Health Exposure Study Recommendation

For the Garfield Avenue Chromium Site
Jersey City, New Jersey

Prepared in compliance with Section XVI, Paragraph 49(g),
Partial Consent Judgment Concerning The PPG Sites
(Civil Action No.: HUD-C-77-05)

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Chromium Cleanup Partnership

N.J. DEPARTMENT OF ENVIRONMENTAL PROTECTION
CITY OF JERSEY CITY
PPG INDUSTRIES
COURT-APPOINTED SITE ADMINISTRATOR

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DISCLAIMER

NOTE: The authors of this report do not claim any expertise in the field of human exposure to chromium or chromium-related waste or by-products. This report was prepared pursuant to Paragraph 49 of the Partial Consent Judgment Concerning the PPG Sites dated June 26, 2009, which authorized the Site Administrator to recommend a health exposure study, if necessary. The preliminary recommendations made in this report should not be construed to provide medical advice or an assessment of exposure risks. The recommendations proposed in this report are those of the Site Administrator and are not necessarily those of the parties to the Settlement or experts who were consulted for this report.

ASSESSMENT AUTHORS

The background review and assessment was directed and co-authored by W. Michael McCabe, however, the recommendations are solely those of McCabe. McCabe is the independent, Court-appointed Site Administrator for the cleanup of 20 PPG chromium waste sites in Hudson County, New Jersey. McCabe also is the Principal of McCabe & Associates - a private consulting firm addressing energy and environmental policies, projects and opportunities at the community, state and federal levels. He brings 35 years of experience in energy and environmental policy leadership to the position, including a term as former USEPA Deputy Administrator and Regional Administrator of the EPA's Mid-Atlantic Region under President Clinton. Before joining EPA, McCabe served as then-Sen. Joe Biden's director of communications and projects, representing Biden throughout the state of Delaware. Prior to working with Biden, McCabe served in leadership positions on Congressional committee and Member staffs specializing in environmental and energy issues.

Co-author Ciara O'Connell is an independent environmental consultant for McCabe & Associates who has worked since 1999 on a variety of environmental issues including estuary policy, solid waste policy and permitting, air permitting and compliance, brownfield redevelopment, and RCRA Part B facility permitting. From 1996 through 1998, she worked as a program environmental scientist for Environmental Alliance, Inc., where she specialized in Title V, hazardous waste and solid waste permitting for facilities in Delaware, Pennsylvania, Maryland and Virginia. Prior to that, Ms. O'Connell worked as a program analyst in DNREC's Pollution Prevention Program. Ms. O'Connell received a Masters of Environmental Management from Yale University in 1995.

HEALTH STUDY RECOMMENDATIONS - EXECUTIVE SUMMARY

I. BACKGROUND

Chromium Cleanup Settlement

On June 26, 2009, a Partial Consent Judgment was entered with the Superior Court of New Jersey, binding the New Jersey Department of Environmental Protection, PPG Industries, Inc., and the City of Jersey City to work together to remediate 20 chromium sites in Hudson County for which PPG is responsible. The unique collaborative arrangement created by the settlement was designed to "remediate the soils and sources of contamination at the PPG Sites as expeditiously as possible with a five (5)-year goal for completion."[1]

To help meet this objective, the position of independent Site Administrator with oversight responsibilities was established. The responsibilities vested in this position include developing a judicially enforceable 5-year master schedule, facilitating parties' progress in meeting master schedule milestones, hiring an independent technical consultant, maintaining regular communications with community representatives, and communicating community concerns to the partnership. Environmental consultant and former USEPA Deputy Administrator W. Michael McCabe was appointed to this position by court order in July 2009.

As part of the Duties and Responsibilities of Site Administrator, a provision was included in the Consent Judgment requiring him to:

> *"Review previous and ongoing health studies concerning the health impacts of chromium in Hudson County and consult with experts in the field and, if necessary, to recommend a protocol for a future medical study (health exposure study), that would monitor the people living within the vicinity of the Garfield Avenue Site to ascertain chromium exposure risks…."*[2]

An extensive review of existing health study literature and research was conducted to form the foundation for the recommendations in this report.

Health Exposure Study Scope and Criteria

The following questions formed the basis for the scope and criteria of what type of health exposure study, if any, would be appropriate for residents living in the vicinity of the Garfield Avenue Site.

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[1] Partial Consent Judgment Concerning The PPG Sites (Civil Action No.: HUD-C-77-05), June 26, 2009, p. 7, X.8

[2] Ibid, p. 18, XVI. 49 (g)

1. Will the data gathered to detect a specific contaminant (hexavalent chromium) aid in the prevention of disease or health effect?

2. How will the information be used to: a) protect community health, b) address community concerns; and c) take appropriate action?

3. Are there programs/resources in place to act on findings, if necessary?

4. What follow-up will occur and who is responsible?

These questions are answered below in the context of the recommended Community Health Exposure Prevention and Testing Program.

Community Concern

Jersey City has a long history of exposure to chromium processing and the use of chromate chemical production waste (CCPW), a by-product generated from the production of sodium dichromate, as construction fill material. CCPW contains hexavalent chromium, Cr(VI), which may cause lung cancer in humans and has been linked to other health effects, such as respiratory and dermal conditions. These health effects have generally been observed and studied in worker populations that have been exposed to high levels of Cr(VI) over a long duration.[3] Low level ambient exposure of the type that may be present in the Garfield Avenue community and possible related health effects have been the subject of limited research. Importantly, no research results have established a clear causal link between health effects and exposure to background levels of chromium for residents living near waste sites. Where associations have been observed, they may be attributed to chance or other factors, such as smoking, and, therefore, are not definitive.

According to information developed by NJDEP, three chromite ore-processing plants, which operated for approximately 70 years between 1905 and 1971, generated more than two million tons of waste disposed of in Hudson County. One of these plants was operated by PPG at its former chromium chemical production facility location at Garfield Avenue in Jersey City.

CCPW has been found at residential, commercial and industrial locations. Chromate waste from the Hudson County facilities was used as fill in preparation for building foundations, roadway construction, filling of wetlands, sewer construction and other construction and development projects. Chromate contamination has been found in a variety of places including the walls and floors of buildings, interior and exterior building surfaces, surfaces of driveways and parking lots and in the surface and subsurface of unpaved areas.

[3] ATSDR Toxicological Profile for Chromium, Draft for Public Comment, September 2008, www.atsdr.cdc.gov/toxprofiles/tp7.html#bookmark03

In the late 1980s, more than 200 waste sites in Hudson County were identified and investigated and since then have either been cleaned up, capped or determined not to pose a threat to public health until they can be remediated. In Jersey City, 145 residential and industrial sites were identified and during the 1990s; 50 sites - nearly 40 percent – were cleaned up.[4] The rest, which are awaiting cleanup, have been stabilized through interim measures or lay deep enough underground not to cause ongoing community exposure.

Most of the site remediation occurred only after legal action directed cleanup through Administrative Consent Orders (ACO). Cleanup priority was directed at known residential sites, which have since been remediated. However, remediation of large industrial waste sites in Jersey City, such as the Garfield Avenue Site, has only been addressed through further legal action. The largest industrial site, a 34-acre site along banks of the Hackensack River owned by the Honeywell International, Inc., is nearing cleanup completion after the Interfaith Community Organization (ICO) won a lawsuit in 2003 requiring expedited remediation.

Despite considerable activity in the 1990s to deal with the legacy of chromium waste in Hudson County, little data exists to characterize background levels of chromium in the air before sites began to be cleaned up and capped. Subsequent sampling, though limited, shows chromium at levels far below those considered to be a health danger. As described in more detail later in this report, household dust studies conducted by the Environmental and Occupational Health Sciences Institute (EOHSI) show that chromium-tainted dust in homes near waste sites was reduced by as much as 85 percent following site remediation.[5] More recent studies show dust levels at homes near waste sites in Jersey City at levels comparable to homes in New Brunswick where there is no legacy of chromium processing sites.[6]

The most effective way of addressing potential problems associated with waste sites is to clean them up. That is the objective of the court settlement and 5-year master schedule. Nonetheless, the ubiquity of chromium waste in Jersey City and the associated health concerns of the Garfield Avenue Site community argue for a combination of actions linked to planned remediation activities that will:

- ✓ Assess current exposure conditions to measure against future conditions;
- ✓ Protect the community from new exposure;

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[4] Chromate Chemical Production Waste Sites Status, May 1, 2009, NJDEP, Division of Remediation Management and Response

[5] Freeman, N. et al., *Reduction in Residential Chromium Following Site Remediation,* J. Air & Waste Manage. Assoc. 50:948-953, June 2000

[6] NJDEP, Office of Science, *Characterization of Hexavalent Chromium Concentrations in Household Dust in Background Areas*, June 2009 http://www.state.nj.us/dep/dsr/chromium/bckgrd-cr.pdf

- ✓ Map residential soil samples to determine levels of contamination above background, if any;
- ✓ Share quality-assured information with maximum transparency;
- ✓ Collect information that can objectively characterize the likelihood of residents' exposure to dangerous levels of chromium;
- ✓ Integrate results collected with existing data to provide more complete assessment of residents' exposure.

II. SCOPE AND METHODS OF THE HEALTH EXPOSURE STUDY ASSESSMENT

The health exposure study assessment was completed for the specific community of residents living in the vicinity of the Garfield Avenue Site in Jersey City. As such, the scientific literature review initially focused on past and current studies looking at chromium (Cr) and hexavalent chromium-contamination and possible Cr(VI)-mediated health effects in Jersey City and Hudson County. The review was further expanded to include studies of other Cr(VI)-exposed communities in the United States and abroad, as well as studies of workers occupationally exposed to Cr(VI), research on the carcinogenicity of Cr(VI), and sources on Cr(VI)'s toxicity and toxicology.

In considering the appropriateness of a health exposure study and its potential format, literature was reviewed regarding biomarkers, biomonitoring, screening tests for specific health endpoints, health study options and protocols. More than 50 scientific studies were reviewed.

Federal and state environmental and health agency databases and websites (e.g., USEPA, CalEPA, NJDEP, ATSDR) provided valuable sources of background and insight into the science, policy, technical and logistical complexities of chromium-related issues.

As required by the Consent Judgment, the assessment included interviews with local, regional and national experts and practitioners in the areas described above in order to gain additional insight into the current understanding of how Cr(VI) behaves in the environment, how it acts in human subjects and how body burdens can be measured and interpreted. Close to 20 individuals were contacted with expertise in the following areas: risk assessment, toxicology, environmental and occupational medicine, pharmacology, heavy metal carcinogenesis, cancer screening, biomarker research, environmental epidemiology, and biological monitoring.

The information gleaned from this review and research was used to inform the Site Administrator's recommendations regarding a future health study for the residents living in the vicinity of the Garfield Avenue Site. The following paragraphs summarize key health studies. A more complete examination of these and other studies follows the Executive Summary.

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III. PUTTING HEALTH STUDIES IN CONTEXT

Studies in Hudson County

Over the past two decades, the Jersey City community has been the focus of numerous health studies looking at exposure to chromium from CCPW sites and potential related health effects. Beginning in 1990, researchers from NJDEP, New Jersey Department of Health (NJDOH) and the Environmental and Occupational Health Sciences Institute (EOHSI) began collaborating on the first of a series of studies that measured chromium in household dust in homes located near CCPW sites and measured chromium in urine samples collected from residents of these homes.

The data from these studies showed a correlation between proximity to CCPW sites and the level of total chromium in household dust.[7] They also showed that children in households with elevated total chromium in dust had higher Cr in their urine.[8]

A follow-up at homes near CCPW sites that had been remediated showed significant declines in total Cr in household dust, essentially down to background levels.[9] In one example, homes that had previously been identified as having had high (> 500 ppb) or medium (100-400 ppb) levels of total Cr in house dust, showed an approximately 85% decline in Cr concentrations post-remediation.[10]

In 2006, due to continuing public concern over potential Cr(VI) exposure from the remaining unremediated CCPW sites in Jersey City, EOHSI initiated a new two-phase study of potential Cr(VI) exposure. In Phase I, 100 homes were sampled for Cr(VI) in household dust, which

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[7] Lioy, P., et al. *Microenvironmental Analysis of Residential Exposure to Chromium-Laden Wastes in and Around New Jersey Homes* Risk Analysis 12(2), 287-299, 1992

[8] Stern, A, et al. *Residential Exposure to Chromium Waste – Urine Biological Monitoring in Conjunction With Environmental Exposure Monitoring,* Env. Research 58, 147-162, 1992

[9] Freeman, N. et al., *Reduction in Residential Chromium Following Site Remediation,* J. Air & Waste Manage. Assoc. 50:948-953, June 2000

[10] Ibid

averaged 3.7 µg/g (ppm), with a maximum value of 90.4 µg/g.[11] To provide "background levels" with which to compare the Cr(VI) levels found in household dust in Jersey City, EOHSI collected dust samples from 20 homes in the New Brunswick area, an urban setting unaffected by CCPW sites. Cr(VI) was detected in all of the homes sampled, with an average of 4.6 ppm and a maximum of 56.6 ppm.[12]

Researchers found no significant difference in the household dust Cr(VI) concentrations between the background area and Jersey City. Sources of the Cr(VI) in both areas are undefined. It is possible that at least some of the Cr(VI) in the dust came from materials inside the house, such as older wooden furniture and structural elements.[13] Furthermore, "comparison of the relationship of Cr(VI) with Cr(III) concentrations in the background locations and Jersey City suggested that COPR [CCPW] was not a major source of Cr(VI) in house dust in Jersey City."[14]

Currently, the second phase of the two-phase study is underway. EOHSI is actively recruiting homes with children 6 years old and younger in which to collect household dust samples for Cr(VI) measurements and to collect urine samples from children.

A final health study of note pertaining to this community is a study of lung cancer incidence in Jersey City that was completed by New Jersey Department of Health and Senior Services (DHSS). Using an individual's residential address at the time of a cancer diagnosis as a surrogate for exposure potential, the study examined whether lung cancer incidence rates differ within Jersey City based on distance from CCPW sites. The study looked at lung cancer incidence data from the New Jersey State Cancer Registry over the 25-year period of 1979 to 2003.

Based on the internal comparison within Jersey City, an increased risk of lung cancer incidence was found for populations living in close proximity to historic CCPW sites, although the increases were not statistically significant, meaning the differences in rates are low enough that they could be explained by chance. While the results suggest that living closer to CCPW sites is a potential risk factor for the development of lung cancer, the findings do not prove a cause-effect relationship. The study authors comment: "it is important to note that the historic potential

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[11] Lioy, P. and Gochfeld, M., *Final Report: Chromium Exposure and Health Effects in Hudson County: Phase I*, November 2008, http://www.state.nj.us/dep/dsr/chromium/chrom-exposure-phase%201.pdf

[12] NJDEP, Office of Science, *Characterization of Hexavalent Chromium Concentrations in Household Dust in Background Areas*, June 2009 http://www.state.nj.us/dep/dsr/chromium/bckgrd-cr.pdf

[13] Ibid

[14] Ibid

exposures described in this investigation do not represent the current conditions in the city, since considerable remediation of the CCPW sites has occurred."[15]

Studies in California

While the Consent Judgment only required a review of health studies limited to Hudson County, it is essential to review any current health research that could have a bearing on potential exposure in Jersey City. As a result, several health studies sponsored by the Agency for Toxic Substances and Disease Registry (ATSDR) for two California communities with inhalation exposures to Cr(VI) compounds were evaluated for their relevance to Jersey City exposure patterns. In both California communities, residents were exposed to ambient levels of Cr(VI) from chromium plating operations at levels much higher than Jersey City.

A cancer registry review completed for the Willits, CA community near the Abex/Remco facility (which operated between 1963 and 1995) did not find a statistically significantly elevated number of cancers. The number of lung cancers and respiratory cancers was greater than the number expected, but the difference was not large enough to be distinguished from a difference that could occur by chance.[16] Similarly, a mortality data review did not find statistically significant increases in mortality.[17] On the basis of air modeling, estimated annual Cr(VI) concentrations ranged between 50.0 *n*g/m^3 and 10,000 ng/m^3 for 1968-1975 and ranged between 20.0 *n*g/m^3 and 1,000 ng/m^3 (and possibly as high as 20,000 ng/m^3 or higher) for 1976-1989.[18]

Similar findings were made for the residents living near the Chrome Crankshaft and J&S Chrome Plating operations in Bell Gardens, CA, which operated between 1953 and 1999. No excess cancer rates that could be attributed to the facilities were found.[19] During the years before air emissions were reduced (due to the closure of J&S Chrome Plating and to the installation of air control devices at Chrome Crankshaft), estimated annual average Cr(VI) concentrations in air

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[15] ATSDR, *Analysis of Lung Cancer Incidence Near Chromium-Contaminated Sites in New Jersey (a/k/a Hudson County Chromium Sites), Jersey City, Hudson County, New Jersey*, September 2008, www.atsdr.cdc.gov/HAC/pha/Chromium-Contaminated%20Sites%(NJ)%20093008.pdf

[16] ATSDR, *Evaluation of Health Studies Possibilities and Limitations at the Abex/Remco Hydraulics Facility (07/11/06)* http://www.ehib.org/cma/projects/AbexHC.pdf

[17] Ibid

[18] California Department of Health Services, *Public Health Assessment: Evaluation of Exposure to Historic Air Releases From the Abex/Remco Hydraulics Facility, Willits, Mendocino County, California* (July 2004) http://www.ehib.org/cma/projects/AbexRemcoFinalAirPHA.pdf

[19] California Department of Health Services, *Review of Cancer Rates in the Vicinity of Chrome Crankshaft Company and J and S Chrome Plating Company (January 2003)* http://www.atsdr.cdc.gov/hac/pha/pha.asp?docid=13&pg=0

ranged from 0.16 ng/m^3 to 15.16 ng/m^3; Measured samples (while both facilities were still operating) ranged from non-detect to 430 ng/m^3.[20]

Because occupational exposures to Cr(VI) compounds have been shown to cause asthma in some workers, some residents have expressed concern that environmental exposures to Cr(VI) could also cause asthma in children. A retrospective cohort study in one of the California communities examined whether children exposed to airborne Cr(VI) had higher risk of asthma based on attendance at schools located next to two chromium-emitting facilities.[21]

Air modeling estimated annual average air concentrations of 0.1216 *u*g/m^3 and 0.00002 *u*g/m^3 for high and low exposure periods. The highest Cr(VI) air concentration measured in the neighborhood was 0.430 *u*g/m^3. Analysis did not support an association between the development of asthma among children and exposure to airborne Cr(VI) by attending a school next to a Cr(VI)-emitting facility.[22]

Notes on Biomonitoring and Screening

Biomarkers are much in the news lately as potentially promising ways of detecting exposure to contaminants or as early evidence of health effects.

