CHROMIUM MEDICAL SURVEILLANCE PROJECT

FINAL TECHNICAL REPORT

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REPORT SUMMARY

Background

One of the most important hazardous waste problems in New Jersey has been the potential for human exposure to chromium contaminated soils and dust, in parts of Hudson County, New Jersey. Waste material (called "slag") was created by three chromite ore smelting facilities that operated in Hudson County from around 1900 to the 1970s. Approximately 2 to 3 million tons of this slag, which still contained potentially hazardous levels of chromium, was used as fill material in residential, recreational, public, commercial and industrial areas. To date, more than 160 separate waste sites containing chromium smelting slag have been identified in and around Hudson County. Many of the chromium waste sites have undergone or are undergoing remediation to decrease human exposure to and environmental contamination with chromium.

The New Jersey Department of Health (NJDOH) designed and conducted a screening project to find out if exposure to chromium was occurring and to provide medical evaluations to people who live and/or work on or near chromium waste sites. This project was named the Chromium Medical Surveillance Project (CMSP).

Human Exposure Potential The use of the chromium slag in the 1950s and 1960s, as fill in a wide variety of locations, created many means and pathways by which people could be exposed to chromium in the slag. Persons living or working in the vicinity of chromium waste sites may have been exposed through inhalation, accidental ingestion, or direct skin contact with contaminated dusts and/or soils. The ability of some forms of chromium to concentrate in surface soils and on the inside surface of walls greatly increased the potential for people to come in contact with chromium.

The magnitude of past exposures is not known. Remediation during the past several years has reduced the potential for exposure to contaminated soils.

Public Health Concerns Chromium can exist in several chemical states, and can form many different chemical compounds. Exposure to some forms of chromium have been shown to cause more serious adverse health effects than others. Chromium in its most
common and natural state, trivalent chromium, is found in small quantities in a person’s
diet. However, hexavalent chromium is a poison. The most serious health effect of
exposure to hexavalent chromium is an increase in the risk of lung cancer. Chromium
exposure also may result in asthma, skin rashes, skin irritation or ulcers, nasal irritation or
ulcers, nasal septum perforations, or damage to the kidneys.

Screening for Chromium Exposure and Health Effects An appropriate public health
response to a cancer-causing substance in the environment is to screen for and minimize
exposure to that substance. Although lung cancer is the most serious health effect of
exposure to chromium, a practical medical screening method for lung cancer does not exist.
Medical screening methods can be used to detect irritative or corrosive effects (such as
nasal septum perforations) and allergic effects (such as skin rashes).

Because chromium is removed relatively rapidly from the human body following
excess exposure, screening for exposure to chromium is limited to relatively recent
exposure. A review of available indicators of chromium exposure revealed that analyzing
urine for chromium was the best available means of finding out if a person had been
exposed to chromium. The urine chromium test, which was used in the CMSP, reflects
exposure in the previous one or two days.

Goals of the Project

The purposes of the Chromium Medical Surveillance Project were:

1) To provide clinical and laboratory services to resident and worker populations
identified by the New Jersey Department of Environmental Protection (NJDEP) and
NJDOH as potentially exposed to chromium from waste sites in and around Hudson
County. This involved:
   * identifying individuals and groups that may be experiencing current exposure to
     chromium so that interventions to reduce exposure can be undertaken,
   * identifying those individuals in need of follow-up evaluation based on observations
     of potential chromium-related health effect, and
   * providing follow-up medical evaluations for those individuals with possible
     exposure to and health effects from chromium.
2) To provide a public health basis for judgments regarding the population impact of chromium waste exposure in Hudson County, and to assist in decision-making regarding necessary actions for exposure reduction.

**Project Design**

Before starting to screen potentially exposed persons, NJDOH had to complete certain groundwork. The NJDOH had to develop the capacity to analyze large numbers of samples for chromium at low levels of detection (0.2 micrograms per liter, or μg/l), since analytical methods capable of detecting low level exposure are non-routine and not available commercially. NJDOH also conducted a "baseline survey" of 317 persons from many parts of New Jersey before the screening in Hudson County, since the range of normal urine chromium concentrations were not well known for persons of all ages.

**Participant Selection** NJDOH identified 14 residential areas and 78 workplaces to be targeted for screening services under this project. Clinical and laboratory services were offered to all persons determined by NJDOH to live or work on or near the chromium waste sites. The CMSP included intensive outreach to notify people of their eligibility to participate. Residential populations were notified of their eligibility by door-to-door outreach, and through their churches, civic leaders, and schools. Newspaper advertisements and press releases were also used. Worker populations were notified of their eligibility for screening services through their employers.

Screenings were conducted at the Jersey City Medical Center, a mobile medical van, or in local facilities. All urine chromium analyses were conducted by the NJDOH Environmental and Chemical Laboratory Service.

**Screening and Follow-up Evaluations** People who participated in the medical screening were (1) given a screening physical examination of the skin and nasal passages (2) asked to supply a urine sample, and (3) asked to complete a questionnaire.

During the screening operations, decisions were made about who to refer for high urine chromium levels. These decisions were made on the basis of the "excess" urine chromium. "Excess" urine chromium is defined as the amount that the observed concentration exceeded a predicted or expected individual concentration. Expected
concentrations were (1) based on the person’s age, sex, weight, chromium supplement intake, and activities, and the diluteness of the person’s urine sample, and (2) calculated from a statistical model using information from the baseline survey. If a person’s observed level was more than 0.5 μg/l higher than the expected, then the person was referred for follow-up medical evaluation. This cutoff level was chosen such that 98% of the baseline survey population had an “excess” value less than 0.5 μg/l.

Participants who showed signs of potential chromium-related physical effects at the screening physical examination were also referred for follow-up medical evaluation. These decisions were based on criteria specified in a screening examination protocol, including history of allergies, asthma or chronic skin rashes, or an observation by the physician of skin or nasal problems potentially related to chromium exposure.

The follow-up medical evaluations were conducted by physicians from the Environmental and Occupational Health Clinical Center (EOHCC) of the Environmental and Occupational Health Sciences Institute (EOHSI). During the follow-up medical evaluations, participants received a review of their medical history, physical examination, laboratory tests of urine and blood, repeat urine chromium tests, tests of lung function, and if needed, examination by a dermatologist.

Many participants, including those who were referred for follow-up medical evaluation, were also offered testing of their household dust for chromium content. These tests were conducted by scientists from EOHSI under a research contract with NJDEP, and results of these tests are not included in this project report.

Participants in the screening project were informed of all of their screening and follow-up medical evaluation results. Individual data collected in the screening program has been and will continue to be kept completely confidential.

Results of the screening and follow-up medical evaluations were analyzed in a number of ways. These included examining differences in the proportions of persons referred for follow-up evaluation among different screened groups, and comparing the distribution of urine chromium concentrations among groups. The group comparisons of urine chromium distribution were done after using statistical methods to adjust for differences among groups in factors unrelated to waste site exposure that might affect urine
chromium levels. These potential confounding factors include urine diluteness, age, sex, race, household smoking, intake of chromium supplements or beer, self-reported medical conditions, and activities possibly related to chromium exposure (such as a hobby or job involving welding).

Results of the Chromium Medical Surveillance Project
* A total of 2,224 individuals participated in the screening project which began in January 1992. Screening evaluations were completed by June 1993, and follow-up evaluations were completed by the end of September 1993. The screened population consisted of 939 workers at targeted workplaces, 811 persons from targeted residential areas, 224 persons who lived close to a targeted residential area or whose workplace was within a targeted residential area, 101 persons from a school in a targeted residential area, and 178 persons not assignable to any of the above groups. (Twenty-nine people both lived in a targeted residential area and worked at a targeted workplace.)
* Of the 2,224 participants, 2,205 were examined by a physician. Of this 2,205, 44 (2%) were referred for follow-up medical evaluation on the basis of a potential chromium-related finding, most often related to a skin problem. Of the 2,224 participants, 11 provided a sample that was too small in volume to analyze for chromium. Of the remaining 2,213, 223 (10%) were referred for follow-up medical evaluation on the basis of the urine chromium test. The proportions of persons referred differed according to workplace and residential area (see discussion below).
* A total of 266 participants were referred for follow-up medical evaluations. (One person was referred on the basis of both the physical examination and the urine chromium concentration.) Of these, 184 (69%) received the follow-up medical evaluation.
* Most of the persons undergoing the follow-up medical examinations revealed no apparent clinical effects attributable to chromium exposure. However, for six persons, chromium was suspected to be a possible cause or contributing factor in their clinical conditions. Five of the six were employed at screened workplaces, while one was from a targeted residential area. Four of the six were found to have skin conditions possibly related to chromium, while three had persistent nasal allergies.
The average urine chromium levels of all screened groups (residents, persons associated with residential areas, workers, non-targeted persons) were higher than those from the baseline survey, after adjusting for potential confounding factors. However, most persons in most targeted residential areas and workplaces did not appear to be currently exposed to unusual amounts of chromium from the waste sites or any other source. Analysis of adjusted urine chromium levels in specific age groups shows that the reasons for overall increases among screening groups differ according to age group.

Children age five and under living near chromium sites showed increased urine chromium concentrations. In comparison to the baseline survey children, the average adjusted urine chromium concentration was higher in resident children by 0.13 µg/l (0.33 vs. 0.20 µg/l), a difference that is not likely to be due to chance. Elevations were also observed in children associated with these residential areas (primarily living just outside the defined targeted area).

Older children (age six to 18) within targeted residential areas also showed evidence of exposure to chromium, but the increase was less than that observed in smaller children. Among adults age 19 to 60, adjusted urine chromium in residents, those associated with residential areas, and workers showed small but statistically significant increases relative to adults from the baseline survey. No evidence of exposure was observed among older adults (over age 60) in any screened group.

Detailed examination of urine chromium levels revealed seven specific workplaces and two sections of residential areas where further environmental evaluation is necessary to identify possible on-going sources of exposure. The two residential sections are close to the sites of the original chromium smelters in Jersey City. Two of the seven workplaces have been identified as priorities for further environmental investigation. Further remediation steps may be necessary to reduce or eliminate identified exposure sources.

**Interpretation**

The CMSP has found little evidence of clinically observable chromium-induced health effects, but found evidence of low levels of exposure to chromium among some participants living or working in the vicinity of chromium waste sites. The findings
generally reflect exposure levels in the vicinity of chromium waste sites after some degree of remediation has occurred. In residential areas, most waste sites had been excavated and replaced with clean fill material; in most workplaces, interim remedial measures had been performed. Because the amount of urine chromium data prior to remediation is limited, it is not possible to assess chromium exposure as it may have occurred in the past, although exposures are likely to have been higher before remediation.

The biological and public health significance of low level exposure is uncertain, and is dependent on the chemical form of the chromium and on the route of exposure (inhalation, ingestion, or skin contact). The potential for harm is by far the greatest for inhalation of hexavalent chromium compounds, since it is this chemical form and exposure route that is associated with long-term risk of lung cancer. The chemical form and route of exposure may vary or have varied from place to place, making it difficult to generalize about site risks.

It is important to distinguish between statistical distinctions in exposure levels and biologically or clinically important distinctions. Although group differences in urine chromium concentration may indicate increases in exposure, these differences may or may not be indicative of the potential for observable health problems. In addition, average group differences may not reflect exposure in all members of the group. Current exposure, where it exists, appears to be limited to a few individuals at any given time.

The future risk of lung cancer in this population, due to past or current levels of exposure, is not known and, because of population mobility and the long latency period of the disease, will be difficult to measure. The risk cannot be assessed accurately from the limited knowledge of exposure patterns before remediation. Evidence of exposure in small children and, to a lesser degree, in adults, in some areas, indicates that vigilance in investigation and remediation of chromium waste sites and associated contamination must be a priority to prevent additional risk from accruing in the population.

**Recommendations**

1) The NJDEP should conduct environmental evaluations of some specific residential area locations. The NJDEP and NJDOH should consider carefully the results of
the interior dust chromium tests already conducted in many households by scientists from EOHSI, with particular attention to households with small children, and households in the two residential sections with high urine referral proportions. In the two residential sections, the NJDEP should conduct exterior inspections and other environmental sampling for chromium to identify potential sources of chromium exposure. If a chromium waste site-related exposure source is found, the NJDEP should take steps to reduce the potential for exposure.

2) The NJDEP should sponsor thorough industrial hygiene investigations at the seven identified workplaces, including exterior and interior inspections and sampling for chromium. Such evaluations have already occurred at some of these workplaces. While each workplace needs to be evaluated, two workplaces should receive the highest priority.

3) At all workplaces on or near chromium waste sites, the NJDEP and employers should continue to monitor the effectiveness of interim remedial measures until permanent remedial measures at the sites have been implemented.

4) The screening methods utilized in this project were successfully applied. However, there is a need for research to find and validate the application of biological markers of long-term exposure to chromium, and sensitive markers of adverse health effects from such exposure. To the extent possible, NJDOH and NJDEP should cooperate with research projects designed to find sensitive markers of exposure to and effects of chromium.

5) The screening project provided a one-time evaluation of the potentially exposed population. In conjunction with the residential communities and workplaces, the NJDOH should encourage the appropriate federal agencies to examine the feasibility of studying long-term health risks, including lung cancer, among populations with a history of potential exposure to chromium.
1. BACKGROUND

1.1 Chromium Waste in Hudson County

From 1905 to 1976, three facilities in Hudson County, New Jersey extracted commercially useful chromium compounds from chromite ore. These smelting facilities, two in Jersey City and one in Kearny, produced almost 2 million tons of chromium compounds. In the process, an estimated 2 to 3 million tons of waste material were also produced (Burke et al., 1991). The waste slag from the facilities, still containing 20,000 to 70,000 milligrams of chromium per kilogram of waste (mg/kg), was subsequently used as fill material at over 160 known sites in and around Hudson County. Much of the distribution of chromium waste took place during the 1950s and 1960s (NJDEP, 1989a). The majority of the chromium waste sites are located in the cities of Jersey City, Kearny and Bayonne, with a small number of sites scattered in other nearby cities. An overview map showing the location of known chromium waste sites and a list of the sites are found in Appendix A.

Local health officials began to document the existence of these chromium waste sites in the early 1980s, and brought them to the attention of state environmental and health officials. Subsequent environmental investigations conducted under the authority of the New Jersey Department of Environmental Protection (NJDEP) identified high concentrations of chromium at diverse sites. These sites included open lots in residential areas, commercial zones, industrial parks, recreational areas, and rights-of-way (NJDEP, 1989b).

The NJDEP has identified three corporations as the parties responsible for the cleanup of the chromium waste sites: Allied-Signal, Inc., PPG Industries, Inc., and Maxus Energy Corporation. These corporations have signed administrative consent orders with the NJDEP for the purposes of conducting investigations and remedial actions at the chromium waste sites. Before and during the conduct of the New Jersey Department of Health’s (NJDOH) Chromium Medical Surveillance Project (CMSP), remediation of many of the chromium waste sites was occurring as a result of the orders. Chromium waste deposits in
most of the residential sites were excavated and transported to hazardous waste storage facilities. At many other waste sites, temporary measures to reduce further environmental contamination or human exposure have been undertaken, such as paving with asphalt, construction of barriers, or sealing of walls and floors, while permanent remedial decisions are being developed.

1.2 Human Exposure Potential

The distribution of chromium waste during the 1950s and 1960s to diverse residential, commercial, and industrial locations created a large variety of potential exposure conditions. Chromium concentrations in materials at or near waste sites have ranged from less than 100 to over 50,000 mg/kg. Prior to the initiation of interim or permanent remediation, direct contact with chromium waste is likely to have occurred in a variety of areas and via a variety of routes. Inhalation of, ingestion of, and dermal contact with chromium contaminated dusts was possible for individuals living and/or working in the vicinity of contaminated areas. Since the area’s groundwater and surface water are not used for potable water, drinking water was not contaminated by the chromium waste sites. Specific information on environmental sample data available for the chromium waste sites may be obtained from the NJDEP.

The magnitude of exposure to chromium is likely to have varied through time and from place to place, depending not only on the concentrations of chromium at the waste sites, but also on physical and environmental site conditions, the behaviors and activities of potentially exposed persons, and the status of remedial efforts. Given the extreme variety of exposure conditions and human activities from waste site to waste site, it is difficult to generalize about past exposure potential.

The following examples illustrate the variety of potential exposure conditions. Workers at facilities with vehicle traffic on unpaved or poorly paved chromium waste surfaces may have inhaled chromium-contaminated dusts derived from soils with chromium concentrations of 1,000 to 10,000 mg/kg. Children living near unpaved lots filled with chromium waste frequently played on these surfaces, and may have been exposed through inhalation of dusts, direct contact with the waste material, and/or ingestion of contaminated
soil. Chromium concentrations in soils from sites in residential areas ranged from less than 1,000 to over 15,000 mg/kg. At a softball diamond and adjacent playground, children and adults were in frequent contact with soils containing chromium concentrations from 1,000 to 5,000 mg/kg. Migration of chromium compounds into buildings may have led to exposure inside workplaces and homes.

At any given site, behaviors and activities can affect both the magnitude and route of exposure to chromium. For example, dermal contact with and inhalation of dusts may be particularly influenced by differences in individual activity, such as household or workplace cleaning (Lioy et al., 1992). Hand-to-mouth ingestion of dusts is substantially greater for younger children than for older children or adults (Hawley, 1985).

Excavation of residential sites and interim remediation steps at others have undoubtedly reduced the potential for human exposure and further environmental degradation. However, several transport mechanisms may have acted to redistribute chromium-contaminated dusts from the original deposition sites during the period the sites were unremediated. Probable transportation mechanisms include wind and water erosion, truck or automobile traffic, construction, demolition, and pedestrian tracking of dirt into buildings (Lioy et al., 1992). This redistribution of chromium from original deposition sites complicates assessment of the source and magnitude of exposure and the scope of necessary remediation.

1.3 Chemical Characteristics of Chromium

Chromium exists in several valence states and can combine with other elements to form numerous chemical compounds. In addition to the metallic state, two important states are trivalent chromium and hexavalent chromium. Trivalent chromium is the most common form in nature, and is a trace component of many soils and foods. Hexavalent chromium, in contrast, is rare in nature except as a result of human activities. Trivalent and hexavalent chromium form numerous compounds that are important to many industries, including pigments, metal plating, leather tanning and steel production (ATSDR, 1993; Shupack, 1991).

Most trivalent compounds are insoluble in water. However, hexavalent compounds
may be soluble. Although most of the chromium in the waste slag is in the trivalent form, hexavalent compounds are also present (Burke et al., 1991) and, due to their increased water solubility, hexavalent chromium compounds (the more hazardous form of chromium) have concentrated in areas where human contact is much more likely. Hexavalent chromium compounds have been carried toward the surface soil by evaporating water and have formed yellow blooms (called "chromium blooms") on the surface. Hexavalent compounds have concentrated in surface water, turning the water a bright yellow color. Additionally, hexavalent compounds have been carried via capillary action through masonry and have concentrated and crystallized on the interior walls adjacent to sites and in cracks in floors built upon chromium waste (Burke et al., 1991).

1.4 Biologic and Toxicologic Characteristics of Chromium

Minute amounts of trivalent chromium are necessary in the metabolism of carbohydrates and lipids. There has been no established biological importance of hexavalent chromium, which has been demonstrated to generate toxic effects in the lungs and other tissues.

1.4.1 Absorption, Distribution and Excretion of Chromium

Absorption. Chromium may be absorbed through the respiratory tract following inhalation of chromium-containing compounds. However, the efficiency of absorption is dependent on the physical and chemical characteristics of the inhaled particle, including particle size, valence state of the chromium, and solubility of the particular chromium compounds (ATSDR, 1993). In general, hexavalent chromium compounds are more rapidly and efficiently absorbed than trivalent compounds. Inhaled, unabsorbed chromium compounds may accumulate in lung tissues (Raithel et al., 1993; Tsuneta et al., 1980; WHO, 1988).

Chromium may also be absorbed through the gastrointestinal tract. Trivalent chromium compounds found in the diet are poorly absorbed through the gastrointestinal tract. Absorption efficiency of chromium varies from about 0.5% to 2%, and is inversely related to chromium content of the diet such that a relatively constant amount (approximately 0.2 micrograms per day) is absorbed under normal dietary conditions.
(Anderson and Kozlovsky, 1985). The daily North American diet contains approximately 10 to 40 micrograms (µg) of chromium (Anderson and Kozlovsky, 1985). Intake of dietary supplements containing 200 µg of trivalent chromium would result in increased daily total absorption (Anderson et al., 1982), although the absorption efficiency would remain poor. Hexavalent chromium is thought to be reduced to trivalent chromium in the stomach and is therefore also poorly absorbed in the gastrointestinal tract (ATSDR, 1993).

Both trivalent and hexavalent chromium compounds may be absorbed through the skin. As with other routes of exposure, skin absorption of hexavalent chromium appears to be more efficient (ATSDR, 1993).

**Distribution.** The distribution, metabolism and storage of chromium within the body is complex (Mertz, 1993; ATSDR, 1993; USEPA, 1990; Nieboer and Jusys, 1988; Offenbacher and Pi-Sunyer, 1988).

Absorbed trivalent chromium, which has a poor capacity to pass through cell membranes, is bound primarily to the plasma protein transferrin in the circulation. Chromium is stored to some extent in the tissues, in part as a biologically active complex (Offenbacher and Pi-Sunyer, 1988). This biologically active complex -- the glucose tolerance factor -- is thought to enhance the transport of sugars into cells by facilitating the interaction of insulin with cellular receptors (ATSDR, 1993). Depending on the adequacy of chromium stores, blood chromium levels may increase or decrease in response to sugar meals (Mertz, 1993).

Absorbed hexavalent chromium, which passes through cell membranes readily, is reduced to trivalent chromium either in the plasma or after passage into blood cells or cells of other tissues (Cohen et al., 1993; Wiegand et al., 1988). The chemical process of the reduction of chromium from hexavalent to trivalent is complex, probably involves unstable intermediate valence states, and produces inorganic and organic radicals capable of damaging DNA. Inside the cell, the trivalent chromium may bind to intracellular proteins or DNA, and may be responsible for some of the intracellular toxic effects observed following exposure to hexavalent chromium (LaVelle, 1991; Cohen et al., 1993).

Storage of chromium can occur in exposed persons, particularly in the lungs, liver, kidney, heart and spleen (ATSDR, 1993). Chromium storage has been modeled as a one-,
two- or three-compartment system. A one-compartment model suggests a half-life of 15 to 41 hours (Tossavainen et al., 1980). A two-compartment model includes a short-term compartment with a half-life of two to three days, and a long-term compartment with a half-life of approximately one month (Lindberg and Vesterberg, 1989). Lim et al. (1983) postulate a three-compartment model with half-lives of 0.5 to 12 hours, one to 14 days, and three to 12 months.

**Excretion** Chromium is excreted primarily through the urine. Regardless of the valence state when absorbed, chromium is found in the trivalent state in the urine.

Assuming a daily dietary chromium absorption of 0.2 μg/day (Anderson and Kozlovsky, 1985), a daily loss of the same quantity, and a daily urine volume of 1 to 2 liters, average urine chromium concentrations of 0.1 to 0.2 μg/l would be expected. Following unusually high absorption of chromium, for example by an occupational exposure, a sharp, short-term increase in urine chromium concentration would be observed. This phenomenon is the basis for using urine chromium as an exposure screening tool in the workplace (Nieboer and Jusys, 1988; Franchini et al., 1984). Factors which affect the excretion of chromium are discussed in section 1.5.

### 1.4.2 Health Effects

Ingestion of small amounts of dietary trivalent chromium (50 to 200 μg) is necessary for normal metabolism of carbohydrates and lipids (Mertz, 1993; Offenbacher and Pi-Sunyer, 1988; Anderson, 1986). As discussed above, glucose tolerance factor (GTF), a poorly characterized chromium-containing complex, facilitates the action of insulin in glucose, protein and fat metabolism (ATSDR, 1993). There may be areas in the world where chromium deficiency is a biological concern.

Most information about chromium exposure and adverse human health effects is known from occupational groups with relatively high and sustained exposures or from case reports of acute chromium poisoning. Exposure to chromium may result in adverse outcomes that include irritant, allergic, carcinogenic and other effects. While overexposure to trivalent chromium may result in some of the same effects observed from hexavalent chromium, the trivalent form is considered to be considerably less toxic because of its inability to enter cells except in bound forms. The health risks of chromium exposure have
been the subject of several recent articles and monographs (Cohen et al., 1993; Witmer and Gochfeld, 1991; ATSDR, 1993; IARC, 1990; USEPA, 1990; WHO, 1988).

**Irritant Effects** Exposure of the skin, eyes, mucous membranes, respiratory tract, and gastrointestinal tract to corrosive hexavalent chromium compounds may result in irritation and ulceration. The effect is related to the oxidizing properties of some hexavalent compounds. Irritation of the nasal mucosa may result in ulceration and perforation of the nasal septum (Burrows, 1983). ATSDR (1993) has estimated that chronic exposure to an air concentration of hexavalent chromium of less than 0.02 μg per cubic meter is likely to be without risk of these irritant effects.

Ulcer formation may also occur on the exposed skin, appearing as a small, distinct, slowly healing lesion (Adams, 1983). Chromium exposure may also result in an irritant dermatitis (Adams, 1983).

**Allergic Effects** Chromium exposure may result in an allergic response, expressed as a persistent, eczematous contact dermatitis with variable appearance (Adams, 1983). The dermatitis typically appears on the hands and arms. Among persons with contact dermatitis in the North American population, allergy to chromium is found in ten percent of males and six percent of females (Haines and Nieboer, 1988). Hexavalent compounds are generally more likely than trivalent compounds to induce allergic sensitization, probably because of their greater solubility and dermal absorption (Adams, 1983). Chromium-induced allergic contact dermatitis is considered a type IV cell-mediated immune response; elicitation of the delayed hypersensitivity reaction may result in periods of dermatitis occurring months or years following initial exposure (Adams, 1983; Haines and Nieboer, 1988; Bagdon and Hazen, 1991). Stern et al. (1993) have estimated that the concentration of hexavalent chromium capable of eliciting an allergic reaction in five to 10 percent of sensitized people is approximately 10 mg/l in solution and 10 to 20 mg/kg in solid material.

In addition, there is some evidence that respiratory exposure may result in asthmatic reactions (ATSDR, 1993).

**Carcinogenic Effects** The most severe health effect of chromium exposure is the increased risk of lung cancer resulting from inhalation of hexavalent compounds. Case reports dating to 1890, and numerous epidemiologic studies in several countries since, have
established that hexavalent compounds are human lung carcinogens (IARC, 1990; Langard, 1990; ATSDR, 1993; Yassi and Nieboer, 1988). An increased risk of cancer in other tissues (gastrointestinal tract, nasal and laryngeal cancers) has been reported in some studies but has not been definitively established.

Increased lung cancer risk is associated with exposure to hexavalent chromium in the chromate production, chromate pigment production, chrome electroplating, and chromium ferroalloy production industries. Langard (1990) suggests that cancer risk is highest for exposure to soluble hexavalent compounds, although all hexavalent compounds should be considered carcinogens. Occupational exposure to trivalent chromium compounds, on the other hand, has not been associated with increased cancer risk. Based on the occupational studies, the USEPA (1984) has estimated that lung cancer risk increases by 1 case in 10,000 exposed persons (assuming lifetime exposure) with chronic inhalation of air containing 0.008 ìg of hexavalent chromium per cubic meter.

**Mutagenic Effects** Various compounds of trivalent and hexavalent chromium have been tested for mutagenicity in bacterial and mammalian cell assays. In general, both trivalent and hexavalent compounds show evidence of mutagenicity in assays involving subcellular systems, while only hexavalent compounds are mutagenic in assays involving intact cells (Cohen et al., 1993; ATSDR, 1993; Nieboer and Shaw, 1988). It is thought that hexavalent chromium may cause mutations through oxidative damage to DNA, or, after chemical reduction to trivalent chromium within the cell, through binding to DNA and interfering with normal cell division. In mammal cell assays, hexavalent chromium induces persistent crosslinks between DNA and proteins in the cell nucleus (Costa, 1991).

**Kidney Effects** Exposure to chromium may also result in damage to the proximal tubules of the kidney (Wedeen and Qian, 1991). Occupational exposure to some chromium compounds has been associated with increased low molecular weight proteins in the urine, including B-2-microglobulin, brush border protein 50, and retinol binding protein (Franchini and Mutti, 1988; Wedeen and Qian, 1991). This tubular proteinuria can be produced by exposure to other metals and other substances and is thought to be reversible, although it may be considered an early sign of progression to renal disease if exposure to the causative agent continues.
1.5 Biological Monitoring for Exposure to Chromium

Chromium may be measured in several biological media, including blood, hair and urine. There are advantages and disadvantages of using each of these media (Diamond, 1988; Kazantzis, 1988; Suzuki, 1988), and each may represent a different aspect of exposure (Gibson and Randall, 1987).

