value of the associated modifications. In a number of cases, Corps officials inserted required documentation in the contract files several months after modifications were issued and only after the ITR reported its findings. The ITR correctly noted the absence of some required documentation. However, we found much of the documentation that the ITR specifically cited as missing—including requests for proposals, independent government estimates, certified cost or pricing data, technical analyses, and price negotiation memorandums—was not required, either because documentation was not relevant to the contract modifications in question . . . Further, the contract itself was not written as precisely as it should have been. Specifically, the original factory test requirements were ambiguous, there were limited provisions for on-site testing, and there were no criteria for acceptance of the pumping systems by the government.

GAO recommended that the USACE:

> Take steps, through additional guidance or otherwise, to reinforce the importance of adherence to sound acquisition practices even during expedited procurements, including ensuring that important contract provisions, such as any required testing, are clear and that the contractor and the government understand what conditions or criteria must be met for successful completion of the contract.

DoD (and the Army) concurred with the recommendation and stated that USACE will review and revise, as necessary, current policies and regulations to ensure that a reasonable period of time is identified for completing and filing contract documents.

We found evidence of Government's project oversight during factory and on-site testing of the pumping systems. The complainant herself was a member of the factory test oversight and site installation teams. Although a supply contract did not require appointment of a contracting officer's representative (COR), USACE appointed the on-site resident engineer as the COR for the pump contract. The USACE stated that a COR was not appointed at the factory, as there was a shortage of qualified personnel.

Analysis: The allegation concerning inadequate documentation was substantiated. Several audits and examinations found significant deficiencies in contract documentation. We consider it appropriate that the Army has taken actions to emphasize the future need for proper documentation, despite project urgency. We found that USACE provided ample project oversight at the factory as well as at the installation sites.

Allegation #10: Original bidders for the contract would not have been rejected if the requirement for factory load testing that was subsequently deleted from the contract had not been in the Request for Proposal.

Facts: The December 31, 2007 GAO Report addressed the issue as follows:

> The testing specifications used for the RFP were nearly identical to those published by ... [the winning contractor], which included an open sump test requirement. After the other manufacturers complained that the open sump test requirement was restrictive because only ... [the winning contractor] had an open sump, the Corps amended the RFP to delete this requirement. This open sump test requirement was incorporated into the contract at the time of award, however because it was offered by ... [the winning contractor] as part of its proposal.

USACE representatives stated that the open sump test requirement was deleted from the RFP and was not a factor in the source selection. It, therefore, had no effect on the original bidders' ability to compete. According to the contracting officer, who was also the Source Selection Official, neither the full scale open sump test nor the contractor facilities was a factor in the final selection of the pump manufacturer. During the source selection, each contractor was judged only on its technical approach, project management expertise, past performance, and small disadvantaged business initiatives. The winning contractor was rated significantly higher on the selection criteria.

The winning contractor's proposal included the conduct of full scale performance testing at the factory and therefore, it was left in the contract.

Analysis: The allegation was not substantiated. Indeed, the requirement for open sump testing that some bidders found objectionable was deleted from the RFP in order to enhance competition. Moreover, the Source Selection Official stated that test facilities were not a factor in judging the bidders.

Allegation #11: The complainant alleged:

> The Task Force Guardian ACE [USACE] team refused to hold the contractor responsible for providing accurate and truthful quality control documentation for pumping equipment, and refused to hold contractor responsible for engaging in misleading and deceptive actions to conceal actual number and nature of failures.

Facts: The contract required the contractor to provide test documentation as follows:

> The Contractor shall provide and maintain an inspection system acceptable to the Government covering the supplies, fabricating methods, and special tooling under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires.

Documentation from the complainant and from the Jacksonville shop inspection reports show problems and corrections at the factory that were not all recorded in the contractor's factory quality control reports. However, the USACE was informed of the problems and corrections were made to address pumping system problems.