Currently, the most reliable biomarkers of Cr(VI) exposure are urine and blood, both of which are indicators of relatively recent exposure. Cr(VI) concentrations in urine and blood (specifically red blood cells) can only indicate potential exposure, but say nothing about the risk of developing specific diseases or conditions.

A new sensitive assay has been developed which is able to specifically identify DNA-protein crosslinks which are caused by Cr(VI). It is currently not known how long it would take to develop the assay to the point where it could be used in a non-laboratory setting and meet the essential criteria for use as a biomarker. As yet, there is not enough evidence to determine what is considered an abnormal level of DPC. And although DNA-protein cross-linking by chromium is known to damage DNA, considered a potential step in the continuum to cancer, DPC as a biomarker cannot yet be used to correlate with a specific cancer or risk of cancer.

While there is much research being conducted in the area of cancer biomarkers, as yet there are no biomarkers for lung cancer or gastrointestinal cancers that are available for the general population. Currently no simple and accurate screening test exists for detecting and diagnosing

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[20] California Department of Health Services, *Review of Cancer Rates in the Vicinity of Chrome Crankshaft Company and J and S Chrome Plating Company (January 2003)* http://www.atsdr.cdc.gov/hac/pha/pha.asp?docid=13&pg=0

[21] ATSDR, *Asthma and Related Respiratory Conditions Among Children: A Study Concerning Attending School Near Two Chromium Plating Facilities [Chrome Crankshaft and J&S Chrome Plating, Los Angeles County]* (February 2005) http://www.ehib.org/cma/projects/CCHealthStudy.pdf

[22] Ibid

lung cancers early. Tests such as chest x-ray, CT scan and sputum collection are not recommended by the National Cancer Institute as screening tests for the general population. Nor are there screening tests for gastrointestinal cancers.

IV. RECOMMENDED COMMUNITY HEALTH EXPOSURE PREVENTION AND TESTING PROGRAM

As per the Consent Judgment, before deciding whether to recommend "a health exposure study for the residents living in the vicinity of Garfield Avenue," relevant health study data was reviewed and the opinions of health and science experts were considered. This information was evaluated in the context of protecting the public's health from potential exposures related to the remediation of the Garfield Avenue Site.

After a thorough review of the data and information collected, the Site Administrator developed a preliminary set of recommendations which were shared with the parties to the settlement. Those recommendations have been largely incorporated into the protective health measures that are planned for cleanup activities at the Garfield Avenue Site. Based on revisions to the cleanup work plan made subsequent to the preliminary recommendations, the Site Administrator believes the protective measures will protect the health and ensure the safety of residents living near the Garfield Avenue Site.

After reviewing scientific studies and expert opinions, the Site Administrator is recommending a Community Health Exposure Prevention and Testing Program. The recommended program will be three-tiered: 1) a comprehensive Air Monitoring Program to ensure the protection of the surrounding community during the remediation of the Garfield Avenue Site; 2) an accompanying health exposure program to determine whether the community is being exposed to Cr(VI) related to the site cleanup; and 3) a mapping project using results from the Residential Inspection Program established by the settlement to outline areas of soil contamination, if detected. In addition, the Site Administrator recommends actions to promote the second phase of the EOHSI household dust study. The details of the Community Health Exposure Prevention and Testing Program are outlined below.

A. AIR MONITORING PROGRAM

The activities associated with excavation, in-situ and/or ex-situ treatment and removal of CCPW from the Garfield Avenue Site present opportunities to generate work site dust. In order to ensure that the health and safety of off-site residents is being protected during these activities, continuous on-site and perimeter monitoring of ambient air will be conducted. The data generated will be independently reviewed and made available in an open and transparent manner. The Air Monitoring Program, as described fully in a separate Air Monitoring Plan that has been reviewed by DEP, will:

- Include measures to control CCPW-containing dust and potential Cr(VI) exposure to off-site residents;
- Establish an Action Level for total particulates and a risk-based concentration goal for Cr(VI) for monitoring in the exclusion (work) zone and at the site perimeter;
- Continuously monitor and document airborne particulate and Cr(VI) levels at on-site locations and at the fenceline (perimeter);
- Establish baseline conditions prior to remedial activities;
- Generate data to confirm successful dust control, as well as evaluate the need to initiate actions to mitigate dust generation in real-time as the excavation proceeds;
- Require program activity and data review by independent Technical Consultant;
- Post air monitoring data on the www.chromecleanup.com website.

A key component of the air monitoring program will be the development of a risk-based concentration limit for Cr(VI) in order to protect residents from exposure to Cr(VI) during remedial activities. The risk-based Cr(VI) concentration limit in ambient air will be calculated using a cancer risk methodology (representing the cumulative average risk over the 5-year duration of the remediation project). Since Cr(VI) cannot be measured in real-time, a surrogate real-time Action Level for total particulates (PM_{10}) will also be calculated. The real-time total particulate concentrations in the Exclusion (Work) Zone will be averaged every five minutes in order to provide site personnel ample time to evaluate dust sources, employ dust control procedures or, when necessary, cease operations in order to prevent off-site exposures to elevated levels of contaminants.

B. COMMUNITY HEALTH EXPOSURE TESTING PROGRAM

In addition to the Air Monitoring Program, health exposure testing for residents is proposed in order to determine whether the community is being exposed to Cr(VI) related to the remedial activities. Blood testing is being offered to respond to community concerns about potential exposures during remediation. It is not being prescribed because of concerns about past exposures. A sampling of area residents' blood would be tested before, during and after cleanup activities to determine whether increases of Cr(VI) above levels of concern were observed. The voluntary program would be open to all residents living in the area from the Garfield Avenue Site west to Ocean Avenue; south to Bayview Avenue and north to Bramhall Avenue. The program will consist of:

- An initial screening for chromium level in red blood cells (blood screening) to be completed before any remedial excavation activities are initiated at the Garfield Avenue Site in order to establish a baseline for comparison purposes;

- Semi-annual blood screenings throughout the period of land-disturbing remedial activities;
- Physical examinations for evidence of medical conditions that indicate a recent exposure to Cr(VI), if red blood cell sampling results are elevated above a level of concern;
- Data management and integration of participant blood data with environmental exposure studies data; and
- Protections for participant privacy.

C. RESIDENTIAL INSPECTION PROGRAM RESULTS MAPPING PROJECT AND EOHSI DUST STUDY PROMOTION

1. Residential Inspection Program Results Mapping Project

As stated earlier, the goal of the recommended Community Health Exposure Prevention and Testing Program is to ensure that the health of residents living in the vicinity of the Garfield Avenue Site is protected during site remediation and into the future. Supporting this goal is the Residential Inspection Program, established by the Consent Judgment to address the concerns of residents living near the PPG sites who suspect chromium waste may be in or on their property. Residents living in the area from the Garfield Avenue Site west to Ocean Avenue, south to Bayview Avenue and north to Bramhall Avenue are eligible to request an inspection under the program. Residential-related properties located within these boundaries, such as daycare centers, school and playgrounds, are also eligible.

The Residential Inspection Program will determine through inspections and sampling if elevated levels of Cr(VI) are present. Chromium waste that exceeds NJDEP standards will at a minimum be cleaned up to standards. In this way, both CCPW on the Garfield Avenue Site and residual CCPW on surrounding residential properties will be removed, thereby helping protect the community's health.

The information collected through site sampling is of great value in determining the extent of CCPW contamination within the Garfield Avenue Site community. The Site Administrator recommends that the Residential Inspection Program Results Mapping Project be developed to share sampling results through location maps and public reports in order to provide the broader community with an accurate picture of residential contamination conditions. Information would be shared with the public through website posting and newsletters, as appropriate.

2. EOHSI Dust Study Promotion

Through various exposure-oriented studies, EOHSI has aided in providing an objective science-based assessment of Cr(VI) exposure to Jersey City residents for the past two decades. Their latest active study is the second phase of an earlier examination of Cr(VI) in household dust,

which was initiated in 2006 in response to continuing public concern over potential Cr(VI) exposure from the remaining unremediated CCPW sites. Because EOHSI found Cr(VI) in household dust in Phase I, suggesting a potential for exposure, they implemented the second phase of the study in 2009. Currently, EOHSI is actively recruiting homes with children 6 years old and younger in which to collect household dust samples for Cr(VI) measurements and to collect urine samples from children.

The Site Administrator recommends that community participation in the EOHSI study be encouraged through promotion activities of the parties to the Consent Judgment.

V. CRITERIA CONSIDERED FOR POTENTIAL HEALTH EXPOSURE STUDY

As stated earlier, a series of criteria-based questions was asked when considering what type of health exposure study, if any, would be appropriate for the residents living in the vicinity of the Garfield Avenue Site. These questions are answered below in the context of the selected comprehensive site-related exposure monitoring program.

Will the data gathered aid in the prevention of disease or health effect?

The data gathered under the recommended Community Health Exposure Prevention and Testing Program will be of two types: biological sample data and air monitoring data. Air monitoring data will be used to document the degree to which remedial activities expose the community to elevated levels of Cr(VI) in ambient air. Biological samples will be used to document whether individuals are being exposed to Cr(VI) in their environment. The data collected will be part of a comprehensive program designed to limit and assess exposure and, therefore, is inherently preventative in nature (even while existing health studies do not clearly establish that adverse health effects result from low levels of exposure for periods of short duration).

How will the information be used to protect community health?

The air monitoring data gathered will be used to protect community health by showing whether there are elevated levels of Cr(VI) dust in ambient air and whether the dust is leaving the remedial site. If it is determined that dust at elevated levels is being generated and leaving the site, work will be stopped until work procedures can be re-evaluated and reconfigured in order to eliminate this problem.

Simultaneously, biological testing can show whether individuals are being exposed to Cr(VI). If this is detected, steps can be taken to identify the route of exposure and/or eliminate the source.

How will the information be used to address community concerns?

One of the community's primary concerns is protection from exposure to Cr(VI) during remediation and the air monitoring data will document actual conditions and show that Cr(VI)

concentrations in ambient air are maintained below target levels. Air monitoring information will be shared with the public through website posting and newsletters.

Biological testing can confirm that individuals are not being exposed to elevated levels as a result of remediation.

How will the information be used to take appropriate action?

The Action Level for PM_{10} will be used to control remediation operations. Because the continuously collected PM_{10} measurements in the Exclusion (Work) Zone are averaged every five (5) minutes, site personnel have ample time to implement corrective actions before Action Levels are exceeded at the site perimeter. Additionally, if air monitoring data indicates that the risk-based Cr(VI) concentration is being exceeded, the project will be shut-down and if necessary reconfigured until PPG can show appropriate measures are in place to prevent further exceedances and to protect human health.

If biological testing shows elevated levels of Cr(VI) in blood samples, a physical exam by a medical professional experienced in environmental and occupational medicine can be conducted to determine if Cr(VI)-mediated health concerns are present in an individual.

Are there programs/resources in place to act on the findings, if necessary?

The Health and Safety Plan and Standard Operating Procedures for the Garfield Avenue Site identify the procedures to be followed if an Action Level is exceeded. The Site Administrator has the authority to order the work at the site stopped until it can be shown that measures are in place to protect the public.

What follow-up will occur and who is responsible?

If air monitoring demonstrates that Cr(VI)-contaminated dust is migrating offsite at concentrations above risk-based levels, PPG is responsible for shutting down remedial operations and revamping procedures to ensure that future remedial activities are protective of human health.

VI. CONCLUSIONS

After reviewing the data in numerous health studies, reports and websites, and after discussing the state of Cr(VI) science with various health experts, a comprehensive Community Health Exposure Prevention and Testing Program is recommended for the residents living in the vicinity of the Garfield Avenue Site. This three-tier protocol is designed to prevent the public from being exposed to elevated levels of Cr(VI) during remediation, provide reassurance to the community that their health is being protected and provide a more complete picture of area residents' current exposure to Cr(VI).

I. INTRODUCTION

A. OVERVIEW

Chromium Cleanup Settlement

On June 26 2009, a Partial Consent Judgment was entered with the Superior Court of New Jersey, binding the New Jersey Department of Environmental Protection, PPG Industries, Inc., and the City of Jersey City to work together to remediate 20 chromium sites in Hudson County for which PPG is responsible. The unique collaborative arrangement created by the settlement was designed to "remediate the soils and sources of contamination at the PPG Sites as expeditiously as possible with a five (5)-year goal for completion."[23]

To help meet this objective, the position of independent Site Administrator with oversight responsibilities was established. The responsibilities vested in this position include developing a judicially enforceable 5-year master schedule, facilitating parties' progress in meeting master schedule milestones, hiring an independent technical consultant, maintaining regular communications with community representatives, and communicating community concerns to the partnership. Environmental consultant and former USEPA Deputy Administrator W. Michael McCabe was appointed to this position by court order in July 2009.

In particular, the Site Administrator has responsibility to:

- Develop a judicially enforceable master schedule, including a timetable for submitting project work plans by PPG, reviewing those documents by an independent technical consultant and issuing subsequent ruling by NJDEP;
- Monitor closely, facilitate and promote partnership progress in meeting master schedule milestones:
- Conduct meetings to resolve issues that might arise;
- Hire an independent technical consultant and experts as needed for the review of PPG's submittals;
- Maintain regular communications with community representatives, soliciting their opinions and ideas; and
- Communicate community concerns to the partnership.

[23] Partial Consent Judgment Concerning The PPG Sites (Civil Action No.: HUD-C-77-05), June 26, 2009, p. 7, X.8

In addition, the Site Administrator was given the responsibility for reviewing chromium-related health studies, consulting with experts in the field and, if necessary, recommending a health exposure study that would monitor people living within the vicinity of one of PPG sites, the Garfield Avenue Site. The work completed to fulfill this requirement is described in detail below.

B. SCOPE OF THE HEALTH EXPOSURE STUDY ASSESSMENT

The health exposure study assessment was completed for the specific community of residents living in the vicinity of the Garfield Avenue Site in Jersey City. As such, the scientific literature review initially focused on past and current studies looking at chromium (Cr) and hexavalent chromium [Cr(VI)] contamination and possible Cr(VI)-mediated health effects in Jersey City and Hudson County. The review was further expanded to include studies of other Cr(VI)-exposed communities in the United States and abroad, as well as studies of workers occupationally exposed to Cr(VI), research on the carcinogenicity of Cr(VI), and sources on Cr(VI)'s toxicity and toxicology.

In considering the appropriateness of a health exposure study and its potential format, literature was reviewed regarding biomarkers, biomonitoring, screening tests for specific health endpoints, health study options and protocols. More than 50 scientific studies were reviewed.

Federal and state environmental and health agency databases and websites (e.g., USEPA, CalEPA, NJDEP, ATSDR) provided valuable sources of background and insight into the science, policy, technical and logistical complexities of chromium-related issues.

As required by the Consent Judgment, the assessment included interviews with local, regional and national experts and practitioners in the areas described above in order to gain additional insight into the current understanding of how Cr(VI) behaves in the environment, how it acts in human subjects and how body burdens can be measured and interpreted. Close to 20 individuals were contacted with expertise in the following areas: risk assessment, toxicology, environmental and occupational medicine, pharmacology, heavy metal carcinogenesis, cancer screening, biomarker research, environmental epidemiology, and biological monitoring.

The information gleaned from this review and research was used to inform the Site Administrator's recommendations regarding a future health study for the residents living in the vicinity of the Garfield Avenue Site.

C. METHODS

The foundation of this assessment rests on an impartial analysis of health studies and other research pertaining to Hudson County, occupational studies, studies of Cr(VI) exposure in other

communities, current research of Cr(VI)-mediated health effects and health screening tests and protocols.

Relevant studies, reports, documents and state and federal agency websites were reviewed for background and insight into the science, policy, technical and logistical complexities of these issues.

The primary source of information comes from health studies and documents referenced throughout the report and interviews with health and science experts. Close to 20 individuals (see a list in Appendix C) were interviewed with expertise in the following areas:

- Risk Assessment
- Toxicology
- Environmental Medicine
- Pharmacology
- Heavy Metal Carcinogenesis
- Cancer Screening and Biomarker Research
- Environmental Epidemiology
- Pharmacokinetics
- Occupational Medicine
- Biological Monitoring
- Environmental Fate and Transport
- Cr(VI) Biomarkers

II. JCO SETTLEMENT: HEALTH EXPOSURE STUDY REQUIREMENT

As part of the Duties and Responsibilities of Site Administrator, a provision was included in the Consent Judgment requiring the Site Administrator to:

> *"Review previous and ongoing health studies concerning the health impacts of chromium in Hudson County and consult with experts in the field and, if necessary, to recommend a protocol for a future medical study (health exposure study), that would monitor the people living within the vicinity of the Garfield Avenue Site to ascertain chromium exposure risks…."*[24]

An extensive review of existing health study literature and research was conducted to form the foundation for the recommendations in this report.

[24] Ibid, p. 18, XVI. 49 (g)

III. HEALTH EFFECTS ASSOCIATED WITH HEXAVALENT CHROMIUM EXPOSURE

The primary sources of information regarding the health effects of Cr(VI) come from studies of occupational exposures, as well as animal studies. The primary health endpoints associated with high levels of exposure to Cr(VI) are summarized below. This discussion is drawn from the ATSDR Public Health Statement for Chromium.[25]

A. NON-CANCER EFFECTS

- ***Respiratory effects***

  The most common health problems in workers exposed to chromium involve the respiratory tract. Breathing high levels of Cr(VI) can irritate the lining of the nose, and cause nose ulcers, runny nose, and respiratory problems, such as asthma, cough, shortness of breath, or wheezing. ATSDR notes: "workers have also developed allergies to chromium compounds, which can cause breathing difficulties and skin rashes."[26]

  Respiratory tract problems similar to those observed in workers have been seen in animals exposed to Cr(VI) via inhalation.

  ATSDR states that "the concentrations causing respiratory problems in workers are at least 60 times higher than levels normally found in the environment."[27]

- ***Stomach and small intestines***

  Health problems seen in animals following ingestion of Cr(VI) compounds include irritation and ulcers in the stomach and small intestine, as well as anemia. Some occupational studies showed stomach pains, cramps and ulcers in workers exposed to Cr(VI) via inhalation.[28]

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[25] ATSDR, Public Health Statement for Chromium, http://www.atsdr.cdc.gov/toxprofiles/phs7.html

[26] Ibid, Section 1.5.

[27] Ibid

[28] ATSDR Toxicological Profile for Chromium, Chapter 3:Health Effects, http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

- ***Male reproductive system***

  Laboratory animals exposed to Cr(VI) have shown sperm damage and damage to the male reproductive system.

- ***Dermal effects***

  Contact with Cr(VI) compounds can produce deleterious effects on the skin and mucous membranes, including irritation, burns, ulcers, allergic dermatitis, and allergic reactions consisting of severe redness and swelling of the skin.