**Chromium in Blood** Chromium may be analyzed in whole blood or in different components of the blood: serum, red blood cells, or white blood cells. Serum chromium may reflect both short term exposure to and body burden of chromium (Gibson and Randall, 1987). Red blood cell and white blood cell chromium may reflect exposures to hexavalent chromium over a period of months (Coogan et al., 1991; Minoia and Cavalleri, 1988; Wiegand et al., 1988).

However, blood sampling for chromium is highly susceptible to sample contamination using standard phlebotomy techniques (Cornelis, 1988; Kazantzis, 1988). Blood samples can become contaminated by chromium on the skin surface, or from chromium contained in the metal needle used to withdraw blood. Blood sampling may be uncomfortable to the donor, particularly for children.

**Chromium in Hair** Hair samples are relatively easy to obtain and can be stored for long periods of time. However, the use of hair chromium analysis to assess occupational or environmental exposure has been limited (Randall and Gibson, 1989). Problems in the use of hair as a biological monitoring specimen include susceptibility to external contamination, the unknown effect of hair treatments, interindividual differences in hair growth rate, and the unknown effect of nutritional factors (Suzuki, 1988).

**Chromium in Urine** Urine is the major excretory pathway for chromium, and urine chromium concentrations are believed to reflect both body burden and recent exposures (Gibson and Randall, 1987). Urine analysis has been used successfully to measure occupational exposure to chromium. Analytical methods used in earlier studies (primarily of occupationally exposed persons) were adequate to detect relatively high exposure levels but were inaccurate at low exposure levels, inflating the apparent levels in unexposed persons by approximately 10-fold (Guthrie et al., 1978; Anderson et al., 1983).

Advances in analytic technology in the last decade (Veillon et al., 1982) have
allowed the use of urine chromium analysis to measure low levels of chromium in nutritional studies (for example, Anderson et al., 1982a; Kumpulainen et al., 1983; Bunker et al., 1984; Morris et al., 1992) and in recent studies to assess occupational exposure to chromium (Randall and Gibson, 1987; Bonde and Christensen, 1991; McAughey et al., 1988). More recently, these methods have been applied to assess environmental exposure (NJDOH, 1989; Bukowski et al., 1992; Stern et al., 1992).

While a 24-hour sample of urine is most desirable, these samples are difficult to obtain reliably. For this reason, spot samples have often been used to assess exposure in occupational or environmental settings. Because the diluteness of spot samples can vary, some means of adjusting for this variability is important in evaluating a sample’s chromium concentration (Diamond, 1988). In some studies of urine chromium, adjustment for diluteness has been made by dividing chromium concentration by creatinine concentration, resulting in a variable expressed as the ratio of concentrations, or micrograms of chromium per gram (µg/g) of creatinine. Under some circumstances, the validity of this practice has been questioned (Berode et al, 1991; Alessio et al, 1985). In particular, chromium/creatinine ratios may be artificially inflated at low levels of creatinine.

Some variation in urine chromium concentration is expected in the population not exposed to chromium waste sites, due to unusual dietary sources (such as mineral supplements), other environmental sources (such as an occupation or hobby), personal characteristics (such as age), medical conditions (such as diabetes) and urine diluteness of the spot sample. Reliable data have been gathered in recent years to indicate a reasonable range to be expected in non-exposed adults. Typical (mean or median) values in adults are likely to range between 0.1 and 0.3 micrograms per liter (µg/l), with most values below 0.5 or 0.6 µg/l (Anderson et al., 1982a; Anderson et al., 1983; Randall and Gibson, 1987; Stern et al, 1992).

Limited data are available on urine chromium levels in the elderly. Bunker et al. (1984) report daily excretion of 0.2 to 0.8 µg/day in 22 healthy subjects age 69 to 85. Published data on the range of "normal" for children using current analytical methods is lacking. Tables 1-1 and 1-2 summarize studies of urine chromium in which concentrations for individuals with no known occupational exposure to chromium are reported. Table 1-1
includes studies using spot samples, while Table 1-2 includes studies using samples of 24-hour or longer collection times.

In adults, prolonged intake of high-chromium (200 μg) mineral supplements appears to increase urine chromium concentrations by approximately 1 μg/l (Anderson et al., 1983; Kumpulainen et al., 1983; Anderson et al., 1982a). Diabetics have been reported to have increased average chromium excretion (1.2 μg/g creatinine compared to 0.44 μg/g creatinine in controls) in 24-hour samples (Morris et al., 1988). Short-term increases in urine chromium excretion have been observed following strenuous exercise. Among runners, mean urine chromium concentrations in spot samples increased from 0.09 μg/g creatinine before the run, to 0.36 μg/g creatinine two hours after the run (Anderson et al., 1982b). Average chromium excretion increased by 0.17 μg/day on a day with heavy exercise (Anderson et al., 1984). Urine chromium excretion has been reported to rise slightly (by 0.04 μg/day) following consumption of a high sugar diet (Koslovsky et al., 1986).

Occupational exposures to chromium compounds may increase the amount of chromium in the urine, depending on the type of work. Because of the recent improvements in analytical technology, historical comparisons of reported concentrations may be misleading. Lead chromate pigment production workers were found to have urine chromium/creatinine ratios of 1.8 to 18 μg/g, and mean ratios of over 100 μg/g creatinine were found among strontium chromate production workers (Mcaughey et al., 1988). Bonde and Christensen (1991) found mean urine chromium/creatinine ratios of 0.6 to 0.95 μg/g creatinine among classes of stainless steel welders. Forty-nine tannery workers were reported by Randall and Gibson (1987) to have urine chromium levels of 0.62 to 2.75 μg/l.

1.6 Previous Medical and Exposure Evaluation by NJDOH

In response to concerns about possible chromium exposure in a Jersey City school, the NJDOH screened students and employees in 1989. Each participant had (1) a directed physical examination of ears, nose, throat, and skin to identify adverse health effects potentially related to chromium exposure, and (2) a urine chromium test with a limit of quantitation of 0.3 μg/l. At the time of screening, neither the children nor adults had been in the school for several weeks, so that urine chromium evaluations reflected potential
exposures in the residential environment.

The screening identified 35 of 97 children and 11 of 68 adults with urine chromium levels above 0.3 μg/l. Of children living on or near city blocks with chromium waste sites (14/26 or 54%), a higher proportion were found to have detectable levels of chromium in their urine than children living on adjacent blocks (19/49 or 39%) and on blocks farther away (2/22 or 9%). There was no apparent age difference in exposure risk among children; boys were somewhat more likely to have chromium above 0.3 μg/l than girls. Among adults, women were more likely to have urine chromium levels above 0.3 μg/l than men, but location of residence relative to a chromium site was not associated with urine chromium levels. No physical examination findings were judged by physicians to be related to known adverse impacts of exposure to chromium (NJDOH, 1989).

1.7 Other Exposure Studies in New Jersey

An exposure assessment study was conducted in four Hudson County residential areas near chromium waste sites (Stern et al., 1992; Liow et al., 1992). Spot urine and household dust samples were obtained from 17 households near waste sites and 11 control households. Lifestyle/activity data were also obtained by questionnaire. The mass and concentrations of total chromium in dust samples were higher in some households near the waste sites. Geometric mean urine chromium levels were similar in households near waste sites compared to controls (0.22 vs. 0.18 μg/g creatinine, respectively). However, the geometric mean urine chromium concentration was elevated in those homes which had the highest concentrations of chromium in household dust (0.31 and 0.36 μg/g creatinine in persons from homes in the upper 25% and upper 10% of dust chromium, respectively).

Bukowski et al. (1992) compared urine chromium/creatinine ratios between 17 state park workers near a chromium site and 36 park workers in other New Jersey counties and found no difference between group arithmetic means (0.60 vs. 0.63 μg/g creatinine, respectively). The mean levels reported in this study are relatively high in both groups compared to other studies, including that of Stern et al. (1991) which used the same laboratory.
1.8 Development of the Chromium Medical Surveillance Project

Because of the potential for widespread exposure to chromium from the Hudson County waste sites, and because of deeply felt community health concerns, a large-scale effort to screen residents and workers for exposure to -- and health effects from -- chromium was judged to be warranted by NIDDOH. In January 1990, the NIDDOH submitted a proposal to conduct such a screening project to the NJDEP Spill Fund. In November 1990, the NJDEP notified the NIDDOH of its approval to initiate the screening project, which was named the Chromium Medical Surveillance Project (CMSP).

**Setting Project Objectives** Because of community concerns about potential effects of chromium exposure, the NIDDOH designed the chromium screening project to identify individuals who may be suffering from chromium exposure-related illnesses. In addition, the NIDDOH decided that screening for current exposure to chromium was an important objective, so that potentially exposed persons could be identified and remedial actions could be effectively targeted.

Physical examinations may be employed to detect some of the effects of exposure to chromium, including irritant and allergic effects such as nasal septal perforation or allergic contact dermatitis. However, since there is no adequate screening method for early detection and treatment of lung cancer, the most serious potential effect of exposure, the appropriate public health response is to minimize exposure, and therefore potential risk.

Exposure screening, then, is an important public health goal when exposure to a carcinogenic metal is suspected (Leonard and Bernard, 1993). The purpose of such screening is to detect those individuals who exhibit evidence of unusual exposure so that attempts to determine the source of the individual’s exposure can be undertaken and exposure reduction measures, if needed, can be implemented. In addition, patterns of activities that may lead to increased exposure may be identified so that recommendations for broader-scale remedial measures -- and risk reduction -- can be developed.

**Screening Project Design Considerations** Ideally, an exposure or health effect screening test would detect all truly exposed or affected persons in a population (100% sensitive), and determine that everyone else is not exposed or affected (100% specific). No screening test meets this ideal; some individuals will be "false positives" on the test, and
some will be "false negatives". To the extent possible, screening projects strive to use tools that are both as sensitive and specific as possible. Often, there is no "gold standard" by which the sensitivity or specificity of a screening test can be measured; instead, tests can be considered relative to other tests or batteries of tests.

It is important to target a screening effort to those individuals at greatest risk of exposure or effect to minimize the number of false positive results relative to the number of true positives. For this reason, those residents living within one to two blocks of a waste site, and those persons whose workplace is designated a chromium waste site, were targeted for screening. This selection process is supported by data from the pilot medical evaluation and the human exposure study described above.

Within a targeted population, some will choose to participate and some will not. Because of this "self-selection," measures of the prevalence of a screened condition among participants will not reflect the prevalence in the entire targeted population, when those who participate are more (or less) likely to have the condition than those who do not. Measures of effect are particularly susceptible to this bias, since persons may choose to participate because of their medical conditions. Objective exposure measures are less likely to be affected by self-selection, since participants are not aware of their personal status.

Choice of Exposure Measure. The NJDOH considered the use of several measures of exposure to chromium. The NJDOH determined that, on balance, the most practical method to measure current exposure to environmental chromium of large numbers of people from dispersed locations is through determination of chromium concentration in spot (one-time) urine samples using a method capable of detecting low concentrations. NJDOH's selection of urine chromium in spot samples was also based on its use in other settings, the reliability of the analytical method, the ability to establish background ranges, and the convenience of sample collection.

Blood chromium was ruled out because of the difficulty of obtaining an uncontaminated sample, the intrusiveness of the sampling procedure, and the possibility that eligible persons would not participate. Further reasons not to use blood chromium as an exposure screening measure were the shortage of reference measures for blood chromium and the difficulty of obtaining a large number of blood samples from persons outside of
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Hudson County to establish reference ranges. Hair chromium was not chosen as a screening tool because of a shortage of scientific experience with this measure.

All measures of chromium in biological specimens (blood, urine, hair) require care in the interpretation of measured concentrations. Avoidance of sample contamination is paramount to ensure that measured concentrations reflect chromium in or excreted from the body. Assuming that measurements reflect exposure, several factors must be considered besides potential exposure to chromium waste sites. These factors include individual chromium exposure from unusual chromium sources in the diet (such as mineral supplements rich in chromium), other sources (such as a hobby or occupation), medical conditions (such as diabetes), activities which affect chromium excretion (such as strenuous exercise) and personal characteristics (such as age). Urine chromium measures from spot samples also require consideration of the diluteness of the spot sample, as discussed above in section 1.5.

To examine the quantitative effect of such factors, and to be able to account for these factors in deciding whether the urine chromium concentration in a screened person might reflect exposure to chromium from a waste site, a baseline survey was conducted outside of Hudson County before screening in potentially exposed areas. In addition, the baseline survey was conducted to provide information on factors that might confound group comparisons of average urine chromium levels (Bukowski et al., 1991).

Choice of Effect Measures. As described in section 1.4.2, chromium exposure has been related to several adverse health effects, including lung cancer, irritation and corrosion of the skin and nasal tissues, allergic contact dermatitis and asthma, and damage to the kidney.

The NJDOH decided against screening for lung cancer since there are no practical methods to screen for lung cancer in a community setting and the early detection of lung cancer does not necessarily improve prognosis. The occurrence of lung cancer in the communities can be determined from the New Jersey State Cancer Registry. However, it is difficult to study the incidence of lung cancer with respect to possible community or workplace exposures to chromium, because of the lack of information on individual residential, workplace or exposure history, the mobility and migration of people into and
out of targeted areas, and the long latency period of lung cancer.

Physical examination for other potential chromium exposure-related health effects is possible. Since most of these physical effects are not specific to chromium exposure, diagnosis of chromium-related illness should be made by specialists trained in occupational or environmental medicine, dermatology, or other specific fields. The screening design allows for an efficient use of physician resources, in which non-specialist physicians make observations for the purposes of referral to the specialists, who can then employ more detailed testing for diagnostic purposes.

Signs of the irritant or corrosive effects of some chromium compounds (that is, nasal mucosal changes and skin ulcers) can be detected. These conditions might not be attributable to exposure to chromium waste since other exposures or conditions can produce similar effects. Signs of the allergic response to chromium compounds may also be detected through a finding by a dermatologist of persistent allergic contact dermatitis and confirmation with a patch test of chromium sensitivity. Effects on the kidney, such as reversible proximal tubule damage, can be assessed by testing urine samples for low molecular weight proteins.
2. GOALS AND OBJECTIVES

The following were the goals and related objectives of the Chromium Medical Surveillance Project:

Goal 1: To provide clinical and laboratory services to resident and worker populations identified by NJDEP and NJDOL as potentially exposed to chromium from waste sites in and around Hudson County. These services should be used to identify individuals and groups that may be experiencing current exposure to chromium so that interventions to reduce exposure can be undertaken, and to identify those individuals in need of follow-up evaluation based on observations of potential chromium-related health effects.

Objectives

a: Develop and implement specific protocols and associated instruments for use in the screening project, including screening and follow-up examinations, urine analysis, and referral criteria.

b: Conduct a baseline survey of urine chromium concentrations in an area outside of Hudson County to establish expected ranges of urine chromium and the factors that affect that level.

c: Identify those populations that should be screened on the basis of residential or workplace proximity to known chromium waste sites.

d: Provide clinical screening services through a local clinic and a mobile medical clinic; and provide follow-up evaluations through a clinic specializing in occupational and environmental medicine.

e: Analyze large numbers of urine samples for trace concentrations of chromium.

f: Develop and implement outreach strategies and methods to enhance participation in the screening project.

g: Develop a data management system to organize collected information for analysis, facilitate participant tracking and notification, and provide for confidentiality of
individual data.

h: Provide referrals for follow-up environmental evaluation to identify sources of suspected exposure to chromium.

i: Provide periodic summaries of the progress of the screening project to local officials and other interested parties.

Goal 2: To provide a public health basis for judgments regarding the population impact of chromium waste exposure in Hudson County, and to assist in decision-making regarding necessary actions for exposure reduction.

Objectives

a: Evaluate collected data to describe the pattern of exposure to chromium, so that specific locations and/or behavioral factors that are associated with chromium exposure can be identified.

b: Develop and issue recommendations for remedial measures or behavioral changes that may lead to meaningful exposure reduction.
3. METHODS

The CMSP was conducted under the direction of the Environmental Health Services (EHS) of the NJDOH. The screening project consisted of a screening evaluation and, for those who met certain specified criteria, a follow-up evaluation. The screening evaluation consisted of a limited physical examination and the collection of a urine sample to be tested for chromium concentration. Participants also completed a questionnaire to provide information necessary to interpret the urine sample. The follow-up evaluation consisted of a more thorough physical examination, urine and blood analyses, a lung function test, and (for those with potential chromium-related skin problems) a dermatologic evaluation. The project design is summarized in Tables 3-1 and 3-2.

A "baseline survey" of individuals living outside of Hudson County was also conducted as part of the CMSP, to provide a basis for comparison of urine chromium concentrations. Participants in the baseline survey were asked to submit a urine sample and complete a questionnaire. Procedures used in the baseline survey were identical to those used in the screening of the target populations.

The CMSP was designed and conducted in recognition of the importance of quality assurance. Careful attention was paid to the development of specific protocols and procedures for screening and follow-up medical examinations, urine sample collection, handling and analysis, and data management and reporting, as described in the sections below.

3.1 Selection of Participants

3.1.1 Baseline Survey

An age-stratified, non-random sample of individuals living outside of Hudson County, New Jersey was selected for inclusion in the baseline survey. To the extent practical, participants were chosen to include a diversity of ages so that the relationship between age and urine chromium level could be assessed. Pre-school and school age children were selected from child care facilities and school districts; attempts were made to
include children from both north and south New Jersey. Adult populations were obtained from among employees of two county health departments. Older participants were recruited from senior day centers.

Organizations (child care facilities, school districts, health departments, senior centers) were contacted to request cooperation in the baseline survey. Once organizational cooperation was obtained, individuals were given an introductory letter and consent form (Appendix B). For children under the age of 18, parental consent to participate was required. Those who consented to participate were asked to fill out a questionnaire and submit a sample of their urine (see section 3.2). Unlike the screened population, no physical examinations were conducted for baseline survey participants.

### 3.1.2 Target Population for Screening

Populations currently living or working in the vicinity of the known chromium waste sites were offered the complete screening evaluation described in section 3.2. Distinct residential area and workplace populations were the targets of the screening project.

**Residential Areas** Eligible residential area populations were defined by drawing one- to two-block buffers around known chromium waste sites. In this way, individuals living or working on specific city blocks and street segments were made eligible for the CMSP screening evaluation. Fourteen residential areas containing variable numbers of chromium waste sites were defined: eleven in Jersey City and three in Bayonne (Table 3-3). Figures 3-1 and 3-2 show the locations of the residential areas targeted for screening in Jersey City and Bayonne, respectively. Lists of street segments and maps of block areas were produced to facilitate outreach to the targeted communities. Street maps of the fourteen areas showing approximate chromium waste site locations and eligibility boundaries are provided in Appendix A.

Each residential area was assigned a code number, and each participant living within the area was assigned this code relating her or him to the targeted residential area. In this report, participants living within a targeted residential area are designated as "residents".

Populations living or working in a targeted residential area were notified of their eligibility by door-to-door outreach. Outreach workers attempted to deliver an introductory letter and/or flyer to each household in a targeted area. To the extent practical, outreach
was conducted during both daytime and evening hours to increase the frequency of personal contact. Response to outreach was monitored by inspection of the residential locations of screened persons in the weeks following the outreach efforts. When necessary to increase participation, return visits were made to communities to deliver reminders of the availability of screening services. Outreach staff kept a "Daily Participant Recruitment Log" (Appendix B) which documented the address visited and nature of the contact.

Additional measures to enhance residential participation were undertaken on an areageneric basis, and at times included joint sponsorship of special screenings with community organizations or local institutions. On several occasions, outreach workers distributed general information about chromium screening services at health fairs and other community events.

In advance of door-to-door efforts, outreach workers also placed paid newspaper advertisements listing the specific street segments targeted for outreach. In the final months of screening, advertisements with comprehensive street lists were placed in local newspapers.

Workplaces Workplaces on or near chromium waste sites were identified with the assistance of the NJDEP and the NJDOH Occupational Health Service (OHS). A total of 78 workplaces were targeted for screening: 33 in Jersey City, 36 in Kearny, 7 in Bayonne, 1 in Port Newark, and 1 in Newark. These workplaces are listed in Table 3-4. Activities at workplaces varied, including warehousing, trucking, public works, manufacturing, and commercial or office work. One workplace used chromium compounds in on-site operations; screening at this workplace was limited to six workers not involved with these operations since the objective was to assess potential for exposure to chromium from the waste sites. In other workplaces, some jobs may have involved exposure to chromium through such activities as welding.

OHS and EHS staff contacted workplace employers to inform them of the availability of chromium screening for their employees, and asked their cooperation in notifying employees of their eligibility to participate in the CMSP. When employers agreed to cooperate in the project, they were given the option of sharing employee lists with EHS staff so that materials could be mailed to the employees' home, or distributing materials
prepared by EHS staff to individual employees at the workplace. Outreach materials included an introductory letter, fact sheet, and consent form. Workplaces were offered screening either on-site through the NJDOH medical van or through the Jersey City Medical Center (see section 3.2.1).

Each workplace was assigned a unique code number, and each participant was assigned this code relating him or her to the targeted workplace. In this report, participants from these workplaces are designated as "workers".

Other Participants. The Regional Day School (RDS), located within a targeted residential area, served children from throughout the county, not just those residing close to the school. In this report, staff and students from the RDS are treated as a distinct screening group.

Although the CMSP was designed to screen only those currently living or working on or near chromium waste sites, no one was refused a screening evaluation who appeared at a screening site.

Some screened individuals resided just outside of a targeted residential area; some worked within a targeted residential area (but did not work at a targeted workplace); and some were former residents (within six months) of a targeted residential area. In this report, these participants are collectively designated as "associates".

In addition, some participants could not be defined as residents, workers or associates. In this report, these participants are designated as "non-targeted".

3.2 Screening Evaluation

3.2.1 Facilities for Screening Evaluations

Evaluations of participants in the Baseline Survey were conducted at the participants' schools, offices or other facilities.

Screening evaluations of participants from the target populations were offered at the Jersey City Medical Center (JCMC) or through a mobile medical van. The JCMC is the largest hospital in Jersey City and is centrally located. The JCMC Chromium Clinic operated a variable number of hours per week, but in most weeks two or three three-hour clinic sessions were scheduled. During periods of high demand for screening evaluations,
additional clinic sessions were added. Screening hours included daytime, evening and weekend periods. The Chromium Clinic consisted of a reception and interviewing station, a waiting area, an examining room, and a bathroom. The clinic was staffed by JCMC physicians, a coordinator, and interviewers. JCMC physicians were provided detailed training by physicians from the Environmental and Occupational Health Clinical Center (EOHCC) (see section 3.3), including the background of the chromium waste problem, community public health concerns, the recognition of chromium-related conditions, and proper application of the screening examination protocol (see section 3.2.6). Clinic staff were provided training by EHS in the procedures and protocols of the CMSP.

Special residential area and workplace screening evaluations were offered through the use of the NJDOH mobile medical van. The medical van contained an examining room, a small bathroom, and an area for administering the questionnaire. The van was equipped with running water, a holding tank for wastewater, and an electric generator to operate lights, heat, and air conditioning. The van was staffed by physicians from EOHCC or JCMC, and by coordinators and interviewers from the EHS or JCMC.

Some residential area participants were also offered screening evaluations in their homes. These individuals were the household members of selected children who had participated in the pilot evaluation described in section 1.6. Some residential area participants were also screened using a neighborhood facility (such as a school or church) instead of the mobile van.

3.2.2 General Screening Evaluation Procedures

A "screening evaluation" consisted of the completion of a questionnaire, the collection of a urine sample to test for chromium concentration, and a limited physical examination. A screening evaluation was considered complete if a urine sample was collected and a questionnaire was completed. A "participant" is defined as an individual who completed a screening evaluation.

After obtaining informed consent, a participant or parent was asked to complete an age-appropriate questionnaire (see section 3.2.4). Each participant was then asked to submit a urine sample, and was offered a limited physical examination by a licensed physician. The urine sample was analyzed for chromium and measures of diluteness, and a judgment
was made whether the chromium concentration indicated possible exposure to an unusual source of chromium. Participants were informed of the results of their physical examination and urine chromium test, and a referral for follow-up evaluation (see section 3.3) was made if certain criteria were exceeded. These procedures are discussed in detail in the sections below.

3.2.3 Informed Consent and Participant Identification Procedures

Informed consent was obtained from each participant aged 18 years or older. For those under 18 years, informed consent was obtained from the parent, guardian or relative. The consent form explained the purpose of the project, the components of the physical examination, the purpose of the questionnaire, and the meaning of the urine chromium test. The consent form also assured the participant that test results were confidential, that she/he could limit or stop participation at any time, and that the urine would be tested only for chromium and measures of diluteness. A sample consent form is found in Appendix B.

After obtaining a signed consent form, the participant’s name, Social Security number (or unique substitute) was listed in the daily "Screening Evaluation Log" (Appendix B). The participant was assigned a unique, five-digit sample identification (SID) number which was also entered on the Screening Evaluation Log. An age-appropriate questionnaire was labeled with the SID and the participant’s name, address and Social Security number were also entered on dated screening physical examination forms.

3.2.4 Questionnaire

Two questionnaires were used, one for children age 10 or less (to be completed by the parent or guardian), and one for participants age 11 and over (Appendix B). The questionnaires gathered the following information: personal, residential and demographic information, characteristics of housing and other environmental factors, and use of dietary supplements (section I); occupation and workplace (section II, ages 11 and over) or parent or guardian information (section II, ages 10 and under); limited medical history (section III); and activities in the past 48 hours, including time spent at home, work or school, cleaning, hobbies, exercise, and diet (section IV). Questions related to workplace activities, exercise and the use of beer, wine and cigarettes were not asked of participants aged 10 or under.
The participant or parent was asked to fill out section I through III of the questionnaire. A trained interviewer reviewed this portion, and if necessary, completed these sections with the participant. The interviewer then administered section IV of the questionnaire.

Completed questionnaires were coded and entered into the CMSP data management system (see section 3.4). All entered data were checked and, if necessary, corrected by another staff person against the original questionnaire.

3.2.5 Urine Sample Collection and Handling

After completion of the questionnaire, the participant was asked to submit a spot urine sample according to procedures outlined in "Procedure for Obtaining Urine Samples" (Appendix B). The participant was given a clean, acid-washed, unlabelled, capped urine cup (which was provided by the NJDOH Laboratory) and directed to the bathroom. The participant was given instructions to wash and dry her/his hands, to remove the cap from the cup, to urinate into the cup, to replace the cap, and to return the filled cup. Upon receipt of the sample, the JCMC or EHS staff affixed the pre-printed SID label to the urine cup, and assured that the SID number was the same as on the questionnaire and Screening Evaluation Log. The SID number and time of day was then entered on the "Request for Sample Analysis" batch request form. The sample was placed in an individual plastic bag, sealed, and deposited in an iced cooler or refrigerator until delivery to the NJDOH Laboratory for analysis.

For each screening session, a field blank and trip blank were used to monitor contamination during urine sample collection. The NJDOH laboratory supplied EHS staff with acid-washed containers filled with distilled water which were used for trip blanks and field blanks. Trip blanks were used to monitor laboratory contamination of urine containers and to ensure proper handling of specimens en route to site-specific screenings and to their destination at the laboratory. A trip blank was an unopened acid-washed container filled with distilled water which was labeled with an identification number, placed in an individual plastic bag and put in the cooler just before beginning the trip to the screening site or to the laboratory. Field blanks were used to monitor contamination during specimen collection. An empty, acid-washed container was taken into the lavatory where
urine was to be collected, filled with water from a laboratory-prepared container, and left opened until a urine specimen had been obtained by one participant. At that time the lid was replaced and the container was handled as a urine specimen.

Sample batches were transported by EHS staff to the NJDOH Laboratory. Each sample batch was accompanied by the Screening Evaluation Log, a Request for Sample Analysis, and Sample Chain of Custody Record form (Appendix B). For samples collected by JCMC staff, custody was transferred to EHS staff prior to transportation. Samples were delivered to the NJDOH Laboratory sample receiving area, where the accompanying paperwork was examined for completeness and custody was transferred.

3.2.6 Screening Physical Examination

Each participant was offered a screening physical examination (see Table 3-1 and "Screening Examination Protocol", Appendix B). The examination consisted of a brief review of relevant portions of the questionnaire, a directed medical history, and a limited physical examination of the skin, nose, and throat. The consent form and questionnaire were assembled for the physician prior to the screening physical examination.

The medical history was directed to the following areas: history of asthma, chronic unrelenting allergies, skin ulceration, chronic dermatitis, nasal ulceration, and nasal septal perforation. The physician examined the nasal mucosa for any lesions, with particular attention to ulceration or perforation of the anterior nasal septum. Oral mucosa were also examined for ulceration or tonsillar inflammation. The physician also examined the skin on potentially exposed surfaces, including the arms, legs, hands, feet, and upper torso, for skin ulcers, related scars, or dermatitis. The physician discussed any health concerns of the participant.