Analysis: The allegation was partially substantiated. The contractor's documentation did not include every problem and correction. However, the Jacksonville QC team also provided documentation and USACE took corrective actions when they became aware of the problems. We found insufficient evidence to conclude that the contractor engaged in deception to conceal equipment failures. We agree with the December 31, 2007, GAO report recommendation:

> Develop procedures to ensure that any contract related documentation, including that related to contract pricing, is completed and filed within a reasonable period of time

Allegation #12: The USACE team personnel refused to hold the contractor responsible for hydraulic oil with foreign object contamination (metal shavings, etc.), and hydraulic pipe flushing procedures that caused hydraulic oil to solidify within the hydraulic system.

In the complainant's October 13, 2006 Declaration the complainant alleged:

> We have had issues of the hydraulic oil in the hydraulic system of the pumps in the field turning to a Jell-O (like Jell-O shots) consistency and requiring every part of every pumping equipment component to be flushed and refilled...during an inspection of the hydraulic reservoir there was discovered a large amount of hydraulic oil in the bottom that had turned to a Jell-O like consistency (4" thick slab about 1.5' x 4'). In addition, during the inspection of the Denison hydraulic pumps there was observed large number of pumps that had a jelly like substance through out their internal workings. It was later discovered by our testing lab that the Jell-O like substance was caused by a reaction of calcium and water within the hydraulic oil. The calcium was introduced by the pickling compound used in the hydraulic piping provided by [...the contractor] and the water was present by virtue of the hydraulic system not being 100% contained [...the contractor's] own flushing procedure caused the pickling compound to be introduced to the hydraulic oil, and the subsequent introduction of water caused the reaction to occur. [...The contractor] stated during a meeting on this subject that they did not feel it necessary to rectify this problem and would not take measures to correct it. When I asked [...the contractor] if the jell-O like hydraulic oil met the specifications of the hydraulic oil required by the Denison hydraulic pump and Rineer motors, they did not answer. My understanding was the government was to bear the cost of flushing/cleaning/refilling all the hydraulic pumping systems because [...the contractor] refused to do so (a day before I left New Orleans three contracts were being awarded to outside contractors to perform the needed flushing/cleaning/refilling). This cost, and all associated costs, should be born by [...the contractor].

Facts: The contract incorporated several FAR clauses by reference and stated:

> All supplies furnished under this contract will be free from defects in material or workmanship and will conform to all requirements of this contract.

The contract stated that the contracting officer may require, by written notice, the prompt correction or replacement of any supplies. Even though the contract does not specifically mention hydraulic oil, the above clause applies to the hydraulic oil.

Numerous impurities were noticed in the hydraulic system installed at the sites. The impurities were attributed to slag from welding operations and metal shavings from sawing and pipe cutting operations entering hydraulic pipes during the building of pipe racks by the on-site contractors.

Additionally, a jelly like substance in the hydraulic fluid reservoirs, on the tank filters, and hydraulic pumps located at Orleans and London Avenue canals was observed. Testing of the filter indicated a high level of Calcium, Boron, and Silicon, which was believed to be the result of the oils used in the pickling process. Additionally, the suction strainers and hydraulic fluid reservoirs contained large amounts of metal particles. USACE personnel informed us that

the hydraulic pump units were shipped to the New Orleans sites with hydraulic oil in the reservoirs. During installation of HPUs additional hydraulic fluid from a local supplier was added. When the two hydraulic fluids mixed, a jello like substance formed. An analysis of the hydraulic fluids revealed that the two hydraulic fluids had different consistencies. The contractor replaced the hydraulic fluid but insisted that the hydraulic system was clean and did not require further flushing and cleaning. The contract did not specify a specific procedure for flushing and cleaning the hydraulic pipes. Therefore, the USACE decided that long-term reliability would be best served by requiring a cleaning process that was not specified in the contract. In July 2006 two contract modifications were issued to implement new cleaning and flushing of hydraulic piping at the three installation sites.