B. CANCER

- ***Respiratory***

  The Department of Health and Human Services (DHHS), the International Agency for research on Cancer (IARC), and the EPA have determined that Cr(VI) compounds are known human carcinogens.

  Occupational exposure to Cr(VI) has been shown to cause lung cancer, and less consistently nasal cancer. Numerous animal studies have shown Cr(VI) to cause lung cancer and other respiratory tract cancers.

- ***Gastrointestinal***

  In July 2008, the National Toxicology Program published results of its two-year studies on the ingestion of Cr(VI) in drinking water by rats and mice. The study found clear evidence of carcinogenic activity in the oral cavity of rats and in the small intestine of mice.[29]

  In another study, an increase in stomach tumors was observed in humans environmentally exposed to Cr(VI) in drinking water.[30]

[29] National Toxicology Program, National Institutes of Health, NTP Technical Report on the Toxicology and Carcinogenesis Studies of Sodium Dichromate Dihydrate in F344/N Rats and B6C3F1 Mice (Drinking Water Studies), July 2008 http://ntp.niehs.nih.gov/files/546_WEB_FINAL.pdf

[30] ATSDR Toxicological Profile for Chromium, Chapter 2: Relevance for Public Health, http://www.atsdr.cdc.gov/toxprofiles/tp7-c2.pdf

C. EFFECTS IN CHILDREN

Very few studies have looked at the effects of Cr(VI) exposure on children. ATSDR says, "it is likely that children would have the same health effects as adults. It is unknown whether children would be more sensitive than adults to the effects of chromium."[31]

A retrospective cohort study in one California community examined whether children exposed to airborne Cr(VI) had higher risk of asthma based on attendance at schools located next to two chromium-emitting facilities.[32] Analysis did not support an association between the development of asthma among children and exposure to airborne Cr(VI) by attending a school next to a Cr(VI)-emitting facility.

There are no studies showing that Cr(VI) causes birth defects in humans. In animal studies, exposure to high doses of Cr(VI) during pregnancy caused miscarriage, low birth weight, and impaired development of the skeletal and reproductive systems.[33]

IV. STUDIES REVIEWED AND RESULTS

Under the Consent Judgment's health study requirement, the first task for the Site Administrator is to review previous and ongoing health studies concerning the health impacts of chromium in Hudson County. As such, the study authors initially focused on studies pertaining directly to Jersey City and Hudson County. The literature review was then expanded to include studies of communities elsewhere in the United States and abroad which had been environmentally exposed to hexavalent chromium. Studies of occupational exposures were reviewed, as were a variety of sources on biological monitoring, health screening, chromium toxicology and other relevant topics.

A. STUDIES SPECIFIC TO HUDSON COUNTY, NEW JERSEY

The study authors' review of health studies began with more than 20 technical reports and papers pertaining specifically to exposure and health studies conducted in Hudson County dating from

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[31] ATSDR, Public Health Statement for Chromium (September 2008) http://www.atsdr.cdc.gov/toxprofiles/phs7.html#bookmark06

[32] ATSDR, *Asthma and Related Respiratory Conditions Among Children: A Study Concerning Attending School Near Two Chromium Plating Facilities [Chrome Crankshaft and J&S Chrome Plating, Los Angeles County]* (February 2005) http://www.ehib.org/cma/projects/CCHealthStudy.pdf

[33] ATSDR Toxicological Profile for Chromium, Chapter 2: Relevance for Public Health, http://www.atsdr.cdc.gov/toxprofiles/tp7-c2.pdf

1989 and continuing through to the present. The list of studies specific to Hudson County is presented in Appendix A.

1. Health Studies in the 1990s

- ***Whitney Young Jr. School***

The first study to examine potential exposure to Cr(VI) in Jersey City was a study that looked at adults and schoolchildren at the Whitney Young Jr. School in Jersey City (PS#15). In June 1989, following reports of visual evidence of Cr on school walls, the New Jersey Department of Health (NJDOH) conducted a screening assessment of 165 adults and schoolchildren which included a visual exam of skin, nose and throat and a spot urine test "intended to provide an indication of potential recent exposure to chromium in the community."[34] In addition, researchers collected and analyzed samples of air, dust, soil and crystals scraped from basement walls.

The physical exams did not identify any conditions that could be specifically linked to chromium exposure and there was no evidence of chromium contamination of the basement walls. Thirty-six percent of children and 16 percent of adults showed Cr in urine above the detection limit of 0.3 µg/L. While there was no relationship for adults between urine Cr levels and residential proximity to Cr-contaminated sites, this was not the case for children. The proportion of children having detectable levels of Cr in the urine was highest among those living closest to known Cr-contaminated waste sites.[35]

- ***Chromium Medical Surveillance Project (CMSP)***

The Young School study ultimately led to the development of the Chromium Medical Surveillance Project (CMSP), which was conducted between January 1992 and June 1993. Based on proximity to known chromium waste sites, the NJDOH identified 14 residential areas and 78 workplaces to target for medical screening to assess exposure to chromium. A total of 2,224 individuals participated in the screening project. Those who participated were 1) given a screening physical exam of the skin and nasal passages (to look for irritant or allergic effects), 2) asked to supply a urine sample for a urine Cr test; and 3) asked to complete a questionnaire.[36] NJDOH also conducted a baseline urine survey of 317 persons living in various parts of New Jersey. Pertinent results included:

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[34] New Jersey Department of Health , *Medical Evaluation of Children and Adults of the Whitney Young Jr. School Jersey City, New Jersey* (December 1989)

[35] Ibid

[36] Fagliano, J. and Savrin, J., New Jersey Department of Health, *Chromium Medical Surveillance Project: Final Technical Report*, October 1994

- Of 806 residents and 934 workers who submitted urine samples, 158 adults and children had elevated urine Cr levels (more than 0.5 µg/L higher than the expected value) and were referred for follow-up evaluation.
- Of 800 residents and 938 workers who received the screening physical examination, 32 were referred for follow-up evaluation.
- Of those referred for follow-up examinations, six revealed clinical effects potentially attributable to Cr exposure. Five of the six were employed at screened workplaces and one was from a targeted residential area. Four of the six had skin conditions possibly related to Cr and three had persistent nasal allergies, but none had nasal perforations.
- Average urine chromium levels for all screened groups were higher than those from the control group; differences between screened and control groups were less as age increased
- The average urine Cr differences were greatest for children under 6 years of age: resident children (0.33 µg/L) vs. control children (0.20 µg/L)

▪ ***Household Dust Exposure Studies***

In 1990, researchers from EOHSI, NJDEP and NJDOH began collaborating on the Hudson County Chromium Exposure Assessment Study which attempted to estimate exposure to Cr from various media. During the summer of 1990, samples were collected of outdoor air, indoor air and household dust from homes near four chromium contaminated processing waste (CCPW) sites and from control homes, and analyzed for total Cr. At the same time, spot samples of urine were collected from residents.

The data showed a correlation between proximity to CCPW sites and the level of total chromium in household dust.[37] They also showed that children in households with elevated total chromium in dust had higher Cr in their urine.[38]

Household dust sampling was also offered to many participants of the Chromium Medical Surveillance Project. The testing was completed by EOHSI under a contract with NJDEP. Nineteen percent of individuals screened in the CMSP participated in what was called the Chromium Household Dust Study. EOHSI and NJDEP researchers found Cr concentrations in household dust and Cr loadings were higher in homes near CCPW sites than in control homes outside Hudson County (New Brunswick).[39] Further analysis of the data showed Cr

[37] Lioy, P., et al. *Microenvironmental Analysis of Residential Exposure to Chromium-Laden Wastes in and Around New Jersey Homes* Risk Analysis 12(2), 287-299, 1992

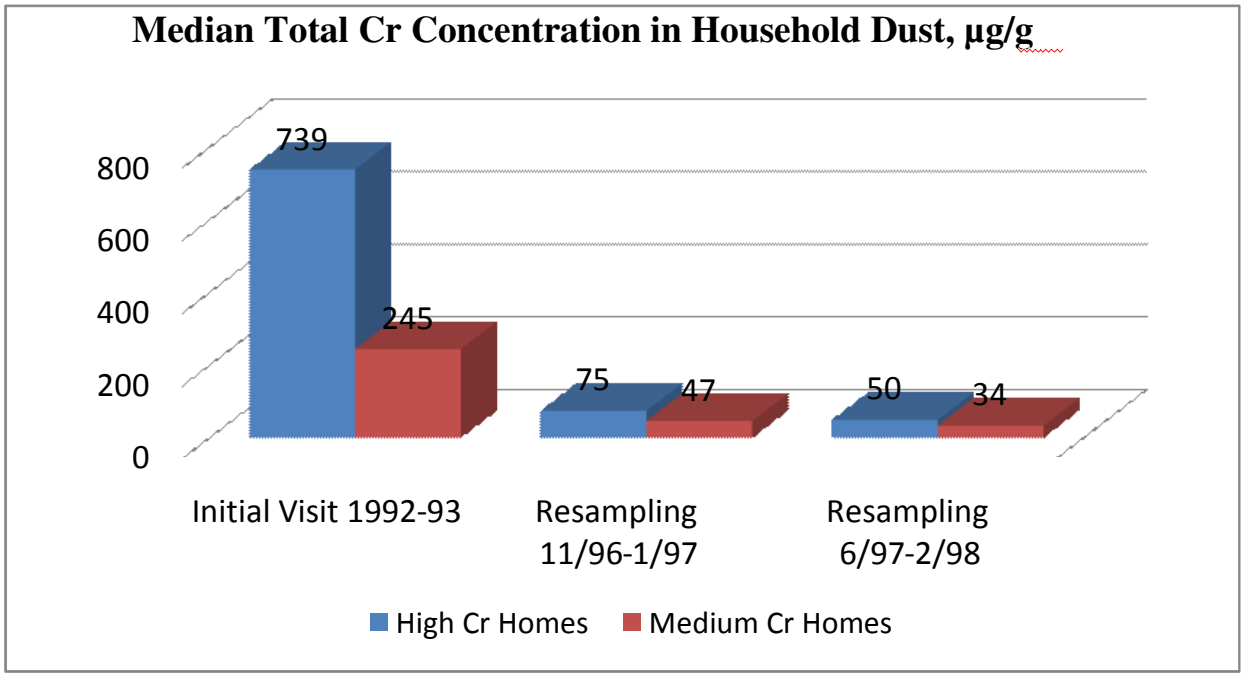
[38] Stern, A, et al. *Residential Exposure to Chromium Waste – Urine Biological Monitoring in Conjunction With Environmental Exposure Monitoring,* Env. Research 58, 147-162, 1992

[39] Freeman N., et al. *Exposure to Chromium Dust from Homes in a Chromium Surveillance Project*, Archives of Environmental Health, May 1997

concentration in household dust was a predictor of urine Cr across the entire age range of residents, particularly for children 10 years and younger.[40]

A follow-up at homes near CCPW sites that had been remediated showed significant declines in total Cr in household dust, essentially down to background levels.[41] In the 1992-93 Chromium Household Dust Study, homes were identified as having had high (> 500 ppb), medium (100-400 ppb) or low (< 100 ppb) levels of total Cr in house dust. Between November 1996 and February 1998, 23 homes from the original group were re-sampled. Homes that previously had high-level and medium-level total Cr concentrations in house dust showed an approximately 85% decline in Cr concentrations post-remediation. As seen in Figure 1 below, in high-level homes the median Cr concentration declined from 749 ppb to 50 ppb; in medium-level the median Cr Concentration declined from 245 ppb to 34 ppb.[42]

Figure 1: Reduction in Residential Chromium Following Remediation



[40] Stern A, et. al., *The Association of Chromium in Household Dust with Urinary Chromium in Residences Adjacent to Chromate Production Waste Sites,* Env. Health Perspectives, Vol 106, Num. 12, December 1998

[41] Freeman, N. et al., *Reduction in Residential Chromium Following Site Remediation,* J. Air & Waste Manage. Assoc. 50:948-953, June 2000

[42] Ibid

- ***Measurements of Cr(VI) Air Concentrations***

Several studies published between 1991 and 1997 considered the health hazards posed to workers working on and near CCPW sites and to residents living near CCPW sites. As part of these studies, researchers measured Cr(VI) air concentrations in a number of occupational and residential settings in Hudson County. Results from sampling included:

- Indoor air and outdoor air on a partially paved CCPW site with heavy truck traffic:[43] ranged from 0.57 to 27 ng/m^3; geometric mean was 2.5 ng/m^3
- Indoor and outdoor air at industrial sites in Hudson County contaminated with CCPW:[44] overall means of 3.0 ng/m^3 (indoor) and 9.9 ng/m^3 (outdoor)
- Indoor air in Jersey City residences distant from CCPW sites:[45] 0.38-3.3 ng/m^3, mean of 1.2 ng/m^3.
- Background air concentrations at an urban industrial site in Newark, NJ and background air concentrations at an undeveloped commercial property in Lyndhurst, Hudson County, NJ; both sites were geographically close to Jersey City CCPW sites but distant enough not to be influenced by particulate emissions from the sites:[46] Concentrations in Newark ranged from 0.2 to 3.8 ng/m^3; Concentrations in Lyndhurst ranged from 0.4 to 1.7 ng/m^3

- ***Study of DNA-Protein Cross-links***

In 1994, a team of researchers from NYU and Robert Wood Johnson Medical School examined the levels of DNA-protein cross-links (DPC) in lymphocytes of 33 individuals determined to be at risk for Cr(VI) exposure due to their residence in Hudson County. DPC are considered potential biomarkers for Cr(VI) exposure, since Cr(VI) is a cross-linking agent.[47] The study found elevated levels of DPC in Hudson County residents when compared with DPC in controls living in non-contaminated areas. However, because the assay used to identify DPC is not

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[43] Paustenbach, D. et al., *An Assessment and Quantitative Uncertainty Analysis of the Health Risks to Workers Exposed to Chromium Contaminated Soils*, Toxicology and Industrial Health (1991) 7: 159-196

[44]Falerios, M. et al*., Airborne Concentrations of Trivalent and Hexavalent Chromium from Contaminated Soils at Unpaved and Partially-Paved Commercial/Industrial Sites*, J. Air & Waste Manage. Assoc. (1991) 42:40-48

[45] Finley, B, et al., *Field Validation for Sampling and Analysis of Airborne Hexavalent Chromium,* Appl. Occup. Environ. Hyg. (1993) 8(3), 191-200

[46] Scott, P. et al. *Background Air Concentrations of Cr(VI) in Hudson County, New Jersey: Implications for Setting Health- Based Standards for Cr(VI) in Soil*, J. Air & Waste Manage. Assoc. 47:592-600

[47] Taoli, E. et al. *Increased DNA-Protein Crosslinks in Lymphocytes of Residents Living in Chromium-Contaminated Areas*, Biological Trace Research, Vol. 50, 1995

specific to Cr(VI), it is not possible to say whether the DPC were caused by Cr(VI) or by other agents which can also cause DPC, such as formaldehyde.

2. Household Dust Studies (2006-2009)

- ***Hudson County – Phase I***

Due to continuing public concern over potential Cr(VI) exposure from the remaining unremediated CCPW sites in Jersey City, EOHSI initiated a new two-phase study of potential Cr(VI) exposure in 2006. By this time, analytic methods to measure Cr(VI) had been developed and were used to specifically measure Cr(VI) in homes. In Phase I, EOHSI researchers collected dust samples from 100 homes in Jersey City between November 2006 and May 2008, with two to three samples collected in each home. Cr(VI) was found in all homes, with an average of 3.7 µg/g (ppm), and a maximum value of 90.4 µg/g. Six homes had a single high sample over 20 ppm, with no home having more than one sample over 20 ppm. With repeat sampling, two homes continued to be high (above 20 ppm).[48]

- ***Hudson County – Phase II (Ongoing)***

Since EOHSI did find Cr(VI) in household dust in Phase I, suggesting a potential for exposure, they implemented the second phase of the study in 2009. EOHSI is actively recruiting homes with children 6 years old and younger in which to collect household dust samples for Cr(VI) measurements and to collect urine samples from children.

- ***Background Study of Household Dust***

EOHSI also completed a background study to compare the Cr(VI) levels found in household dust in Jersey City with those in homes another urban New Jersey area. EOHSI researchers collected household dust samples from 20 homes in the New Brunswick area between April and September 2008, with three samples collected in each home. Cr(VI) was detected in all of the homes samples, with an average of 4.6 ppm and a maximum of 56.6 ppm. Only one home had a single high sample (over 20 ppm).[49]

Researchers found no significant difference in the household dust Cr(VI) concentrations between the background area and Jersey City. Sources of the Cr(VI) in both areas are undefined and their identification was not part of the design. It is possible that at least some of the Cr(VI) in the dust came from materials inside the house, such as older wooden furniture and structural elements.[50]

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[48] Lioy, P. and Gochfeld, M., *Final Report: Chromium Exposure and Health Effects in Hudson County: Phase I*, http://www.state.nj.us/dep/dsr/chromium/chrom-exposure-phase%201.pdf

[49] NJDEP, Office of Science, *Characterization of Hexavalent Chromium Concentrations in Household Dust in Background Areas*, June 2009 http://www.state.nj.us/dep/dsr/chromium/bckgrd-cr.pdf

[50] Ibid

Other sources are also possible, such as construction materials and cement, atmospheric deposition (from traffic, power generating plants) and from soil contaminated with Cr(VI) from sources such as fertilizer and sludge. Furthermore, "comparison of the relationship of Cr(VI) with Cr(III) concentrations in the background locations and Jersey City suggested that COPR (CCPW) was not a major source of Cr(VI) in house dust in Jersey City."[51]

3. Lung Cancer Incidence Study (2008)

In response to community concerns about the cancer implications of potential Cr(VI) exposure from CCPW sites, the New Jersey Department of Health and Senior Services (DHSS), with assistance from NJDEP, completed a study of lung cancer incidence in Jersey City. The study examined whether lung cancer incidence rates differ within Jersey City based on distance from CCPW sites. The study looked at lung cancer incidence data from the New Jersey State Cancer Registry over the 25-year period of 1979 to 2003. Residential proximity to CCPW sites at the time of an individual's cancer diagnosis was used as a surrogate for exposure potential.

First, NJDEP characterized the potential for residential Cr(VI) exposure in Jersey City. Based on measured or estimated Cr(VI) concentration, the CCPW sites were classified into three categories: 1) Cr(VI) > 900 ppm; 2) Cr(VI) concentration less than 900 ppm; and 3) no available Cr(VI) concentration. Site boundaries were mapped with 300-foot buffers drawn around the boundaries. Then the proportion of the residential area in each census block group that fell within a 300-foot buffer of each of the Cr(VI) concentration categories was calculated.