The examining physician made a referral for follow-up medical evaluation if certain conditions were found, as specified in the protocol:

1) history of any of the following conditions, temporally related to possible chromium exposure:

* chronic unrelenting allergies
* asthma
* chronic dermatitis
2) a physical finding of skin or nasal ulceration, a scar consistent with a chromium-induced ulcer, or nasal septum perforation.

The physician filled out the "Screening Examination / Referral Report" and the "Patient Information: Screening Examination" forms (Appendix B). At the time of the examination, the participant was given a copy of the latter, which contains a summary of the physician’s examination and whether a referral for follow-up evaluation was made.

At the end of the examination, the physician discussed a number of ways in which the participants could reduce potential exposure to chromium from waste sites. Each participant or parent received this information in printed form as well (Appendix B). This flyer also provided the telephone numbers of the EHS and NJDEP for more information.

Upon completion of the physical examination, the JCMC or EHS staff completed the Screening Evaluation Log checklist and assembled all corresponding paperwork into an individual participant record folder. Folders were flagged of those participants who were referred for follow-up medical evaluation by the physician. In addition, urine samples collected from these referred participants were assigned priority for urine chromium analysis.

The EHS coded and entered the contents of the "Screening Examination / Referral Report" into the CMSP data management system (section 3.4).

3.2.7 Handling of Participant Records

At the end of a screening session at the JCMC clinic, copies of individual medical record folders were assembled for weekly pick-up by EHS staff. Copies of Screening Evaluation Logs, Daily Participant Recruitment Logs and Substitute Social Security Logs were also provided to EHS. When screenings were conducted by EHS staff, participant materials were assembled and transported to the EHS office. The contents of individual record folders flagged for follow-up evaluation were copied and sent to EOHCC.

3.2.8 Analysis of Urine

Urine samples were submitted to the NJDOH Environmental and Chemical Laboratory Service for analysis. Upon receipt, samples were logged into the Laboratory sample tracking system, immediately tested for specific gravity, and frozen for later analysis of creatinine and chromium. All sample handling, analyses, and record-keeping was
conducted in accordance with the standard quality assurance guidelines contained in the latest NJDOH Standard Operating Procedure (SOP) Manual (NJDOH, 1992). The urine chromium analytical method and selected excerpts of the SOP Manual are found in Appendix B.

The specific gravity was measured on all urine samples at the time of sample receipt using a urinometer.

Creatinine and chromium analyses were conducted on previously frozen samples as soon as practicable and within time limits specified by the NJDOH SOP Manual. Creatinine is stable for 30 days in refrigerated urine, and for six months in the frozen state. Chromium is stable for two weeks in refrigerated urine and indefinitely in the frozen state (NJDOH, 1992).

Creatinine was analyzed using a spectrophotometric method. Creatinine is reacted with an alkaline sodium picrate solution, and the absorbance of the chemical complex is read at 490 nm with a Perkin-Elmer Lambda 4 C ultraviolet-visible spectrophotometer. Standard curves are prepared by linear regression analysis of measurements on known creatinine solutions of zero, 0.5, 1.0 and 2.0 grams per liter (g/l). Creatinine concentrations in urine samples are computed and reported by the instrument. The method is recommended for creatinine values in the range of 0.025 to 5.0 g/l, and has a detection limit of 0.005 g/l. Quality control samples (urine matrix spiked with a known amount of creatinine) were prepared monthly and analyzed with each run of samples.

Urinary chromium analysis was performed by atomic absorption spectrometry using graphite furnace atomization and utilizing the method of standard additions (Veillon et al., 1982). Each sample was run with known additions of zero, 0.5, 1.0 and 2.0 micrograms of chromium per liter (μg/l). Each level of addition was run in triplicate. Chromium concentrations in the urine samples were computed by the Laboratory’s software. Quality control included the preparation of a standard curve for each new set of standards. In addition, two controls, one at normal level and one at 1.0 μg/l were analyzed with each run of samples. See Appendix B for more details on the Laboratory quality assurance program. The limit of quantitation, defined as the lowest level that could be accurately reported, was 0.20 μg/l.
The NJDOH Laboratory entered results into a central database and downloaded results to diskettes as groups of sample results were produced and confirmed. The data were in a form compatible with the CMSP data management system. Upon receipt of a diskette, EHS staff uploaded the diskette contents, checked for duplicate reports, and prepared the data for analysis. Data were also received in the form of paper print-outs from the NJDOH Laboratory central database.

3.2.9 Judgments on Screening Urine Chromium Results

For each screened individual, a decision had to be made on whether the urine chromium concentration was elevated. One way to make this decision would be to establish a single cut-off value of urine chromium for all participants. However, this method would not account for differences among participants with respect to demographic characteristics, sample diluteness or other factors affecting urine chromium concentration. Alternatively, decisions could be made on the basis of a cut-off value of the ratio of chromium and creatinine concentrations. This method, while adjusting for a measure of diluteness, would not take into account other factors potentially affecting the concentration.

Therefore, the CMSP established a decision-making method, described below, in which an "expected" concentration would be computed for each participant, taking into account sample diluteness and relevant personal, behavioral, and environmental characteristics. Expected levels would be based on multivariate regression analysis of the data collected in the baseline survey. A judgment would then be made based on the magnitude of the difference ("excess") between the observed and expected concentration for each screened individual.

Analysis of Baseline Survey Data  The questionnaire and urine analysis data from the Baseline Survey were analyzed to estimate the distribution of background urine chromium concentration and the factors that influence this distribution.

Predictive multiple linear regression models for urine chromium were developed for males and females. Since baseline chromium values were skewed to high values, the natural logarithm of chromium (with an approximately normal distribution) was used as the dependent variable. Measures of urine diluteness (creatinine, specific gravity), age group and weight were entered into the models and interactions among these variables were
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explored. (Separate models by sex were developed because of apparent interactions among sex, age and creatinine in the baseline data.) Additional variables determined by questionnaire (see section 3.2.4) were then entered into the models to determine dilution-, weight- and age-adjusted contributions to urine chromium concentration. Final models for each sex included variables and biologically plausible interaction terms that reached or approached statistical significance in one or both sexes.

The models generated "expected" urine chromium values for each baseline participant. Since the models were based on the logarithm of urine chromium, expected values were generated on the logarithmic scale. Therefore, the "excess" urine chromium concentration was calculated by taking the antilogarithm of the expected value, and subtracting this from the observed concentration. Then the frequency distribution of the excess values in the baseline population was generated to determine an appropriate excess level to serve as a decision basis for referral in the target screened populations (see section 4.1.3).

**Decisions on Screened Participants.** Individual urine results from the target screened populations were processed to determine if the observed concentration of chromium indicated potentially unusual exposure, taking into account the factors specified in the models. A spreadsheet was constructed consisting of ranges for importation of selected data on each individual, calculation of expected urine chromium levels based on the regression model coefficients generated from the baseline data, and calculation of excess urine chromium values as described above.

As a check on the judgments made by this method, other decision-making methods were examined and tested periodically during the screening project, including the use of unadjusted urine chromium concentrations and the chromium/creatinine ratio. At the end of the screening project, decisions based on the excess method (which used information from the baseline survey only) were compared to decisions that might have been made based on adjusted urine chromium values (computed from models developed after all data were analyzed). Comparisons of these methods are detailed in Appendix C.

**3.2.10 Notification of Urine Chromium Results**

After an individual urine chromium result was evaluated as described above, a letter
signed by the project manager was mailed to the participant. The letter contained the urine chromium concentration and the judgment whether follow-up evaluation was warranted. Letters were generated using an automated system that extracted the decision and key individual information from the questionnaire and urine analysis databases, and were verified for accuracy before sending. Individual letters were sent to the participant or to the participant’s parent or guardian if under age 18. If a notification letter was returned by the post office, other attempts were made to notify the participant of the results. These attempts included contact of the participant by telephone to obtain updated residence information, checking for address inaccuracies by comparison with reported residences of screened family members, checking directory assistance for changed telephone numbers, and written requests to the local Postal Service office for address forwarding information.

3.3 Follow-up Evaluation

The follow-up evaluation was offered only to those participants who were referred on the basis of the screening physical examination or the urine chromium test. This evaluation consisted of a follow-up medical examination and the opportunity for an environmental evaluation. The purpose of the follow-up medical examination was to determine, to the extent possible, whether the referred participant exhibited signs of adverse effects from chromium exposure.

Follow-up medical evaluations were conducted at the Environmental and Occupational Health Clinical Center (EOHCC) in Piscataway, New Jersey. The EOHCC is part of the Environmental and Occupational Health Sciences Institute (EOHSI), a joint program of Rutgers University and the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School. The clinic includes a reception area, three interviewing rooms, three examining rooms, specialized testing areas, a laboratory and a lavatory. The EOHCC is staffed by a physician board certified in occupational medicine and internal medicine and by a certified occupational health nurse.

3.3.1 Follow-up Medical Examination

Copies of record folders for participants who were referred on the basis of a finding on the screening physical examination or a urine chromium concentration were sent to
EOHCC by EHS. The referred participants were contacted by EOHCC staff to schedule an appointment for the examination. Participants scheduled for follow-up examinations were offered transportation from Hudson County to Piscataway by a commercial patient transportation company, paid for by the CMSP.

The follow-up evaluation is summarized in Table 3-2. After the referred participant (or parent) completed a standard EOHCC consent form, the participant received a medical examination including: a thorough medical history; a physical examination; blood and urine analysis to assess kidney and liver function; spirometry to assess lung function; and another dermatologic examination. Those who had been referred on the basis of a skin finding, or who exhibited a skin finding in this examination, were also examined by a board-certified dermatologist experienced in diagnosing and treating occupational and environmental diseases. The dermatologist made a case-by-case determination of the need for a patch test for chromium sensitivity.

A repeat spot urine sample was also collected for urine chromium analysis, and, when feasible, arrangements were made for collection of a 24-hour urine sample. Urine chromium, specific gravity and creatinine analyses were conducted by the NJDOH Laboratory as described in section 3.2.8.

Details of the follow-up medical examination are found in Appendix B, "Protocol for Follow-up Medical Examination at the Environmental and Occupational Health Clinical Center".

Referred participants were notified at the time of examination and/or by letter of any abnormal condition observed and whether the examining physician believed that chromium exposure was a contributing factor to the condition. The referred participants were advised of the need for appropriate medical follow-up of any abnormal conditions observed, whether chromium-related or not. Using a standard format, the EOHCC provided the EHS with a summary of only those examination results relevant for assessing chromium exposure-related effects (see Appendix B).

3.3.2 Follow-up Environmental Evaluation

Participants who were referred on the basis of a high urine chromium concentration were offered free dust analysis of their home to assess whether indoor contamination with
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Chromium is an exposure source. This evaluation was not a direct part of the CMSP, but was made available to participants through this project.

The environmental evaluations were conducted by the Exposure Measurement and Assessment Division of EOHSI. The specific protocol for this evaluation was developed for a separate EOHSI research effort funded by NJDEP, details of which are not included in this CMSP report. Results of these analyses, which are not yet completed, are also not contained in this report. Participants are being notified of the results of the environmental dust evaluation by letter, directly from EOHSI.

3.4 Data Management and Analysis

3.4.1 Data Management

A data management system was developed to facilitate the collection, organization, analysis, and retrieval of information. The EHS has a local area network of personal computers containing word processing, graphics, mapping, spreadsheet, database management and statistical analysis software. Software utilized for this project included dBase, Lotus 1-2-3, SPSS-PC, Atlas*Pro, Harvard Graphics, and WordPerfect. The network is secured with user passwords to protect the confidentiality of databases and documents.

Separate databases linked by common fields were developed to include data from questionnaires, urine analyses, screening physical examinations, and follow-up medical examinations. Data from the questionnaires and physical examination forms were coded, entered and independently checked for accuracy of entry before use. For each database, a codebook was prepared describing its contents and instructions for computer coding. Programs were also prepared so that routine analyses and data manipulations could be conducted efficiently.

3.4.2 Data Analysis

During the conduct of the screening project, data were extracted from the databases to: 1) monitor the number of participants screened and the referral frequencies by screening group or specific targeted workplace or residential area; 2) make individual decisions for urine chromium referral during the project; and 3) track the status of participants referred
for follow-up evaluation.

After all data were collected from baseline and targeted screening groups, data were extracted from the databases to: 1) describe the characteristics of the project participants; 2) analyze and compare the distributions of urine chromium in screening groups, with and without adjustments for potential confounding factors; and 3) develop multiple linear regression models to examine the influence of living or working near chromium waste sites on the average urine chromium concentration.

**Screening Physical Examinations** Periodically, data from the screening physical examination database were extracted to examine the referral frequencies by institution (JCMC and EOHCC) and by individual physician. These data were also used to monitor the frequency of -- and criteria used to make -- the referrals for follow-up evaluation. Referral frequencies were also examined with respect to age group, sex, screening group, and specific targeted residential area or workplace.

**Urine Referral Decision-making** Urine chromium data from the baseline survey were analyzed as described in section 3.2.9 and "Urine Referral Criteria" (Appendix B). As discussed in section 3.2.9, data for persons in the target population was extracted from the questionnaire and urine analysis databases for the purpose of developing an expected urine chromium level, determining whether the "excess" level was high, and whether a referral for follow-up evaluation should be made.

Referral frequencies were examined with respect to age group, sex, screening group, and specific residential area or workplace. Apparent clustering of elevated urine chromium concentrations was also examined at the city block and household level.

**Distributions of Unadjusted Urine Chromium Concentrations** Unadjusted urine chromium concentration distributions were examined for each of the baseline and screened groups (that is, residents, associates, workers, non-targeted, and RDS), and for specific targeted residential areas and workplaces. Urine chromium values at several percentile levels (median, 60th, 75th, 90th and 95th) were generated, overall and by sex and age category. In addition to the median, several other measures of central tendency were derived from the data, including the arithmetic mean, the 5% trim mean (in which the upper and lower 2.5% of the data in a sample are excluded from the arithmetic averaging), and
the geometric (logarithmic) mean. (Both the trim and geometric means minimize distortion of the average that may be caused by a few extreme values.) For chromium levels below the quantitation limit of 0.2 µg/l, a value of 0.10 µg/l was assigned for the purpose of generating the mean values.

Examination of Participant Characteristics for Potential Confounding. After all target population and baseline survey data were collected, data were extracted from the questionnaire, screening physical examination and urine analysis databases. Demographic and other characteristics of the baseline and screened groups were compiled and compared. The distributions of urine chromium results in both baseline and screened groups were examined across levels of a variety of demographic and other factors to assess the potential for confounding in the data set.

Calculation of Adjusted Urine Chromium Concentrations. Based on the data collected from both the baseline survey and the screened populations, a multiple linear regression model of the logarithm of urine chromium was developed, and coefficients for each factor were used to calculate the adjusted value for each participant. These adjustments were made to eliminate the potential confounding by age, sex, measures of diluteness and other factors. Adjusted urine chromium concentrations were derived by normalizing each participant on the overall median value of creatinine, specific gravity and weight, and on a standard category for sex, age group and other factors:

\[
\text{Adj}(U-Cr) = e^{[\text{LnObs}(U-Cr) - \sum (\beta_i * X_i)]}
\]

Where:
- \(\text{Adj}(U-Cr)\): Adjusted urine chromium concentration (µg/l)
- \(\text{LnObs}(U-Cr)\): The natural logarithm of the observed urine chromium concentration (µg/l)
- \(\beta_i\): Regression coefficient for factor \(X_i\)
- \(X_i\): Factor affecting urine chromium concentration; if a continuous variable, \(X_i\) is centered at the median; if a dichotomous variable, \(X_i\) takes the value 0 or 1

For those participants whose unadjusted value was below the quantitation limit of 0.20 µg/l, adjustments were made up or down from 0.10 µg/l.

Since the magnitude of the adjustment for some potential confounding factors might
vary in different age groups, age group-specific models were also developed (rather than complicate the overall model with numerous age*factor interaction terms). For each participant, a second adjusted value was calculated based on these models, using age group-specific medians and standard categories for sex and other factors.

As described for unadjusted values, adjusted urine chromium values at several percentile levels were generated, overall and by age category. Arithmetic, trim and geometric means were also calculated.

**Comparisons of Urine Chromium Concentrations** Comparisons of urine chromium distributions among the baseline and screened groups were made in several ways. Because of the pronounced skew to high values, geometric (rather than arithmetic) means of baseline and screened were compared by t-test, which gives the probability that two distributions are distinct. By convention, a probability less than 0.05 was considered "statistically significant". Confidence intervals (95%) on the geometric means were computed for graphic presentation.

Quantile-quantile (QQ) plots were also generated for visual comparison of divergences between two distributions. In a QQ plot, chromium values at equivalent percentile levels in two distributions are paired and plotted against each other. If two distributions were similar, the QQ plot would track along the line defined by $x=y$. Conversely, if distributions are dissimilar throughout, the QQ plot would not track along such a line. If distributions were similar except at the upper extreme, the QQ plot would track along the $x=y$ line but veer up or down at the upper end. Inspection of the QQ plot can therefore reveal differences between distributions that may not be apparent from simple comparison of the average values.

**Regression Models to Assess Screening Group Differences** Data were also analyzed by multiple linear regression to examine the influence of membership in screening groups (baseline, residents, workers, associates and non-targeted) on the average concentration of urine chromium, while adjusting for factors such as urine sample diluteness and personal, behavioral and environmental variables. The natural logarithm of the chromium concentration was used as the dependent variable. Separate models were developed for each of four age groups (children up to five years of age, children between
six and 18 years of age, adults between 19 and 60 years of age, and adults over age 60 years). Variables defining membership in screening groups were entered into the regression models first, then potential confounding factors were added both to examine their influence on the site-related coefficients and to estimate their independent relationship to urine chromium.

A regression model was also developed within the "worker" screening group, to examine the differences in average urine chromium concentrations among the screened workplaces. In this model, individual workplaces with elevated urine chromium concentrations or elevated urine referral proportions were compared to the other workplaces combined. Coefficients in this model represent the differences in geometric mean urine chromium concentrations in the individual workplace relative to the comparison workplaces.

Similarly, regression models were also developed within the "residents" screening group to examine differences in average urine chromium among specific residential areas, for all residents and for specific age groups.

3.5 Protection of Participants

Draft protocols, consent forms and questionnaires were presented to the NJDOH Institutional Review Board on December 20, 1989, and approval was granted on December 26, 1989. Participants in the screening evaluation filled out a consent form prior to the physical examination and urine sample collection (see section 3.2.3). Participants also completed a standard EO/HHC consent form prior to receiving the follow-up medical examination (see section 3.3.1).

All questionnaires, medical records and urine testing results are considered confidential medical information, and are kept in locked file cabinets. Only those staff directly involved with the CMSP have access to the file cabinets. Databases are maintained in a confidential manner through controlled-access computer files.

Data summaries were developed by the EHS and shared with local health officials, NJDEP and other interested parties (e.g., employers) as appropriate. Personal identifiers have been and will continue to be removed from any summary or published material.
3.6 Reporting Results

**Individual Results**  Individual results were communicated to participants as described above in sections 3.2.6, 3.2.10, 3.3.1 and 3.3.2.

**Summary Reports**  Workplace employers received a summary report(s) of the results of the screening evaluations of the employees. Individual information was not made available to the employer. Quarterly CMSP status reports were generated for NJDEP and for local public officials and other interested parties.

**Preliminary Communication of Results**  EHS staff notified NJDEP when screening or follow-up evaluation data indicated the need for specific environmental investigation of a workplace, residential area, or residence.

**Final CMSP Report**  A draft final report of the CMSP was prepared for internal and external peer review by public health scientists. Following peer review and incorporation of reviewer comments, the final report of the CMSP has been made available to the public.
4. RESULTS

4.1 Baseline Survey

4.1.1 Participants

A total of 317 persons participated in the Baseline Survey conducted at 12 locations between June and December 1991. A list of dates, locations, number and age range of participants is provided in Table 4-1a. The participants were screened in seven counties of New Jersey, representing both northern and southern parts of the state and both urban and suburban areas.

The distribution of participants by sex, age, and race is presented in Table 4-2a. The baseline population was composed of 142 (45%) males and 175 (55%) females. Nineteen children age 5 and under (6% of the total) participated in the baseline survey. A large proportion of baseline participants were children between the ages of 6 and 18 (194 or 61%), reflecting the intent of the survey to target age groups for which little data on urine chromium distribution existed. Sixty-six participants (21%) were in the age range 19 to 60, while 38 (12%) were over the age of 60.

The distribution of factors possibly affecting urine chromium levels is given in Table 4-3. Only 4 individuals (1%) reported recent mineral supplement intake containing 30 μg or more of chromium. Almost 14% of baseline participants over the age of 11 reported personal smoking, half of whom smoke more than one pack per day. Almost 7% reported that more than one pack of cigarettes is smoked per day in the home. Among those over age 11, 29 (15%) reported consumption of some beer or wine in the past two days. Eight (3%) reported engaging in some hobby or job-related activity in the past two days that may involve exposure to chromium.

4.1.2 Unadjusted Urine Chromium Concentrations – Baseline Group

Two individuals (both under age 18) provided insufficient quantities of urine for analysis so the total number of analyzed urine chromium levels from the baseline population was 315.

Nearly half (46%) of the baseline survey samples contained chromium below the
limit of quantitation (0.2 μg/l). The average (arithmetic, 5% trim, and geometric means) unadjusted urine chromium concentrations by age and sex group are presented in Table 4-4a, together with chromium levels at selected percentiles (median, 60th, 75th, 90th and 95th). Overall, the 5% trim mean was 0.23 μg/l, and the geometric mean was 0.20 μg/l. Half of the unadjusted baseline values did not exceed 0.20 μg/l, 90% did not exceed 0.53 μg/l, and 95% did not exceed 0.70 μg/l. The geometric mean and 95% confidence interval is plotted in Figure 4-1. Examination of these distributions reveals that unadjusted levels were quite similar between males and females, although differences among age groups were apparent. Levels were highest in the 6-10 year age group and lowest in the adult age groups. Many of the participants in the 6-10 year group had high creatinine and specific gravity, indicating that samples from this age group were of relatively concentrated urine.

Unadjusted urine chromium values were compared across levels of other potential confounding variables among the baseline population (Table 4-5). For several factors, few baseline participants reported the potential confounder, limiting interpretation. Nonetheless, most factors examined show no relationship to the geometric mean unadjusted urine chromium or show no consistent increases across percentile levels, including chromium supplement intake, household and personal smoking, beer or wine drinking, and strenuous exercise. Geometric mean and 90th percentile urine chromium levels were higher among those with recent (past 48 hours) exposure to dust: attic, garage or basement cleaning, sweeping at work, and working in a perceived dusty environment.

4.1.3 Development of Urine Referral Criteria

The urine chromium models for males and females developed as described in section 3.2.9 are presented in Table 4-6. The frequency distribution of excess values of the baseline survey participants is provided in Table 4-7. Based on this frequency distribution of excess values from baseline survey participants, a reasonably extreme value was selected such that only two percent of the baseline population exceeded it. That excess value was 0.5 μg/l. That is, if a screened individual’s measured urine chromium concentration was more than 0.5 μg/l greater than the expected value, considering the participant’s personal characteristics, urine diluteness, and other potential exposure sources, then that participant was to be referred for follow-up evaluation. For example, suppose that the model generated
a predicted value of 0.25 μg/l for a screened person. If her observed value was greater than 0.75 μg/l, then she would be referred.

Appendix C includes a comparison of individual decisions made on the basis of this excess method with decisions that might have been made based on the 98th percentile of the unadjusted urine chromium and chromium/creatinine ratios in the baseline population. Appendix C also includes a comparison of decisions that were made by this excess method compared to those that might have been made based on adjusted urine chromium values, computed after all data from the CMSP were collected. In general, the methods were similar in the numbers and identities of referrals. However, the chromium/creatinine ratio would have yielded referrals that the other methods did not, since samples with low levels of creatinine were likely to have artificially inflated ratios (see Appendix C and Discussion).

4.1.4 Adjusted Urine Chromium – Baseline Group

The urine chromium concentration of each participant’s sample was adjusted as described in section 3.4.2. Adjustment coefficients are detailed in Table 4-9. The distribution of the adjusted urine chromium concentrations are found in Table 4-10a and shown in Figure 4-2. Upon adjustment, the overall adjusted geometric mean was 0.19 μg/l. The geometric mean and 95% confidence interval is plotted in Figure 4-3. Half of the adjusted values did not exceed 0.18, while the 90th and 95th percentile levels were 0.41 and 0.56 μg/l, respectively. Also in Table 4-10a are age-group specific adjusted urine chromium values (see Table 4-9). Geometric mean adjusted values were 0.20, 0.24, 0.17 and 0.23 μg/l for children age 1 to 5, children age 6 to 18, adults age 19 to 60, and adults over age 60, respectively.

4.2 Screening Evaluations

4.2.1 Participants

A total of 2,224 individuals participated in the screening project. Thirteen of these individuals were also screened on two occasions, resulting in a total of 2,237 screening evaluations. The JCMC Chromium Clinic personnel performed 1,141 screening evaluations, while EOHCC and EHS staff performed 1,096 screening evaluations. Table 4-
1b lists the dates, locations and number of participants for each month of screening. Screening at the JCMC commenced on January 13, 1992 and ended on March 27, 1993. Screenings arranged by EHS staff began on January 6, 1992 and were completed by November 20, 1992 (with the exception of a special screening session at the Regional Day School (RDS) in Jersey City on June 4, 1993). The JCMC staff conducted 123 screening sessions at the Chromium Clinic, 11 sessions using the NJDOH mobile medical van in residential areas, and 2 sessions at the Regional Day School. The EHS and EOHCC staff conducted 52 screening sessions, including 44 using the mobile van at targeted workplaces, 7 in residential areas, and 1 at the Regional Day School. Quarterly screening totals ranged from 286 in January-March 1992 to 537 in July-September 1992 (Figure 4-4). Over 300 were screened in June 1992.

The screened population of 2,224 was composed of 939 individuals from targeted workplace populations ("workers"), and 811 from targeted residential areas ("residents"). Twenty-nine individuals both worked in a targeted workplace and lived in a targeted residential area, and are included in both the "residents" and "workers" groups. Another 224 screened persons were categorized as "associates" of residential areas (see section in 3.1.2). In addition, 101 persons were screened from the Regional Day School (RDS); 14 of these individuals also lived in a targeted residential area. Another 178 individuals were categorized as "non-targeted" participants.

The distribution of the 2,224 screened individuals by age, sex and race are provided in Tables 4-2a and 4-2b. The majority of the screened population was between the ages of 19 and 60 (73%), but substantial numbers of children and older adults were screened as well (372 persons (17%) under age 19 and 224 persons (10%) over age 60). Of course, most (879 or 94%) of the workplace population was in the age interval 19-60. Among persons screened from non-workplace areas, 749 (58%) were in the age interval 19-60, 368 (29%) were under 19, and 167 (13%) were over age 60. Overall, more screened participants were male (57%) than female (43%). However, persons screened from non-workplace areas were more likely to be female (57%), while those from workplaces were predominantly male (77%). The screened population was racially and ethnically diverse, including persons reporting their race or ethnicity as Black (38%), White (40%), Hispanic
(15%), Asian (4%), and other (3%). The race or ethnicity of fourteen individuals was not reported. Non-workplace and workplace populations were dissimilar with respect to race. The workplace population was 21% Black, 52% White, 22% Hispanic, 3% Asian, and 3% other. The non-workplace screened population, in contrast, was 50% Black, 32% White, 10% Hispanic, 4% Asian, and 3% other. Among the non-workplace populations, age, sex and race distributions were not substantially different.

The distribution of factors in the screened population (other than living or working near a chromium waste site) possibly affecting urine chromium levels is given in Table 4-3. Forty-four individuals (2%) reported recent mineral supplement intake containing 30 μg or more of chromium. However, many of those reporting supplement intake either did not report the brand of supplement or the chromium content of the brand could not be ascertained. About 25% of screened participants over the age of 11 reported personal smoking, almost half of whom smoked more than one pack per day. About 5% of all screened participants reported that more than one pack of cigarettes is smoked per day in the home by household members combined. Among those over age 11, 452 (23%) reported consumption of some beer or wine in the past two days; 234 (11%) reported engaging in some hobby or job-related activity in the past two days that may involve exposure to chromium.

Overall, the screened population differed from the baseline population with respect to age, sex and race composition (Table 4-2a). Differences in the distribution of other factors possibly related to chromium exposure are generally slight (Table 4-3); screened persons were more likely to report hobbies or jobs with potential chromium exposure and work in dusty conditions. Stratified analyses and adjustments based on multivariate regression have been used to account for the potential confounding effects of these factors in group comparisons (section 4.2.4).