Analysis: The allegation was not substantiated. The USACE enforced contract provisions. The contractor replaced the contaminated hydraulic fluid that had turned into jell-O like substance but insisted that the hydraulic system was clean and did not require further flushing and cleaning. The USACE realized that the contract did not specify a specific procedure for flushing the hydraulic pipes. Therefore, USACE determined that for long term reliability the system required a more thorough cleaning to prevent metal particles and other impurities from getting into the hydraulic pump units. The additional cleaning was accomplished through contract modifications at Government expense.

Allegation #13: The hydraulic piping supplied by the contractor is not in accordance with accepted industry standards.

Facts: Sub-section 2.4 of the contract stated the hydraulic piping requirements as follows:

> Hydraulic lines connecting the power unit to the pumping unit shall be a combination of black steel pipe and reinforced hose and shall be installed in accordance with the drawings and as specified herein. Supply pipe shall be ASTM A106, Schedule 80 seamless black steel pipe, and return pipes shall be ASTM A106, Schedule 40 seamless black steel pipe...

USACE representatives stated that the contractor supplied the pipes to the standards specified in the contract. The contract required pipe meeting American Society for Testing and Materials (ASTM) A106. ASTM A106 is a material properties specification which is verified by mill certifications. The properties identified in ASTM A106 are used in the formulas of the American Society of Mechanical Engineers (ASME) codes B31.1 and B31.3 to determine the pipe size.

However, the ITR stated, "The hydraulic piping does not meet the requirements of ASME B31.1..." and recommended, "...that a certified hydraulic systems inspector determine if the system is free of shock loading and certify that the system as built is safe to operate for the intended use."

In response to the recommendation made in the ITR, USACE hired a professional engineer who performed an evaluation to determine the suitability of the hydraulic piping system design and construction. The consultant was advised by an ASME representative that code B31.3, not code B31.1, was the proper code for this application. Using the formulas found in ASME code B31.3 and the properties of ASTM A106 pipe, the consultant determined that the piping was in accordance with the appropriate industry standard. In addition, he tested the installed piping system at 1.5 times the design pressure (4500 psi) and observed no failure in piping and found the system working satisfactorily. The professional engineer concluded that the hydraulic piping system, design, and construction were suitable for transmitting power from the diesel engine to the vertical water pumps. Shock loading in the drive was not an issue. There were no rapid closing valves in the oil power system. Engineering calculations indicated that the pipe envelope did not present a safety hazard. In summary, the professional engineer found the existing hydraulic pipes adequate.

In addition, another consultant analyzed the adequacy of the ASTM A106 Schedule 80 black steel pipe used as hydraulic conduits for the pumps. He stated in his report:

> Based on the above observations and ...[the contractor representative] e-mail dated May 18, 2006, we believe that the 3" diameter Sch. 80 seamless black steel pipe is adequate for the hydraulic conduits for the hydraulic pumps at the 17th Street Canal Interim Pump Station.

Analysis: The allegation was not substantiated. The hydraulic pipes supplied by the contractor met the contractual specifications and accepted industry standards. The ASME advised that the correct standard for this purpose was ASME B31.3.

Allegation #14: The complainant alleged:

> ...they [the contractor] referred to my mandated 100% presence for pump testing oversight by USACE QA [Quality Assurance] personnel, including full QA and photographic documentation of all ongoing pump equipment testing, to be excessive, unnecessary, and somehow detrimental to getting pumps delivered to the City of New Orleans.

Facts: The USACE representatives told us that the contract did not specify the extent of oversight during factory testing. The contract states:

> Full size factory testing shall be witnessed by the Government prior to shipment of the pumps.

The contract also includes by reference FAR 52.246-2 which states:

> The Government has the right to inspect and test all supplies called for by the contract, to the extent practicable, at all places and times, including the period of manufacture, and in any event before acceptance. The Government shall perform inspections and tests in a manner that will not

> unduly delay the work The Government assumes no contractual obligation to perform any inspection and test for the benefit of the Contractor unless specifically set forth elsewhere in this contract.