Census block groups were aggregated into "exposure intensity groups" of "none, low or high" based on the proportion of the residential part of the block group located within the 300-foot buffers around the CCPW sites.[52] NJDHSS then compared the incidence of lung cancer in the exposure intensity groups to 1) the cancer incidence for the whole state during 1979-2003 and 2) to the lung cancer incidence in non-exposed groups in Jersey City during the same period.

Based on the internal comparison within Jersey City, an increased risk of lung cancer incidence was found for populations living in close proximity to historic CCPW sites, although the increases were not statistically significant. Rates of lung cancer in high exposure areas as compared to no exposure areas were 7% to 17% higher for males and 0% to 10% higher for females depending on how "high exposure intensity" was defined. However, statistically the differences in rates are low enough that they could be explained by chance.

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[51] Ibid

[52] ATSDR, *Health Consultation: Analysis of Lung Cancer Incidence near Chromium-Contaminated Sites in New Jersey (a/k/a Hudson County Chromium Sites), Jersey City, Hudson County, New Jersey* (September 2008) http://www.atsdr.cdc.gov/HAC/pha/Chromium-ContaminatedSitesinNJ/Chromium-Contaminated%20Sites%20(NJ)%20093008.pdf

While the results suggest that living closer to CCPW sites is a potential risk factor for the development of lung cancer, these findings do not prove a cause-effect relationship. The study authors comment: "it is important to note that the historic potential exposures described in this investigation do not represent the current conditions in the city, since considerable remediation of the CCPW sites has occurred."[53]

Dr. Jerald Fagliano, one of the study authors, also pointed out that the report, *Cancer Incidence Rates in New Jersey's Ten Most Populated Municipalities, 1998-2002,* shows how cancer rates in New Jersey cities compare to each other and to the state. "Overall cancer rates in Jersey City were lower than the state for both males and females, but were similar to other cities like Paterson, Elizabeth and Edison Township. Cancers of the prostate, breast, lung (females), bladder (males and females), melanoma (males and females), thyroid (females), and kidney (males) were statistically significantly low compared to the state. Cervical cancer was statistically significantly high. In general, cancer rates appear to be similar to other cities with similar race/ethnicity composition and socioeconomic conditions."[54]

4. Gastrointestinal Cancer Incidence Study

Given the National Toxicology Program's 2008 finding that ingesting Cr(VI)-contaminated drinking water increases the risk of oral and small intestine cancers in rats and mice, the ATSDR analysis of lung cancer incidence report recommended that NJDHSS consider completing a similar study for the incidence of gastrointestinal cancers in Jersey City.

Following this recommendation, NJDHSS completed an analysis of gastrointestinal (GI) cancers for the 28-year period 1979-2006 using the same methods as the lung cancer incidence study (using address at time of diagnosis as a surrogate for exposure potential and grouping residential areas into exposure intensity groups – see discussion above, IV.A.3). The study looked at the incidence of the following GI cancers: oral, esophageal, stomach, and small intestine. Results of the study are expected in the second half of 2010.

B. HEALTH STUDIES OUTSIDE NEW JERSEY

Outside Hudson County, New Jersey a few other areas of the country have experienced significant Cr(VI) contamination issues, in particular California. While the majority of California's cases involve Cr(VI) contamination of drinking water, ATSDR has completed a few analyses of California communities exposed to Cr(VI) in air. Studies were also reviewed for communities in China and Sweden.

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[53] Ibid

[54] Cancer Incidence Rates in New Jersey's Ten Most Populated Municipalities, 1998-2002, http://www.state.nj.us/health/ces/documents/cancer_municipalities.pdf

1. Community Exposure Studies - California

The study authors looked at ATSDR studies of two California communities impacted by airborne exposures to Cr(VI) from chrome plating facilities.

- ***Abex/Remco Hydraulics Facility in Willits, California***

The Abex/Remco hydraulics facility located in Willits, California operated a chromium plating operation between 1963 and 1995.

The California Department of Health Services (now Department of Public Health), Environmental Health Investigations Branch (EHIB) completed a Public Health Assessment (PHA) to determine whether historic air releases of Cr(VI) from the facility between 1963 and 1995 could have harmed residents.

The report concluded that releases of Cr(VI) in the air from the facility posed a public health hazard during the period chromium plating operations were conducted (1963 to 1995). Air modeling data suggest potential non-cancer health effects and some increased risk of cancer (primarily lung). On the basis of air modeling, estimated Cr(VI) concentrations were:[55]

- The estimated annual average concentrations of Cr(VI) for 1968 – 1975 ranged between 50.0 *n*g/m^3 and 10,000 ng/m^3, depending on location in the community, with concentrations decreasing further away from the facility. ATSDR further determined that the average Cr(VI) concentrations in the adjacent community could have been between 1,000 ng/m^3 and 50,000 ng/m^3.[56]
- From 1976-1989: estimated annual average Cr(VI) concentrations ranged between 20.0 ng/m^3 and 1,000 ng/m^3, depending on location in the community. ATSDR further determined Cr(VI) concentrations during this time were likely higher than modeled due to operational issues at the facility (e.g., broken or faulty air control equipment) and could be as high as 20,000 ng/m^3 (or higher) in the community nearest the facility.[57]
- From 1990-1995: estimated annual average Cr(VI) concentrations ranged between 0.02 ng/m^3 and 0.5 ng/m^3, depending on location in the community. ATSDR further "determined that Cr(VI) concentrations during this time were likely 450 times higher than modeled, due to operational issues identified during source testing."[58]

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[55] California Department of Health Services, *Public Health Assessment: Evaluation of Exposure to Historic Air Releases From the Abex/Remco Hydraulics Facility, Willits, Mendocino County, California* (July 2004) http://www.ehib.org/cma/projects/AbexRemcoFinalAirPHA.pdf

[56] Ibid, p.19.

[57] Ibid.

[58] Ibid.

A cancer registry review completed for the community did not find a statistically significantly elevated number of cancers overall. The number of lung cancers and respiratory cancers was greater than the number expected, but the difference was not large enough to be distinguished from a difference that could occur by chance.[59] Similarly, a mortality data review did not find statistically significant increases in mortality.[60]

As a follow-up to the PHA, the CDHS evaluated potential epidemiological health studies and other exposure research studies for the Willits community. The study concluded that despite the past exposure hazard (and indeterminate current and future exposure hazards), "method limitations in satisfying the criteria for scientific validity limits the potential for research studies, including the relatively small size of the most highly exposed population, the difficulty in accurately defining a study population, and the fact that exposure ceased so long ago."[61] Except possibly an exposure registry or case reports, Type-2 (analytical epidemiological studies) and Type-1 studies (descriptive epidemiological studies) were not recommended. The report also noted that it could be possible to conduct exposure-related research studies, such biomonitoring in body tissues/organs, participation in early cancer biomarker or Cr-related proteomics testing, depending on community interest and the state of the science.[62]

Finally, a panel of science and medical experts considered the feasibility of conducting medical monitoring among Willits residents who had been exposed to Cr(VI), convened under the auspices of the University of California, San Francisco with the CDHS. The panel recommended notification of exposed residents, access to a registered nurse trained in environmental health, health education and counseling, access to medical care by qualified local medical practitioners, referral where appropriate to an occupational and medical medicine expert, and provision of the healthcare services at no extra charge if care was not otherwise provided as part of a person's insurance plan.[63] Ultimately these recommendations were never implemented.

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[59] ATSDR, *Evaluation of Health Studies Possibilities and Limitations at the Abex/Remco Hydraulics Facility (07/11/06)* http://www.ehib.org/cma/projects/AbexHC.pdf

[60] Ibid

[61] Ibid

[62] Ibid

[63] ATSDR, *Expert Panel Report: Recommendations for Conducting Medical Monitoring for Residents of Willits, California and Workers Exposed to Hexavalent Chromium and Volatile Organic Compounds from the Abex/Remco Hydraulics Facility (11/30/06)* http://www.ehib.org/cma/projects/MMReportFinal.pdf

- ***Chrome Crankshaft and J&S Chrome Plating***

Two former chromium plating facilities, Chrome Crankshaft, Inc. and J&S Chrome Plating, were located adjacent to each other in the town of Bell Gardens, Los Angeles County California. Chrome Crankshaft operated from 1963 to 1999; J&S Chrome Plating operated from 1953 to 1991.

The California Department of Health Services (now Department of Public Health), Environmental Health Investigations Branch (EHIB) completed a Public Health Consultation on cancer rates in areas that could have been affected by exposures from the two facilities.[64]

No excess cancer was found in children in any geographical area studied. No excess cancer was found in any group of Hispanics (males or females in any areas). Similarly, in the area downwind of the facilities, cancer rates were what would be expected under usual circumstances. Rates of cancer overall and lung cancer in the immediate area where Chrome Crankshaft and J&S Chrome Plating are located were lower than expected for white males, but white females had slightly higher than expected lung cancer.

No excess cancer rates that could be attributed to the facilities were found. The report noted: "Because the ambient air levels in the community near Chrome Crankshaft and J&S Chrome Plating were much lower than those found to cause lung cancer in workers, it is unlikely that cancers among residents were caused by exposure to these facilities."[65]

During the years before air emissions were reduced (due to the closure of J&S Chrome Plating and to the installation of air control devices at Chrome Crankshaft), the estimated annual average Cr(VI) concentrations in air ranged from 0.16 ng/m^3 to 15.16 ng/m^3. Measured samples (while both facilities were still operating) ranged from non-detect to 430 ng/m^3.[66]

- ***Childhood Asthma Incidence in Relation to Cr(VI) exposures***

In the fall of 2000, the California Department of Health Services, began a health study of children in two schools, Suva Elementary School and Suva Intermediate School, located next to Chrome Crankshaft, Inc. and J&S Chrome Plating, which collectively operated between 1953 and 1999. The retrospective cohort study examined whether children exposed to airborne Cr(VI)

[64] California Department of Health Services for ATSDR, *Review of Cancer Rates in the Vicinity of Chrome Crankshaft Company and J and S Chrome Plating Company (January 2003)* http://www.atsdr.cdc.gov/hac/pha/pha.asp?docid=13&pg=0

[65] Ibid

[66] Ibid

had higher risk of asthma based on attendance at schools located next to two chromium-emitting facilities in a low-income community.[67]

Air modeling resulted in estimates of 0.1216 *u*g/m^3 and 0.00002 *u*g/m^3 for annual average air concentration levels for high exposure (school attendance prior to emission controls) and low exposure (school attendance post-emission controls) periods.[68] Air sampling in 1988 found levels of Cr(VI) on the Suva School property ranging up to 0.430 *u*g/m^3.[69] Air sampling in 1998, after Chrome Crankshaft Company added air scrubbers, found substantially lower levels of Cr(VI), ranging from non-detect to 0.0011 ug/m^3.[70]

A take-home questionnaire provided data on 2,736 children (86% participation rate) regarding asthma, respiratory symptoms, potential risk factors, and historical exposures. Prevalence of asthma in the community was similar to or lower than that reported for other communities, although there may have been undiagnosed asthma in the population. Analysis did not support an association between the development of asthma among children and exposure to airborne Cr(VI) by attending a school next to a Cr(VI)-emitting facility.[71]

2. Community Exposure Studies – Outside the U.S.

In addition to the community studies in New Jersey and California, study authors also considered studies of environmentally exposed communities outside the U.S. Results differed depending on route of exposure and dose.

China

In 1987, researchers in Liaoning Province, China reported elevated mortality rates for all cancers, lung cancer and stomach cancer between 1970 and 1978 for residents living in villages with Cr(VI)-contaminated drinking water.[72] Operations at the Jinzhou Iron Alloy Plant, a ferrochromium factory in the province, began in 1959; by 1965 water in drinking water wells in

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[67] ATSDR, *Asthma and Related Respiratory Conditions Among Children: A Study Concerning Attending School Near Two Chromium Plating Facilities [Chrome Crankshaft and J&S Chrome Plating, Los Angeles County]* (February 2005) http://www.ehib.org/cma/projects/CCHealthStudy.pdf

[68] Ibid

[69] Ibid

[70] Ibid

[71] Ibid

[72] Beaumont, J. et. al , *Cancer Mortality in a Chinese Population Exposed to Hexavalent Chromium in Drinking Water*, January 2008, Epidemiology Volume 19(1), p. 13.

some nearby villages turned yellow.[73] Cr(VI)-contaminated wastewater, leaking factory equipment and stockpiled chromium ore residue were identified as sources of groundwater contamination.[74] Cr(VI) concentrations in drinking water wells ranged as high as 20 mg/L.[75]

Between 1987 and 2006 some controversy swirled around the study beginning when Zhang and a colleague published a 1997 follow-up in the Journal of Occupational and Environmental Medicine (JOEM) finding no elevated cancer mortality for exposed villages.[76] In 2006, JOEM retracted the more recent paper when "financial and intellectual input to the paper" by ChemRisk, a U.S. consulting firm hired by chromium industry clients, was revealed.[77]

In January 2008 a group of researchers from California EPA's Office of Environmental Health Hazard Assessment reevaluated the available original data. Their reanalysis confirmed the findings of increased mortality from stomach cancer for residents in exposed areas compared to the rate for residents in unexposed areas and in Liaoning Province.[78] The lung cancer mortality rate in exposed areas was not significantly elevated when compared to the rate in unexposed areas, but was elevated when compared to the rate in the province as a whole. Mortality from cancers other than stomach and lung was not increased, although mortality from all cancers combined was elevated for the exposed areas compared to the rate for Liaoning Province.[79]

Sweden

Researchers in a 1980 Swedish study looked at lung cancer mortality in residents living near two ferrochromium plants and exposed to chromium through inhalation. The Cr (total) concentration in air in the most polluted areas ranged from 100 to 400 ng/m^3, approximately 50 to 100 times higher than the concentration in unexposed rural areas at the time of the study.[80] The study evaluated 810 lung cancer deaths between the years 1961-1975. When population density was

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[73] Zhang, J. and Li, X., *Investigation and Study of Chromium Pollution in Jinzhou*, Chinese Journal of Preventive Medicine, 1987, Volume 21, Issue 5, p.1.

[74] Beaumont, J. et. al. p. 13

[75] Zhang, J. and Li, X., p. 2.

[76] Smith, A. *Hexavalent Chromium, Yellow Water, and Cancer: A Convoluted Saga*, Epidemiology, January 2008, Volume 19 (1), p. 24.

[77] Brandt-Rauf, P. Editorial retraction. Journal of Occupational and Environmental Medicine. 2006; 48: 749.

[78] Beaumont, J. et. al., p. 18.

[79] Ibid, p. 19

[80] Axelsson G. and Rylander R., *Environmental Chromium Dust and Lung Cancer Mortality*, Env. Research 23 (1980), 469-476.

controlled for, no association was found between lung cancer mortality rates among the exposed population and the rest of the country.[81]

3. Occupational Exposure Studies

Inhalation Exposure

Most occupational studies of workers exposed to Cr(VI) pertain to the inhalation route. Non-cancer respiratory effects were observed at concentrations ranging from to 0.002 to 0.414 mg/m^3 and included: asthma, cough, irritated and perforated nasal septum, nasal ulceration, runny nose, nose bleed, nasal mucosa atrophy and decreased lung function. Gastrointestinal effects (stomach pains, cramps, ulcers and gastritis; chronic tonsillitis and pharyngitis) were observed at 0.004 to 0.414 mg/m^3. These effects may be due to workers mouth breathing and swallowing chromate dust[82] and/or to "large inhaled Cr(VI)-laden particulates [which] would be expected to be cleared from the lung …and then swallowed," where presumably they could affect the gastrointestinal tract.[83]

Hepatic (liver) and renal (kidney) effects have also been observed at Cr(VI) air concentrations of $\geq$ 0.01 mg/m^3 and 0.004 mg/m^3, respectively. Information is limited or evidence is weak for cardiovascular and reproductive effects after inhalation exposure in occupational settings.

Numerous studies note increased incidences in lung or respiratory system cancers among workers exposed to Cr(VI)[84], as well as increased lung cancer mortality[85], particularly in chromate production, chromate pigment production and chromium plating industries.[86] Data compiled by ATSDR showed workers chronically exposed to Cr(VI) via inhalation began to have increased risks for lung cancer at concentrations as ranging from 0.1 to 0.5 mg/m^3.[87]

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[81] Ibid, p.469.

[82] ATSDR, Toxicological Profile for Chromium, Draft for Public Comment, September 2008, Chapter 3: Health Effects, p.84. http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

[83] Sedman, R. et al., *Review of the Evidence Regarding the Carcinogenicity of Hexavalent Chromium in Drinking Water,* Journal of Environmental Science and Health, Part C, 24:155-182, 2006

[84] ATSDR, Toxicological Profile for Chromium, Draft for Public Comment, September 2008, Chapter 3: Health Effects http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

[85] Luippold, R. et al. *Lung Cancer Mortality Among Chromate Production Workers*, Occupational and Environmental Medicine, 2003, 60:451-457

[86] Sedman, R. et al., p.168.

[87] ATSDR, Toxicological Profile for Chromium, Draft for Public Comment, September 2008, Chapter 3: Health Effects, Table 3-1. http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

ATSDR notes: "Chromium dose-response relationships have been reported for chromate production workers, but not for other categories of chromium workers."[88] In studies of chromate production workers, increased risks of respiratory cancers are associated with increased cumulative exposure to Cr(VI).[89]

At least one study of workers at four facilities exposed to Cr(VI) during chromite ore processing found, in addition to increased risk of lung cancer, increased risks of nasal cavity/sinus cancer, as well as a cluster of bladder cancer at one facility.[90] Risks for stomach cancer were weakly associated with exposure to chromate dust in another study which looked at cancer mortality in workers in a Newark, New Jersey chromium pigment factory.[91]

Table I below shows the air concentrations of Cr(VI) at which lung cancer and non-cancer health effects began to be observed in different occupational studies.

Ingestion Exposure

In a 1950s study by T.F. Mancuso, workers in an Ohio chromate plant exposed to both Cr(VI) and Cr(III) dust reported gastrointestinal effects, including gastric ulcers, gastritis, and stomach pain. Due to high dust levels, workers breathed through their mouths, subsequently ingesting chromium dust.[92] A 1967 study by L. Hanslian et al. of workers in chromium electroplating facilities in Czechoslovakia also found stomach pain, ulcers, gastritis, and stomach cramps, as well as chronic tonsillitis and pharyngitis (sore throat).[93]

Dermal Exposure

The results of dermal exposures to Cr(VI) in occupational settings are well-documented, particularly for chromate production and chrome plating. Dermal exposure health effects include irritated skin, skin ulcers, scarring, penetrating holes, dermatitis, and burns. Eye irritation and oral effects (oral swelling, thickening of lips and gums, gingivitis, and periodontis) have also been reported in Cr(VI)-exposed workers.[94]

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[88] Ibid, Chapter 3: Health Effects, p. 99.

[89] Ibid, p.101.