4.2.2 Screening Physical Examinations

Of the 2,224 individuals screened, 2,205 were examined by a physician using the screening examination protocol. Forty-four individuals (2.0 percent) were referred for follow-up medical evaluation on the basis of a physical finding on the screening examination (Figure 4-5). Most of the referrals were made on the basis of an abnormal
finding on the skin. The distribution of these 44 individuals by age, sex and target screening population are given in Table 4-11.

Each participant was asked by the physician to rate her/his health relative to others she/he knows. One-third of those responding (687 of 2,073) judged their health to be better, 59% the same, and 8% worse. More non-targeted participants (12%) judged their health worse, compared to residents (8%), workers (6%), and associates (8%). Among adults over age 18, 15% of non-targeted participants rated their health worse, compared to 10% of residents, 6% of workers, and 9% of associates.

Based upon a discussion with the participant, the physician reported a history of the following conditions in the 2,205 examined participants: asthma in 139 (6.3%); chronic unrelenting allergies in 328 (15%); skin ulceration in 16 (0.7%); chronic dermatitis in 184 (8.3%); nasal ulceration in 9 (0.4%); and nasal septal perforation in 6 (0.3%). In adults, history of allergy and history of dermatitis were more common among non-targeted participants compared to residents, workers, or associates.

Upon physical examination, the physician identified one or more abnormalities of the skin in 311 (14%) of the participants. Skin ulcers were identified in 13 (0.6%), dermatitis in 129 (5.9%) and other conditions in 194 (8.8%). A nasal or pharyngeal abnormality was found in 125 (5.7%) of the participants. Of these, nasal ulcers were found in 5 (0.2%), and nasal perforations in 10 (0.5%). Screened physicians observed multiple conditions in some participants.

Among adults over age 18, dermatitis was observed more frequently in non-targeted participants (12%) than in residents (7%), workers (6%), or associates (7%). Nasal septal perforations were found only among adults, in 0.7% of non-targeted participants, 0.7% of residents, 0.4% of workers, and 0.6% of associates.

Not all participants with the conditions listed above were referred for follow-up evaluation because the screening physical examination protocol specified that conditions should be temporally related to possible chromium exposure (for example, no referral was made for a condition that was present before a participant began work at a targeted

\footnote{Four of six reporting a history of nasal perforation were found to have one upon examination, and six additional perforations were identified among those not reporting a history. Of these, four were referred for follow-up evaluation.}
workplace). In addition, screening physicians may not have made a referral if the observed or reported condition was clearly unrelated to chromium exposure (for example, allergies to other known substances).

Of the 44 participants referred on the basis of the physical examination, 27 (61%) reported a history of dermatitis, 8 (18%) reported a history of chronic unremitting allergies, 3 (7%) reported a history of asthma, 7 (16%) reported a history of skin ulceration, and 6 (14%) reported a history of nasal ulceration; 23 (66%) had dermatitis at the time of the examination, 9 (20%) had skin ulceration at the time of examination, 5 (11%) had a nasal ulcer at the time of examination, and 4 (9%) had a nasal perforation upon examination.

The proportion of referred participants differed by age group and sex (Table 4-11). No participant under the age of 11 (0/209) was referred on the basis of a screening physical examination finding, while only 0.6% (1/157) of those aged 11-18 were referred. Among adults, 2.4% (20/840) of those aged 19-40, 2.3% (18/777) of those aged 41-60, and 2.3% (5/222) of those aged 61 and over were referred. Males (2.5%) were more likely than females (1.4%) to be referred on the basis of a physical finding. Among adults, 2.8% (30/1062) of males and 1.7% (13/777) of females were referred.

Referral proportions also differed across screening group categories, with the highest referral proportion among the non-targeted group (Table 4-11). Among adults over age 18, 1.9% (18/936) of workers, 2.5% (14/571) of targeted residents, 2.9% (5/174) of individuals associated with residential areas, and 3.7% (5/136) of non-targeted persons were referred.

Referral proportions by specific residential area and workplace also showed variation, although the small numbers of referrals in each area preclude meaningful statistical comparison.

Seven physicians from the Jersey City Medical Center and the University of Medicine and Dentistry of New Jersey conducted the screening physical examinations (one other JCMC physician performed one examination). The referral proportions for physicians from each institution are presented in Table 4-12. Referral proportions were nearly identical between institutions (2.1 percent for EOHCC physicians, 1.9 percent for JCMC physicians), but differed among individual physicians, ranging from 0.3 to 5.1 percent.
4.2.3 Unadjusted Urine Chromium Concentrations -- Screened Groups

Of the 2,224 persons screened, 11 produced urine samples that were too small in volume to be analyzed by the laboratory. Consequently, results will be presented for 806 targeted residents, 223 persons associated with residential areas, 934 workers, 28 persons who both lived and worked in targeted areas, 177 non-targeted persons, and 101 persons from the Regional Day School. For the 13 individuals who were screened twice, only the first of two urine samples will be included in this description.

The distribution of the 2,213 analyzed urine chromium concentrations of the entire screened population is described in Table 4-5. Approximately half (48%) of the urine samples contained chromium below the level of quantitation (0.20 μg/l). For all screened groups combined, the geometric mean unadjusted urine chromium concentrations was 0.23 μg/l, and the median, 75th and 90th percentile values were 0.21, 0.42 and 0.76, respectively. For each screened group, the arithmetic, 5% trim, and geometric means are presented in Tables 4-4b through 4-4g, together with the median, 60th, 75th, 90th and 95th percentile values. Within each group, the data for each age-sex category is also presented. Geometric means and 95% confidence intervals are plotted in Figure 4-1.

The unadjusted urine chromium geometric mean was 0.24 μg/l for residents, 0.24 μg/l for associates, 0.20 μg/l for workers, and 0.22 μg/l for non-targeted persons. Median values for these groups were 0.23, 0.24, <0.20 and 0.20, respectively. Among the 28 who both lived and worked in a targeted area, the geometric mean was 0.22 μg/l and the median was <0.2 μg/l. The 90th and 95th percentile values were 0.81 and 1.19 μg/l for residents, 0.73 and 1.08 μg/l for associates, 0.67 and 1.13 μg/l for workers, and 0.74 and 1.13 μg/l for non-targeted persons. Among those both living and working in targeted areas, 90th and 95th percentile values were 1.34 and 1.91 μg/l. Among those screened from the Regional Day School, the geometric mean and median values were 0.34 and 0.36 μg/l, while the 90th and 95th percentile values were 1.26 and 1.40 μg/l.

Among residents, unadjusted urine chromium levels were higher among females in most age groups, comparing the geometric means and percentile levels. This sex difference was largest among children age 1-5. Among associates, no consistent sex-related pattern was apparent. Among workers, females and males appeared similar except in the upper 10 percent of the distribution, where female values were higher. The sex differences were
strongest among workers over 40 years of age. Among non-targeted persons, no sex
difference was apparent.

Among residents, geometric mean and median unadjusted urine chromium levels
were highest among children age 1-5 compared to other age categories, particularly among
the female children screened as noted above. In the associates group, unadjusted urine
chromium was also highest in the age 1-5 group, although the contrast among ages was not
as strong as that in the residents. Among workers, there was little difference in unadjusted
urine chromium concentration across age groups. Among the non-targeted group,
unadjusted urine chromium was highest in adults over age 60. The lowest average levels
among residents, associates and non-targeted persons were among adults age 19 to 60.

As was observed in the baseline population, few potential confounding factors
appeared to be related to the unadjusted urine chromium in the screened population (see
Table 4-5).

4.2.4 Excess Urine Chromium -- Screened Groups

The excess urine chromium concentration is the unadjusted urine chromium
concentration minus the expected urine chromium concentration, calculated as described in
sections 3.2.9 and 4.1.3. To the extent possible, the expected value accounted for
differences due to urine diluteness, personal and demographic characteristics, and other
sources of possible chromium exposure. This measure was used during the course of the
CMSP to make judgments on the need for referral for follow-up evaluation. Of the 2,213
individuals whose urine samples could be analyzed for chromium concentration, 216 (9.8%)
had excess urine chromium levels above 0.5 µg/l and were referred to the EOHCC and
EOHSI for follow-up medical and environmental evaluation. Three additional persons were
referred although the excess level did not exceed 0.5 because of reasons specific to each
individual, and four were referred on the basis of a second screening evaluation, bringing
the total referred on the basis of the urine chromium concentration to 223 (10.1%) (Figure
4-5). One participant was referred on the basis of both the screening physical examination
and the excess urine chromium level.

Nine percent of screened males and 11% of screened females had excess levels that
exceeded 0.5 µg/l. The frequency distribution of excess urine chromium for the entire
screened population is presented in Table 4-7. Most screened participants (80% of males and 75% of females) had excess levels less than or equal to 0.2 µg/l. The distribution of referred participants by age group, sex and target group is found in Table 4-8.

The screened population was 5.1 times as likely to have an excess level above 0.5 µg/l (216/2,213) compared to the baseline population (6/315). Screened females were 19 times as likely to have an excess above 0.5 µg/l relative to baseline females (104/951 compared to 1/174). Screened males were 2.5 times as likely to have an excess above 0.5 µg/l relative to baseline males (112/1,262 compared to 5/141).

Among the screened groups, 18% (5/28) of those both living and working in targeted areas were referred on the basis of excess urine chromium, while proportions among residents (11% or 87/806), associates (8.5% or 19/223) and workers (8.1% or 76/934) were lower. Ten percent (18/177) of non-targeted participants were referred. The highest referral proportion was among the RDS population (24/101 or 24%). This unusually high proportion is attributable entirely to the first RDS screening (February 1993) in which 34% (20/59) were referred. In the second RDS screening in June 1993, 9.5% (4/42) were referred. (See chapter 5 for a description of follow-up activities in response to the February 1993 RDS screening.)

Excluding persons from RDS, the referral proportions among the screened population differed by age group. The highest proportion was among children age 1 to 5 (12/68 or 18%). Proportions were similar in the other groups: 9.1% (23/253) in age group 6 to 18, 9.0% (142/1573) in age group 19 to 60, and 8.3% (18/218) in those over age 60. In children age 1 to 5, referral proportions were higher among residents (11/52 or 21%) than associates (1/12 or 8%) and non-targeted children (0/4).

Referral proportions also varied among specific residential areas and workplaces. Among the five residential areas where more than 50 persons (residents and associates combined) were screened (Dwight St., Lafayette, Grand St., Metro Field, Cambridge Ave. and Bramhall Ave./Communipaw #23), the Lafayette area had the highest proportion of residents (23/142 or 16%) and associates referred (6/38 or 16%). The lowest was the Cambridge Ave. area (2/36 or 6% of residents, and 0/24 associates). Referral proportions were between 9% and 11% for residents in the remaining areas.

When referral proportions were examined by block within the residential areas, two
residential sections stood out. In the Lafayette area, 7 of 17 (41%) screened residents of Woodward St. between Lafayette St. and the railroad tracks were referred for follow-up evaluation. In the Metro Field area, 9 of 46 (20%) screened participants who lived on Stegman Parkway between West Side Ave. and Stegman Terrace, or on Stegman Court or Stegman Place, were referred. Both of these residential sections are close to the sites of the original chromium smelters in Jersey City.

Among workplaces, two had high referral proportions: ICI Americas (now Zeneca, Inc.) in Bayonne (11/37 or 30%) and Cloroben/Standard Chlorine in Kearny (6/29 or 21%). Other workplaces with large numbers screened that showed relatively high referral proportions were Levy and Sons in Jersey City (13/92 or 14%), and Degen Co. in Jersey City (3/17 or 18%). Although the referral proportion at Baldwin Steel in Jersey City was not exceptional (7/74 or 9.5%), several individual levels were among the highest observed in the screened population.

4.2.5 Adjusted Urine Chromium -- Screened Groups

Adjusted values were derived from overall and age group-specific models (Table 4-9). Individual values were adjusted to overall and age-specific medians of continuous variables and to standard values of other variables as described in Table 4-9. The distributions of adjusted urine chromium levels among screened groups are presented in Tables 4-10b through 4-10g, and are displayed in Figure 4-2. The overall adjusted urine chromium geometric mean was 0.23 µg/l for residents, 0.22 µg/l for associates, 0.22 µg/l for workers, and 0.22 µg/l for non-targeted persons. Median values for these groups were 0.21, 0.20, 0.19 and 0.20, respectively. Among those who both lived and worked in a targeted area, the geometric mean was 0.23 µg/l and the median was 0.18 µg/l. The 90th and 95th percentile values were 0.66 and 0.94 µg/l for residents, 0.57 and 0.97 µg/l for associates, 0.63 and 1.02 µg/l for workers, and 0.64 and 0.84 µg/l for non-targeted persons. Among those both living and working in targeted areas, 90th and 95th percentile values were 1.28 and 1.68 µg/l. Among those screened from the Regional Day School, the geometric mean and median values were 0.33 and 0.34 µg/l, while the 90th and 95th percentile values were 1.02 and 1.53 µg/l.

Based on the overall adjustment, the geometric mean adjusted urine chromium
concentration in each of the screened groups was higher than in the baseline group, and these mean differences were statistically significant (Figure 4-3). Inspection of the quantile-quantile (QQ) plot of these distributions with respect to the baseline group (Figure 4-6) shows that all screened groups diverge in a similar manner from the baseline group. The 4 resident distribution diverges the most through the first 85%, and the associates diverge the least in that range. However, in the upper 5% of the distributions, associates, workers and residents continue to diverge from the baseline group, while the non-targeted group converges.

Examination of the adjusted values using age-specific models reveals different patterns in different age groups. Tables 4-10b through 4-10g contain distributions of adjusted values, and Figure 4-7 contains plots of geometric means and 95% confidence intervals by screening group and age group.

Among children age 1 to 5, the geometric mean adjusted value among both residents and associates was 0.33 μg/l, while among the four non-targeted children the geometric mean was 0.19 μg/l. The median value among the residents was higher than among associates (0.36 vs. 0.25 μg/l), while values in the upper percentiles were higher among associates. Compared to the baseline group, mean differences were statistically significant only for the residents (p=0.006). The p-value for the difference in means between the associates and baseline group was 0.085, approaching statistical significance. A QQ plot of screened groups relative to the baseline group (Figure 4-8a) reveals that the residents diverge from the baseline at a relatively low order in the distribution, while associates remain similar to the baseline group through approximately the first three quartiles.

Among children age 6 to 18, the geometric mean adjusted values were 0.27, 0.21 and 0.27 μg/l among residents, associates, and non-targeted children, respectively. In this age group, none of the means are statistically different from the baseline group mean (0.24 μg/l). A QQ plot reveals that the distributions of both residents and non-targeted children diverge somewhat from the baseline (though not enough to statistically differentiate the group means), while that of the associates is similar to the baseline (Figure 4-8b).

Among adults age 19 to 60, the geometric mean adjusted values for residents, associates and workers are all 0.22 μg/l, while that of the non-targeted group is 0.20 μg/l. These means are statistically different from the baseline group for all screened groups.
except the non-targeted. Because of the large screened populations in this age group, there is power to distinguish even small mean differences. The QQ plot for this age group (Figure 4-8c) shows divergences relative to the baseline primarily in the upper 20 percent of the distributions; the pattern of divergence is similar for all groups although that of the non-targeted group is less pronounced.

Among adults over age 60, geometric mean adjusted values are 0.25, 0.24, 0.20 and 0.30 µg/l for residents, associates, workers and non-targeted persons, respectively. None of the group means are statistically different from the baseline group mean in this age group (0.23 µg/l). Inspection of the QQ plot (Figure 4-8d) shows similarity among the screened and baseline groups through the first 95% of the distributions. The relatively high geometric mean in the non-targeted group is attributable to one individual with an extreme urine chromium value.

4.2.6 Regression Analyses of Urine Chromium Among Screening Groups

Screening Group Membership
Regression models were developed for each of four age groups: 1 to 5, 6 to 18, 19 to 60, and 61 and over. Unlike the models used for computing adjusted urine chromium concentrations, membership in a screening group (resident, associate, worker, non-targeted, baseline) is considered. (The RDS population was not included in this analysis). These models are presented in Table 4-13.

In age group 1 to 5, being a resident in a targeted area is a statistically significant predictor of urine chromium concentration, adjusting for measures of diluteness, weight, sex, race group and household smoking. The model estimates that being a resident contributed on average 0.12 µg/l (p=0.023) to the geometric mean urine chromium concentration. Children in the associate category are estimated to have a similar magnitude increase, but this estimate is less precise as indicated by the higher p-value. Non-targeted children cannot be distinguished from the baseline children, although the number of children in this group is small. Household cigarette smoking is also associated with urine chromium concentration, but is not a confounder since its inclusion does not affect the estimate of site-related associations.

In age group 6 to 18, site-related differences in average urine chromium concentration were observed among residents (0.05 µg/l; p=0.011) and non-targeted
participants (0.6 μg/l; p=0.086), compared to the baseline group. No increase was observed among the associates. Chromium supplement intake (30 μg or more) is associated with urine chromium concentration in this age group, but few individuals reported this factor.

Among adults age 19 to 60, the regression model indicates that geometric mean urine chromium concentrations are increased (relative to baseline) in residents, associates, and workers by approximately 0.04 μg/l, adjusting for measures of diluteness and demographic and other factors. The non-targeted population is not statistically different from the baseline group. Other predictors of interest include household smoking, self-reported diabetes, and engaging in a hobby or job with possible chromium exposure in the past 48 hours. Inclusion of these factors in the models did not affect the magnitude of site-related associations, that is, the factors do not act as confounders in the data set. In adults age 61 and over, no site-related associations were observed nor were any interactions apparent. Consumption of more than 2 bottles of beer in the past 48 hours was a statistically significant predictor of urine chromium concentration in this age group. While not statistically significant, associations were also observed with chromium supplement intake and self-reported history of cancer.

Specific Workplaces A regression model including only those participants coded as "workers" revealed that some of the workplaces had statistically significantly elevated average urine chromium concentrations than other workplaces that were sampled (Table 4-14). These workplaces included ICI Americas, Cloroben/Standard Chlorine, Trumbull Asphalt, Airdock Systems, Baldwin Steel, and Levy and Sons Warehouse. The average increase in urine chromium ranged from 0.36 μg/l at ICI Americas to 0.05 μg/l at Levy and Sons Warehouse, compared to workers from screened workplaces not listed above.

Specific Residential Areas A regression model including only those participants coded as "residents" of all ages did not reveal any specific residential area where the average urine chromium concentration was significantly higher than the others. No residential area showed a statistical elevation in ages 1 to 5, 6 to 18, or in a combined analysis of ages 1 to 18, although the small number of children screened in some areas makes statistical interpretation difficult. In the adult population (age 19 to 60) elevated urine chromium levels were observed for participants living in the Metro Field area. No
residential area showed significant elevations among older adults (age over 60).

4.3 Results of Follow-up Medical Examinations

As described above, 44 persons were referred on the basis of a physical examination finding and 223 on the basis of the urine chromium test; one individual was referred for both reasons. Of the 266 individuals referred for follow-up medical evaluation at the EOHCC, 184 (69%) received examinations (Figure 4-9), including 28 of 44 (64%) physical examination referrals and 156 of 223 (70%) urine chromium referrals. (Twenty-one referred participants refused follow-up evaluation, sixty either did not respond to attempts at contact, could not be contacted, or did not keep scheduled appointments, and one died.)

Standard batteries of urine and blood tests were conducted to assist the examining physician in interpreting and diagnosing observed conditions, including medical conditions not related to chromium exposure. Repeat spot urine samples were collected upon examination from 176 of the 184. Of 132 participants asked to collect a 24-hour urine sample, "complete" (defined here as 800 milliliters or more in total volume) 24-hour samples were collected from 62 participants and "partial" (less than 800 ml) 24-hour samples were provided by 19 individuals. Blood samples were collected from 149 persons. Of 132 participants who completed lung function testing, 125 had valid spirometry results. Twenty-three participants were examined by a dermatologist, and one was given a patch test for chromium sensitivity.

**Follow-up Physical Examination** Twelve (6.5%) of 184 participants were found to have abnormal lung conditions, 81 (44%) were found to have abnormal skin conditions, and 25 (14%) were found to have abnormal nasal conditions upon follow-up medical examination. The examining physician judged that the conditions found in four persons may have been related to chromium exposure.

**Urine and Blood Analyses** Urine and blood analyses indicated a variety of medical conditions not judged by the examining physician to be related to chromium exposure, including diabetes, kidney disease, liver diseases, and infections.

β₂-microglobulin tests were conducted on 158 repeat spot urine samples. Of these, 12 (8%) were considered above the normal range for this parameter. However, the reason
for the elevated levels in these 12 participants was judged by the examining physician not to be related to potential chromium exposure.

**Repeat Spot and 24-Hour Urine Chromium Analyses** The distribution of the 176 unadjusted urine chromium concentrations among the repeat spot urine samples was similar to that of screening spot samples from the entire screened population. The percentile concentrations of the repeat spot samples were somewhat higher among those who were referred for follow-up evaluation on the basis of a high screening spot urine chromium test, compared to those referred on the basis of a physical examination finding. The 75th, 90th and 95th percentile values of the repeat spot samples were 0.35, 0.61, and 0.83 µg/l among urine referrals and 0.24, 0.61, and 0.65 µg/l among physical exam referrals.

The complete 24-hour urine samples were similar in concentration to the repeat spot samples. Among those referred for high initial urine chromium, the 75th, 90th and 95th percentile values were 0.30, 0.57, and 0.75 µg/l. All of the seven 24-hour samples from those referred on the basis of a physical finding were below the quantitation limit of 0.20 µg/l.

A total of 176 participants had both an initial and a repeat urine test. Of these, among the 140 persons whose initial spot urine chromium was greater than 0.75 µg/l, 9 (6.4%) were above this value on the second spot test. In contrast, only one (2.8%) of the 36 whose initial spot test was less than or equal to 0.75 µg/l were above this value on the second test. A total of 62 participants had both an initial spot test and a complete 24-hour test. Of these, all of the four individuals with 24-hour samples containing more than 0.50 µg/l had initial spot samples above 0.75 µg/l.

**Spirometry** Spirometry values were considered abnormal for 26 (21%) of 125 participants with valid tests. The examining physician considered chromium exposure to be a possible or probable cause of lung function problems in two of these 26.

**Dermatologist Examination** Of the twenty-three persons examined by the dermatologist, all were found to have abnormal skin conditions at the time of examination. Chromium exposure was ruled out as a probable cause of the condition for all but one participant. Patch testing of this individual was not positive for chromium.

**Overall Assessment** In 178 (97%) of the 184 persons given follow-up examinations, chromium-related effects could not be detected by EOHCC. Based on the physical
examination or medical history, six (3%) were judged by the examining physician to have medical conditions for which chromium exposure could not be ruled out as a contributing cause. Of these six, five were employed at screened workplaces and one was from a targeted residential area. Three had been originally referred on the basis of a physical examination finding, and three had been referred on the basis of an elevated initial spot urine chromium concentration.

Four of the six had dermatologic conditions potentially related to chromium. Only one of the four was examined by the dermatologist, however, and this person did not test positive for chromium sensitivity. Three of the six had persistent respiratory allergies.
5. DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Project Findings

The Chromium Medical Surveillance Project screened over 2,200 persons, most of whom were living or working near chromium waste sites in and around Hudson County, New Jersey. The screening project found the following with respect to potential exposure to chromium:

1) The average urine chromium levels of all screened groups (residents, persons associated with residential areas, workers, non-targeted persons) were higher than those from the baseline survey, adjusting for urine diluteness, sex, age group, and other potential confounding factors. Stratified examination of adjusted urine chromium levels in specific age groups shows that the reasons for overall increases among screening groups differ according to age group.

2) *Children* age five and under living near chromium sites show increased urine chromium concentrations relative to their peers. In comparison to the baseline survey children, the adjusted urine chromium geometric mean concentration was higher in resident children by 0.13 μg/l (0.33 vs. 0.20 μg/l), a difference in means that is not likely to be due to chance. Elevations were also observed in children associated with residential areas (primarily living just outside the defined targeted area), while non-targeted children age 1-5 showed no elevation. However, numbers of children in these latter two categories were too small for meaningful statistical evaluation. This finding in resident children indicates the potential for children in specific areas to be exposed to chromium. For this age group, remedial efforts completed at the time of screening may not have been sufficient.

3) *Older children* (age six to 18) within targeted residential areas showed evidence of exposure to chromium, but the increase was less than that observed in smaller children. The difference between this finding and that in younger children may indicate that exposure is related to greater interior or exterior dust contact -- either through ingestion or inhalation -- of younger children.

4) *Among adults* age 19 to 60, adjusted urine chromium in residents, those
associated with residential areas, and workers showed small but statistically significant increases relative to adults from the baseline survey. Non-targeted persons showed intermediate chromium levels and were not statistically distinguishable from either the baseline or the screened groups.

5) No evidence of exposure was observed among older adults (over age 60) in any screened group, relative to the baseline group. The highest geometric mean adjusted urine chromium level was among the non-targeted population, but this average increase was attributable to a few individuals with high levels.

6) Detailed examination of the referral proportions, adjusted urine chromium levels, and/or regression analysis results revealed specific workplaces and sections of residential areas where further environmental evaluation is necessary to identify possible on-going sources of exposure. Further remediation steps may be necessary to reduce or eliminate identified exposure sources.

Sections of two targeted residential areas need further environmental investigation, each adjacent to the two former chromium smelter sites in Jersey City. These residential sections showed relatively high referral proportions based on urine chromium levels. The first area is Woodward St. between the railroad tracks and Lafayette Avenue, and the second area is defined by Stegman Court, Stegman Place, and Stegman Parkway between West Side Avenue and Stegman Terrace.

Two workplaces in particular have been identified for further environmental investigation: the Chloroben/Standard Chlorine facility, which is located close to the original smelter site in Kearny, and the ICI Americas (now Zenea, Inc.) facility in Bayonne. Participants from these sites had high referral proportions and high average urine chromium levels relative to those from other workplaces screened. Five other workplaces showed evidence of exposure -- either a high referral proportion, relatively high average urine chromium levels, or individuals with particularly high urine chromium levels -- and also need additional environmental evaluation; Levy and Sons Warehouse, Degen Co., Airdock Systems, and Baldwin Steel in Jersey City, and Trumbull Asphalt in Kearny.

7) Because of the unusually high proportion of referrals in the first Regional Day School screening, NJDEP, NJDOH and EOHSI exposure scientists conducted an
environmental evaluation to determine a possible source of exposure of the unusual finding. There was no evidence of chromium from waste sites in the dusts at the school, nor was there any evidence of a previously unknown waste site in the vicinity of the school. Two potential sources, both possibly episodic, could not be ruled out: scrap metal fires in an abandoned lot across the street from the school, and certain arts materials containing chromium compounds used within the school. These findings were presented in detail in a letter from NJDOH to the principal of the Regional Day School.

8) Most of the persons undergoing the follow-up medical examinations revealed no apparent clinical effects attributable to chromium exposure. However, for six persons, chromium was suspected to be a possible cause or contributing factor in their clinical conditions. Physicians provided appropriate advice and further referrals to participants with medical findings, whether or not the findings were related to chromium exposure.

5.2 Factors to Consider in the Interpretation of Findings

The CMSP has further demonstrated the utility of using the urine chromium test as a measure of human exposure (NJDOH, 1989; Stern et al., 1992). In addition, the NJDOH Laboratory has demonstrated that the analytical methods, with careful attention to quality assurance, can be applied on a large scale. Several factors should be considered in interpreting the results of the CMSP, as discussed below.

5.2.1 Urine Chromium as a Screening Measure of Exposure

Control for Confounding Factors The processes used to control for potential confounding (the excess approach used during the project to make individual decisions and the calculation of adjusted chromium levels in the overall data analysis) was important under some circumstances. At the individual level, adjustment through the excess approach mattered for persons whose unadjusted chromium ranged between approximately 0.7 and 1.0 μg/l. The lowest unadjusted value that triggered a referral was 0.67 μg/l, while the highest unadjusted value that did not trigger a referral was 1.03 μg/l. The proportion referred increased through this range of unadjusted urine chromium values: 20/54 (37%) between 0.70 and 0.79 μg/l, 23/27 (85%) between 0.80 and 0.89 μg/l, and 24/25 (96%) between 0.90 and 0.99 μg/l. At the group comparison level, adjustment was especially
important among the targeted worker population (compare Figures 4-1 and 4-3). As a group, workers showed relatively dilute urine compared to both baseline and other screened adults, so that standardizing to median values on diluteness parameters served to increase the adjusted urine chromium level.

As described in section 1.5, correction for diluteness has frequently been done by dividing the chromium concentration by the creatinine concentration, so that the measure is expressed as micrograms of chromium per gram of creatinine in the urine. The validity of this procedure has been questioned because of artificial inflation ("over-correction") of the ratio at low creatinine levels (see Appendix C). In the CMSP, correction for diluteness was done through the use of multivariate regression modeling, in which creatinine and specific gravity were included as predictive factors along with other potential confounding factors. In addition, regression modeling allowed for exploration of differences in the magnitude of correction by age group and sex, and such interactions were included in the models presented in Table 4-6 (baseline data) and Table 4-9 (adjustment models).