In response to the contractor's expressed concerns regarding the complainant's oversight activities, USACE assessed the issue and included the following statement in a contract modification:

> Inspectors are to be notified of the initiation of test with enough time to travel between test sites and witness the beginning and ending of all tests, even if only one inspector is on duty at that time.

Analysis: We confirmed that the contractor raised objections to the complainant's rigorous oversight activities because the original contract intent was not clear regarding the extent to which Government representatives would be involved in pump testing. We concluded that USACE management reasonably attempted to balance the need for Government involvement in testing with the need to avoid the type of interference which could slow production. The USACE decision to modify the contract to require the Government representative to witness the beginning and end of each test was an acceptable approach.

Conclusion and Actions Taken or Planned

The New Orleans Temporary Outfall Canal Pumps were procured and installed under emergency conditions. The project team made many hurried decisions that sometimes left protocol and documentation lacking. However, our review revealed a dedicated effort by committed professionals, including the complainant, to procure, debug, and install a temporary outfall canal pumping system to help protect the people of New Orleans. According to information we obtained, this was the largest pumping system ever procured by the USACE, having a 60-inch water pump diameter. The largest pumps previously procured by the USACE had a 42-inch diameter.

As indicated in this report, we found several of the allegations were substantiated. Testing at the factory and on-site disclosed numerous deficiencies that were corrected by the contractor at no cost to the Government, or through contract modification when necessary. Furthermore, the effort to produce and install the pumping systems on an expedited basis resulted in the failure to properly document the contract files However, we consider these deficiencies performance-related shortcomings that did not rise to the level of a serious violation of law or regulation, abuse of authority, or gross mismanagement. Nor did they result in a gross waste of funds or a danger to public health or safety. Accordingly, we found insufficient basis to make a referral to the Attorney General pursuant to Section 4(d) of the IG Act or to recommend disciplinary action against any Government employee.

The Army is implementing recommendations that were made by the GAO to improve the management of future expedited projects as set forth below. We make no additional recommendations.

GAO REPORT 08-288, 'ARMY CORPS OF ENGINEERS: KNOWN PERFORMANCE ISSUES WITH NEW ORLEANS DRAINAGE CANAL PUMPS HAVE BEEN ADDRESSED, BUT GUIDANCE ON FUTURE CONTRACTS IS NEEDED,' DATED DECEMBER 31, 2007, (GAO CODE 360879)

DEPARTMENT OF DEFENSE RESPONSE TO THE RECOMMENDATIONS

Recommendation 1: We recommend that the Secretary of Defense require the Chief of Engineers to:

Take steps, through additional guidance or otherwise, to reinforce the importance of adherence to sound acquisition practices even during expedited procurements, including ensuring that important contract provisions, such as any required testing, are clear and that the contractor and the government understand what conditions or criteria must be met for successful completion of the contract.

DOD RESPONSE: CONCUR: The U.S. Army Corps of Engineers will send a memo to all Corps offices reinforcing the importance of adherence to sound engineering practices even during expedited procurements. The memo will relate lessons learned and emphasize the need for technical specifications, such as those required for equipment testing, to be clear so that the contractor and the government understand what conditions or criteria must be met for successful completion of the contract. The anticipated date to transmit the memo is 14 March 2008.[2]

Recommendation 2:
Develop procedures to ensure that any contract related documentation, including that related to contract pricing, is completed and filed within a reasonable period of time.

DOD RESPONSE: CONCUR: The U.S. Army Corps of Engineers will review and revise, as necessary, current policies and regulations to ensure that a reasonable period of time is identified for completing and filing contract documents. Estimated completion date is 30 May, 2008.[3]

[2] The memo was distributed to all USACE districts and divisions on February 25, 2008
[3] The USACE completed revisions of policies and regulations on February 27, 2008