[90] Rosenman, K and Stanbury, M. *Risk of Lung Cancer Among Former Chromium Smelter Workers*, American Journal of Industrial Medicine, December 1998, Volume 29, Issue 5, p. 491-500.

[91] Hayes, R. et al. *Cancer Mortality Among a Cohort of Chromium Pigment Workers*, American Journal of Industrial Medicine, Volume 16, Issue 2, p. 127-133.

[92] ATSDR, Toxicological Profile for Chromium, Draft for Public Comment, September 2008, Chapter 3:Health Effects, p. 156. http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

[93] Ibid

[94] Ibid, p. 196.

Table I Concentrations of Chromium in the Air and Associated Health Effects in Occupational Studies	
Cancer Health Effects	**Concentrations in the air, ug/m^3 Cr(VI)**
Lung cancer	100 to 500
Non-Cancer Health Effects	
Respiratory: asthma, bronchitis, pharyngitis, decreased lung function	2.0
Nasal: nosebleed, runny nose, nasal septum perforation and ulceration	2.0
Dermal: skin irritation, dermatitis, ulceration (a)	5.0
Gastric: stomach irritation (ulcer), stomach cramps	4.0 - 5.0
Renal: changes in kidney function	4.0

- Unless otherwise indicated, source is ATSDR, Toxicological Profile for Chromium, Sept. 2008, Chapter 3: Health Effects, Table 3-1.
(a) ATSDR, Chapter 3: Health Effects, Table 3-5

C. BIOMARKERS AND SCREENING

Since community concern is high regarding potential exposure to Cr(VI) and Cr(VI)-related health effects, logical questions are:

- What are the ways to measure whether an individual has been exposed to Cr(VI)?
- Can a test for Cr(VI) exposure be used to quantify risks for a specific illness or health endpoint?
- Are there ways to measure for Cr(VI)-mediated health effects?
- Are there screening tests available for diseases that are associated with Cr(VI) exposure, such as lung cancer or gastrointestinal cancers?

In seeking answers to these questions, the study authors reviewed numerous articles, as well as state and federal health and environmental agency websites. In addition, they communicated with biomarker researchers, cancer researchers, epidemiologists and state environmental health practitioners.

The first three questions are concerned with biological markers, or biomarkers. Biomarkers are characteristics or substances that can be measured in parts of the body and evaluated as

indicators of events in biologic systems. They "are observable end points that indicate events in the processes leading to disease."[95]

Biomarkers are typically classified into three groups: markers of exposure, markers of effect and markers of susceptibility. There are also some biomarkers that fall somewhere between markers of exposure and markers of effect. To be useful, biomarkers need to be sensitive, specific, robust and practical.

Biomarkers relevant for Cr(VI) are discussed below.

1. Biomarkers of Exposure

Biomarkers of exposure are used to detect exposure to a substance. A biomarker of exposure is a foreign substance or its metabolite(s) or the product of an interaction between a foreign substance and some target molecule or cell that can be measured in an individual.[96] Exposure to Cr(VI) can be measured in urine, blood, hair, nails, and expired air; however, urine and blood (whole, serum and red blood cells) are considered the most reliable exposure indicators.[97]

Urine

It is important to note that all measurable Cr in biological samples is in the form of Cr(III). Even under conditions of high exposure to Cr(VI), upon absorption into biological fluids or tissues, Cr(VI) is quickly reduced to Cr(III).[98] Because of this, it is difficult to tell whether the source of Cr measured in urine is Cr(VI) or Cr(III). This is further confounded by the fact that Cr(III) is an essential nutrient, and also a popular supplement. As such, dietary sources of Cr(III) can significantly influence urine Cr concentrations. The inability to differentiate between exposure to Cr(III) and Cr(VI) in urine reduces its utility as a biomarkers in low-level Cr exposure scenarios and "makes it difficult to perform risk analysis at environmental exposure levels."[99]

Also of note, while urine has the benefit of being non-invasive, as well as easy to collect and analyze, it can only indicate very recent Cr(VI) exposure, generally in the past 1 to 2 days.

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[95] Ward, J. and Henderson, R. *Identification of Needs in Biomarker Research*, Environmental Health Perspectives 104, Supplement 5, October 1996

[96] ATSDR, Toxicological Profile for Chromium, Draft for Public Comment, September 2008, Chapter 3: Health Effects http://www.atsdr.cdc.gov/toxprofiles/tp7-c3.pdf

[97] Ibid, p. 276

[98] Zhitkovich, A. *Chapter nineteen: Chromium: Exposure, toxicity and biomonitoring approaches,* In Biomarkers of Environmentally Associated Disease: Technologies, Concepts and Perspectives, by Samuel H. Wilson, CRC Press, (2002) , p. 275

[99] Ibid

Red Blood Cells (RBCs)

Cr(VI) that enters the bloodstream is readily taken up by red blood cells, whereas Cr(III) has a poor ability to cross plasma membranes.[100] Therefore, the Cr content inside RBCs can be used as a specific biomarker of exposure to Cr(VI), potentially measuring the cumulative dose of Cr(VI) over the lifespan of the red blood cell, up to 120 days. While considerably longer than for urine, red blood cell Cr content is still a biomarker of relatively recent exposure.

Anecdotally, it can more difficult to obtain participation from individuals in epidemiological studies when collecting blood rather than urine.[101] Also, care needs to be taken when collecting blood to ensure samples are not contaminated with Cr(VI) from stainless steel needles; plastic needles can be used to eliminate this problem. Confounding from Cr(VI) contamination in laboratory equipment and methods also needs to be avoided.

Other Notes about Biomarkers of Cr(VI) Exposure

Unlike lead and cadmium which accumulate in the body, Cr(VI) does not. Consequently, as Dr. Michael Gochfeld of EOHSI pointed out, there are no ways of testing for historic exposure to Cr(VI).[102]

ATSDR's Toxicological Profile for Chromium notes that "higher than normal levels of chromium in blood or urine may indicate that a person has been exposed to chromium. However, increases in blood and urine chromium levels cannot be used to predict the kind of health effects that might develop from that exposure."[103] Cr(VI) concentrations in urine and blood (specifically red blood cells) can only indicate potential exposure, but say nothing about the risk of developing specific diseases or conditions.

2. Biomarkers of Effect

Biomarkers of effect indicate a biological response to an exposure.

DNA-protein cross-links (DPC)

DNA-protein cross-links (DPC) occur when a toxic chemical reacts with two cellular molecules, DNA and proteins, causing them to become (covalently) stably attached to each other.[104] If the crosslink cannot be repaired, the resulting DNA damage can be the precursor to chromosomal damage, and potentially carcinogenesis.

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[100] Ibid

[101] Personal communication, Dr. Kathy Black, EOHSI.

[102] Personal communication, Dr. Michael Gochfeld (EOHSI), September 23, 2009.

[103] ATSDR, Public Health Statement for Chromium, September 2008, Section 1.8, http://www.atsdr.cdc.gov/toxprofiles/phs7.html

[104] Personal communication with Anatoly Zhitkovich, February 4, 2010.

Cr(VI) is known to cause formation of DPC. Since DPC formation indicates DNA damage, some have recognized its potential utility as biomarker of effect or initial screening tool in Cr(VI)-exposed populations.[105] Several studies have found elevated DPC in the lymphocytes of both occupational populations exposed to Cr(VI), such as welders and chrome platers, as well as in residential populations who lived near sites contaminated with Cr(VI). [106] However, many other agents can produce DPC, including formaldehyde, arsenic trioxide, copper sulfate, and UV light.[107] Consequently, without an assay specific to Cr(VI), the presence of DPC could not be solely attributed to Cr(VI)-exposure.

Recently, Anatoly Zhitkovich of Brown University, developed a sensitive assay which is able to specifically identify DPC which are caused by Cr(VI). As noted above, Cr(VI) is readily taken into cells where it is reduced to Cr(III). In the reduction process it forms a wide assortment of DNA-adducts, abnormal chemical modifications where DNA is covalently bonded to Cr(III). A fraction of these Cr(III)-DNA adducts capture proteins and are converted to protein-Cr(III)-DNA cross-links.[108] Discovery of this three-step process and the role of Cr(III) in "bridging" DNA and protein were essential in Zhitkovich's new assay, which is able to quantify not only total DPC, but the percentage of DPC which are caused by Cr(VI).[109] It is currently not known how long it would take to develop the assay to the point where it could be used in a non-laboratory setting and meet the essential criteria for use as a biomarker (such as robustness, high throughput, economy, practicality and minimally invasive).

The lifespans of lymphocytes vary widely, depending on the type of lymphocyte (e.g., T-cell or B-cell) and subgroups within those types, from a few days to a few years. Therefore it is currently unknown how far back in time an exposure to Cr(VI) could be assessed using DPC as biomarkers.

As yet, there is not enough evidence to determine what is considered an abnormal level of DPC. And although DNA-protein cross-linking by chromium is known to damage DNA, a potential

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[105] Zhitkovich, A. et al. *Utilization of DNA-protein cross-links as a biomarker of chromium exposure*, Environmental Health Perspectives, 1998 August; 106 (Suppl 4): 969–974

[106] Costa, M., Zhitkovich, A., et al. *Monitoring Human Lymphocytic DNA-Protein Cross-links as Biomarkers of Biologically Active Doses of Chromate*, Environmental Health Perspectives, Vol 104, Supplement 5, October 1996

[107] Ibid

[108] Macfie, A., Hagan, E., Zhitkovich, A. *Mechanism of DNA-Protein Cross-Linking by Chromium*, Chemical Research in Toxicology, October 2009 (online).

[109] Personal communication with Anatoly Zhitkovich, January 11, 2010.

step in the continuum to cancer, DPC as a biomarker cannot yet be used to correlate with a specific cancer or risk of cancer.

Cancer Biomarkers

One class of effects about which residents are especially concerned is cancer. As cited earlier in this report, exposure of workers to Cr(VI) via inhalation is associated with increased risk of developing lung cancer, and possibly other cancers, such as stomach. The National Toxicology Program's studies of the ingestion of Cr(VI) in drinking water by rats and mice showed a higher incidence of gastrointestinal tumors in both animals.[110] Consequently, the study authors looked at the availability of biomarkers for early detection of these cancers.

Lung cancer biomarkers

Lung cancer has the highest mortality of any cancer in the United States. Early-stage lung cancers also show few symptoms and tend to spread rapidly before they are found.[111]

The National Cancer Institute's Early Detection Research Network, which specializes in research on biomarkers of early cancer and cancer risk notes that are no validated molecular biomarker tests for the early detection of lung cancer.[112]

One problem with some potential lung cancer biomarkers is that they lack specificity. "Several DNA and protein biomarkers have been identified, but most previously discovered biomarkers are correlated with the general process of carcinogenesis and immune responses. Therefore, many of these biomarkers are found in other types of cancers, and thus are not specific to lung cancer."[113]

Many potential lung cancer biomarker tests in development are at different stages of discovery, evaluation and validation. Some look promising, but none are commercially available yet. Some examples of biomarkers projects in the pipeline are[114]:

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[110] National Toxicology Program, National Institutes of Health, NTP Technical Report on the Toxicity Studies of Sodium Dichromate Dihydrate, January 2007 http://ntp.niehs.nih.gov/ntp/htdocs/ST_rpts/TOX72.pdf

[111] Wistar Institute, News Release: Wistar-Led Research Team Discovers Genetic Pattern That Indicates Early-Stage Lung Cancer, December 1, 2009, http://wistar.org/news_info/pressreleases/pr_12.01.09.htm

[112] National Cancer Institute, Early Detection Research Network, Fourth Report, January 2008. http://edrn.nci.nih.gov/docs/progress-reports/edrn_4th-report_200801.pdf

[113] Cho J, Sung H. *Proteomic Approaches in Lung Cancer Biomarker Development*, Expert Rev Proteomics. 2009;6(1):27-42

[114] National Cancer Institute, Early Detection Research Network, Fourth Report, January 2008. http://edrn.nci.nih.gov/docs/progress-reports/edrn_4th-report_200801.pdf

- Validation of protein markers (autoantibodies) of lung cancer
- Circulating DNA methylation markers (a panel of genes)
- Mitochondrial DNA mutations associated with lung cancer that are detectable in blood

Particularly promising research is the recent discovery by Wistar Institute researchers of immune system markers in the blood which indicate early-stage lung tumors in people at high risk for developing lung cancer. The findings could potentially lead to a simple blood test to detect lung cancer in its earliest phases, when it can be most successfully treated.[115]

Currently no simple and accurate screening test exists for detecting and diagnosing lung cancers early, such as mammography for breast cancer or colonoscopy for colon cancer. Tests such as chest x-ray, CT scan and sputum collection are not recommended by the National Cancer Institute as screening tests for the general population. Dr. Melvin Tockman, Professor of Oncology and Medicine at the University of South Florida, confirmed that "there is no test approved for lung cancer screening of the general population. Neither CT or chest x-ray is approved for lung cancer screening in the general population."[116] There are several reasons for this, including:[117]

- Neither chest x-ray and sputum cytology or CT scans have not been shown to reduce lung cancer mortality
- Chest x-rays and CT scans both expose individuals to radiation
- False-positive tests may lead to anxiety and invasive diagnostic procedures, such as percutaneous needle biopsy (lung biopsy) or thoracotomy (chest surgery). These follow-up procedures have potential serious complications including partial collapse of the lung, bleeding, infection, pain, chest nerve damage and discomfort.
- CT and x-ray screening may detect small tumors that would never become life threatening. This phenomenon, called overdiagnosis, puts some screening recipients at risk from unnecessary biopsies or surgeries as well as unnecessary treatments for cancer, such as chemotherapy or radiation therapy.

Currently several observational studies are evaluating the effectiveness of low-dose helical computed tomography (LDCT) at detecting stage I lung cancers. In the Early Lung Cancer Action Project (ELCAP) LDCT detected almost six times as many stage I lung cancers as chest

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[115] Wistar Institute, News Release: Wistar-Led Research Team Discovers Genetic Pattern That Indicates Early-Stage Lung Cancer, December 1, 2009, http://wistar.org/news_info/pressreleases/pr_12.01.09.htm

[116] Personal communications with Dr. Melvyn Tockman, 10/28/09 and 10/30/09.

[117] National Cancer Institute, Lung Cancer Screening, Evidence of Benefit (webpage) http://www.cancernet.gov/cancertopics/pdq/screening/lung/HealthProfessional/page4

x-rays and most tumors were no larger than 1 cm in diameter. The effectiveness of LDCT has not yet been evaluated in a controlled clinical trial.[118]

Gastrointestinal cancer biomarkers

As yet, with there are no biomarkers available for oral, esophageal, stomach or small intestine cancers. As with lung cancer, there are biomarkers in development that are at different stages of discovery, evaluation and validation. Some projects include validation of a saliva-based assay for oral cancer and research on methylated DNA in plasma for early detection of esophageal adenocarcinoma.[119]

3. Biomarkers of Susceptibility

Biomarkers of susceptibility detect and measure an individual's susceptibility (whether innate or induced) to the effects of exposure to a toxicant.[120] Examples include the activity of specific enzymes involved in activating or detoxifying a specific chemical, or the capacity to repair certain DNA damage. No biomarkers of susceptibility were identified specific to Cr(VI).

V. EXPERTS CONSULTED

As stated earlier, one piece of the Consent Judgment's health study requirement is that the Site Administrator "speak to experts in the field". As such, the study authors communicated with technical experts that could contribute to their understanding of:

- Exposure pathways and exposure routes (past, current and future remediation-related)
- Potential chromium-related health risks and outcomes (cancer and non-cancer)
- The status of relevant biomonitoring techniques, for example:
  - biomonitoring in body fluids and body tissues
  - biomarkers for early cancer detection
  - biomarkers for chromium-related changes in protein expression
  - radiological screening tests
- Health study protocols to mitigate health effects

The study authors looked for experts with experience in:

- Conducting research in occupational and environmental epidemiology
- Evaluating environmental exposures and health outcomes

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[118] Ibid

[119] National Cancer Institute, Early Detection Research Network, Fourth Report, January 2008, p. 44. http://edrn.nci.nih.gov/docs/progress-reports/edrn_4th-report_200801.pdf

[120] Ibid

- Quantifying risk
- Developing medical screening and surveillance programs
- Developing community environmental health education modules for health care providers

Ultimately, 19 health and science experts were consulted with experience in the following areas:

- Risk Assessment
- Toxicology
- Environmental Medicine
- Pharmacology
- Heavy Metal Carcinogenesis
- Cancer Screening & Biomarker Research
- Environmental Epidemiology
- Pharmacokinetics
- Occupational Medicine
- Biological Monitoring
- Environmental Fate and Transport
- Cr(VI) Biomarkers

Appendix C contains a list of the experts consulted and their affiliations.

VI. PUTTING THE HEALTH STUDIES IN CONTEXT

The data gathered from the review of health studies and discussions with experts was used to evaluate exposure scenarios for the Garfield Avenue Site community in general terms. For the residents of this community, there are three periods of potential exposure to Cr(VI) to consider: past exposure, current exposure, and future exposure. Readers of this study should understand that this discussion is presented in general terms and does not constitute a true risk assessment for the residents of the community.

A. PAST EXPOSURE

The history of chromate processing at the Garfield Avenue Site and the use of CCPW throughout the area, causes residents concern about potential Cr(VI)-related health effects. The household dust studies of the early 1990s demonstrated that increased proximity to Jersey City CCPW waste sites was equated with increased total Cr concentrations in house dust and elevated levels of total Cr in the urine of children living in these homes. However, follow-up studies also demonstrated that once CCPW sites had been remediated, previously studied homes located near the sites showed dramatic decreases in total Cr concentrations upon re-sampling. These results suggest that as CCPW sites were remediated and the source of chromium eliminated, potential exposures to chromium also declined.

Ambient Air Cr(VI) Concentrations

A few studies published between 1991 and 1997 did collect air samples for Cr(VI) in occupational and residential settings in Hudson County. Although not specifically in the

Garfield Avenue Site, these samples provide a general idea of conditions that may have existed in the area at the time.

- Indoor air and outdoor air on a partially paved CCPW site with heavy truck traffic:[121] Cr(VI) concentrations ranged from 0.57 to 27 ng/m^3; geometric mean was 2.5 ng/m^3
- Indoor air in Jersey City residences distant from CCPW sites:[122] Cr(VI) concentrations ranged from 0.38-3.3 ng/m^3, mean was 1.2 ng/m^3. (Intended as "background" concentrations for comparison with air samples on CCPW-contaminated industrial sites)
- Background air concentrations in Newark, NJ and Lyndhurst, Hudson County, NJ ranged from 0.2 to 3.8 ng/m^3 in Newark and ranged from 0.4 to 1.7 ng/m^3 in Lyndhurst.[123]

These numbers suggest that in an urban setting there is some low level of background Cr(VI), even in indoor air. In the absence of actual data from the Garfield Avenue Site or the neighborhood from the 1990s, the study authors surmise that ambient air concentrations would have been in the 10s of ng/m^3. (The most recent Cr(VI) concentration in ambient air on the Garfield Avenue Site that is publicly available is 2.14 ng/m^3 collected in September 2007).