With the exception of age and measures of diluteness, the potential for confounding was limited; few factors examined appear related to urine chromium, and of these, none show strongly different distributions among screening and baseline groups. Multiple linear regression analysis showed that estimates of association between screening group and urine chromium were generally unaffected by inclusion of potential confounders.

The baseline and screened groups differed with respect to age and race composition. Age differences were controlled for in the analyses either through inclusion of age group terms in regression models or stratification by age group. Terms for age group were included in the models used to generate the excess urine chromium levels and in the overall model for computation of adjusted urine chromium concentrations. In addition, data were stratified into four age groups for development of age-specific adjustment models and in the age-specific regression analyses. Race was included in the age-specific adjustment models, but was not a statistically significant factor.

In the regression models, other factors found to be related to urine chromium concentration included household cigarette smoking, a hobby or job involving potential chromium exposure, diabetes, history of cancer, beer intake, and chromium supplement
intake.

**Quantitation Limit** Although the test is capable of measuring very low levels of urine chromium, 48% of the participants had urine chromium levels below the limit of quantitation. This is not important in the context of screening, where the purpose is to detect the individuals at the high end of the exposure distribution. However, in making group comparisons, the assumption of a single concentration of chromium (0.10 μg/l) for all samples below the quantitation limit may affect the predictive abilities of statistical models. However, it is unlikely that this assumption would lead to spurious associations with respect to site-related variables.

**Sensitivity and Specificity of the Urine Chromium Test** There is no "gold standard" by which the sensitivity and specificity of the urine chromium test can be measured. Indeed, the "standard" may differ depending on whether short- or long-term exposure patterns are being investigated. With respect to short-term exposure (measured in hours to days), the urine chromium test, after appropriate adjustment procedures are employed, probably has good sensitivity ("truly exposed" test positive).

External contamination during urine sample collection could have resulted in false positives (lower specificity). To minimize the possibility of external sample contamination, collection procedures were evaluated through the use of trip and field blanks (see section 3.2.5). Of 306 blanks collected, only two showed quantifiable chromium (0.21 μg/l and 0.45 μg/l). These samples were collected on different days during follow-up evaluations at the EOHCC. None of the spot urine samples taken on the same days at that facility appeared to be elevated. Therefore, specificity of the urine chromium test was probably good.

Because the urine chromium test reflects a short time window after exposure, the test is not applicable to the assessment of longer-term exposure. There may be participants who have experienced exposure in the past but did not test "positive" in one particular spot urine sample. Comparing distributions of urine chromium concentrations at the group level would increase the overall sensitivity by identifying groups of persons at risk of exposure that would not be evident if examination was restricted to the individual level.

**Chromium Site Remediation** The findings of the CMSP generally reflect exposure
levels in the vicinity of chromium waste sites after some degree of remediation has occurred. In residential areas, most waste sites had been excavated and replaced with clean fill material; in most workplaces, interim remedial measures had been performed. Because the amount of urine chromium data prior to remediation is limited, it is not possible to assess chromium exposure as it may have occurred in the past, although exposures are likely to have been higher before remediation.

**Repeat Spot Urine Results**  Repeat spot urine samples from follow-up medical evaluations were typically lower in chromium than in the screening urine sample among those referred for a previously high urine chromium level. This may reflect a true reduction in urine chromium concentrations for the individual, due to either previous intermittent exposure(s) or because remediation has reduced environmental levels of chromium. Or, it may reflect a "regression to the mean" in which those participants whose screening samples reflected the peak of their intra-individual variation were selected for follow-up examination, and the repeat sample reflected a more typical individual level, on average. However, chromium levels in repeat samples were higher among those referred on the basis of a high urine chromium concentration compared to those referred for a screening physical finding. The screening sample tests, therefore, appear to have identified subgroups with higher chromium exposure.

**5.2.2 Biological and Clinical Significance of Exposure**

Because of the large number of participants in the screening project and baseline survey, there was sufficient statistical power to detect small group mean differences, particularly for the age group 19 to 60. Consequently, it is important to distinguish between statistical distinctions and biologically or clinically important distinctions. Although group differences in urine chromium concentration may indicate increases in exposure, these differences may not be indicative of the potential for health problems. In addition, average group differences may not reflect exposure in all members of the group. For example, the group mean differences in adults appeared to be driven by the upper percentiles of the distribution. Current exposure, where it exists, is likely to be limited to a few individuals at any given time.

The biological and public health significance of intermittent, low level exposure is
uncertain, and is dependent on the chemical form of the chromium (trivalent or hexavalent) and on the route of exposure (inhalation or ingestion). Clearly, the potential for harm is by far the greatest for inhalation of hexavalent chromium compounds, since it is this chemical form and exposure route that is associated with long-term risk of lung cancer. As discussed in section 1.2, the chemical form and route of exposure may vary depending on site conditions and human behaviors, making it difficult to generalize about site risks.

Importantly, past exposure levels are likely to have been higher prior to site remediation. However, since these levels cannot be assessed with certainty, the biological significance of peak exposures in the past cannot be determined with confidence.

The future risk of lung cancer in this population is not known and, because of population mobility and the long latency period of the disease, will be difficult to measure. Certainly, the risk cannot be assessed accurately from the limited knowledge of exposure patterns prior to remediation, although approximations may be attempted. Evidence of exposure in small children and, to a lesser degree, in adults, in some areas, indicates that vigilance in investigation and remediation of chromium waste sites and associated contamination must be a priority to prevent additional risk from accruing in the population.

5.2.3 Medical Findings

The CMSP has shown little evidence of clinically observable chromium-induced health effects in those currently living or working near chromium waste sites. This finding needs to be interpreted with caution. As with the urine chromium test, there is no "gold standard" and the sensitivity and specificity of this aspect of the screening project need to be considered.

Sensitivity and Specificity of Physical Examinations The sensitivity and specificity of examinations differ for each potential effect. Among those screened, both the sensitivity and specificity of the examinations for irritant or corrosive effects such as nasal septal perforation or skin ulceration are probably high, since the effects are relatively easy to detect. The sensitivity of the screening physical examination for allergic contact dermatitis is also probably high, but the specificity is probably not high, since other allergens can produce similar effects. However, the follow-up medical examination involving a board-certified dermatologist serves to improve the specificity of the overall screening project for
this effect.

Individual screening examination physicians had different referral proportions, although these proportions were similar between the two institutions that provided screening physicians. Differences in individual referral proportions could be due to differences in the populations examined, or to differences in professional judgments within the bounds of the Screening Examination and Referral protocol. Both "false positive" and "false negative" referral decisions might result from differences in physician judgment.

Selection of Participants Outreach was conducted to encourage people who lived and worked in particular areas of Jersey City and Bayonne to participate in the CMSP. Not all targeted people chose to participate. In addition, it was the policy of the CMSP not to exclude people who chose to participate but who did not live or work in targeted locations; these participants have been considered separately in this report. In anticipation of the self-selection of the participants both within and outside of the targeted areas, the CMSP was not designed to measure the prevalence of chromium-related illness in targeted areas. In the context of a screening project, self-selection of participants could serve to enhance the efficiency of screening.

5.3 Conclusions

1) The average urine chromium concentration was higher in screened populations compared to the baseline survey population. However, at the time of screening, most persons in most targeted residential areas and workplaces did not appear to be currently exposed to unusual amounts of chromium from the waste sites or any other source.

2) The screening project found evidence of chromium exposure to children under age six in residential areas near chromium waste sites. To a lesser extent, evidence of exposure was also found among older children and adults in residential areas. While the average increase in exposure levels is unlikely to be related to specific clinically detectable effects, the long-term risk from such exposure (or previous, unmeasured exposure) is difficult to assess.

3) Chromium exposure appears to be elevated in parts of the Metro Field and Lafayette residential areas in Jersey City. These residential sections are close to the
locations of the original chromium smelters in Jersey City.

4) The screening project found evidence of exposure to adults at certain workplaces in Kearny, Bayonne and Jersey City: Cloroben/Standard Chlorine, ICI Americas, Levy and Sons Warehouse, Degen Co., Airdock Systems, Trumbull Asphalt, and Baldwin Steel.

5) The screening methods utilized in this project were successfully applied. However, there is a need for research to find and validate the application of biological markers of long-term exposure to chromium, and sensitive markers of adverse health effects from such exposure.

6) The screening project provided a cross-sectional evaluation of the population during one period of time. There is a need for long-term follow-up of populations identified as potentially exposed to chromium.

5.4 Recommendations

1) The NJDEP and NJDOH should consider carefully the results of the interior dust chromium tests already conducted in many households by scientists from EOHSI, with particular attention to households with small children, and households in the two residential sections with high urine referral proportions. In the two residential sections, the NJDEP should conduct exterior inspections and other environmental sampling for chromium to identify potential sources of chromium exposure. If a chromium waste site-related exposure source is found, the NJDEP should take steps to reduce the potential for exposure.

2) The NJDEP should sponsor thorough industrial hygiene investigations at the seven identified workplaces, including exterior and interior inspections and sampling for chromium. Such evaluations have already occurred at some of these workplaces. While each workplace needs to be evaluated, ICI Americas and Cloroben/Standard Chlorine should receive the highest priority.

3) At all workplaces on or near chromium waste sites, the NJDEP and employers should continue to monitor the effectiveness of interim remedial measures until permanent remedial measures at the sites have been implemented.
4) To the extent possible, NJDOH and NJDEP should cooperate with research projects designed to find sensitive markers of exposure to and effects of chromium.

5) In conjunction with the residential communities and workplaces, the NJDOH should encourage the appropriate federal agencies to examine the feasibility of studying long-term health risks, including lung cancer, among populations with a history of potential exposure to chromium.
REFERENCES


R - 3


Table 1-1. Average and range of spot urine chromium concentrations in persons without occupational exposure to chromium reported in published scientific papers.

<table>
<thead>
<tr>
<th>Author and Year Published (Country)</th>
<th>Number of Persons</th>
<th>Sample Type</th>
<th>Average# (units)*</th>
<th>Range (units)*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nomiyama et al. (1980) (Japan)</td>
<td>47</td>
<td>spot</td>
<td>0.15 µg/l</td>
<td></td>
<td>22/47 spot samples &lt; 1 µg/g; 41/47 spot samples &lt; 2 µg/g</td>
</tr>
<tr>
<td>Anderson et al. (1982b) (U.S.-Maryland)</td>
<td>9</td>
<td>spot</td>
<td>0.09 µg/g</td>
<td>0.04-0.36 µg/l</td>
<td>samples taken before running</td>
</tr>
<tr>
<td>Randall et al. (1987) (Canada)</td>
<td>43</td>
<td>spot</td>
<td>0.24 µg/l</td>
<td>0.16-0.31 µg/l</td>
<td>all &lt; 0.46 µg/g</td>
</tr>
<tr>
<td>McAughey et al. (1988) (United Kingdom)</td>
<td>20</td>
<td>spot</td>
<td>0.18 µg/g</td>
<td>0.13-0.26 µg/g</td>
<td></td>
</tr>
<tr>
<td>Minoia et al. (1988) (Italy)</td>
<td>310</td>
<td>spot</td>
<td>0.59 µg/l</td>
<td>0.08-2.10 µg/l</td>
<td></td>
</tr>
<tr>
<td>238</td>
<td></td>
<td>spot</td>
<td>0.52 µg/l</td>
<td>0.05-1.90 µg/l</td>
<td></td>
</tr>
<tr>
<td>Bonde et al. (1991) (Denmark)</td>
<td>28</td>
<td>spot</td>
<td>0.33 µg/g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bukowski et al. (1991) (U.S.-New Jersey)</td>
<td>52</td>
<td>spot</td>
<td>0.59 µg/g median</td>
<td>&lt;0.09-2.0 µg/g</td>
<td></td>
</tr>
<tr>
<td>Stern et al. (1992) (U.S.-New Jersey)</td>
<td>24</td>
<td>spot</td>
<td>0.18 µg/g geometric</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Average is arithmetic mean unless otherwise noted.

* µg/l: micrograms chromium per liter of urine; µg/g: micrograms chromium per gram of creatinine
Table 1-2. Average and range of 24 hour (or longer) urine chromium concentrations in persons without occupational exposure to chromium reported in published scientific papers.

<table>
<thead>
<tr>
<th>Author and Year Published (Country)</th>
<th>Number of Persons</th>
<th>Sample Type</th>
<th>Average# (units)*</th>
<th>Range (units)*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nomiyama et al. (1980) (Japan)</td>
<td>198</td>
<td>24 hour</td>
<td>0.41 µg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anderson et al. (1982a) (U.S.-Maryland)</td>
<td>76</td>
<td>24 hour</td>
<td>0.20 µg/l 0.12 µg/g</td>
<td>0.05-0.58 µg/l 0.03-0.43 µg/g</td>
<td>~67/76 &lt; 0.3 µg/l ~71/76 &lt; 0.3 µg/g after 3 months of high-chromium diet supplementation</td>
</tr>
<tr>
<td></td>
<td>76</td>
<td>24 hour</td>
<td>1.13 µg/l 0.70 µg/g</td>
<td>0.05-3.1 µg/l 0.23-3.3 µg/g</td>
<td></td>
</tr>
<tr>
<td>Anderson et al. (1983) (U.S.-Maryland)</td>
<td>42</td>
<td>24 hour</td>
<td>0.18 µg/l 0.22 µg/d</td>
<td></td>
<td>after high-chromium diet supplementation</td>
</tr>
<tr>
<td></td>
<td>46</td>
<td>24 hour</td>
<td>0.98 µg/l 0.99 µg/d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kumpulainen et al. (1983) (Finland)</td>
<td>10</td>
<td>24 hour</td>
<td>0.11 µg/l</td>
<td>0.06-0.20 µg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>24 hour</td>
<td>0.17 µg/d</td>
<td></td>
<td>diabetics</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>24 hour</td>
<td>0.29 µg/d 1.33 µg/d</td>
<td></td>
<td>20 µg Cr/d suppl. 200 µg Cr/d suppl.</td>
</tr>
<tr>
<td>Anderson et al. (1984) (U.S.-Maryland)</td>
<td>9</td>
<td>24 hour</td>
<td>0.20 µg/d</td>
<td></td>
<td>non-run day</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>24 hour</td>
<td>0.37 µg/d</td>
<td></td>
<td>run day</td>
</tr>
<tr>
<td>Bunker et al. (1984) (United Kingdom)</td>
<td>23</td>
<td>5 day</td>
<td>0.4 µg/d</td>
<td>0.2-0.8 µg/d</td>
<td>elderly subjects</td>
</tr>
<tr>
<td>Saner et al. (1984) (Turkey)</td>
<td>12</td>
<td>24 hour</td>
<td>0.22 µg/l 0.26 µg/g 0.31 µg/d</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 1-2, continued

<table>
<thead>
<tr>
<th>Author and Year Published (Country)</th>
<th>Number of Persons</th>
<th>Sample Type</th>
<th>Average# (units)*</th>
<th>Range (units)*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson et al. (1985) (U.S.-Maryland)</td>
<td>32</td>
<td>7 day</td>
<td>0.19 µg/d</td>
<td>0.07-0.32 µg/d</td>
<td></td>
</tr>
<tr>
<td>Offenbacher et al. (1985) (U.S.-New York)</td>
<td>19</td>
<td>24 hour</td>
<td>0.19 µg/d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koslovsky et al. (1986) (U.S.-Maryland)</td>
<td>37</td>
<td>24 hour</td>
<td>0.24 µg/d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morris et al. (1988) (United Kingdom)</td>
<td>37</td>
<td>24 hour</td>
<td>0.28 µg/d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morris et al. (1988) (United Kingdom)</td>
<td>11</td>
<td>24 hour</td>
<td>0.44 µg/g</td>
<td></td>
<td>high sugar diet</td>
</tr>
</tbody>
</table>

# Average is arithmetic mean unless otherwise noted.

* µg/l: micrograms chromium per liter of urine; µg/g: micrograms chromium per gram of creatinine
### Table 3-1. Components of Screening Evaluation, Including Criteria for Referral for Follow-up Evaluation

<table>
<thead>
<tr>
<th>Examination/Test</th>
<th>Purpose</th>
<th>Criteria for Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Physical Examination</td>
<td>To identify individuals with possible chromium-related health effects and provide a referral for follow-up evaluation; to inform participants about chromium health risks and exposure avoidance</td>
<td>History of chronic unrelenting allergies, asthma or chronic dermatitis, temporally related to possible chromium exposure, or Physical findings of skin ulceration or related scarring, nasal ulceration, or nasal septal perforation</td>
</tr>
<tr>
<td>Urine Chromium (Spot Sample)</td>
<td>To assess recent exposure to chromium</td>
<td>Excess urine chromium concentration exceeding 0.5 µg/l (see text sections 3.2.9 and 4.1.3)</td>
</tr>
</tbody>
</table>
Table 3-2. Components of Follow-up Medical Evaluation

<table>
<thead>
<tr>
<th>Examination/Test</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Examination</td>
<td>To re-examine participants for conditions observed during the screening examination; to determine the general health status; to identify conditions in need of referral for further examination or attention</td>
</tr>
<tr>
<td>(Including Medical History)</td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td>To conduct a standard battery of urine analyses (ketones, proteins, glucose, blood, bilirubin) to determine general health status, kidney function, liver function, and diabetes; to assess damage to the proximal tubules of the kidney (β₂-microglobulin)</td>
</tr>
<tr>
<td>Blood Analysis</td>
<td>To conduct a standard battery of blood analyses (complete blood count, liver enzymes, blood urea nitrogen, and blood creatinine) to determine general health status, liver function, and kidney function</td>
</tr>
<tr>
<td>Spirometry</td>
<td>To evaluate lung capacity and elasticity; to identify respiratory diseases, airway abnormalities, asthma, or interstitial fibrosis</td>
</tr>
<tr>
<td>Examination by Dermatologist</td>
<td>To evaluate whether skin conditions identified in screening or follow-up physical examinations are or could be due to chromium exposure</td>
</tr>
<tr>
<td>Repeat Urine Chromium (Spot Sample)</td>
<td>To assess recent exposure to chromium</td>
</tr>
<tr>
<td>Urine Chromium (24-hour Sample)</td>
<td>To assess recent exposure to chromium</td>
</tr>
</tbody>
</table>
Table 3-3. Residential Areas Targeted for Chromium Screening

<table>
<thead>
<tr>
<th>City</th>
<th>Area</th>
<th>NJDEP Site Codes</th>
<th>Map Code*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jersey City</td>
<td>Dwight St.</td>
<td>28,29,37,74, 75,89,102,123, 129</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Lafayette</td>
<td>6,12,13,18,22, 39,114,127, 128,151,159, 160,161</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Grand St.</td>
<td>10,11,80,81, 82,83,84,85</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Metro Field</td>
<td>173</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Fisk St.</td>
<td>79</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Communipaw #24</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Cambridge Ave.</td>
<td>38</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Bramhall Ave.</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Communipaw #23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Kearney Ave.</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Ninth St.</td>
<td>96</td>
<td>9</td>
</tr>
<tr>
<td>Bayonne</td>
<td>Isabella Ave.</td>
<td>138,158,162</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>East 52nd St.</td>
<td>164</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Sunset Ave.</td>
<td>144</td>
<td>13</td>
</tr>
</tbody>
</table>

* Map codes refer to Figures 3-1 and 3-2, which map the locations of the targeted residential areas in Jersey City and Bayonne, respectively. Appendix B includes detailed maps of each residential area.
Table 3-4. Workplaces Targeted for Chromium Screening

<table>
<thead>
<tr>
<th>City</th>
<th>Workplace</th>
<th>NJDEP Site Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jersey City</td>
<td>RAH Transportation*</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Dieterle &amp; Victory*</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Airdock Systems*</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Levy &amp; Sons*</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>F &amp; M Exxon*</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Degen Co.*</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td>Modern Village Development Corp.</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>Bob Ciasulli Honda*</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>Inter Ocean Express Corp.</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td>Jersey City Incinerator Authority*</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td>Baldwin Steel*</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>Recycling Specialists*</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>Fashionland*</td>
<td>107</td>
</tr>
<tr>
<td></td>
<td>Albanil Dyestuff*</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>Cathy Daniels*</td>
<td>114</td>
</tr>
<tr>
<td></td>
<td>E.C. Warehouse</td>
<td>114</td>
</tr>
<tr>
<td></td>
<td>NJDMV Driver Testing Center*</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td>Ryerson Steel</td>
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</tr>
<tr>
<td></td>
<td>Trader Horn</td>
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<td>Garfield Auto Parts</td>
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<td>Roosevelt Lanes</td>
<td>124</td>
</tr>
<tr>
<td></td>
<td>Delphic-Killeen Transportation Systems, Inc.*</td>
<td>125</td>
</tr>
<tr>
<td>City</td>
<td>Workplace</td>
<td>NJDEP Site Codes</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Jersey City,</td>
<td>Frank B. Ross Co., Inc.*</td>
<td>133</td>
</tr>
<tr>
<td>continued</td>
<td>Apex Management</td>
<td>134</td>
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<tr>
<td></td>
<td>Vitarroz Corp.</td>
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<tr>
<td></td>
<td>Rudolf Bass, Inc.*</td>
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<tr>
<td></td>
<td>ABF Freight</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>Talarico Used Cars, Inc.*</td>
<td>143</td>
</tr>
<tr>
<td></td>
<td>Clean Machine Car Wash*</td>
<td>157</td>
</tr>
<tr>
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<td>Continental Craftsman Corp.</td>
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</tr>
<tr>
<td></td>
<td>Colonial Concrete, Inc.</td>
<td>163</td>
</tr>
<tr>
<td></td>
<td>Tempesta &amp; Sons, Inc.*</td>
<td>165</td>
</tr>
<tr>
<td></td>
<td>EG&amp;G Dynatrend*</td>
<td>173</td>
</tr>
<tr>
<td>Kearny</td>
<td>PJT Transport</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>American President Lines</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>Emco Stainless, Inc.</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>T.J. McDermott*</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Interstate Freightways</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Goldie’s Automotive</td>
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<tr>
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<td>Clinton Cartage, Inc.</td>
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<tr>
<td></td>
<td>Universal Chemicals, Inc.*</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>Alden Leeds, Inc.*</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>Allied Universal, Inc.*</td>
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<tr>
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<td>Unified Universal*</td>
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Continued next page
<table>
<thead>
<tr>
<th>City</th>
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<th>NJDEP Site Codes</th>
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* Workplace screening on-site with NJDOH mobile medical van
Table 4-4a. Distribution of Unadjusted Urine Chromium Concentration (μg/l) by Age and Sex

**Group: Baseline**

<table>
<thead>
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<th>Empirical Percentile</th>
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<td>0.22</td>
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<td>6 - 10</td>
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<tr>
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@ Data not presented for age-sex groups with five or fewer persons
Table 4-4b. Distribution of Unadjusted Urine Chromium Concentration (μg/l) by Age and Sex

**Group:** Residents of Targeted Areas (including 28 individuals who also worked in a targeted workplace but excluding those who were affiliated with the Regional Day School)

<table>
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<th>Empirical Percentile</th>
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### Table 4-4c. Distribution of Unadjusted Urine Chromium Concentration (µg/l) by Age and Sex

**Group: Screened, Not Resident in but Associated with Targeted Residential Area**

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<td>61 - 75</td>
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<td>0.68</td>
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</tbody>
</table>

# Includes screened persons who lived within a block of the edge of a targeted residential area, those whose workplace was within a targeted residential area, and those whose former residence (within six months) was within a targeted area.

* Includes 1 male and 4 females age 76+
Table 4-4d. Distribution of Unadjusted Urine Chromium Concentration (µg/l) by Age and Sex

* Group: Workers at Targeted Workplaces (including 28 individuals who also lived in a targeted residential area)

<table>
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<th>Empirical Percentile</th>
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<td>0.37</td>
<td>0.24</td>
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<tr>
<td>Female</td>
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<tr>
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<td>0.33</td>
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<td>41 - 60</td>
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<td>0.22</td>
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</table>

* Includes 3 males age 11-18 and 2 males age 76+
Table 4-4c. Distribution of Unadjusted Urine Chromium Concentration (μg/l) by Age and Sex

Group: Lived in Targeted Residential Area and Worked at Targeted Workplaces

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<td>Trim</td>
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<tr>
<td>Age</td>
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<td>Female</td>
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<td>0.34</td>
<td>0.27</td>
</tr>
<tr>
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<td>0.42</td>
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@ Data not presented for age-sex groups with five or fewer persons
Table 4-4f: Distribution of Unadjusted Urine Chromium Concentration (µg/l) by Age and Sex

Group: Regional Day School

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* Includes 2 males and 1 female age 1-5, and 1 male and 4 females age 61-75
@ Data not presented for age-sex groups with five or fewer persons
Table 4-4g. Distribution of Unadjusted Urine Chromium Concentration (µg/l) by Age and Sex

**Group: Screened But Not Identified with a Targeted Residential Area or Workplace**

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* Includes 1 male and 3 females age 1-5, and 1 male and 3 females age 76+
Table 4-5. Distribution of Unadjusted Urine Chromium Concentration (μg/l) by Demographic and Other Characteristics for Baseline and Screened Groups

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Table 4-6. Regression Models Based on Baseline Survey Data Used for Calculation of Excess Chromium Concentration

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<td>Intercept</td>
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Variable definitions:

Creatinine: in grams per liter of urine, centered at 1.0 g/l
Specific gravity: centered at 1.02
Ln(Weight): natural logarithm of weight in pounds, centered at 100 lbs.
Age 61+: 1 if age > 60, 0 if not
Chromium supplement intake: 1 if intake of supplement containing more than 30 micrograms of chromium in past 48 hours, 0 if not or unknown
House sweeping: 1 if swept, vacuumed or dusted inside the house in past 48 hours, 0 if not or unknown
Attic/garage cleaning: 1 if cleaned attic, garage or basement in past 48 hours, 0 if not or unknown
Dusty work: 1 if swept or cleaned inside the workplace, or worked with soil at workplace, or washed equipment or vehicles at workplace, or self-reported work in a dusty setting in the past 48 hours, 0 if not or unknown
Hobby/job: 1 if reported hobbies or jobs involving pressure-treated wood, boilers, refrigeration equipment, welding, metal working, fabric dyes, tanning leather, cement, plating, ceramics, laboratory chemicals or glass making in past 48 hours, 0 if not or unknown
Intercept: natural logarithm of mean urine chromium concentration when all model variables equal 0
Table 4-7. Frequency Distributions of Excess Urine Concentrations in Baseline and Screening Groups

<table>
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<th>EXCESS URINE CHROMIUM (µg/l)</th>
<th>BASELINE N (Cumulative %)</th>
<th>SCREENING GROUPS N (Cumulative %)</th>
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<td>TOTAL</td>
<td>315 (100)</td>
<td>2,213 (100)</td>
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<td>174 (55)</td>
<td>1,035 (46)</td>
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<td>0.11 - 0.20</td>
<td>25 (88)</td>
<td>209 (78)</td>
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<td>15 (93)</td>
<td>114 (83)</td>
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<td>7 (95)</td>
<td>91 (87)</td>
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<td>0.41 - 0.50</td>
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<td>61 (90)</td>
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<td>0.91 - 1.00</td>
<td>0 (99)</td>
<td>9 (95)</td>
</tr>
<tr>
<td>&gt; 1.00</td>
<td>2 (100)</td>
<td>99 (100)</td>
</tr>
</tbody>
</table>

Note: The 216 participants in shaded cells in table have excess values exceeding 0.5 µg/l and were referred for follow-up medical evaluation. Seven additional participants were referred (see text section 4.2.4).
Table 4-8. Excess Urine Chromium Referral Proportions by Age Group, Sex and Target Screening Group

<table>
<thead>
<tr>
<th>Population</th>
<th>Number of Participants</th>
<th>Number (%) Referred</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 5</td>
<td>71</td>
<td>12 (17)</td>
</tr>
<tr>
<td>6 - 10</td>
<td>138</td>
<td>19 (14)</td>
</tr>
<tr>
<td>11 - 18</td>
<td>161</td>
<td>19 (12)</td>
</tr>
<tr>
<td>19 - 40</td>
<td>843</td>
<td>66 (7.8)</td>
</tr>
<tr>
<td>41 - 60</td>
<td>777</td>
<td>85 (11)</td>
</tr>
<tr>
<td>61 +</td>
<td>223</td>
<td>18 (8.1)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>950</td>
<td>104 (10.9)</td>
</tr>
<tr>
<td>Male</td>
<td>1,263</td>
<td>115 (9.1)</td>
</tr>
<tr>
<td><strong>Target Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residents</td>
<td>806*</td>
<td>87 (10)</td>
</tr>
<tr>
<td>Associates</td>
<td>223</td>
<td>19 (8.5)</td>
</tr>
<tr>
<td>Workers</td>
<td>934*</td>
<td>76 (8.1)</td>
</tr>
<tr>
<td>Non-Targeted</td>
<td>177</td>
<td>18 (10)</td>
</tr>
<tr>
<td>RDS</td>
<td>101</td>
<td>24 (24)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,213</td>
<td>219 (9.9)**</td>
</tr>
</tbody>
</table>

* Includes 28 individuals who both lived and worked in a targeted area, 5 (18%) of whom were referred.