In trying to determine whether the levels of Cr(VI) in Jersey City may have posed a threat to residents in the past, the study authors looked for studies of communities that were also environmentally-exposed to Cr(VI) in air. Two California communities located near chromium plating facilities, the Abex/Remco facility in Willits, CA and the Chrome Crankshaft/J&S Chrome Plating facilities in Bell Gardens, CA, were evaluated under ATSDR. Air sampling and air modeling completed for these communities, as well as cancer registry analyses performed for both communities also provide some data with which to evaluate the Garfield Avenue community.

- In Willits, CA Abex/Remco operated from 1963-1995; air modeling led to estimated annual average Cr(VI) concentrations ranging between 50.0 *n*g/m^3 and 10,000 ng/m^3, for 1968 – 1975 and from 20.0 ng/m^3 and 1,000 ng/m^{3}for 1976-1989 (and possibly as high as 20,000 ug/m^{3}or higher).[124] A cancer registry review completed for the Willits

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[121] *An Assessment and Quantitative Uncertainty Analysis of the Health Risks to Workers Exposed to Chromium Contaminated Soils*, Paustenbach, D. et al., Toxicology and Industrial Health (1991) 7: 159-196

[122] *Field Validation for Sampling and Analysis of Airborne Hexavalent Chromium,* Finley, B, et al., Appl. Occup. Environ. Hyg. (1993) 8(3), 191-200

[123] *Background Air Concentrations of Cr(VI) in Hudson County, New Jersey: Implications for Setting Health-Based Standards for Cr(VI) in Soil,* Scott, PK et al., J. Air & Waste Manage. Assoc. (1997) 47:592-600

[124] California Department of Health Services, *Public Health Assessment: Evaluation of Exposure to Historic Air Releases From the Abex/Remco Hydraulics Facility, Willits, Mendocino County, California* (July 2004) http://www.ehib.org/cma/projects/AbexRemcoFinalAirPHA.pdf

community found the number of lung cancers and respiratory cancers was greater than the number expected, but did not find the elevation statistically significant.[125]

- In Bell Gardens, CA two former chromium plating facilities, Chrome Crankshaft, Inc. and J&S Chrome Plating, operated from 1963 to 1999 and 1953 to 1991, respectively. A Public Health Consultation found that in the area downwind of the facilities, cancer rates were what would be expected under usual circumstances. Rates of cancer overall and lung cancer were lower than expected for white males, but white females had slightly higher than expected lung cancer. No excess cancer rates that could be attributed to the facilities were found.[126] Measured samples (while both facilities were still operating) ranged up to 430.0 ng/m^3.[127]
- In 2000, the California Department of Health Services completed a retrospective cohort study examining whether schoolchildren exposed to airborne Cr(VI) had higher risk of asthma based on attendance at schools located next to the two chromium-emitting facilities in Bell Gardens, CA.[128] The highest Cr(VI) air concentration measured in the neighborhood of the schools was 430 ng/m^3. Prevalence of asthma in the community was similar to or lower than that reported for other communities. Analysis did not support an association between the development of asthma among children and exposure to airborne Cr(VI) by attending a school next to a Cr(VI)-emitting facility.[129]

Lung Cancer

Many residents are aware of the fact that occupational exposure to Cr(VI) has been linked to an increased risk of developing lung cancer. Consequently, some residents fear that past exposure to CCPW may have put them at higher risk for developing lung cancer too. Some points to consider:

- Occupational exposures to Cr(VI) associated with development of lung cancer, according to ATSDR's Toxicological Profile for Chromium, range from 100 to 500 ug/m^3.

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[125] ATSDR, *Evaluation of Health Studies Possibilities and Limitations at the Abex/Remco Hydraulics Facility (07/11/06)* http://www.ehib.org/cma/projects/AbexHC.pdf

[126] California Department of Health Services, *Review of Cancer Rates in the Vicinity of Chrome Crankshaft Company and J and S Chrome Plating Company (January 2003)* *http://www.atsdr.cdc.gov/hac/pha/chromecrankshaft/jsc_p1.html*

[127] Ibid

[128] ATSDR, *Asthma and Related Respiratory Conditions Among Children: A Study Concerning Attending School Near Two Chromium Plating Facilities [Chrome Crankshaft and J&S Chrome Plating, Los Angeles County]* (February 2005) http://www.ehib.org/cma/projects/CCHealthStudy.pdf

[129] Ibid

- No studies are available showing cause-and-effect between environmental exposure to Cr(VI) and development of lung cancer (including ATSDR's studies referred to above).
- A lung cancer incidence study completed by NJDHSS for Jersey City found that higher incidence of lung cancer for residents living close to CCPW sites were not considered statistically significant.
- The study authors also looked at whether biomarkers and/or screening techniques for early lung cancer detection were available or recommended for this community. While there are biomarkers in various stages of development, none are yet available for general use. In addition, the National Cancer Institute does not currently recommend the use of chest x-ray, sputum analysis and/or CT scanning for use as lung cancer screening tools for the general population.

GI Cancer

The NTP study of Cr(VI) in drinking water (as sodium dichromium dihydrate) showed evidence of oral cancer in rats and evidence of stomach cancer in mice. In light of this, it is reasonable to consider residents' concerns that in the past children may have been exposed to Cr(VI)-contaminated soil through incidental ingestion and may have experience potential health effects. Some points to consider:

- In the study, a statistically significant increase of oral cancers only occurred at the highest does tested (516 mg/L) in both male and female rats.
- A statistically significant increase of small intestine tumors only occurred at the highest dose tested in male mice (257.4 mg/L) and at the two highest doses tested in female mice (172 and 516 mg/L).
- Cr(VI) researcher Dr. Silvio DeFlora pointed out in his comments on the NTP study that "the highest concentration tested (516 mg/L) would correspond to the intake of about 1 g sodium dichromate dehydrate every day for two years in a 70 kg man."[130] These are huge doses.
- As with lung cancer, there are no biomarkers for gastrointestinal cancers (oral, esophageal, stomach or small intestine) currently available.

B. CURRENT EXPOSURE

Currently the Garfield Avenue Site is covered by a network of caps which prevent contaminated soil from coming in contact with ambient air. It is the opinion of several of the experts to whom the study authors spoke that the residents' current exposure to CCPW is minimal to none. After

[130] Public Comments on TR546 (Sodium Dichromate Dihydrate), Silvio DeFlora, May 2007, http://ntp.niehs.nih.gov/files/TR546_Cmts_SilviodeFlora03May07.pdf

having walked the site, Dr. Max Costa, a nationally-renowned Cr(VI) researcher and expert witness, supported this conclusion.[131] Recent household dust studies by EOHSI suggest that the Garfield Avenue Site is not a source of Cr(VI) in the homes in the neighborhood and that ambient air concentrations of Cr(VI) are extremely low:

- A sample taken by EOHSI staff on the Garfield Avenue Site in September 2007 measured Cr(VI) in the air at 2.14 ng/m^3.[132] To compare: Occupational inhalation exposures to Cr(VI) starting at 2 ug/m^3 (almost 100 times higher than the ambient air measurement) have been associated with non-cancer nasal, respiratory, renal, hepatic and gastric effects. Occupational exposures to Cr(VI) ranging from 100 to 500 ug/m^3 (almost 50,000 to 250,000 times higher than the ambient air measurement) have been associated with lung and other respiratory cancers.
- Comparison of Cr(VI) in household dust from homes in Jersey City and homes in New Brunswick found similar concentrations. Study results suggest that the source of Cr(VI) in Jersey City homes is something other than CCPW.

Furthermore, the Residential Inspection Program has been initiated to address the concerns of those residents who worry that there may be residual Cr(VI) contamination on their property. This program will determine through inspections and sampling if elevated levels of Cr(VI) are present. Any exceedances will be remediated to the DEP-prescribed standard.

C. FUTURE EXPOSURE

Concerns exist that once the capping is removed and remediation begins, dust will be created from underlying soil which could blow off the site and contaminate the neighborhood. In order to prevent this from happening, PPG is required to implement a robust air monitoring program to measure levels of Cr(VI) and total particulates on the site and at the site fenceline to ensure that no elevated levels are leaving the property. To ensure that off-site receptors will be protected, the air monitoring program will require:

- The development of a risk-based Cr(VI) concentration limit in ambient air using an EPA methodology (or comparable methodology) for cancer risk (representing the cumulative average risk over the duration of the remediation project).

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[131] Personal communication with Dr. Max Costa, October 1, 2009.

[132] *Final Report: Chromium Exposure and Health Effects in Hudson County: Phase I* , Lioy, P. and Gochfeld, M., Environmental and Occupational health Sciences Institute, November 2008 http://njedl.rutgers.edu/ftp/PDFs/5778.pdf

- The calculation of an Action Level for total dust (as a surrogate for Cr(VI)) for monitoring in the excavation work zone and at the site perimeter. If monitoring detects that the Action Level has been exceeded, steps will be taken to identify the source of particulates, reduce the dust, or if necessary, stop work until measures can be taken to bring dust levels down below the Action Level.

- Constant monitoring of airborne particulate levels at on-site locations and perimeter locations during any remedial activities that disturb the site soil;

- Comparison of analytical data to the risk-based concentration to ensure there are no exceedances.

These measures will minimize exposure of the community to Cr(VI) contaminated soil as throughout the remediation process, and will ensure the protection of public health.

Additionally, as mentioned above, if the Residential Inspection Program detects elevated concentrations of Cr(VI) on residential properties, the contamination will be remediated, eliminating any further exposures.

VII. RECOMMENDED COMMUNITY HEALTH EXPOSURE PREVENTION AND TESTING PROGRAM

In considering whether to recommend "a health exposure study be conducted for the residents living in the vicinity of Garfield Avenue" as per the Consent Judgment, the Site Administrator conferred with numerous health and science experts and reviewed dozens of studies, both specific to Hudson County, New Jersey and more broadly on Cr(VI) exposure and related health effects. After a thorough review of the data and information collected, the Site Administrator developed a preliminary set of recommendations which were shared with the parties to the settlement. Those recommendations have been largely incorporated into the protective health measures that are planned for cleanup activities at the Garfield Avenue site. Based on revisions to the cleanup work plan made subsequent to the preliminary recommendations, the Site Administrator believes the protective measures will protect the health and ensure the safety of residents living near the Garfield Avenue site.

The Site Administrator recommends a Community Health Exposure Prevention and Testing Program. The recommended program will be three-tiered: 1) an expanded Air Monitoring Program to ensure the protection of the surrounding community during the remediation of the Garfield Avenue Site; 2) an accompanying health exposure and testing program to determine whether the community is being exposed to Cr(VI) related to the site cleanup; and 3) a mapping project using results from the Residential Inspection Program established by the settlement to

outline areas of soil contamination, if detected. In addition, the Site Administrator recommends actions to promote the second phase of the EOHSI household dust study.

The preliminary details of the Community Health Exposure Prevention and Testing Program are outlined below.

A. AIR MONITORING PROGRAM

The activities associated with excavation, in-situ and/or ex-situ treatment and removal of CCPW from the Garfield Avenue Site present opportunities to generate work site dust with the potential to migrate off-site into the surrounding community. Under DEP regulations governing site remediation, PPG is required to develop an Air Monitoring Plan (AMP) to protect the health and safety of residents during ground intrusive activities. The Site Administrator is recommending an expanded program with specific elements added to the final AMP in order to ensure that elevated levels of Cr(VI) are not migrating off the site. These elements include:

- Calculation of a risk-based concentration limit for Cr(VI) based on long-term exposure (greater than one year);
- Calculation of a specific Action Level for total dust monitoring in the exclusion (work) zone and at the site perimeter;
- Establishment of baseline conditions prior to remedial activities;
- Continuous monitoring of airborne total particulates and Cr(VI) levels at on-site locations and at the fenceline (perimeter);
- Use of monitoring data to confirm successful dust and Cr(VI) control, as well as evaluate the need to initiate actions to mitigate dust generation in real-time as the excavation proceeds;
- Web-posting of monitoring data for access by the public; and
- Program activity and data review by the independent Technical Consultant.

PPG has submitted to DEP a revised AMP entitled *Air Monitoring Workplan for Ground Intrusion Activities at the Garfield Avenue Site in Jersey City, New Jersey*, dated January 2010. In the following discussion of recommended elements for the expanded AMP, comparison will be made to PPG's proposed plan.

1. Risk-Based Concentration Limit for Cr(VI)

The Site Administrator recommends that a risk-based concentration limit for Cr(VI) be developed for the Garfield Avenue Site project based on the total number of days of ground intrusive activities. This risk-based concentration limit would represent the permissible <u>average</u> air concentration of Cr(VI) over the entire period of intrusive remedial activities. The

concentration of Cr(VI) would be measured continuously at the excavation zone and at the site perimeter, and would be compared to the risk-based concentration limit. The measured Cr(VI) at a given monitoring location could exceed the risk-based concentration limit temporarily, provided that the long-term average concentration remains below the risk-based concentration limit.

To calculate the risk-based concentration limit, the Site Administrator recommends the use of EPA risk assessment methodology for estimating cancer risk, representing the cumulative average risk over the duration of the excavation activities. The relationship between the concentration of Cr(VI) in air and estimated risk is evaluated using established risk assessment techniques and default values set by the EPA. Honeywell, Inc. employed this methodology to calculate a risk-based concentration limit for Cr(VI) at its recently completed five-year CCPW excavation at 441 Route 440 in Jersey City (the Former Roosevelt Drive-In Site).

PPG's January 2010 Air Monitoring Plan does present a concentration limit for Cr(VI) in ambient air (called an "acceptable air concentration") of 0.91 $\mu g/m^3$; however, it was developed using a calculation for short-term exposures (less than one year) and a chronic inhalation Reference Concentration (RfC) for non-cancer endpoints. The calculation is predicated on the assumption that intrusive remedial activities will take place over 120 days. However, a preliminary assessment of the total number of intrusive work days in the project (derived from the Master Schedule), estimates a total of 690 days over approximately 5 years, with an average of 138 days per year. Because the total number of days exceeds one year, the short-duration calculation is not valid for this project.

Consequently, DEP has developed a revised acceptable air concentration for Cr(VI) at the Garfield Avenue Site. DEP's calculation follows EPA's risk assessment methodology, utilizing a longer exposure duration (5 years, 138 days per year) and assuming a 1×10^{-6} (1 in 1 million) increased cancer risk. It also incorporates air dispersion modeling to account for dissipation in Cr(VI) particulate mass (due to settling, wind patterns, moisture content, etc.) prior to reaching the site perimeter. The revised air concentration is 49.12 ng/m^3. This value is more than 100 times lower (i.e., more protective) than the current OSHA permissible exposure limit (PEL) for Cr(VI) of 5.0 ug/m^3.[133]

[133] The permissible exposure limit (PEL) is an occupational exposure standard and is the concentration of a contaminant in air, calculated as an 8-hour time-weighted average (TWA), above which a worker shall not be exposed. According to CFR 1910.1026(c), "the employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 5 micrograms per cubic meter of air (5 $\mu g/m^3$)", calculated as an 8-hour TWA. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=13096#1910.1026(c)

Based on plan revisions made subsequent to preliminary recommendations on this topic, the Site Administrator feels that this new risk-based air concentration will protect the health and ensure the safety of residents living near the Garfield Avenue site.

2. Action Levels and Early Warning System

In order to protect members of the community from adverse health impacts of Cr(VI) and particulates, the Site Administrator recommends the development of an Action Level for dust and Cr(VI) for the time frame encompassing intrusive site activities. Since Cr(VI) cannot be measured in real-time, a surrogate real-time Action Level for total particulates (PM_{10}) would be calculated. The Action Level is the concentration of particulates in ambient air which triggers a re-evaluation, limitation or cessation of dust-generating activities on the site until air concentrations can be reduced.

PM_{10} at the eight perimeter locations will be measured continuously and reported as 15-minute averages and compared to the Action Level. As an added measure of safety, the continuous PM_{10} measurements in the Exclusion (Work) Zone will be reported as 5-minute averages. Exceedances of the Action Level in the Exclusion Zone will advise site safety personnel of the need for additional evaluations or dust control measures at the dust source, before the Action Level is reached at the site perimeter. This will act as a kind of early warning system and provide additional time to evaluate the dust source, employ aggressive dust control procedures or curtail operations in order to prevent elevated offsite exposures.

Existing soil analytical data will be used to establish the initial Action Level criteria for the project. Air monitoring data collected during the first several months of excavation activities may be used to better define the relationship between Cr(VI) and ambient measured dust levels and may be used to further evaluate or refine the dust Action Level and the locations for real-time air monitoring.

PPG's January 2010 Air Monitoring Workplan proposed an Action Level for total particulates (as a surrogate for Cr(VI)) that relied on a calculation for short-duration activities that is not appropriate for this long-term project (see above discussion under 1.) DEP has since calculated a new Action Level of 333 ug/m^3 based upon the actual concentration of hexavalent chromium in the site soils. This calculation is considered acceptable for the derivation of site-specific total particulate action levels, provided analytical results for co-located hexavalent chromium samples do not exceed 49.12 ng/m^3.

Based on cleanup work plan revisions made subsequent to preliminary recommendations on this topic, the Site Administrator feels that this new Action Level will protect the health and ensure the safety of residents living near the Garfield Avenue site.

3. On-Site and Perimeter Monitoring

Throughout the excavation activities, dust generation will be monitored visually and with particulate monitoring instruments, including direct-reading "real-time" monitors and filter cassette samplers, which will collect airborne dusts for subsequent laboratory analysis of Cr(VI) and total particulates. The Site Administrator recommends a two-tier approach to evaluating airborne contaminant levels to effectively ensure that potential airborne contamination from the excavation area will be detected prior to impacting any residents. A combination of fixed and mobile monitoring equipment will be used to sample and monitor at both of the recommended areas: the excavation zone and the site perimeter.

Monitoring data indicating that airborne particulates are present above Action Levels will require re-evaluation of site activities, a re-evaluation of work practices of individual workers, and/or changes in dust management practices. Work will be halted if conditions require.

Exclusion (Work) Zone Monitoring

Real-time air monitoring for PM_{10} will be collected continuously (5-minute data averages for 8-to-10 hours per day, 5 days per week) at four exclusion zone locations. The continuous data collection of PM_{10} levels will serve as real-time a surrogate for Cr(VI). The locations of the four exclusion zone monitoring stations will encircle the area where daily site intrusive activity will be performed, and will be relocated as necessary throughout the program. All real-time data from exclusion zone stations will be continuously telemetered to the central air monitoring station (as 5-minute data averages) located on the site property and subsequently compared to the Action Level developed for the site. Corrective actions will be being taken if/when any of these locations exceed an action level.

In addition to the continuous data collection for particulates, daily (5 days per week) integrated sampling for particulates (PM_{10}) and Cr(VI) will be conducted at the four exclusion zone locations. The Site Administrator recommends comparing measured concentrations to the Action Level and the risk-based concentration limit for Cr(VI).

Site Perimeter Monitoring

PPG's current Air Monitoring Workplan proposes site perimeter monitoring to demonstrate that excavation activities and materials handling operations do not result in ambient air concentrations of total particulates above the Action Level reaching nearby residences or businesses. The Site Administrator recommends expanding this to include a risk-based concentration limit (screening level) for Cr(VI).

Under the expanded plan, real-time air monitoring for PM_{10} will be conducted continuously (24 hours per day, 7 days per week) at four fixed site perimeter locations, as well as at four mobile perimeter air monitoring locations (for 8-to-10 hours per day, 5 days per week). All real-time data will be compared to the Action Level. In addition, daily integrated sampling (8-to-10 hours per day, 5 days per week) will be conducted for PM_{10} and Cr(VI). Measured concentrations will be compared to the Action Level and the risk-based concentration limit for Cr(VI).

PM_{10} at the eight perimeter air monitoring locations will be measured on a continuous basis and reported as 15-minute averages. If a 15-minute average PM_{10} concentration exceeds the Action Level at the site perimeter or if airborne dust is observed leaving the property boundaries, additional evaluations and dust control measures at the point identified as causing the elevated readings will be implemented. Work may continue at this point at the discretion of the site safety personnel.

A second 15-minute average PM_{10} concentration exceeding the Action Level at the site perimeter will be cause for intrusive activities at the point identified as causing the elevated readings to halt and be reevaluated. Work will resume provided that dust suppression measures and other controls are successful in reducing the concentrations to less than the Action Level at all perimeter stations for 15 minutes and in preventing visible dust from migrating beyond the work site.

Baseline Monitoring

The Site Administrator recommends that prior to the initiation of excavation activities, baseline monitoring be performed for at least five consecutive days to quantify "background" levels of Cr(VI) and total particulates. The anticipated 5-day baseline sampling program will involve collection of 24-hour PM_{10} data from the four fixed site perimeter locations plus collection of 8-to-10 hour PM_{10} data at the four mobile site perimeter locations and the four exclusion zone locations. Integrated PM_{10} and Cr(VI) samples from the eight perimeter and four exclusion zone sampling locations will be collected from 8:00 am to 5:00 pm. In scheduling the baseline monitoring to be performed, weather conditions that reflect normal weather patterns are required. Meteorological data will also be collected (24 hours per day) for the entire five-day baseline period.

Table II		
Recommended Program Element	**PPG's Air Monitoring Workplan (January 2010)**	**Comments**
Baseline Monitoring	Yes – 5 consecutive days prior to initiation of the ground intrusive remedial activities.	Recommend use of baseline data as background.
Development of Risk-Based Concentration Limit (Screening Level) for Cr(VI)	Plan proposes an acceptable air concentration (AAC) for Cr(VI) of 910 ng/m^3; however this is not offered as a level against which monitoring data for Cr(VI) will be compared. Furthermore, the AAC is determined using a calculation for short-term projects and for non-cancer endpoints.	DEP's revised site-specific risk-based concentration limit for Cr(VI) of 49.12 ng/m^3, developed using EPA's cancer risk-based calculation for long-term exposure, is acceptable to the Site Administrator.
Exclusion (Work) Zone Monitoring	Yes –mobile monitoring stations for real-time PM_{10} and integrated samples for PM_{10} and Cr(VI)	Approved.
Site Perimeter Monitoring	Yes – 7-day monitoring for real-time PM_{10} and 5-day integrated samples for PM_{10} and Cr(VI)	Approved.
Action Level established by:	AMP uses a calculation for a non-carcinogenic endpoint and short duration activities that is not appropriate for this long-term project to calculate (1) an acceptable air concentration and (2) a related particulates Action Level concentration.	DEP's proposed revised Action Level, based upon the actual concentration of hexavalent chromium in the site soils, is acceptable to the Site Administrator.
Action Level – Exclusion (Work) Zone	DEP's revised value for the Action Level is 333 *u*g/m^3	Approved.
Action level – Site Perimeter	DEP's revised value for the Action Level is 333 *u*g/m^3	Approved.
Early Warning System	Continuous PM_{10} data will be averaged every 5-minutes in the Exclusion (Work) Zone to provide ample time for site personnel to take corrective action prior to a perimeter 15-minute PM_{10} concentration exceeding the Action Level.	Approved.

B. COMMUNITY HEALTH EXPOSURE TESTING PROGRAM

In addition to the Air Monitoring Program, the Site Administrator recommends instituting real-time health exposure testing in order to determine whether the community is being exposed to Cr(VI) related to the remedial activities at the Garfield Avenue Site. The program will be voluntary and open to all residents living in the area from the Garfield Avenue Site west to Ocean Avenue; south to Bayview Avenue and north to Bramhall Avenue. The program will consist of:

- An initial screening for chromium level in red blood cells (blood screening) to be completed before any remedial excavation activities are initiated at the Garfield Avenue Site in order to establish a baseline for comparison purposes;
- Semi-annual blood screenings throughout the period of land-disturbing remedial activities;
- Physical examinations for evidence of medical conditions which indicate a recent exposure to chromium, if red blood cell sampling results are elevated;
- Data management and integration of participant blood data with environmental exposure data; and
- Protections for participant privacy.

1. Blood Screening

Blood screening for chromium measures the level of chromium in red blood cells (RBCs). It is considered the most accurate method for assessing an individual's exposure to hexavalent chromium within the previous 60 to 120 days prior to specimen collection. [The life span of a red cell is approximately four months].

Health Questionnaire

All participants will complete a confidential health questionnaire designed to help program personnel understand individual factors that may influence the concentration of chromium in the blood. The questionnaire may be used to assess possible sources for chromium exposure or other causes of elevated blood chromium levels.

Collection Frequency

During the baseline period prior to the start of remedial activities, and then semi-annually throughout the Garfield Avenue Site remediation, participating residents will provide a blood sample to be analyzed for the presence of chromium. Attempts will be made to collect semi-

annual samples during a dry period when potential dust exposure might be higher (although strict dust control procedures will be implemented throughout the remediation). A final sample will be collected approximately six months after remediation has been completed. This time frame would allow all of the red blood cells that might have absorbed hexavalent chromium to be replaced.

The Site Administrator also recommends conducting baseline testing with a small group of volunteers living outside of Jersey City in order to establish a background mean and variability. Participants will be recruited from a New Jersey city similar in size, degree of industrialization and socio-economic makeup to Jersey City, but without known historical or existing Cr(VI) contamination. Blood sampling of these "background" volunteers will be accomplished within the first six months of the program. Collection procedures, laboratory analysis and data management will be the same as those for the primary program participants.

Collection Procedures

In order to control the testing, the Site Administrator will identify one or two locations where sample collection will occur (e.g., the Metropolitan Family Health clinic). One or two phlebotomists will be identified to draw the blood and perform the sample collection according to strict chain-of-custody procedures. Each sampling event is expected to occur over 2 to 3 days.

The phlebotomist's job would include labeling the collection tube, drawing the blood, having the participant verify the name on the tube, and having the participant sign a chain-of-custody (COC) form. In addition, a third-party testing program manager (discussed below) will provide an individual on-site to oversee the collection, answer questions from participants, initiate the chain-of-custody, and collect the tubes and COC forms for shipping to the laboratory on a daily basis.

Blood will be drawn, spun down to provide the red blood cells and placed inside trace metal-free tubes (to avoid potential Cr(VI) contamination) within two hours of collection. Each day's samples will be sent by courier in a refrigerated cooler.

Laboratory Analysis

The distribution of blood chromium values in non-exposed individuals will be used to set an "elevated" criterion, most likely the 95^{th} percentile of the non-exposed distribution. Collected samples will be analyzed for chromium in red blood cells using Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). The analyses will be performed by a CLIA-certified clinical toxicology laboratory.

Follow-Up

The laboratory will send the test results directly to a third-party testing program manager,

identified by the Site Administrator. The Site Administrator has had extensive discussions with Dr. Paul Lioy and Dr. Michael Gochfeld of the Environmental and Occupational Health Sciences Institute (EOHSI) regarding their potential role as testing program manager. Dr. Lioy and Dr. Gochfeld, who have worked with the Jersey City community on issues of hexavalent chromium contamination for more than twenty years, are willing and able to administer the testing program. Given their record of experience and their established relationship with the community, EOHSI is the appropriate group to manage participant recruitment, oversee sample collection, perform laboratory QA/QC and evaluate the data that the program generates.

EOHSI will provide written results to each participating resident and will make available a health professional with experience in environmental and occupational medicine to answer any questions each participant might have regarding the results. If an elevated RBC chromium level is not detected, the participant's semi-annual testing will be complete.

If chromium is detected in the blood sample at an elevated level, the participant will be offered a medical examination, as described below.

2. Medical Examination

If laboratory analysis detects an elevated RBC chromium level, the participating resident will be offered a medical examination by a medical professional with experience in environmental and occupational medicine (e.g., physician or nurse practitioner) to evaluate for medical conditions which indicate a potential recent exposure to chromium, such as dermatitis, ulcers and nasal septum perforations.

As part of the medical follow-up, participants will review the questionnaire completed during the baseline testing with the examining medical professional. Furthermore, the participant will be required to share medical records with the medical professional to determine whether confounding conditions exist that might contribute to an elevated level. Review of medical records will not only assist in evaluating the source of elevated chromium levels, but it will also help protect the integrity of the testing program as it relates to other participants. Participants' privacy will be protected. Medical information will only be reviewed by the attending medical professional.

The participating resident will receive written results of the examination from the examining medical professional, who will also be available to answer any questions related to the examination. If any medical conditions potentially related to chromium exposure are identified, the participating resident will be referred to a qualified physician for further evaluation.

3. Data Management, QA/QC & Administration

A cornerstone of the testing program will be sound data management and program management. As mentioned previously, the Site Administrator has identified EOHSI to oversee blood sample

collection, perform laboratory QA/QC, and run data management. EOHSI's responsibilities would include:

a. Assisting in the recruitment of program participants and encouraging sustained participation;
b. Insuring that the blood drawing facility(s) operates on a time schedule;
c. Announcing the times of blood drawing to the program participants;
d. Overseeing each blood draw session, initiating the chain of custody, and shipping the samples;
e. Maintaining the participant database;
f. Receiving the results of the RBC chromium analyses and entering them in the database;
g. Informing participants of their results by letter (with explanation)
h. Reviewing laboratory QA/QC performance (typically an outside laboratory validates 5% of samples);
i. Linking participant blood data to environmental exposure data;
j. Providing periodic reports to the Site Administrator and participants on the progress of screening, the results, and the linkage to environmental monitoring; and,
k. Providing an overall report to the Site Administrator, PPG, DEP, the City of Jersey City, and the Garfield Avenue community with the results

To provide a further level of program oversight, an additional physician specializing in occupational and environmental medicine will audit and oversee the program, specifically focusing on elements related to blood sampling, chain-of-custody, and laboratory procedures.

C. RESIDENTIAL INSPECTION PROGRAM, RESULTS MAPPING PROJECT AND EOHSI DUST STUDY PROMOTION

1. Residential Inspection Program Results Mapping Project

As stated earlier, the goal of the recommended Community Health Exposure Prevention and Testing Program is to ensure that the health of residents living in the vicinity of the Garfield Avenue Site is protected during site remediation and into the future. Supporting this goal is the Residential Inspection Program, established by the Consent Judgment to address the concerns of residents living near the PPG sites who suspect chromium waste may be in or on their property. Residents in homes within 400 feet of PPG cleanup sites in Jersey City and Bayonne, including the Garfield Avenue Site, are eligible to request an inspection under the program. Residential-

related properties located within these boundaries, such as daycare centers, school and playgrounds, are also eligible.

The Residential Inspection Program will determine through inspections and sampling if elevated levels of Cr(VI) are present. Chromium waste that exceeds NJDEP standards will, at a minimum, be cleaned up to standards. In this way, both CCPW on the Garfield Avenue Site and residual CCPW on surrounding residential properties will be removed, thereby helping protect the community's health.

The information collected through site sampling is of great value in determining the extent of CCPW contamination within the Garfield Avenue Site community. The Site Administrator recommends that the Residential Inspection Program Results Mapping Project be developed to share sampling results through location maps and public reports in order to provide the broader community with an accurate picture of residential contamination conditions. Information would be shared with the public through website posting and newsletters, as appropriate.

2. EOHSI Dust Study Promotion

Through various exposure-oriented studies, EOHSI has aided in providing an objective science-based assessment of Cr(VI) exposure to Jersey City residents for the past two decades. Their latest active study is the second phase of an earlier examination of Cr(VI) in household dust, which was initiated in 2006 in response to continuing public concern over potential Cr(VI) exposure from the remaining unremediated CCPW sites. Because EOHSI found Cr(VI) in household dust in Phase I, suggesting a potential for exposure, they implemented the second phase of the study in 2009. Currently, EOHSI is actively recruiting homes with children 6 years old and younger in which to collect household dust samples for Cr(VI) measurements and to collect urine samples from children.

The Site Administrator recommends that community participation in the EOHSI study be encouraged through promotion activities of the parties to the Consent Judgment.

VIII. CRITERIA CONSIDERED FOR POTENTIAL HEALTH EXPOSURE STUDY

In considering what type of health exposure study, if any, would be appropriate for the residents living in the vicinity of the Garfield Avenue Site, the Site Administrator considered the following questions.

1. ***Will the data gathered to detect a specific contaminant (chromium waste) aid in the prevention of disease or health effect?***

2. ***How will the information be used a) to protect community health, b) address community concerns; and c) take appropriate action?***

3. ***Are there programs/resources in place to act on findings, if necessary?***

4. ***What follow-up will occur and who is responsible?***

These questions are answered below in the context of the selected comprehensive site-related exposure monitoring program.

Will the data gathered aid in the prevention of disease or health effect?

The data gathered under the recommended Community Health Exposure Prevention and Testing Program will be of two types: biological sample data and air monitoring data. Air monitoring data will be used to document the degree to which remedial activities expose the community to elevated levels of Cr(VI) in ambient air. Biological samples will be used to document whether individuals are being exposed to Cr(VI) in their environment. The data collected will be part of a comprehensive program designed to limit and assess exposure and, therefore, is inherently preventative in nature (even while existing health studies do not clearly establish that adverse health effects result from low levels of exposure for periods of short duration)

How will the information be used to protect community health?

The air monitoring data gathered will be used to protect community health by showing whether there are elevated levels of Cr(VI) dust in ambient air and whether the dust is leaving the remedial site. If it is determined that dust at elevated levels is being generated and leaving the site, work will be stopped until work procedures can be re-evaluated and reconfigured in order to eliminate this problem.

Simultaneously, biological testing can show whether individuals are being exposed to Cr(VI). If this is detected, steps can be taken to identify the route of exposure and/or eliminate the source.

How will the information be used to address community concerns?

One of the community's primary concerns is protection from exposure to Cr(VI) during remediation and the air monitoring data will document actual conditions and show that Cr(VI) concentrations in ambient air are maintained below target levels. Air monitoring information will be shared with the public through website posting and newsletters.

Biological testing can confirm that individuals are not being exposed to elevated levels as a result of remediation.

How will the information be used to take appropriate action?

The Action Level for PM_{10} will be used to control remediation operations. Because the continuously collected PM_{10} measurements in the Exclusion (Work) Zone are averaged every five (5) minutes, site personnel have ample time to implement corrective actions before Action Levels are exceeded at the site perimeter. Additionally, if air monitoring data indicates that the risk-based Cr(VI) concentration are being exceeded, the project will be shut-down and if necessary reconfigured until PPG can show appropriate measures are in place to prevent further exceedances and to protect human health.

If biological testing shows elevated levels of Cr(VI) in blood samples, a physical exam by a medical professional experienced in environmental and occupational medicine can be conducted to determine if Cr(VI)-mediated health concerns are present in an individual.

Are there programs/resources in place to act on the findings, if necessary?

The Health and Safety Plan and Standard Operating Procedures for the Garfield Avenue Site identify the procedures to be followed if an Action Level is exceeded. The Site Administrator has the authority to order the work at the site stopped until it can be shown that measures are in place to protect the public.

What follow-up will occur and who is responsible?

If air monitoring demonstrates that Cr(VI)-contaminated dust is migrating offsite at concentrations above risk-based levels, PPG is responsible for shutting down remedial operations and revamping procedures to ensure that future remedial activities are protective of human health.

IX. CONCLUSIONS

After reviewing the data in numerous health studies, reports and websites, and after discussing the state of Cr(VI) science with various health experts, a comprehensive Community Health Exposure Prevention and Testing Program is recommended for the residents living in the vicinity of the Garfield Avenue Site. This three-tier protocol is designed to prevent the public from being exposed to elevated levels of Cr(VI) during remediation, provide reassurance to the community that their health is being protected and provide a more complete picture of area residents' current exposure to Cr (VI).