** Referred numbers include only those referred on the basis of their first screening evaluation urine sample. Thirteen persons were screened twice. Of these, four were referred only on the basis of their second evaluation. The total proportion of individuals referred was therefore 223 of 2,213 (10.1%).
Table 4-9. Regression Models for Calculation of Adjusted Urine Chromium Concentrations

Adjusted values are computed from model coefficients, normalized to overall and age-specific medians of the continuous variables (centered values) and to the "0" values of the other factors (see variable definitions below).

<table>
<thead>
<tr>
<th>Model</th>
<th>Variable</th>
<th>Coefficient</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Intercept</td>
<td>-1.503</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.334</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.204</td>
<td>0.0004</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.157</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.122</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Age 1-5</td>
<td>0.209</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>Age 6-18</td>
<td>-0.126</td>
<td>0.087</td>
</tr>
<tr>
<td></td>
<td>Age 61+</td>
<td>0.284</td>
<td>0.0001</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>0.155</td>
<td>0.054</td>
</tr>
<tr>
<td></td>
<td>Household Smoking</td>
<td>0.101</td>
<td>0.021</td>
</tr>
<tr>
<td></td>
<td>Hobby/Job</td>
<td>0.179</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Age 1-5 * Creatinine</td>
<td>0.598</td>
<td>0.041</td>
</tr>
<tr>
<td></td>
<td>Age 6-18 * Creatinine</td>
<td>-0.165</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>Age 61+ * Creatinine</td>
<td>-0.066</td>
<td>0.57</td>
</tr>
<tr>
<td></td>
<td>Age 1-5 * Spec. Grav.</td>
<td>-0.104</td>
<td>0.58</td>
</tr>
<tr>
<td></td>
<td>Age 6-18 * Spec. Grav.</td>
<td>0.148</td>
<td>0.095</td>
</tr>
<tr>
<td></td>
<td>Age 61+ * Spec. Grav.</td>
<td>0.253</td>
<td>0.043</td>
</tr>
<tr>
<td></td>
<td>Age 1-5 * Ln(Weight)</td>
<td>-0.267</td>
<td>0.49</td>
</tr>
<tr>
<td></td>
<td>Age 6-18 * Ln(Weight)</td>
<td>-0.177</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Age 61+ * Ln(Weight)</td>
<td>-0.445</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Sex * Creatinine</td>
<td>-0.129</td>
<td>0.019</td>
</tr>
<tr>
<td></td>
<td>Sex * Specific Gravity</td>
<td>0.070</td>
<td>0.29</td>
</tr>
</tbody>
</table>

| Age 1-5 | Intercept                       | -1.234      | <0.0001 |
|         | Creatinine                      | 0.874       | 0.003   |
|         | Specific Gravity                | 0.117       | 0.49    |
|         | Ln(Weight)                      | -0.468      | 0.16    |
|         | Sex                             | -0.313      | 0.048   |
|         | Race                            | 0.067       | 0.72    |
|         | Household Smoking               | 0.335       | 0.096   |

| Age 6-18 | Intercept                       | -1.313      | <0.0001 |
|          | Creatinine                      | 0.136       | 0.0024  |
|          | Specific Gravity                | 0.350       | <0.0001 |
|          | Ln(Weight)                      | -0.376      | 0.0001  |
|          | Sex                             | -0.030      | 0.69    |
|          | Race                            | -0.091      | 0.24    |
|          | Household Smoking               | -0.002      | 0.98    |
|          | Chromium Supplement Intake      | 1.04        | 0.20    |
|          | Hobby/Job                       | 0.059       | 0.82    |

*Continued next page*
Table 4-9, Continued

<table>
<thead>
<tr>
<th>Model</th>
<th>Variable</th>
<th>Coefficient</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 19-60</td>
<td>Intercept</td>
<td>-1.529</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.269</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.234</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.141</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.167</td>
<td>0.0005</td>
</tr>
<tr>
<td></td>
<td>Race</td>
<td>0.001</td>
<td>0.99</td>
</tr>
<tr>
<td></td>
<td>Household Smoking</td>
<td>0.112</td>
<td>0.035</td>
</tr>
<tr>
<td></td>
<td>Chromium Supplement Intake</td>
<td>-0.116</td>
<td>0.49</td>
</tr>
<tr>
<td></td>
<td>Hobby/Job</td>
<td>0.204</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>0.256</td>
<td>0.009</td>
</tr>
<tr>
<td></td>
<td>History of Cancer</td>
<td>0.122</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>Beer Drinking</td>
<td>0.016</td>
<td>0.78</td>
</tr>
<tr>
<td>Age 61+</td>
<td>Intercept</td>
<td>-1.440</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.184</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.536</td>
<td>0.0001</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.412</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.252</td>
<td>0.044</td>
</tr>
<tr>
<td></td>
<td>Race</td>
<td>0.023</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Household Smoking</td>
<td>0.118</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>Chromium Supplement Intake</td>
<td>0.323</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>Hobby/Job</td>
<td>0.060</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>-0.028</td>
<td>0.87</td>
</tr>
<tr>
<td></td>
<td>History of Cancer</td>
<td>0.303</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>Beer Drinking</td>
<td>0.630</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Variable definitions:

Creatinine: in grams per liter of urine, centered at: Overall, 1.20 g/l; Age 1-5, 0.50 g/l; Age 6-18, 1.46 g/l; Age 19-60, 1.21 g/l; Age 61+, 0.99 g/l
Specific gravity: centered at: Overall, 1.022; Age 1-5, 1.022; Age 6-18, 1.025; Age 19-60, 1.021; Age 61+, 1.019
Ln(Weight): natural logarithm of weight in pounds, centered at: Overall, 159 lbs; Age 1-5, 36 lbs; Age 6-18, 95 lbs; Age 19-60, 171 lbs; Age 61+, 171 lbs
Sex: 1 if male, 0 if female
Race: 1 if white, 0 if not white
Age 1-5: 1 if age < 6, 0 if not; Age 6-18: 1 if age 6 to 18, 0 if not; Age 61+: 1 if age > 60, 0 if not
Diabetes: 1 if self-reported diabetes, 0 if not or unknown
History of cancer: 1 if self-reported history of cancer, 0 if not
Household smoking: 1 if less than 10 cigarettes smoked in house per day, 0 if 10 or more
Chromium supplement intake: 1 if intake of supplement containing more than 30 micrograms of chromium in past 48 hours, 0 if not or unknown
Hobby/job: 1 if reported hobbies or jobs involving pressure-treated wood, boilers, refrigeration equipment, welding, metal working, fabric dyes, tanning leather, cement, plating, ceramics, laboratory chemicals or glass making in past 48 hours, 0 if not or unknown
Beer drinking: 1 if intake of 2 or more bottles in past 48 hours, 0 if not or unknown

Intercept: natural logarithm of mean urine chromium concentration when all model variables equal 0
Table 4-10b. Distribution of Adjusted Urine Chromium Concentration (µg/l), Overall and by Age Group

**Group: Residents of Targeted Areas** (including 28 individuals who also worked in a targeted workplace but excluding those who were affiliated with the Regional Day School)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Arith</td>
<td>Trim</td>
<td>Geom</td>
<td>X50</td>
<td>X60</td>
<td>X75</td>
<td>X90</td>
</tr>
<tr>
<td>All</td>
<td>806</td>
<td>0.50</td>
<td>0.27</td>
<td>0.23@</td>
<td>0.21</td>
<td>0.26</td>
<td>0.39</td>
<td>0.66</td>
</tr>
<tr>
<td>1 - 5</td>
<td>52</td>
<td>0.41</td>
<td>0.38</td>
<td>0.33*</td>
<td>0.36</td>
<td>0.45</td>
<td>0.52</td>
<td>0.66</td>
</tr>
<tr>
<td>6 - 18</td>
<td>182</td>
<td>0.40</td>
<td>0.32</td>
<td>0.27</td>
<td>0.27</td>
<td>0.34</td>
<td>0.51</td>
<td>0.71</td>
</tr>
<tr>
<td>19 - 60</td>
<td>465</td>
<td>0.34</td>
<td>0.26</td>
<td>0.22@</td>
<td>0.19</td>
<td>0.23</td>
<td>0.35</td>
<td>0.66</td>
</tr>
<tr>
<td>61 +</td>
<td>107</td>
<td>1.55</td>
<td>0.28</td>
<td>0.25</td>
<td>0.21</td>
<td>0.24</td>
<td>0.43</td>
<td>0.69</td>
</tr>
</tbody>
</table>

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

# 0.1 > p ≥ 0.05
* 0.05 > p ≥ 0.005
@ p < 0.005
Table 4-10c. Distribution of Adjusted Urine Chromium Concentration (µg/l), Overall and by Age Group

Group: Screened, Not Resident in but Associated with Targeted Residential Area+

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean Arith</th>
<th>Mean Trim</th>
<th>Mean Geom</th>
<th>Empirical Percentile X50</th>
<th>X60</th>
<th>X75</th>
<th>X90</th>
<th>X95</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>223</td>
<td>0.39</td>
<td>0.25</td>
<td>0.22*</td>
<td>0.20</td>
<td>0.24</td>
<td>0.34</td>
<td>0.57</td>
<td>0.97</td>
</tr>
<tr>
<td>1 - 5</td>
<td>12</td>
<td>0.48</td>
<td>0.40</td>
<td>0.33#</td>
<td>0.25</td>
<td>0.29</td>
<td>0.54</td>
<td>0.77</td>
<td>2.21</td>
</tr>
<tr>
<td>6 - 18</td>
<td>35</td>
<td>0.27</td>
<td>0.24</td>
<td>0.21</td>
<td>0.22</td>
<td>0.26</td>
<td>0.36</td>
<td>0.47</td>
<td>0.80</td>
</tr>
<tr>
<td>19 - 60</td>
<td>147</td>
<td>0.41</td>
<td>0.25</td>
<td>0.22*</td>
<td>0.20</td>
<td>0.25</td>
<td>0.36</td>
<td>0.57</td>
<td>1.11</td>
</tr>
<tr>
<td>61+</td>
<td>29</td>
<td>0.42</td>
<td>0.26</td>
<td>0.24</td>
<td>0.21</td>
<td>0.24</td>
<td>0.35</td>
<td>0.77</td>
<td>0.99</td>
</tr>
</tbody>
</table>

+ Includes screened persons who lived within a block of the edge of a targeted residential area, those whose workplace was within a targeted residential area, and those whose former residence (within six months) was within a targeted area.

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

# \( 0.1 > p \geq 0.05 \)
* \( 0.05 > p \geq 0.005 \)
@ \( p < 0.005 \)
Table 4-10d. Distribution of Adjusted Urine Chromium Concentration (μg/l), Overall and by Age Group

**Group: Workers at Targeted Workplaces** (including 28 individuals who also lived in a targeted residential area)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean Arith</th>
<th>Mean Trim</th>
<th>Mean Geom</th>
<th>Empirical Percentile X50</th>
<th>X60</th>
<th>X75</th>
<th>X90</th>
<th>X95</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>934</td>
<td>0.39</td>
<td>0.26</td>
<td>0.22@</td>
<td>0.19</td>
<td>0.23</td>
<td>0.35</td>
<td>0.63</td>
<td>1.02</td>
</tr>
<tr>
<td>19 - 60</td>
<td>874</td>
<td>0.39</td>
<td>0.25</td>
<td>0.22@</td>
<td>0.19</td>
<td>0.23</td>
<td>0.35</td>
<td>0.62</td>
<td>1.09</td>
</tr>
<tr>
<td>61 +</td>
<td>57</td>
<td>0.26</td>
<td>0.23</td>
<td>0.20</td>
<td>0.19</td>
<td>0.21</td>
<td>0.32</td>
<td>0.46</td>
<td>1.07</td>
</tr>
</tbody>
</table>

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

- # 0.1 > p ≥ 0.05
- * 0.05 > p ≥ 0.005
- @ p < 0.005
Table 4-10e. Distribution of Adjusted Urine Chromium Concentration (µg/l), Overall and by Age Group

Group: Lived in Targeted Residential Area and Worked at Targeted Workplaces

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Arith</td>
<td>Trim</td>
<td>Geom</td>
<td>X50</td>
<td>X60</td>
<td>X75</td>
<td>X90</td>
</tr>
<tr>
<td>All</td>
<td>28</td>
<td>0.41</td>
<td>0.32</td>
<td>0.23</td>
<td>0.18</td>
<td>0.20</td>
<td>0.41</td>
<td>1.28</td>
</tr>
<tr>
<td>19 - 60</td>
<td>28</td>
<td>0.40</td>
<td>0.31</td>
<td>0.22</td>
<td>0.18</td>
<td>0.19</td>
<td>0.40</td>
<td>1.29</td>
</tr>
</tbody>
</table>

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

- # $0.1 > p \geq 0.05$
- * $0.05 > p \geq 0.005$
- @ $p < 0.005$
Table 4-10f. Distribution of Adjusted Urine Chromium Concentration (μg/l), Overall and by Age Group

**Group: Regional Day School**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean</th>
<th>Empirical Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Arith</td>
<td>Trim</td>
</tr>
<tr>
<td>All+</td>
<td>101</td>
<td>0.51</td>
<td>0.42</td>
</tr>
<tr>
<td>6 - 18</td>
<td>46</td>
<td>0.71</td>
<td>0.64</td>
</tr>
<tr>
<td>19 - 60</td>
<td>47</td>
<td>0.45</td>
<td>0.34</td>
</tr>
</tbody>
</table>

+ Includes 2 males and 1 female age 1-5, and 1 male and 4 females age 61+

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

- # $0.1 > p \geq 0.05$
- * $0.05 > p \geq 0.005$
- @ $p < 0.005$
Table 4-10g. Distribution of Adjusted Urine Chromium Concentration (µg/l), Overall and by Age Group

Group: Screened But Not Identified with a Targeted Residential Area or Workplace

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean Arith</th>
<th>Mean Trim</th>
<th>Mean Geom</th>
<th>Empirical Percentile X50</th>
<th>Empirical Percentile X60</th>
<th>Empirical Percentile X75</th>
<th>Empirical Percentile X90</th>
<th>Empirical Percentile X95</th>
</tr>
</thead>
<tbody>
<tr>
<td>All+</td>
<td>177</td>
<td>0.54</td>
<td>0.25</td>
<td>0.22*</td>
<td>0.20</td>
<td>0.23</td>
<td>0.35</td>
<td>0.64</td>
<td>0.84</td>
</tr>
<tr>
<td>6 - 18</td>
<td>33</td>
<td>0.36</td>
<td>0.33</td>
<td>0.27</td>
<td>0.26</td>
<td>0.38</td>
<td>0.48</td>
<td>0.72</td>
<td>1.00</td>
</tr>
<tr>
<td>19 - 60</td>
<td>115</td>
<td>0.29</td>
<td>0.23</td>
<td>0.20#</td>
<td>0.17</td>
<td>0.20</td>
<td>0.28</td>
<td>0.53</td>
<td>0.78</td>
</tr>
<tr>
<td>61+</td>
<td>25</td>
<td>1.07</td>
<td>0.32</td>
<td>0.30</td>
<td>0.23</td>
<td>0.25</td>
<td>0.40</td>
<td>0.85</td>
<td>0.88</td>
</tr>
</tbody>
</table>

+ Includes 4 individuals age 1-5

Note on adjustment: Each participant urine chromium concentration was adjusted in two ways: 1) to median and standard values of the entire combined screened and baseline populations, and reported in the "All" line in the table, and 2) to the appropriate age group-specific median and standard values of the combined screened and baseline populations, and reported in the other rows of the table. See Table 4-9 for details.

#, *, @: The following symbols indicate probabilities that chance alone is responsible for the difference in the geometric mean compared to the baseline group:

# 0.1 > p ≥ 0.05
* 0.05 > p ≥ 0.005
@ p < 0.005
Table 4-11. Screening Physical Examination Referral Proportions by Age Group, Sex and Target Screening Group

<table>
<thead>
<tr>
<th>Population</th>
<th>Number of Participants</th>
<th>Number (%) Referred</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 5</td>
<td>72</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>6 - 10</td>
<td>137</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>11 - 18</td>
<td>157</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>19 - 40</td>
<td>840</td>
<td>20 (2.4)</td>
</tr>
<tr>
<td>41 - 60</td>
<td>777</td>
<td>18 (2.3)</td>
</tr>
<tr>
<td>61 +</td>
<td>222</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>944</td>
<td>13 (1.4)</td>
</tr>
<tr>
<td>Male</td>
<td>1,261</td>
<td>31 (2.5)</td>
</tr>
<tr>
<td><strong>Target Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residents</td>
<td>800*</td>
<td>14 (1.8)</td>
</tr>
<tr>
<td>Associates</td>
<td>221</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Workers</td>
<td>938*</td>
<td>18 (1.9)</td>
</tr>
<tr>
<td>Non-Targeted</td>
<td>174</td>
<td>6 (3.4)</td>
</tr>
<tr>
<td>RDS</td>
<td>101</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,205</td>
<td>44 (2.0)</td>
</tr>
</tbody>
</table>

* Includes 29 individuals who both lived and worked in a targeted area, none of whom were referred on the basis of the screening physical examination.
Table 4-12. Screening Physical Examination Referral Proportions by Physician and Institution

<table>
<thead>
<tr>
<th>Institution/Physician</th>
<th>Number of Examinations</th>
<th>Number (%) Referred</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EOHCC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>359</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>B</td>
<td>90</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>C</td>
<td>117</td>
<td>6 (5.1)</td>
</tr>
<tr>
<td>D</td>
<td>193</td>
<td>8 (4.2)</td>
</tr>
<tr>
<td>Sub-total</td>
<td>759</td>
<td>16 (2.1)</td>
</tr>
<tr>
<td><strong>JCMC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>315</td>
<td>14 (4.4)</td>
</tr>
<tr>
<td>F</td>
<td>457</td>
<td>7 (1.5)</td>
</tr>
<tr>
<td>G</td>
<td>673</td>
<td>6 (0.9)</td>
</tr>
<tr>
<td>Sub-total*</td>
<td>1,446</td>
<td>28 (1.9)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,205</td>
<td>44 (2.0)</td>
</tr>
</tbody>
</table>

* Includes one examination and referral by an eighth physician.
<table>
<thead>
<tr>
<th>Model</th>
<th>Variable</th>
<th>Coefficient</th>
<th>Average Increase</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 1-5</td>
<td>Intercept</td>
<td>-1.556</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.890</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.546</td>
<td></td>
<td>0.092</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.348</td>
<td></td>
<td>0.026</td>
</tr>
<tr>
<td></td>
<td>Household Smoking</td>
<td>0.438</td>
<td></td>
<td>0.029</td>
</tr>
<tr>
<td></td>
<td>Resident in Targeted Area</td>
<td>0.455</td>
<td>0.12</td>
<td>0.023</td>
</tr>
<tr>
<td></td>
<td>Associated with Residential Area</td>
<td>0.449</td>
<td>0.12</td>
<td>0.094</td>
</tr>
<tr>
<td></td>
<td>Non-Targeted Group</td>
<td>-0.191</td>
<td>-0.04</td>
<td>0.63</td>
</tr>
<tr>
<td>Age 6-18</td>
<td>Intercept</td>
<td>-1.528</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.223</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.275</td>
<td></td>
<td>0.0004</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.320</td>
<td></td>
<td>0.0006</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.103</td>
<td></td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Chromium Supplement Intake</td>
<td>1.10</td>
<td></td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Resident in Targeted Area</td>
<td>0.217</td>
<td>0.05</td>
<td>0.011</td>
</tr>
<tr>
<td></td>
<td>Associated with Residential Area</td>
<td>0.001</td>
<td>0.00</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>Work in Targeted Workplace</td>
<td>0.735</td>
<td>0.24</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Non-Targeted Group</td>
<td>0.257</td>
<td>0.06</td>
<td>0.86</td>
</tr>
<tr>
<td>Age 19-60</td>
<td>Intercept</td>
<td>-1.712</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.269</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.224</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.136</td>
<td></td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.171</td>
<td></td>
<td>0.0007</td>
</tr>
<tr>
<td></td>
<td>Household Smoking</td>
<td>0.116</td>
<td></td>
<td>0.029</td>
</tr>
<tr>
<td></td>
<td>Hobby/Job</td>
<td>0.209</td>
<td></td>
<td>0.0008</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>0.267</td>
<td></td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>Resident in Targeted Area</td>
<td>0.182</td>
<td>0.04</td>
<td>0.046</td>
</tr>
<tr>
<td></td>
<td>Associated with Residential Area</td>
<td>0.205</td>
<td>0.04</td>
<td>0.067</td>
</tr>
<tr>
<td></td>
<td>Work in Targeted Workplace</td>
<td>0.192</td>
<td>0.04</td>
<td>0.036</td>
</tr>
<tr>
<td></td>
<td>Non-Targeted Group</td>
<td>0.114</td>
<td>0.02</td>
<td>0.33</td>
</tr>
<tr>
<td>Age 61+</td>
<td>Intercept</td>
<td>-1.453</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Creatinine</td>
<td>0.163</td>
<td></td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Specific Gravity</td>
<td>0.551</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Ln(Weight)</td>
<td>-0.366</td>
<td></td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>-0.196</td>
<td></td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Chromium Supplement Intake</td>
<td>0.344</td>
<td></td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>History of Cancer</td>
<td>0.316</td>
<td></td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Beer Drinking</td>
<td>0.660</td>
<td></td>
<td>0.008</td>
</tr>
<tr>
<td></td>
<td>Resident in Targeted Area</td>
<td>0.064</td>
<td>0.02</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Associated with Residential Area</td>
<td>0.042</td>
<td>0.01</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>Work in Targeted Workplace</td>
<td>-0.175</td>
<td>-0.04</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>Non-Targeted Group</td>
<td>0.238</td>
<td>0.06</td>
<td>0.32</td>
</tr>
</tbody>
</table>

*Continued next page*
Table 4-13, continued

* Increase relative to average urine chromium in baseline group, as estimated by the model intercepts.

Note: Dependent variable for all models is the natural logarithm of the urine chromium concentration. Models were constructed by stepwise inclusion of site-related variables, followed by measures of diluteness and demographic characteristics, and followed by other potential confounders. After examination of interaction between site variables and other factors, models were simplified.

The proportion of the variation in urine chromium explained by each model is:

- Age 1 - 5: \( r^2 = 0.38 \)
- Age 6 - 18: \( r^2 = 0.19 \)
- Age 19 - 60: \( r^2 = 0.17 \)
- Age 61+: \( r^2 = 0.25 \)

Variable definitions:

- **Resident in targeted area**: 1 if "resident", 0 if not (see section 3.1.2)
- **Associated with residential area**: 1 if "associate", 0 if not (see section 3.1.2)
- **Work in targeted workplace**: 1 if "worker", 0 if not (see section 3.1.2)
- **Non-targeted group**: 1 if "non-targeted", 0 if not (see section 3.1.2)
- **Creatinine**: in grams per liter of urine, centered at: Age 1-5, 0.50 g/l; Age 6-18, 1.46 g/l; Age 19-60, 1.21 g/l; Age 61+, 0.99 g/l
- **Specific gravity**: centered at: Age 1-5, 1.022; Age 6-18, 1.025; Age 19-60, 1.021; Age 61+, 1.019
- **Ln(Weight)**: natural logarithm of weight in pounds, centered at: Age 1-5, 36 lbs; Age 6-18, 95 lbs; Age 19-60, 171 lbs; Age 61+, 171 lbs
- **Sex**: 1 if male, 0 if female
- **Diabetes**: 1 if self-reported diabetes, 0 if not or unknown
- **History of cancer**: 1 if self-reported history of cancer, 0 if not
- **Household smoking**: 1 if less than 10 cigarettes smoked in house per day, 0 if 10 or more
- **Chromium supplement intake**: 1 if intake of supplement containing more than 30 micrograms of chromium in past 48 hours, 0 if not or unknown
- **House sweeping**: 1 if swept, vacuumed or dusted inside the house in past 48 hours, 0 if not or unknown
- **Hobby/Job**: 1 if reported hobbies or jobs involving pressure-treated wood, boilers, refrigeration equipment, welding, metal working, fabric dyes, tanning leather, cement, plating, ceramics, laboratory chemicals or glass making in past 48 hours, 0 if not or unknown
- **Beer drinking**: 1 if intake of 2 or more bottles in past 48 hours, 0 if not or unknown

**Intercept**: natural logarithm of mean urine chromium concentration when all model variables equal 0
Table 4-14. Results of Regression Analyses of Worker Populations.

<table>
<thead>
<tr>
<th>Workplace (Number Screened)</th>
<th>Increase in Average Urine Chromium (µg/l)*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICI Americas (37)</td>
<td>0.36</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Cloroben/Standard Chlorine (29)</td>
<td>0.13</td>
<td>0.001</td>
</tr>
<tr>
<td>Trumbull Asphalt (15)</td>
<td>0.12</td>
<td>0.028</td>
</tr>
<tr>
<td>Airdock Systems (39)</td>
<td>0.06</td>
<td>0.032</td>
</tr>
<tr>
<td>Baldwin Steel (74)</td>
<td>0.05</td>
<td>0.014</td>
</tr>
<tr>
<td>Levy and Sons Warehouse (92)</td>
<td>0.05</td>
<td>0.014</td>
</tr>
</tbody>
</table>

* Increase relative to average urine chromium of 0.19 µg/l. This level represents the average concentration of all other "workers" standardized to median values of measures of diluteness and weight, and adjusted for sex and exercise.
Figure 3-1. Jersey City Residential Areas
Targeted for Chromium Screening

KEY to MAPS
(Appendix A)
1 Dwight Street Area
2 Lafayette Area
3 Grand Street Area
4 Metro Field & Fisk St. Areas
5 Communipaw (#24) Area
6 Cambridge Area
7 Brannham & Communipaw (#23) Areas
8 Kearney Avenue Area
9 Ninth St. Area

New Jersey Department of Health
Environmental Health Service

Miles
0 0.5 1
Figure 3-2. Bayonne Residential Areas
Targeted for Chromium Screening

KEY to MAPS
(Appendix A)

11 Isabella Ave. Area
12 East 52nd St. Area
13 Sunset Ave. Area

New Jersey Department of Health
Environmental Health Service
Figure 4-1. Unadjusted Urine Chromium Concentration by Screening Group

Urine Chromium (ug/l)

0.3

0.25

0.2

0.15

BASE (315) RES (806) ASSOC (223) WORK (934) NON (177)

1 95% CI * Geo. Mean

"Base" = Baseline; "Res" = Residents; "Assoc" = Associates; "Work" = Workers; "Non" = Non-targeted
See text section 4.2.1 for definitions
Figure 4-2. Distribution of Adjusted Urine Chromium by Screened Group

Percent

Scaled Urine Chromium (ug/l)

Non-Targeted (n=177)
Workers (n=934)
Associates (n=223)
Residents (n=806)
Baseline (n=315)

Only portions of distributions above 0.19 are shown.
Figure 4-3. Adjusted Urine Chromium Concentration by Screening Group

Urine Chromium (μg/l)

95% CI * Geo. Mean

Screening Group (N)

BASE (315) RES (806) ASSOC (223) WORK (934) NON (177)

"Base" = Baseline; "Res" = Residents; "Assoc" = Associates; "Work" = Workers; "Non" = Non-targeted

See text section 4.2.1 for definitions
Figure 4-4. Number of Persons Screened by Quarter

Figure 4-5. Results of Screening Evaluations

Physical Examination

No Findings
2,161

Referred
44

Urine Chromium Test

Less than Action Level
1,990

Referred
223
Figure 4-6. Quantile-Quantile Plot: Adjusted Urine Chromium Concentrations by Screening Group

Urine Chromium (ug/l): Target Group Distributions

- RESIDENTS (n=806)
- ASSOCIATES (n=223)
- WORKERS (n=934)
- NON-TARGETED (n=177)

Urine Chromium (ug/l): Baseline Group Distribution (n=315)

Quantiles plotted: 50, 55, 60, 65, 70, 75, 80, 85, 90, 92.5, 95, 97.5
Dashed line is line of equivalence to baseline distribution
Figure 4-7. Adjusted Urine Chromium Concentrations by Age and Screening Group

Urine Chromium (ug/l)

Age 1-5
Age 6-18
Age 19-60
Age 61 +

Base (18) Res (12) Assoc (35) Non (6)
Base (195) Res (147) Assoc (115) Non (115)
Base (60) Res (41) Assoc (115) Work (94) Non (21)
Base (39) Res (157) Assoc (71) Work (71) Non (21)

95% CI  * Geo. Mean

"Base"=Baseline; "Res"=Residents; "Assoc"=Associates; "Work"=Workers; "Non"=Non-targeted
See text section 4.2.1 for definitions
Figure 4-8a. Quantile-Quantile Plot: Adjusted Urine Chromium Concentrations by Screening Group
Age 1 - 5

Urine Chromium (ug/l): Target Group Distributions
- □ RESIDENTS (n=52)
- △ ASSOCIATES (n=12)

Urine Chromium (ug/l): Baseline Group Distribution (n=18)

Quantiles plotted: 50, 55, 60, 65, 70, 75, 80, 85, 90, 92.5; 95, 97.5 for residents vs baseline only
Dashed line is line of equivalence to baseline distribution
Figure 4-8b. Quantile-Quantile Plot: Adjusted Urine Chromium Concentrations by Screening Group Age 6 - 18

Urine Chromium (μg/l): Target Group Distributions

- RESIDENTS (n=182)
- ASSOCIATES (n=35)
- NON-TARGETED (n=33)

Urine Chromium (μg/l): Baseline Group Distribution (n=193)

Quantiles plotted: 50, 55, 60, 65, 70, 75, 80, 85, 90, 92.5, 95, 97.5
Dashed line is line of equivalence to baseline distribution
Figure 4-8c. Quantile-Quantile Plot: Adjusted Urine Chromium Concentrations by Screening Group
Age 19 - 60

Urine Chromium (ug/l): Target Group Distributions

- RESIDENTS (n=465)
- ASSOCIATES (n=147)
- WORKERS (n=874)
- NON-TARGETED (n=115)

Quantiles plotted: 50, 55, 60, 65, 70, 75, 80, 85, 90, 92.5, 95, 97.5

Dashed line is line of equivalence to baseline distribution
Figure 4-8d. Quantile-Quantile Plot: Adjusted Urine Chromium Concentrations by Screening Group Age 61 +

Urine Chromium (ug/l): Target Group Distributions

- RESIDENTS (n=107)
- ASSOCIATES (n=29)
- WORKERS (n=57)
- NON-TARGETED (n=25)

Quantiles plotted: 50, 55, 60, 65, 70, 75, 80, 85, 90, 92.5, 95
Dashed line is line of equivalence to baseline distribution
Figure 4-9. Results of Follow-up Medical Evaluations

Evaluation Status

- No Response: 35
- Refused: 21
- Deceased: 1
- Appt. not Kept: 25

Chromium-Related Illness

- Ruled Out: 178
- Examined: 184
- Possible: 6
ACKNOWLEDGMENTS

The Chromium Medical Surveillance Project (CMSP) could not have been accomplished without the outstanding cooperation of numerous dedicated individuals in state agencies, the University of Medicine and Dentistry of New Jersey (UMDNJ), and the Jersey City Medical Center (JCMC). The project could not have been initiated or completed without the cooperation of the citizens and local officials of Jersey City, Bayonne and Kearny, and of the numerous employers and employees at workplaces near chromium waste sites.