APPENDIX A –

Cr(VI)-RELATED HEALTH STUDIES SPECIFIC TO NEW JERSEY

Chromium-Related Health Studies and Scientific Literature

Specific to New Jersey

- ***Medical Evaluation of Children and Adults of the Whitney Young Jr. School, Jersey City, New Jersey*** (December 1989) – NJ Dept. of Health, http://www.state.nj.us/dep/dsr/chromium/young.pdf
- ***An Assessment and Quantitative Uncertainty Analysis of the Health Risks to Workers Exposed to Chromium Contaminated Soils*** (1991) Paustenbach DJ, Meyer DM, Sheehan PJ et al. Toxicol. Ind. Health 7, 159-196 http://tih.sagepub.com/cgi/content/abstract/7/3/159
- ***The Health Hazards Posed By Chromium-Contaminated Soils in Residential and Industrial Areas: Conclusions of an Expert Panel*** (April 1991) Paustenbach DJ, Rinehart WE, Sheehan PJ, Reg. Toxic. and Pharm. 13, 195-222 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6WPT-4DDP4D4-BB&_user=8702323&_coverDate=04%2F30%2F1991&_rdoc=7&_fmt=high&_orig=browse&_srch=doc-info(%23toc%236999%231991%23999869997%23521351%23FLA%23display%23Volume)&_cdi=6999&_sort=d&_docanchor=&_ct=8&_acct=C000050221&_version=1&_urlVersion=0&_userid=8702323&md5=f7c81f5a8f0a787f715378b7707f0c50
- ***Chromite ore processing residue in Hudson County, New Jersey*** (May 1991) T Burke, J Fagliano, et. al. Environ. Health Perspect. 92: 131-137 *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1519394/*
- ***Airborne Concentrations of Trivalent and Hexavalent Chromium from Contaminated Soils at unpaved and partially-Paved Commercial/Industrial Sites*** (January 1992) Falerios M, Schild K, Sheehan P et. al. J. Air & Waste Manage. Assoc. 42:40-48 http://secure.awma.org/onlinelibrary/ProductDetails.aspx?productID=10639
- ***Chromium exposure assessment of outdoor workers in Hudson County, NJ*** (July 1992) Bukowski JA, Goldstein MD, Korn LR, et al. Sci. of the Total Environment, 122, 291-300 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6V78-48XT4VY-1SB&_user=8702323&_coverDate=07%2F29%2F1992&_alid=1131087850&_rdoc=8&_fmt=high&_orig=search&_cdi=5836&_sort=r&_docanchor=&view=c&_ct=15&_acct=C000050221&_version=1&_urlVersion=0&_userid=8702323&md5=77208c7492731d3c53d81f7ecb6f6ca1
- ***Microenvironmental Analysis of Residential Exposure to Chromium-Laden Wastes in and Around New Jersey Homes*** (June 1992) Lioy PJ, Freeman NCG, Wainman T, et al. Risk Analysis 12(2), 287-299. http://www3.interscience.wiley.com/journal/119328369/abstract

- ***Residential Exposure to Chromium Waste – Urine Biological Monitoring in Conjunction With Environmental Exposure Monitoring*** (June/August 1992) Stern AH, Freeman NCG, Pleban P, et al. Env. Research 58, 147-162 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6WDS-4G3K8RY-38&_user=8702323&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=8702323&md5=37f00aaa6b0e81860503d4dc6cb84729

- ***Field Validation for Sampling and Analysis of Airborne Hexavalent Chromium*** (March 1993) Finley B, Fehling K, et al. Appl. Occup. Environ. Hyg. 8(3), 191-200 http://direct.bl.uk/bld/PlaceOrder.do?UIN=004813273&ETOC=EN&from=searchengine

- ***Designing a biological monitoring program to assess community exposure to chromium: Conclusions of an expert panel*** (December 1993) Anderson RA, Colton T, Doull J et al. J. Tox and Env. Health, Part A, 40:4, 555-583 http://www.informaworld.com/smpp/content~db=all~content=a916044055

- ***Chromium Medical Surveillance Project: Final Technical Report*** (October 1994) - NJ Department of Health, Div. of Epidemiology, Jerald Fagliano and Jonathan Savrin, http://www.state.nj.us/dep/dsr/chromium/surveillance.pdf

- ***Urinary Excretion of Chromium Following Ingestion of Chromite-Ore Processing Residues in Humans: Implications for Biomonitoring*** (December 1994) Gargas ML, Norton RL, Harris MA, et al. Risk Analysis, Vol. 14, No. 6 http://www3.interscience.wiley.com/journal/119276088/abstract

- ***The Effect of Remediation of Chromium Waste Sites on Chromium Levels in Urine of Children Living in the Surrounding Neighborhood*** (August 1995) Freeman NCG, Wainman T, Lioy PJ, et al. J. Air & Waste Manage. Assoc. 45: 604-614 http://secure.awma.org/onlinelibrary/ProductDetails.aspx?productID=11006

- ***Increased DNA-Protein Crosslinks in Lymphocytes of Residents Living in Chromium-Contaminated Areas*** (December 1995) Taioli E, Zhitkovich A, Kinney P et. al. Biological Trace Element Research, Vol. 50, 175-180 http://www.springerlink.com/content/65u4r8674w185334/

- ***Monitoring Human Lymphocytic DNA-Protein Cross-links as Biomarkers of Biologically Active Doses of Chromate*** (October 1996) Costa M, Zhitkovich A, et. al. Env. Health Perspect. 104(5) *http://ehp.niehs.nih.gov/members/1996/Suppl-5/costa-full.html*

- ***Background Air Concentrations of Cr(VI) in Hudson County, New Jersey: Implications for Setting Health-based Standards for Cr(VI) in Soil*** (May 1997) Scott PK, Finley BL,

Harris MA et al. J. Air & Waste Manage. Assoc. 47:592-600
http://secure.awma.org/onlinelibrary/ProductDetails.aspx?productID=588

- ***Exposure to Chromium Dust from Homes in a Chromium Surveillance Project*** (May 1997) Freeman NCG, Stern AH, Lioy PJ, Archives of Environmental Health http://www.highbeam.com/doc/1G1-19478916.html

- ***Community Exposure and Medical Screening Near Chromium Waste Sites in New Jersey*** (August 1997) Fagliano JA, Savrin J, Udasin I, Gochfeld M, Reg. Tox. And Pharm. 26, S13-S22 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6WPT-45NJS8P-11&_user=8702323&_coverDate=08%2F31%2F1997&_alid=1131081592&_rdoc=61&_fmt=high&_orig=search&_cdi=6999&_sort=r&_docanchor=&view=c&_ct=64&_acct=C000050221&_version=1&_urlVersion=0&_userid=8702323&md5=86f57547593b321e62460ad9cdba549a

- ***The Association of Chromium in Household Dust with Urinary Chromium in Residences Adjacent to Chromate Production Waste Sites*** (December 1998) Stern AH, Fagliano JA, Savrin JE, et. al., Env. Health Perspectives, Vol 106, Num. 12 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533240/pdf/envhper00535-0107.pdf

- ***Reduction in Residential Chromium Following Site Remediation*** (June 2000) Freeman NCG, Lioy PJ, Stern AH J. Air & Waste Manage. Assoc. 50:948-953 http://secure.awma.org/onlinelibrary/ProductDetails.aspx?productID=385

- ***Analysis of Lung Cancer Incidence Near Chromium-Contaminated Sites in New Jersey (a/k/a Hudson County Chromium Sites)*** (September 2008) – NJ Department of Health and Senior Services and NJ DEP for ATSDR, Jerald Fagliano, MPH, PhD (principal author), http://www.atsdr.cdc.gov/HAC/pha/Chromium-ContaminatedSitesinNJ/Chromium-Contaminated%20Sites%20(NJ)%20093008.pdf

- ***Chromium Exposure and Health Effects in Hudson County: Phase I*** (December 2008) – Environmental and Occupational Health Sciences Institute (EOHSI), Paul Lioy, PhD and Michael Gochfeld, MD, PhD (principal investigators), http://njedl.rutgers.edu/ftp/PDFs/5778.pdf

- ***Characterization of Hexavalent Chromium Concentrations in Household Dust in Background Areas*** (March 2009) – EOHSI and NJDEP, Office of Science and Research, http://www.state.nj.us/dep/dsr/chromium/bckgrd-dust-study-report.pdf

- ***Derivation of an Ingestion-Based Soil Remediation Criterion for Cr^{+6} Based on the NTP Chronic Bioassay Data for Sodium Dichromate Dihydrate*** (June 2009) - NJDEP Office of Science, Alan Stern, Dr. P.H., http://www.state.nj.us/dep/dsr/chromium/ingestion-cr.pdf

APPENDIX B –

OTHER Cr(VI)-RELATED HEALTH STUDIES

OTHER Cr(VI)-RELATED HEALTH STUDIES

Cr(VI) in Other U.S. Communities:

- ***Evaluation of Exposure to Historic Air Releases From the Abex/Remco Hydraulics Facility, Willits, Mendocino County, California*** (Final July 2004) - California Department of Health Services, Environmental Health Investigations Branch (EHIB) for ATSDR, http://www.ehib.org/cma/projects/AbexRemcoFinalAirPHA.pdf
- ***Evaluation of Health Studies Possibilities and Limitations at the Abex/Remco Hydraulics Facility*** (July 2006) - California Department of Health Services, Environmental Health Investigations Branch (EHIB) for ATSDR, http://www.atsdr.cdc.gov/HAC/pha/AbexRemcoHydraulicsFacility/Abex-RemcoHydraulicsHC091906.pdf
- ***Expert Panel Report: Recommendations for Conducting Medical Monitoring for Residents of Willits, California and Workers Exposed to Hexavalent Chromium and Volatile Organic Compounds from the Abex/Remco Hydraulics Facility*** (November 2006) – Robert Harrison, UC San Francisco, Division of Occupational and Environmental Medicine, http://www.ehib.org/cma/projects/MMReportFinal.pdf
- ***Review of Cancer Rates in the Vicinity of Chrome Crankshaft Company and J and S Chrome Plating Company*** (January 2003) - California Dept. of Health Services, EHIB, for ATSDR – Marilyn Underwood, PhD and Sumi Hoshiko, MPH (principal investigators), http://www.atsdr.cdc.gov/HAC/PHA/chromecrankshaft/jsc_toc.html
- ***Summary of Evaluation of Exposure to Aerial Emissions from Chrome Crankshaft Company and J&S Chrome Plating Company*** (December 2003) - California Dept. of Health Services, EHIB, for ATSDR, http://www.ehib.org/projects/SuvaAirEnglish.pdf
- ***Asthma and Related Respiratory Conditions Among Children: A Study Concerning Attending School Near Two Chromium Plating Facilities*** (February 2005) - California Dept. of Health Services, EHIB, for ATSDR – Marilyn Underwood, PhD (principal investigator), http://www.ehib.org/cma/projects/CCHealthStudy.pdf
- ***Letter Health Consultation: Evaluation of Chromium in Private Wells, West County Road 112, Midland County, Texas*** (June 2009) – Texas Department of State Health Services for ATSDR, (http://www.tceq.state.tx.us/assets/public/remediation/variousremediationsites/westcr112/cr112_health_consult_060309.pdf

Cr(VI) in Communities Abroad:

- ***Cancer Mortality in a Chinese Population Exposed to Hexavalent Chromium in Drinking Water***, January 2008, Epidemiology Volume 19(1), p. 13, Beaumont, J. et. al ,
- ***Investigation and Study of Chromium Pollution in Jinzhou***, Chinese Journal of Preventive Medicine, 1987, Volume 21, Issue 5, p.1, Zhang, J. and Li, X,
- ***Hexavalent Chromium, Yellow Water, and Cancer: A Convoluted Saga***, Epidemiology, January 2008, Volume 19 (1), p. 24, Smith, A.
- Editorial retraction. Journal of Occupational and Environmental Medicine. 2006; 48: 749, Brandt-Rauf P.
- ***Environmental Chromium Dust and Lung Cancer Mortality***, Env. Research 23, 469-476 (1980), Axelsson G. and Rylander R.

Cr(VI) in Occupational Settings:

- ***Cancer Mortality Among a Cohort of Chromium Pigment Workers***, American Journal of Industrial Medicine, 1989, Volume 16, Issue 2, p. 127-133, Hayes, R. et al.
- ***Risk of Lung Cancer Among Former Chromium Smelter Workers***, American Journal of Industrial Medicine, December 1998, Volume 29, Issue 5, p. 491-500, Rosenman, K and Stanbury, M.
- ***Lung Cancer Mortality Among Chromate Production Workers*****,** Occupational and Environmental Medicine, 2003, 60:451-457, Luippold, R. et al.
- US Department of Labor, Occupational Exposure to Hexavalent Chromium (website), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=18599&p_table=federal_register
- US Department of Labor, Regulations (Standards – 29 CFR) Chromium (VI) 1910.1026, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=13096
- **NIOSH Hexavalent Chromium Criteria Document Update: Occupational Exposure to Hexavalent Chromium, External Review Draft**, September 2008, Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health http://origin.cdc.gov/niosh/review/public/144/pdfs/DRAFT-Criteria-Document-Update-Occupational-Exposure-to-Hexavalent-Chromium.pdf

Biomarkers/Biomonitoring:

- ***Quantitative Interpretation of Human Biomonitoring Data,*** Toxicology and Applied Pharmacology, Volume 231, Issue 1, 15 August 2008, Pages 122-133 Harvey J. Clewell, Yu Mei Tan, Jerry L. Campbell, Melvin E. Andersen, http://www.ncbi.nlm.nih.gov/pubmed/18589468
- ***Proteomic Approaches in Lung Cancer Biomarker Development***, Expert Review of Proteomics. 2009; 6(1):27-42, Je-Yoel Cho; Hye-Jin Sung, http://www.medscape.com/viewarticle/706008
- ***Cr^{VI} exposure and biomarkers: Cr in erythrocytes in relation to exposure and polymorphisms of genes encoding anion transport proteins***. 2008: 13(5):467-477, Qu, Qingshan, Li, Xiaomei, Costa, Max, et. al., http://informahealthcare.com/doi/abs/10.1080/13547500802099574
- ***Early Detection Research Network, Fourth Report***, January 2008, National Cancer Institute, Division of Cancer Prevention, http://edrn.nci.nih.gov/docs/progress-reports/edrn_4th-report_200801.pdf
- ***Chromium: Exposure, Toxicity and Biomonitoring Approaches*** (Chapter 19: From Biomarkers of environmentally-associated disease), 2002, Zhitkovich, A. http://www.crcpress.com/product/isbn/9781566705967;jsessionid=RQyr0eEoUijMNkhG5R2L-Q**

Cr(VI) Carcinogenesis –

- ***Genetic and Epigentic Mechanisms in Metal Carcinogenesis and Cocarcinogenesis: Nickel, Arsenic and Chromium***, Chem. Res. Toxicology 2008, 21, 28-44, Salnikow, K. and Zhitkovich, A., http://pubs.acs.org/doi/pdfplus/10.1021/tx700198a?cookieSet=1
- ***Cancer Mortality in a Chinese Population Exposed to Hexavalent Chromium in Drinking Water***, Epidemiology, 19:1, 12-23, January 2008; Beaumont, J. et al., http://www.informaworld.com/smpp/content~content=a908404497~db=all
- ***Carcinogenicity of Metal Compounds,*** *Handbook on the Toxicology of Metals, 2007, 177-196,* Ke, Q. et al. http://www.elsevier.com/wps/find/bookdescription.cws_home/711433/description#toc
- ***Dietary chromium and nickel enhance UV-carcinogenesis in skin of hairless mice,*** *Toxicology and Applied Pharmacology,* Volume 221, Issue 3, 15 June 2007, 329-338, Uddin, A, et al., http://www.ncbi.nlm.nih.gov/pubmed/17499830
- ***NTP Technical Report on the Toxicology and Carcinogenesis Studies of Sodium Dichromate Dihydrate (CAS No. 7789-12-0) in F344/N Rats and B6C3F_1 Mice (Drinking***

Water Studies), July 2008, National Toxicology Program, http://ntp.niehs.nih.gov/files/546_WEB_FINAL.pdf

- ***Review of the Evidence Regarding Carcinogenicity of Hexavalent Chromium in Drinking Water***, Journal of Environmental Science and Health Part C, 24:155-182, 2006; Sedman, R. et al., http://pdfserve.informaworld.com/597642__748803417.pdf

Chromium (General) –

- ***Draft Public Health Goal for Hexavalent Chromium in Drinking Water***, August 2009, Pesticide & Environmental Toxicology Branch, Office of Environmental Health Hazard Assessment, CA EPA, http://www.oehha.ca.gov/water/phg/pdf/Cr6PHGdraft082009.pdf
- ***Draft Responses to Major Comments on Technical Support Document, Public Health Goal for Hexavalent Chromium in Drinking Water***, September 2009, Pesticide & Environmental Toxicology Branch, Office of Environmental Health Hazard Assessment, CA EPA, http://www.oehha.ca.gov/water/phg/pdf/CrResponse090909.pdf
- ***ATSDR Toxicological Profile for Chromium, Draft for Public Comment***, September 2008 http://www.atsdr.cdc.gov/toxprofiles/tp7.html#bookmark01
- ***Chromium,*** *(chapter in)* ***Handbook on the Toxicology of Metals***, 2007, pp 487-510, S Langard, M Costa, http://www.elsevier.com/wps/find/bookdescription.cws_home/711433/description#toc

APPENDIX C –

HEALTH AND SCIENCE EXPERTS CONSULTED

Health and Science Experts Consulted

- **Barbara Beck**, PhD, DABT, FATS - Gradient Corporation and Harvard University lecturer (toxicology and risk assessment with Cr(VI) expertise)
- **Max Costa**, PhD - Chairman, Dept. of Environmental Medicine, New York University School of Medicine (environmental medicine, pharmacology, heavy metal carcinogenesis, Cr(VI) contamination)
- **Jerald Fagliano**, MPH, PhD - NJ Department of Health & Senior Services, Hazardous Site Health Evaluation Program (environmental epidemiology)
- **Michael Gargas**, PhD - formerly of Sapphire Group (human health risk assessment, biochemical toxicology specific to Cr(VI), inhalation toxicology, pharmacokinetic modeling)
- **Michael Gochfeld**, MD, PhD - Environmental and Occupational Health Sciences Institute (EOHSI), (occupational medicine, environmental toxicology, environmental risk assessment, chromium)
- **Sumi Hoshiko**, MPH - California Department of Public Health, Environmental Health Investigations Branch (environmental epidemiology)
- **Janet Kester**, PhD - NewFields (toxicologist, human health and ecological risk assessment, risk communication)
- **Joseph Landolph**, PhD - University of Southern California, Keck School of Medicine (Cr(VI) carcinogenesis and toxicity)
- **George Lambert**, MD - Director of the NIEHS/EPA Center for Childhood Neurotoxicology and Exposure Assessment; Member, EPA Science Advisory Board (environmental exposures studies, particularly pediatric)
- **Paul Lioy**, PhD - Environmental and Occupational Health Sciences Institute (EOHSI), Exposure Sciences Division (total human exposure measurements using chemical and biological monitoring)
- **Eileen Murphy**, PhD - NJDEP, Division of Science, Research & Technology, former Chair, Chromium Work Group (environmental fate and transport)
- **Louise Showe, PhD** - Wistar Institute (lung cancer biomarker research)
- **Racquel Stephenson**, MPH - ATSDR Region 2, Regional Representative

- **Alan H. Stern**, Dr. PH - NJDEP Office of Science, Research & Technology (biomonitoring, epidemiology, risk assessment, toxicology)
- **Joan Strawson**, MS, JD - Toxicology Excellence in Risk Assessment (toxicology and human health risk assessment)
- **Ronald Teichman**, MD, MPH - Teichman Occupational Health Associates, Inc.; Editorial Board of Journal of Occupational and Environmental Medicine (occupational health, Cr(VI) biomonitoring)
- **Melvyn Tockman**, MD, PhD – H. Lee Moffitt Cancer Center and Research Institute, University of South Florida (lung cancer biomarker research)
- **Marilyn Underwood**, PhD - California Department of Public Health, Environmental Health Investigations Branch (toxicology)
- **Anatoly Zhitkovitch**, PhD - Brown University, Division of Biology and Medicine (Cr(VI)-mediated DNA protein crosslinks and carcinogenicity)