Staff of the Environmental Health Services (EHS) of the New Jersey Department of Health (NJDOH) designed the project and oversaw all project operations. The staff named below worked with exceptional teamwork and mutual support to accomplish their assigned duties:

Patricia Haltmeier coordinated office operations, mobile medical van screening operations, and outreach to workplace populations.

Jacqueline Solomon joined the project in June 1992, oversaw the operations of the JCMC Chromium Clinic, and coordinated outreach to residential populations.

Jonathan Savrin joined the project in June 1992, provided technical consultation and data analyses during the project, and conducted data analyses for the preparation of the final report.

Ronald Polakowski managed project contracts and agreements and provided other administrative support throughout the project.

Hope Perry joined the project in October 1992 and performed data entry, maintained medical files, and provided clerical support.

Jeanette Corbin performed data entry, maintained the medical records files, and provided other clerical support through October 1992.

William Coniglio provided technical consultation in the development of project design, protocols and procedures, through June 1992.

Barbara Guidici coordinated baseline survey operations and clinic personnel training, through January 1992.

Miguel Vidal and Marc Green conducted the residential community outreach and assisted in the JCMC Chromium Clinic screening operations. Audrey Brown coordinated the JCMC Chromium Clinic operations, under the guidance of first Morris Jones and later Joan Dublin.

Dr. Michelle Reisner, Dr. Jayminkumar Patel, and Dr. Scott Chae comprised the capable and dedicated physician team at JCMC who conducted over 1,000 screening evaluations. Dr. Wanda Moody, Dr. Peter Nigro, Dr. James Craner, and Dr. Patrick Joyce of the Environmental and Occupational Health Clinical Center (EOHCC) of UMDNJ also conducted over 1,000 screening evaluations through the mobile medical van.

EOHCC responsibilities were overseen by Dr. Michael Gochfeld. Dr. Iris Udasin and Dr. Gochfeld developed the follow-up medical evaluation protocol. Dr. Udasin coordinated the follow-up medical evaluations and communicated results to the participants. Dr. Lynn Bickley performed dermatologic consultations. Gail Buckler, Judy Gilman, Eileen Birabam and Roberta Philip provided EOHCC clinical and administrative support.

The NJDOH Laboratory developed a unique capacity to perform the high volume of sensitive urine chromium analyses required by the CMSP. Under the direction of Stephen Jenniss and Joseph Wallin, the chromium analyses were developed by Jim Schieferstein and the late William Sauer, and conducted by Mr.
Schieferstein, Kate Maloney, and Khalid Mir. Creatinine and specific gravity analyses were conducted by Nancy Mann, Bill Lawson, and Dr. Addison Rosenkrans. Emma Coefer and Wayne Lecato coordinated sample receipt, Joe Mierzwicki performed quality assurance, and Michael Nuzzo provided data management support.

Dr. Marilyn Howarth and Dr. Marcia Goldoft, formerly of the NJDOH, participated in the development of the screening project design. Dr. Howarth prepared the screening physical examination protocol and training materials for screening physicians.

McCabe Ambulance Services of Bayonne provided transportation from Hudson County to the EOHCC in Piscataway for follow-up medical evaluation participants. John McConnell and Lou Sample of the state Department of Transportation ensured the safe storage and maintenance of the mobile medical van, and Mr. McConnell drove the mobile medical van to workplace and residential area screenings. Leprechaun Truck Repair, Inc. of Jersey City provided cleaning services for the van.

Dr. Judith Klotz and Michael Berry of the EHS provided internal technical review. Dr. Irva Hertz-Picciotto of the University of North Carolina School of Public Health, Dr. Richard Clapp of Boston University School of Public Health, Dr. Ginger Gist of the federal Agency for Toxic Substances and Disease Registry, and Dr. James Melius of the New York State Department of Health provided expert external technical review of the final report draft.

The project was conducted under the leadership of the following individuals in NJDOH: Deputy Commissioner Dr. Leah Z. Ziskin, former Deputy Commissioner Dr. Thomas A. Burke, former Assistant Commissioner Dr. Rebecca T. Parkin, Assistant Commissioner Dr. William E. Parkin, EHS Director James A. Brownlee, and former EHS Acting Director Diana Kiel.

The NJDEP Spill Compensation Fund provided funding for the screening project. The following staff of NJDEP provided important support and advice: Thomas McKee, Frank Faranca, Ron Corcory, Dr. Alan Stern, and Dr. Bob Hazen. Deputy Attorneys General Mike Schuit and Charles Licata provided important legal advice throughout the conduct of the screening project.
CHROMIUM MEDICAL SURVEILLANCE PROJECT

FINAL TECHNICAL REPORT

APPENDICES

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APPENDIX B: Protocols, Procedures and Instruments
APPENDIX C: Comparison of Uribe Chromium Decision-making Methods

Environmental Health Services
Division of Epidemiology, Environmental and Occupational Health Services

New Jersey Department of Health

October 1994
APPENDIX A

Site List and Maps

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# APPENDIX A1

## LIST OF KNOWN CHROMIUM WASTE SITES

The following is a list of known chromium waste sites, according to records of the New Jersey Department of Environmental Protection (NJDEP). Temporary or permanent remedial actions have taken place at many of these sites, and some are no longer considered "active" by NJDEP.

<table>
<thead>
<tr>
<th>NJDEP SITE #</th>
<th>SITE NAME</th>
<th>SITE LOCATION</th>
<th>CITY</th>
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<td>Caven Point 4</td>
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<td>E Interceptor 2</td>
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<td>EINTerceptor 3</td>
<td>Near Secaucus Road</td>
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<td>Trader Horn</td>
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<td>Exxon Company, U.S.A. Bayonne Plant</td>
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<td>Rudolf Bass, Inc.</td>
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Note: Sites 180 through 193, the most recent additions to the list, are not mapped in Appendices A2 or A3.
APPENDIX A@

OVERVIEW CHROMIUM WASTE SITE MAPS

A – 5
Chromium Waste Sites
Jersey City and Vicinity

NOTES
1) Site locations are approximate.

2) Interim or permanent remedial measures have been completed at most sites. Contact NJDEP for current site status.

New Jersey Department of Health
Environmental Health Services

Miles
0 0.5 1
Chromium Waste Sites
Kearny and Vicinity

NOTES
1) Site locations are approximate.
2) Interim or permanent remedial measures have been completed at most sites. Contact NJDEPE for current site status.
Chromium Waste Sites
Bayonne and Vicinity

NOTES
1) Site locations are approximate.

2) Interim or permanent remedial measures have been completed at most sites. Contact NJDEPE for current site status.
APPENDIX A3

MAPS OF RESIDENTIAL SITE AREAS

A-11
Jersey City Residential Areas - Chromium Sites

Map 1: Dwight Street Area
Jersey City Residential Areas - Chromium Sites

Map 2: Lafayette Area

Highways
Railroads
Roads
Sites

Site locations are approximate

Area eligible for screening evaluations

New Jersey Department of Health
Environmental Health Service

Miles
0 0.1 0.2
Jersey City Residential Areas - Chromium Sites

Map 4: Metro Field & Fisk Street Areas

- Highways
- Railroads
- Roads
- Sites

Site locations are approximate

Area eligible for screening evaluations

New Jersey Department of Health
Environmental Health Service

Miles

0 0.1 0.2
Jersey City Residential Areas - Chromium Sites

Map 5: Communipaw #24 Area

Site location is approximate

Area eligible for screening evaluations

New Jersey Department of Health
Environmental Health Service

Miles
0 0.05 0.1
Jersey City Residential Areas - Chromium Sites

Map 7: Bramhall Area & Communipaw #23 Area

- Highways
- Railroads
- Roads
- Sites

Site locations are approximate

Area eligible for screening and evaluations

New Jersey Department of Health
Environmental Health Service

Miles
0 0.05 0.1
# APPENDIX B

Protocols, Procedures and Instruments

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APPENDIX B1

PROTOCOL: SCREENING EXAMINATION AND REFERRAL CRITERIA
CHROMIUM MEDICAL SURVEILLANCE PROJECT

Summary

In order to carry out its public health mission, the New Jersey Department of Health (NJDOH) plans to conduct an evaluation of residents who live on or near sites contaminated by chromium slag. The sites targeted have been identified by the Environmental Health Service and the Department of Environmental Protection as those with high levels of contamination and accessible routes of exposure. Exposure will be assessed by (1) asking residents questions that may identify factors important for exposure to chromium, (2) doing a physical examination limited to those areas affected by chromium (the skin and nasal septum), and (3) analyzing urine specimens for chromium exposure.

This protocol will address the first two of these only, since a separate protocol will be written to address the collection and analysis of urine chromium levels.

Objectives

1. To provide limited physical examinations to detect visible evidence of chromium exposure.
2. To identify patients who have evidence of chromium exposure and provide a system of medical referral.
3. To inform patients about chromium, its health risks and the value and limitations of screening.

Staffing

Physical examinations will be performed by physicians licensed by the State of New Jersey. If medical residents perform the screening physical examinations, an attending physician will be identified to oversee their activities.

Training

Based on NJDOH recommendations for curriculum content, The University of Medicine and Dentistry of New Jersey (UMDNJ) will provide training on the health effects of chromium exposure. All local physicians participating in the screening will receive prescribed training in its entirety prior to seeing patients.

The training sessions will include a series of three lectures: 1) The history of chromium exposure in Hudson County including information on the physical and chemical properties of
chromium as they relate to the scenario in Hudson County. 2) Signs and symptoms of chromium exposure including the long and short term risks of chromium exposure. 3) Limitations of the screening process including analysis of chromium in urine and sensitivity of physical examination findings. Avoidance techniques for reducing subsequent chromium exposure will be included as will specific information regarding the process of form completion and referrals for further evaluation.

**Interviews**

In addition to a questionnaire covering demographics, exposure and dietary information administered in most cases by someone other than the physician, a medical history directed to areas relevant to effects of chromium exposure should be taken by the physician and noted on the medical evaluation form. The content of the relevant medical history will include but need not be limited to: 1) a history of asthma 2) chronic unrelenting allergies 3) skin ulceration 4) chronic dermatitis 5) nasal ulceration 6) nasal septal perforation.

**Materials**

The following materials will be needed for the medical evaluations.

1. Oto-ophthalmoscope
2. Tongue depressor
3. Gown or drape
4. Physical examination forms
5. Consent form
6. Completed questionnaire

**Physical Examinations**

**General Considerations:** The most specific skin and mucosal effects to be associated with chromium exposure are described below. However, exposure may not produce the classic or textbook manifestations described. Therefore, any abnormalities of the skin or mucosa should be noted and described in full. Where possible, a sketch should accompany the written description.

**Nose and Throat Examinations:** Using a light source, the nasal mucosa will be examined looking for any lesions, particularly ulceration or perforation of the anterior nasal septum. In addition, the oral mucosa will be examined looking for ulcerations or tonsillar inflammation in particular. Referral for follow-up evaluation should be made whenever a patient is found to have ulceration of the nasal mucosa or perforation of the nasal septum. In the absence of physical findings in the nose, a history of nasal ulceration temporally related to chromium exposure (while living or working on a chromium site, but not preceding living or working on a chromium site) should prompt referral for follow-up evaluation.
Dermatologic Examinations: A thorough examination of the skin on all potentially exposed surfaces (arms, legs, hands, feet and upper torso) should be performed. Other areas are to be examined if the physician deems it appropriate from the medical history or if the patient requests it. Allergic contact dermatitis from chromium exposure is eczematous, often wide spread and persistent. A pattern resembling nummular eczema may be seen. There may be a marked dryness and lichenification resembling atopic dermatitis. The classic chrome ulcers are small, punched out lesions which are usually painless, heal slowly and leave scars. Referral for follow-up evaluation should be made whenever a patient is found to have a chrome ulcer or a scar for which the patient remembers the history of a prior painless ulcer at that location. Anyone with dermatitis which by history has been relentless or persistent and temporally related to chromium exposure should be referred for follow-up evaluation.

Summary of Conditions Leading to Referral for Further Evaluation

History alone: (These must be temporally related to chromium exposure)
1) chronic unrelenting allergies
2) asthma
3) chronic dermatitis

Physical findings:
1) skin ulceration
2) small round scar consistent with healed chrome ulcer with history of a prior painless ulcer at that site which is temporally related to chromium exposure
3) nasal ulceration
4) nasal septal perforation

Form Completion and Information Communication

Physicians will complete the medical evaluation form at the time that the patient is evaluated. The patient will receive both a verbal and written explanation (medical evaluation form copy) of the physical examination findings from the physician at the time of the visit. The physician will briefly describe the risks of chromium exposure, avoidance techniques and limitations of screening to each patient evaluated. The physician will attempt to answer any questions that the patient has regarding these issues at the time of the visit.

Confidentiality

The format and materials which will be used were approved by the IRB on December 26, 1989.

Informed consent will be obtained from all participants. Interviews will be conducted in a confidential manner. In situations where individual rooms for interviews and examinations are not available, partitions will be used to screen off an area from view. Every effort will be
made to insure that co-workers, management and neighbors are not able to hear the interview.

Participants will be notified in writing of the results of their screening physical examination at the time of the examination. For those who do not speak or read English, every attempt will be made to locate and use a translator for each part of the evaluation as well as to communicate results. No information about individuals will be released unless the Department of Health receives written approval from the individual. All medical information, including laboratory results, will be stored in a locked cabinet. In any reports released by the Department of Health regarding this study, only group summary data will be presented.
APPENDIX B2

PROCEDURE FOR OBTAINING URINE SAMPLES
CHROMIUM MEDICAL SURVEILLANCE PROJECT

A urine sample for chromium testing will be obtained from each participant. The sequence of steps for the proper collection, storage and delivery of urine samples is outlined below.

1. Consent forms are checked to verify written approval and to capture any missing information.

2. The participant is assigned a unique sample identification number.

3. The participant’s name and sample identification number are entered on his or her questionnaire and on the Screening Evaluation Log.

4. The participant is provided with an acid-washed urine specimen container.

5. The participant is instructed in the proper collection of the urine sample and directed to the lavatory. An adult will assist children when needed. Instructions are as follows:

   1. Wash your hands and rinse off the soap completely. Dry your hands with the paper towels provided.

   2. Take the lid off of the cup and place it on a safe surface. Do not touch the inside of the cup or the inside of the lid.

   3. Urinate (pass your water) into the cup. Try to fill the cup half way. It’s O.K. if you can’t fill it half way.

   4. Put the lid back on the cup being careful not to touch the inside of the cup or the lid.

   5. Give the cup to the person who gave you these instructions.

6. When the urine sample is obtained, it is returned along with the participant’s questionnaire to the staff person who assigns the sample identification number (SID) and labels the container with that number.

7. The number on the urine specimen is verified as the same number on the participant’s questionnaire; the date of urine collection is entered on that questionnaire.

8. The Request for Sample Analysis is completed to include the collection date, field number (participant’s sample identification number) and time of urine collection.
9. The urine specimen is placed in a zip-lock bag which is placed in an ice chest with ice.

10. The Screening Evaluation Log is completed to ensure that the urine specimen was received and that the corresponding sample identification number was entered on all forms.

11. The urine samples will be maintained on ice. A NJDOH staff person from the CMSP will assume custody of the samples. This sample custodian will deliver all samples and their corresponding laboratory forms to the sample receiving area of the NJDOH laboratory building in Trenton, New Jersey for transfer of custody.
APPENDIX B3

URINE ANALYSIS METHOD FOR CHROMIUM
CHROMIUM MEDICAL SURVEILLANCE PROJECT

CHROMIUM IN URINE (ATOMIC ABSORPTION, FURNACE METHOD)

1.0 SCOPE AND APPLICATION

1.1 This method applies to the analysis of urine samples for chromium.

1.2 The detection limit is approximately 0.1 ppb with the linear range extending to 6.0 ppb. Higher levels can be determined using dilutions.

2.0 SUMMARY OF METHOD

2.1 The sample is injected directly into the graphite furnace and analyzed using the method of standard additions. No pretreatment is used due to the probability of contaminating the sample when analyzing at these low levels.

3.0 INTERFERENCES

3.1 This method is designed to overcome the inherent interferences found in urine samples. A background correction system capable of operating at the wavelength required (357.9) is necessary. The choices are Zeeman, tungsten-halide continuum or Smith-Hieftje.

4.0 APPARATUS AND MATERIALS

4.1 A single- or dual-channel, single- or double-beam atomic absorption spectrometer having a grating monochromator, photomultiplier detector, adjustable slits, a wavelength range of 190 to 800 nm and provisions for interfacing with a printer, data system or strip chart recorder.

4.2 Furnace parameters:

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<td>5</td>
<td>2700</td>
<td>300</td>
</tr>
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</table>
4.2.6 Purge Gas: Argon
4.2.7 Injection size: 25 microliters

4.2.8 Pyrolytically coated graphite tubes must be used to prevent adsorption of chromium on the graphite surface.

4.3 Chromium hollow cathode lamp.

4.4 Autosampler capable of microliter level injections.

4.5 Graphite furnace capable of reaching the required temperatures.

4.6 A printer, data system or strip chart recorder to maintain a permanent record of the data and so that any problems with the analysis can be easily recognized.

4.7 Pressure-reducing valves to maintain the purge gas at the proper pressure for the instrument.

4.8 Glassware and other containers, including sample containers, shall be cleaned in a bath of 10% nitric acid then rinsed with tap water then distilled water.

5.0 REAGENTS

5.1 Double distilled water to be used for the preparation of all standards and as dilution water.

5.2 Concentrated nitric acid must be of the ultrapure variety to prevent contamination of the samples and standards.

5.3 Argon gas must be of high purity to exclude the possibility of oxygen being in the graphite furnace.

5.4 Stock chromium solution is bought as a certified standard and checked against the previous standard before use.

5.5 Calibration standards are prepared by diluting the stock solution prior to analysis.

6.0 SAMPLE COLLECTION, PRESERVATION AND HANDLING

6.1 Samples shall be collected in precleaned, plastic containers supplied by the laboratory. They will be kept cold until delivery to the laboratory where they will be frozen if not analyzed within 3 days. All samples should be treated as potential biohazards.
7.0 PROCEDURE

7.1 The sample is introduced into the graphite furnace without pretreatment and run using the method of standard additions. The addition levels are 0.0, 0.5, 1.0, and 2.0 ppb. The data obtained will be run through a computer program to calculate the concentration of the sample.

8.0 QUALITY CONTROL

8.1 A standard curve will be prepared by running standard additions on a blank and 4.0 ppb standard to check for proper instrument operation.

8.2 All samples will be run using the method of standard additions to alleviate the matrix and tube aging problems.

8.3 A control sample, purchased from an outside source or prepared in the laboratory, will be run with each batch of samples.

9.0 METHOD PERFORMANCE

9.1 This method was proven by this laboratory by repeated runs of donated urine to prove reproducibility and check tube life.

10.0 REFERENCES

APPENDIX B4

EXCERPTS OF LABORATORY
STANDARD OPERATING PROCEDURE MANUAL
CHROMIUM MEDICAL SURVEILLANCE PROJECT

The following excerpts are taken from the Standard Operating Procedures Manual of the Environmental and Chemical Laboratory Services, Public Health and Environmental Laboratories, New Jersey Department of Health. The manual was issued on January 1, 1987, and these excerpts are from the revised version of March 23, 1992.

CHAPTER 1
QUALITY ASSURANCE POLICY AND OBJECTIVES

A. Management Policy

It is the policy of the Division of Public Health and Environmental Laboratories to generate scientifically valid and defensible data. By adopting the standards of this manual, management is committed to supporting the staff of the Environmental and Chemical Laboratory Services (ECLS) in their endeavor to generate demonstrably valid data.

B. Data Quality Objectives

The goal of ECLS is to produce data that are complete, accurate, precise, and comparable. The objective of this manual is to document the procedures followed by ECLS in the generation of data and to establish minimum data quality standards which the resultant data will meet. Through the establishment of data quality standards and standardization of the laboratory’s operating procedures, it is ECLS’s objective to produce data that are accurate and precise, as well as comparable to data generated by other nationally recognized laboratories.

Management of the Division’s quality assurance program is the responsibility of the Office of Quality Assurance (OQA). To that end, OQA will:

1. Conduct systems audits to ensure that the standards and procedures of this manual are being met;

2. Test the laboratory’s analytical performance through the use of “blind” laboratory performance evaluation samples; and

3. Monitor the overall reliability of ECLS’s analytical results.

This total quality assurance program is designed to document acceptable performance, identify problems that may develop, initiate corrective action, and test the analytical system to verify its performance. The end result is the assurance of the integrity of all analytical results produced by ECLS.
CHAPTER III
SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES

A. Sample Requirements

...Table II lists [parameter groupings, volume of sample, preservation, and holding time requirements] for the non-aqueous matrices. Sample preservation is effected in the field at the time of sample collection...

...ECLS conducts...analyses on samples which do not have regulated requirements...In these instances, it is recommended that samples be collected in accordance with the most recent, scientifically accepted procedure...

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Matrix</th>
<th>Volume Req. by D.O.H</th>
<th>Container</th>
<th>Preservative</th>
<th>Holding Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromium</td>
<td>Urine</td>
<td>20 mls</td>
<td>plastic urine cup (4)</td>
<td>Refrigerate Freeze</td>
<td>2 Weeks, Indefinitely</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Urine</td>
<td>20 mls</td>
<td>plastic urine cup</td>
<td>Refrigerate Freeze</td>
<td>1 Month, 6 Months</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Urine</td>
<td>5 mls</td>
<td>plastic urine cup</td>
<td>Refrigerate</td>
<td>Process immediately upon receipt</td>
</tr>
</tbody>
</table>

Footnotes

4. Acid rinsed by laboratory

B. Sample containers and Preservatives

Most sample containers and preservatives are made available to the sampling agencies by ECLS. These items are maintained in the ECLS sample receiving area located in room L-237 in the Health and Agriculture Laboratory Building...

When a sample collector picks up sample containers from ECLS, the sample custodian will obtain the containers from the locked storage cabinets. Since field sampling personnel are not permitted in laboratory areas other than L-237, items not readily available from the locked storage cabinets will be obtained from the laboratory by the sample custodian.

B - 12
C. Sample Collection

Selection of the appropriate sampling methodology is primarily the responsibility of the sampling agency and is dependent upon the analytical methodology to be employed. However, the Director of ECLS or his designated appointee may be contacted for advice or comments pertaining to the selection and/or modification of sampling methodologies which are required to meet non-routine analytical requests.

At the time of sample collection, the laboratory analysis request form and chain of custody form (if necessary) must be completed and the sample bottles numbered and labeled with the appropriate colored N.J. DOH sample bottle tags.

The sample collector must also indicate on each tag the preservation steps, if any, taken for that particular sample container.

CHAPTER IV
SAMPLE RECEIVERSHIP

A. Sample Scheduling

1. Routine samples are samples whose analytical requests are based on Tables I and II of Chapter III. ECLS has a specific maximum capacity for certain analyses, due to limitations in resources and holding time restrictions; accordingly, agencies must make prior arrangements through the Sample Management Office at least 48 to 72 hours before the anticipated sample collection. Additionally, requests for sample bottles, preservatives, etc. used in the collection of routine samples can also be made through the Sample management Group.

...

B. Routine Sample Receiving

All samples submitted to ECLS for analysis are logged-in at the sample receiving area, room L-237, located on the second floor of the Health and Agriculture (H & A) laboratory building.

ECLS' sample custodians should be present in the receiving area from 9:00 A.M. to 5:00 P.M. Monday through Thursday and from 8:45 A.M. to 4:45 P.M. on Friday.

AT NO TIME ARE NON-LABORATORY PERSONNEL PERMITTED UNESCORTED IN THE LABORATORY BEYOND ROOM L237.

ECLS has trained personnel whose primary function is receiving of samples. Only those designated people are authorized to receive samples. The sample custodians log-in and handle samples as follows:

1. The sample custodian checks the analysis request sheet to determine if the following information has been provided:
   a. Date and time of sample collection;
   b. Name of sample collector; and
   c. Field sample ID number.

...

B - 13
2. The sample custodian checks the sample ID numbers on the bottle tags against the ID numbers on the analysis request sheets. If Chain of Custody (COC) forms are used (discussed in section D), the COC forms are also checked for the appropriate sample ID numbers, bottle identifications, etc. . . .

3. The sample custodian checks the analysis request sheet to determine the number of separate bottled which are required to perform the requested analyses and then checks to determine if these bottles are present.

4. When the sample custodian has determined that all the required bottles are present, the bottles are checked to determine if the proper bottle tags have been affixed and to check for chipped and broken bottles. No bottles with broken or chipped edges or stoppers will be accepted. The samples are also checked for proper preservation.

5. Samples are checked to ensure that there is sufficient volume to perform the requested analyses. If not, the sample collector may determine what parameter(s) are to be deleted from the request.

6. If the above five steps have been completed acceptably, the sample custodian will then enter the sample(s) into the ECLS Laboratory Information Management System (LIMS), also known as LABSAM.

C. Sample Log-in

LABSAM is a mini-computer based laboratory data system consisting of hardware and software modules which perform six major functions; sample logging, test scheduling, result entry, data reporting, long term data storage, and search and retrieval of stored data. As implemented by ECLS, LABSAM is a "two-level" system capable of tracking both batches of samples . . .and the individual samples making up those batches . . .

. . . each batch of samples submitted is represented by a unique batch key and each sample by a unique sample key.

D. Chain of Custody

The analytical results of some samples submitted to ECLS for analysis have the potential of being submitted as evidence in a court of law. These samples are considered physical evidence and as such, their possession must be traceable from the time the samples are collected until they are introduced as evidence in legal proceedings.

A sample is considered under an individual's custody if:

1. It is in his possession;
2. It is in his view, after being in his possession;
3. It is in his possession and then locked up to prevent tampering;
   or
4. It is in a secure area.

Although no formal documentation is maintained on individual sample bottles, custody begins when all sample bottles are first cleaned (as outlined in Chapter IV). Once cleaned, all sample bottles are stored
in a secure area on the 3rd floor of the H&A building by Central Services. The sample bottles are later transferred and locked in the storage cabinets in the hallway outside L237. All sample bottles remain locked in the storage cabinets until they are released to the sampling personnel.

Once the custody of the sample bottles is transferred to the sampling agency, it is the sampling agency’s responsibility to determine if Chain of Custody (COC) of the sample is to formally begin and if so, initiate documentation of the COC using the appropriate COC form. Usually, only those samples which may result in enforcement proceedings or samples which are of significant importance are handled in a formal COC manner.

Sample recipient procedures for samples requiring COC are the same as those used for routine samples (see section IV-B and IV-C above) except that upon completion of receiving the COC samples, the sample bottles are immediately transferred and locked by the sample custodian in the COC refrigerator(s) in room L-416. The COC and analysis request forms are delivered to rooms L-416 and L-418, respectively. However, in the case of COC samples requiring pH, or other analyses with limited, required holding times, the sample custodian may immediately distribute the sample bottle(s) for that parameter to the appropriate analyst and have the analyst sign the COC form for receipt of the bottle(s).

E. Sample Rejection

As stated in sections B, C and D, samples and their corresponding paperwork are checked and reviewed during the sample receipt process. Errors that are found that adversely affect the quality of the analytical data will result in the sample custodian “rejecting” the sample and therefore, the sample will not be analyzed.

The sample custodian will reject samples, fill out a sample rejection form and stamp the appropriate sample analysis request form indicating the reason for the sample rejection under the following instances:

1. Sample was not properly preserved (stamped "NPP").
2. Sample was not properly labeled (stamped "NPL").
3. Sample was submitted in an improper container (stamped "IPC").
4. Sample exceeded holding time (stamped "O").

5. Sample will exceed holding time (stamped "Sample will exceed the recommended holding time for this parameter before the analysis can be performed by the NJDOH laboratory").

... Samples may also be rejected for other reasons affecting data quality and/or reliability, such as:

1. Date and time of sample collection and/or name of sample collector not indicated on the sample request form;
2. Sample bottle not submitted for the requested analysis;

...
CHAPTER V
INTERNAL SAMPLE HANDLING

A. General

Just prior to midnight of each working day, the LIMS executes certain time scheduled programs whose functions are to provide print-outs of the samples logged in during the previous day.

The "New Arrivals" printout lists the following information on each sample submitted: the sample key (or laboratory sample number), the field number, the batch number, the date and time of collection, whether the sample is a chain of custody or priority=, and the tests requested.

In addition to the "new arrivals" printout, the system prints out a "Backlog and Receiving Report" [for each laboratory section, which includes] the tests carried out by that laboratory section, the total existing backlog for that test, the date of the oldest sample, the sample number of the oldest sample, the number of samples received the previous day at the test [identification code].

B. Routine Samples

As the analytical results are produced they are reviewed by the analyst and the analyst’s supervisor and are then entered into the LIMS.

Prior to the preparation of the final data report packages, trace metal and general chemistry results undergo a final review by their respective section supervisors. The trace metal section supervisor prints out the final report form and reviews the results prior to forwarding them to the data management section.

C. Chain of Custody (COC) Samples

Chain of Custody samples are received in room L237 and, after log-in, are placed in locked refrigerators in room L416. When an analyst needs an aliquot of a COC sample, a sample custodian unlocks the COC refrigerator(s) while the analyst draws an aliquot or takes possession of the sample container.

The sample custodian then relocks the refrigerator(s) and, together with the analyst documents the transfer of custody by filling out the appropriate sections of the COC form. The aliquot, or sample container, then remains with the analyst or analyst’s group until the analysis is completed.
CHAPTER VI
GENERAL LABORATORY PRACTICES

The Department of Health’s Environmental and Chemical Laboratory Service Unit maintains a high degree of constancy throughout the laboratory for those items which can directly impact the quality of the analytical data produced. Since several of these items are not addressed directly in the methodology quality control sections, they are addressed below.

A. Water, Chemicals and Glassware

1. The distilled and deionized water employed in the laboratory has resistivity values of between 0.5 and 2.0 μmhos/cm at 25°C. The laboratory also maintains a supply of deionized double distilled water, used primarily for metal analyses, and a supply of deionized distilled-deionized water used primarily for organic analysis.

2. Analytical reagent grade chemicals are routinely used in the laboratory. In those instances where analytical reagent grade chemicals are not available, the highest purity reagent available is used. Special high purity reagents are used in the trace metal and trace organic analytical laboratories. . .

3. All glassware used in the laboratory is of the Pyrex-Kimax (borosilicate) type and Class “A” volumetric glassware is employed. Volumetric pipets are rinsed before use with the solution to be transferred. . .

4. All glassware employed by ECLS . . . is initially cleaned by the Central Services (CS) section of the Division of Public Health and Environmental Laboratories. The glassware is subjected to a cleaning cycle that includes:
   a. A pre-rinse cycle of approximately 15 30 sec. in which the glassware is rinsed with demineralized water.
   b. Three ounces of a cleaning detergent is added to the 8 to 9 gallons of water.
   c. An eight minute wash cycle follows.
   d. Three tap water rinses are followed by a deionized water rinse.
   e. The glassware is removed from the washer and dried in an oven at approximately 105°C for 15 minutes.
   f. The glassware is removed from the oven and placed on the shelves in CS for laboratory use or for further cleaning by laboratory personnel prior to use.

5. Glassware used for metal analyses is obtained from CS and is then subjected to the following additional cleaning steps:
   a. Placed in an acid bath containing 1:4 (v/v) nitric acid/water and allowed to soak for at least one hour. This is followed by a tap water rinse.
   b. Placed in an acid bath containing 1:4 (v/v) hydrochloric acid/water and allowed to soak for at least one hour. This is followed by a tap water rinse.
   c. Rinsed with deionized double-distilled water.

The glassware is tap water rinsed after analysis and sent to CS for washing. CS returns the glassware to the metals room after washing. Therefore, the glassware used for metal analyses is “dedicated” glassware. This greatly reduces the possibility of accidentally contaminating the glassware from an unknown source.
Sample bottles used for the routine collection of aqueous samples for trace metal analysis are subjected to the routine CS washing procedure. These containers are then rinsed with 1:1 nitric acid/water, followed by a distilled water rinse.

CHAPTER VII
INSTRUMENTAL MAINTENANCE AND INSTRUMENT QUALITY CONTROL (QC)

The following is a list of the routine maintenance and quality control measures performed by the staff of ECLS. For those analyses that require more detailed instrumental QC, these QC measures are discussed in the methodology section of Chapter VIII.

1. Atomic Absorption Spectrophotometer (AA)
   1. Maintenance

      a. 
      b. For graphite furnace AA, the contact rings are replaced and the quartz windows are cleaned as needed.
   2. Quality Control

      a. During the first week of each month, the instrument response for each analyte is checked against the manufacturer's listed response for that analyte at the specified concentration listed by the manufacturer.
      b. The AA lamps have the date of receipt of the lamp and the date the lamp was first placed in service affixed to the lamp. This allows for easy monitoring of the effective shelf life and operational lifetime of the lamps. Each lamp is warmed up for at least 5 minutes prior to use;
      c. When selecting the wavelength for any particular parameter the wavelength selector is adjusted until maximum scale deflection is achieved;
      d. Checked yearly under service contract.
CHAPTER VIII
ANALYTICAL QUALITY CONTROL AND ANALYTICAL Methodologies

A. Inorganics Testing Quality Control

1. Calibration (Standard) Curves
   a. Atomic Absorption (AA) Analyses

   A reagent blank and a minimum of five standards are analyzed with each day’s analysis. In
   the case of AA analysis by graphite furnace, three separate aliquots of a standard are actually
   analyzed and then averaged.

   The concentrations of the standards along with their corresponding absorbance values are entered
   into the HP 3350 Laboratory Automation System which then constructs the standard curve using
   the method of least squares, and also calculates the coefficient of determination (r²). The
   coefficient of determination is the square of the correlation coefficient. Both coefficients
   measure the strength of the linear relationship among the standard calibration points. An r or
   r² value of 1.0 indicates a perfect linear relationship among the standards. For analyses utilizing
   standard curves, ECLS requires that a coefficient of determination of at least 0.9900 (equivalent
   to a correlation coefficient of 0.995) must be achieved before the analysis of any sample may
   proceed.

   If a coefficient of determination is obtained whose value is less than the above listed value, the
   analyst may selectively reject the absorbance reading of one of the standards and replot the
   standard curve. Analysis can proceed if the appropriate r² is obtained. This may be repeated
   until the minimum of a blank and 4 standards yields an appropriate r² value. If the appropriate
   r² value is not obtained, the analyst must analyze a new series of standards. If this re-analysis
   still fails to generate an acceptable r², the analyst ceases operations and trouble-shooting is
   performed on the system by the analyst, supervisor, and OQA to identify the cause of the
   problem.

2. Control Samples

   Control samples are spiked distilled water samples that are analyzed to determine if the
   analytical method is being performed acceptably. Control samples are treated in the same
   manner as routine samples and are analyzed at the beginning and the end of each analysis
   scheme.

   Control sample stock solutions are prepared periodically by OQA from a set of primary
   standards which are distinctly different from those used by the analyst to prepare standard
   curves. The stock solutions are submitted to the analyst and subsequent dilutions are made to
   prepare at least two working control sample solutions. One control sample is prepared at an
   approximate concentration of the second lowest standard used in the establishment of the
   standard curves. A second control sample is prepared at a concentration level greater than or
   equal to the concentration level of the fourth standard used in the establishment of the standard
   curve.

   The analyst must compile at least 7 and up to twenty data points for each control sample
concentration using the stock solution. This data is reported to OQA for calculation of the average values. Of each concentration level. Control samples having an average value greater than or equal to 10 ppb have an acceptance limit of mean ± 20%. Control samples having an average value of less than 10 ppb have an acceptance limit of mean ± 2 ppb.

Control charts are prepared initially by the Office of Quality Assurance and subsequently by the analysts indicating the average value and acceptance limits for each control sample concentration. The control samples are conspicuously displayed or readily accessible to everyone in the laboratory. The results of all subsequent control samples are plotted on the control chart by the analyst at the time the results are generated.

The analysts check the control charts daily for outliers. Both control samples must be within the acceptance limits before the analysis of any routine sample may be initiated. Failure to achieve this requirement results in the reevaluation of the method by the analyst and supervisor and the reanalysis of the same set of control samples. Likewise, the results of the ending set of control samples must be within the acceptance limit at the end of the analysis scheme before the data of the routine samples can be reported. Failure to achieve this requirement a second consecutive time results in the reevaluation of the method by the analyst, supervisor, and OQA, and if sufficient sample volume exists, reanalysis of both the control and routine samples. If sufficient sample volume does not exist, no data is reported due to poor method performance.

The analysts also check the control charts regularly for adverse trends that may develop with the analysis. For example, if seven or more consecutive readings fall to one side of mean, this would constitute an adverse trend. Another example of an adverse trend would be if there is a steady, gradual decline or increase of the control sample results within the acceptable limits. If an adverse trend appears, the unit supervisor and OQA are notified and steps are taken by the unit supervisor and OQA to determine and correct the cause of the trend.

Completed control charts are submitted to the program coordinator on a monthly basis. The program coordinator then reviews each chart to verify that the analysts are performing the control analyses on a routine basis and are maintaining the required level of achievement. The program coordinator then maintains these charts as a separate quality control file.

4. Method of Standard Addition (MSA)

   a. Data from MSA calculations are generated from readings obtained within the linear range as determined by the calibration curve generated at the beginning of the analytical run.

   b. The sample and three spikes are analyzed consecutively for MSA quantitation (the "initial" spike run data is specifically excluded from use in the MSA quantitation). Only single point injections are required for MSA quantitation but multiple injections are employed.

   c. Spikes should be prepared such that all readings are within the linear range of the instrument.
d. If the coefficient of determination for a particular analysis is less than 0.99, the MSA analyses are repeated once. If the coefficient is still less than 0.99, the results are reported and qualified to indicate a matrix interference. If the coefficient of determination is greater than 0.99, the MSA results are reported.

5. Data Validation

Data validation is conducted by the analyst and his supervisor prior to the reporting of the analytical results. Upon completion of the analytical scheme, the analyst reviews his notebooks to ensure that all the requisite documentation, as listed in Chapter IX, is present. The analyst then checks to ensure that all quality control data is within the required acceptance limits and if not, that the data is appropriately qualified. The analyst then recalculates a minimum of twenty (20) percent of the sample results to check for calculation errors. When the analyst determines that the workbook is complete and accurate, he initializes the data page in the workbook and submits it with any appropriate hard copy data to the supervisor for review and approval. When the supervisor is satisfied with the accuracy and completeness of the data, the workbook is approved and initiated by the supervisor and returned to the analyst. The analyst then releases the data as outlined in Chapter X. No data is reported until this dual validation step is completed.

CHAPTER IX
DATA HANDLING

A. Inorganic Data Handling

1. Laboratory Workbooks - All raw data, calculations, analytical results and QC data are recorded in bound notebooks. All workbooks contain a list of the initials and the corresponding names of all analysts who make any entries in that particular workbook, as well as the definition of any abbreviations used in the book. There are two workbooks which may be associated with each analysis. The reagent workbook... lists the following:

   a. a reference to the method being employed;
   b. a listing of the exact manner in which all the reagents are prepared;
   c. the date of reagent preparation and the analyst's initials; and
   d. any readings and calculations employed during the standardization of any solution along with the appropriate units...

The second workbook contains the following information:

   a. a reference to the method being employed;
   b. on one page is listed, with appropriate column headings and units where necessary.
      i. date the sample was incorporated into the work schedule.
      ii. sample identification number.
      iii. volume of sample taken.
      iv. value of reading obtained during the analysis.
      v. the analyte concentration corresponding to the value of the reading obtained from the standard curve.
vi. any calculations...

vii. any dilutions required during the analysis are listed serially until an on-scale reading is obtained.

viii. final result.

ix. at the end of the day's analyses the analyst enters the date the analyses were performed and initials his work. This signifies that not only did he perform the analyses but he also checked the results to make sure that no calculation errors were made...

c. On the facing page...are listed:

i. workdate,

ii. the method blank, standards and the instrument reading associated with each,

iii. the results of the two control samples along with the acceptable ranges of each,

...

v. the coefficient of determination generated during the production of the standard curve, along with the equation of the computer generated standard curve.

...

3. Instrument Log - an instrument log is maintained for each atomic absorption spectrophotometer. Each day at least one entry is made to indicate the analyses performed on that instrument and/or any maintenance done to the instrument.
APPENDIX B5
URINE CHROMIUM REFERRAL CRITERIA
CHROMIUM MEDICAL SURVEILLANCE PROJECT

1. INTRODUCTION

The New Jersey Department of Health (NJDOH) has embarked on a two-stage screening program of persons potentially exposed to chromium from waste sites in Hudson County, New Jersey. The Chromium Medical Surveillance Project (CMSP) is designed to identify persons currently exposed to unusual amounts of chromium, so that specific remedial efforts can be targeted to reduce further exposure, and to examine individuals for signs of adverse health effects from chromium exposure.

The first stage of the screening program consists of a limited physical examination and a measurement of current exposure to chromium. Those who show evidence of current exposure or chromium-related effect are made eligible for a second stage, or follow-up evaluation. The second stage evaluation consists of a more extensive physical examination and an environmental chromium assessment. This document describes the referral criteria, and their basis, for judging urine chromium concentrations in the first stage of the screening program. A separate document describes the referral criteria to be used in the first stage screening physical examination.

The most practical method of measuring current exposure to environmental chromium is through sensitive determination of chromium concentration in spot (one-time) urine samples. However, the interpretation of the measured concentration requires consideration of several factors besides potential exposure to waste sites. These factors include individual chromium exposure from the diet or other environmental source, personal characteristics (such as age), and urine diluteness of the spot sample. At the time the CMSP was initiated, little information was available to NJDOH regarding how such factors affect urine chromium concentration in a diverse residential or occupational population.

Consequently, in order to make appropriate judgments of urine chromium concentrations in potentially exposed persons screened in Hudson County, NJDOH undertook a Baseline Survey to establish "normal ranges" of urine chromium, and to quantify the effects of urine diluteness, other chromium exposure sources, and personal characteristics. While the literature suggests that normal urine chromium concentrations would vary between 0.1 and 0.3 micrograms per liter (µg/L), such ranges have not been adequately established.

This document first describes the Baseline Survey and the analysis of this data for the purposes of decision-making regarding the urine chromium concentration in the initial screening stage.
2. SUMMARY OF BASELINE SURVEY METHODS AND RESULTS

**POPULATION** An age-stratified non-random sample of New Jersey residents of a wide range of ages was obtained by contacting large child-care centers, public and private schools, employees of local health agencies and senior day centers. Heads of organizations were asked to participate in a survey of urine chromium measurement in order to assist the State in understanding exposure in a contaminated area. Following agreement to participate, introductory letters and consent forms were distributed to individuals (or parents in the case of pre-school and school age children) to obtain individual consent to fill out a questionnaire and submit a urine sample for chromium analysis. Populations were selected from outside of Hudson County and included individuals from south, central and northern parts of the state.

**QUESTIONNAIRE** A questionnaire was administered to all participants (or parents) to obtain information regarding possible chromium exposure sources and personal behaviors that might affect chromium exposure intensity. A self-administered portion of the questionnaire included personal characteristics (e.g., age, race, sex, weight), house characteristics (e.g., interior paint colors, floor level of rooms frequented by the individual, household smoking habits), personal behaviors (e.g., dietary supplementation, pencil chewing), and history of medical conditions (e.g., kidney disease, diabetes).

Another portion of the questionnaire entailed a personal interview to obtain information on activities in the past 48 hours. This section solicited information on time spent at home, work or school, activities related to dust exposures, hobbies related to chromium exposure, intake of dietary supplements, smoking, and consumption of beer and wine.

Questionnaire data were coded and entered into the CMSP data management system using dBase III+, and were checked for accuracy of entry.

**URINE SAMPLE** Urine samples were collected from the participants in the baseline study, stored on ice, and delivered to the NJDOH Public Health and Environmental Laboratory for analysis of specific gravity, creatinine (both measures of urine diluteness), and chromium. Methods for these analyses are described in separate protocols.

Results of analyses were provided on magnetic media to the CMSP staff and uploaded into the data management system. Lab data were related to questionnaire data in dBase III+ through a common sample identification field.

**DATA ANALYSIS** Exploratory data analysis was conducted comparing mean and natural logarithm-transformed urine chromium values by levels of categorical variables (such as age group, sex, vitamin consumption, sweeping), and by scatter-plotting against continuous variables (creatinine, specific gravity, age). This exploration was done to examine potentially important predictor variables and to determine apparent functional relationships among continuous measures.
Multiple linear regression models (using SPSS-PC+ software) were then developed. As chromium values were skewed to high values, the natural logarithm of chromium was used as the dependent variable to produce model errors with a more Gaussian distribution. Measures of urine diluteness (creatinine, specific gravity), age group, sex and weight were entered into the models and confounding and interaction among these variables were explored. If strong effect modification was observed, separate models by level of effect modifier were developed. Additional variables were then entered into the models to determine dilution-, sex- and age-adjusted contributions to urine chromium concentration.

In previous studies, a frequent practice has been to adjust for urine diluteness by dividing chromium concentration by creatinine concentration, resulting in a dependent variable expressed as the ratio of concentrations, or micrograms of chromium per gram of creatinine. In multivariate modeling, this practice eliminates the ability to simultaneously adjust for other factors, or explore interactions. It forces a strong assumption into the model, that of a linear relationship between chromium and creatinine concentrations across the entire range of values, and assumes that this relationship is constant across all ages, weight, gender or other variables.

Final models were developed based on forward- and backward-elimination of variables and biologically plausible interaction terms, until satisfactory predictive abilities were reached.

Cumulative frequency distributions and histograms of excess values for all study participants were then generated from the regressions to examine the range of "unexplainable" quantities of urine chromium in a population not living or working near known chromium waste sites.

RESULTS OF BASELINE SURVEY A total of 317 individuals participated in the Baseline Survey representing a wide variety of ages, geographic areas and both genders. Two individuals provided insufficient quantities of urine for analysis so the total Baseline sample was 315.

Exploratory data analysis indicated that separate regression models needed to be developed for the sexes, since sex appeared to modify the effect of age and urine diluteness measures on chromium concentration. Interactive regression modeling for each sex resulted in a set of independent variables for predicting the natural logarithm of urine chromium concentrations. Final models are provided in Table 1.

From the final models, distributions of excess values (that is, the "unexplained" portion of each individual's urine chromium concentration) were generated. For later application to screened individuals, a spreadsheet was constructed consisting of ranges for importation of selected data on each individual, calculation of expected urine chromium levels based on the regression model coefficients, and calculation of excess urine chromium values.

The cumulative empirical frequency distribution of excess values of the Baseline Survey participants is provided in Table 2.
3. DEVELOPMENT OF URINE CHROMIUM REFERRAL CRITERIA

Based on empirical frequency distribution of excess values from Baseline Survey participants, a value was selected such that approximately 98 percent of the Baseline population did not exceed it. Had there been a clear break in the cumulative distribution defining a distinct group, such a cutpoint would have been chosen. In the absence of such a value, an excess value defining the upper 2% of the Baseline population was chosen.

That excess value is 0.5 μg/l. That is, if a screened individual’s measured urine chromium concentration is 0.5 μg/l greater than the expected value, considering the persons personal characteristics, urine diluteness, and other potential exposure sources, then that person would be referred for follow-up or second-stage evaluation.

Using the Lotus spreadsheet described above, batches of selected data from the screened population are imported, and excess values generated. All individuals whose excess exceeds 0.5 μg/l are then offered follow-up evaluation. Detailed procedures for the manipulation of the data management system are described separately.
TABLE 1. Final multiple regression models for urinary chromium concentrations, by sex.

**FEMALES**

Dependent: Natural logarithm of urinary chromium (µg/l)

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Coefficient</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (1)</td>
<td>0.16</td>
<td>0.0001</td>
</tr>
<tr>
<td>Specific Gravity (2)</td>
<td>0.12</td>
<td>0.09</td>
</tr>
<tr>
<td>Age over 60 (3)</td>
<td>0.38</td>
<td>0.0002</td>
</tr>
<tr>
<td>Natural log of weight (4)</td>
<td>-0.19</td>
<td>0.03</td>
</tr>
<tr>
<td>Creatinine*Age over 60</td>
<td>0.21</td>
<td>0.12</td>
</tr>
<tr>
<td>Swept attic or garage (3)</td>
<td>0.25</td>
<td>0.13</td>
</tr>
<tr>
<td>Took vitamins with Cr (5)</td>
<td>-0.03</td>
<td>0.81</td>
</tr>
<tr>
<td>Swept house (3)</td>
<td>-0.04</td>
<td>0.54</td>
</tr>
<tr>
<td>Worked in dusty envt. (3)</td>
<td>0.20</td>
<td>0.12</td>
</tr>
<tr>
<td>Hobby involving Cr (3)</td>
<td>-0.44</td>
<td>0.08</td>
</tr>
<tr>
<td>Intercept</td>
<td>-1.48</td>
<td>0.0000</td>
</tr>
</tbody>
</table>

**MALES**

Dependent: Natural logarithm of urinary chromium (µg/l)

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Coefficient</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (1)</td>
<td>0.08</td>
<td>0.07</td>
</tr>
<tr>
<td>Specific Gravity (2)</td>
<td>0.10</td>
<td>0.25</td>
</tr>
<tr>
<td>Age over 60 (3)</td>
<td>0.17</td>
<td>0.34</td>
</tr>
<tr>
<td>Natural log of weight (4)</td>
<td>-0.25</td>
<td>0.002</td>
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<tr>
<td>Creatinine*Age over 60</td>
<td>1.24</td>
<td>0.0001</td>
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<tr>
<td>Swept attic or garage (3)</td>
<td>0.12</td>
<td>0.37</td>
</tr>
<tr>
<td>Took vitamins with Cr (5)</td>
<td>0.29</td>
<td>0.12</td>
</tr>
<tr>
<td>Swept house (3)</td>
<td>-0.18</td>
<td>0.04</td>
</tr>
<tr>
<td>Worked in dusty envt. (3)</td>
<td>0.31</td>
<td>0.12</td>
</tr>
<tr>
<td>Hobby involving Cr (3)</td>
<td>-0.40</td>
<td>0.14</td>
</tr>
<tr>
<td>Intercept</td>
<td>-1.46</td>
<td>0.0000</td>
</tr>
</tbody>
</table>

(1) Variable centered at 1.0 g/L
(2) Variable centered at 1.02; increment per hundredth unit
(3) Yes/No
(4) Variable centered at 100 lbs.
(5) Chromium content in excess of 30 µg
## TABLE 2. Cumulative frequency distribution of urinary chromium excess concentrations from the baseline population.

<table>
<thead>
<tr>
<th>Range of Chromium Excess</th>
<th>Number</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.00</td>
<td>174</td>
<td>55.2</td>
</tr>
<tr>
<td>0.01 - 0.10</td>
<td>80</td>
<td>80.6</td>
</tr>
<tr>
<td>0.11 - 0.20</td>
<td>25</td>
<td>88.6</td>
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<tr>
<td>0.21 - 0.30</td>
<td>15</td>
<td>93.3</td>
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<tr>
<td>0.31 - 0.40</td>
<td>7</td>
<td>95.6</td>
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<tr>
<td>0.41 - 0.50</td>
<td>8</td>
<td>98.1</td>
</tr>
<tr>
<td>0.51 - 0.60</td>
<td>0</td>
<td>98.1</td>
</tr>
<tr>
<td>0.61 - 0.70</td>
<td>2</td>
<td>98.7</td>
</tr>
<tr>
<td>0.71 - 0.80</td>
<td>0</td>
<td>98.7</td>
</tr>
<tr>
<td>&gt; 0.80</td>
<td>4</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>315</td>
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</tbody>
</table>
APPENDIX B6

PROTOCOL FOR FOLLOW-UP MEDICAL EXAMINATION AT THE 
ENVIRONMENTAL AND OCCUPATIONAL HEALTH CLINICAL CENTER 
CHROMIUM MEDICAL SURVEILLANCE PROJECT

Introduction

The New Jersey Department of Health (NJDOH) is conducting a Chromium Medical 
Surveillance Project. This screening program is designed to screen selected residents and 
workers in Hudson County for evidence of exposure to chromium and/or adverse physical 
effects potentially related to chromium exposure. Participants in NJDOH’s screening program 
may be referred, by NJDOH or a local contract clinic, to the Environmental and Occupational 
Health Clinical Center (EOHCC) of the University of Medicine and Dentistry of New Jersey 
(UMDNJ) for medical follow-up and indoor dust sampling. This protocol presents the strategy 
for the evaluation of referred participants for medical follow-up.

There are four general criteria that could be used to refer participants for medical 
follow-up. These criteria are:

1) The participant’s urine concentration is above criterion values set by 
   NJDOH. (See "Urine Referral Criteria Protocol")
2) Skin examination of the participant reveals skin ulceration or small round 
   scar consistent with chromium exposure.
3) Nasal examination of the participant reveals a nasal septum perforation 
   or a nasal ulceration.
4) The participant has a history of health effects that could be due to 
   exposure to chromium (chronic unrelenting allergies, asthma, or chronic 
   dermatitis).

Objectives of Medical Follow-up Evaluation

One objective of the medical follow-up evaluation is to provide individual-based 
assistance to participants who may be adversely impacted by exposures to chromium 
contamination. Physicians conducting the follow-up examinations and evaluations will be 
instructed to identify any health effect that may be associated with chromium exposure and 
then to make a judgement whether or not the health effect is due to chromium exposure. 
Further assistance to the participants will be in the form of medical referrals for non-chromium 
related conditions, health education, or a better understanding of the causes of their medical 
condition.

Another objective of the medical follow-up evaluation is to provide the NJDOH with 
information, which can be used as a basis for judgements regarding the impact of chromium 
wait exposure.
Procedure of Examination

EOHCC will receive referrals' names, addresses, phone numbers, and reasons for referral from NJDOH. Within 10 working days after receipt of a referral's information, EOHCC will contact the referred participant to make an appointment for the follow-up examination. EOHCC will maintain records of their efforts to contact each referral. These records will include the referral's name, the date the effort was made, the method of contact used, and the date of the referral's appointment at EOHCC. If a referral refuses the follow-up examination, EOHCC will document the refusal and include it in the referral's file.

Transportation to the EOHCC will be provided by a contract transportation vendor, unless the participant would rather transport her/himself. EOHCC will contact the contract transportation vendor with the dates and times that the referred participants will need to be transported, along with the names and addresses of the referred participants. On the day of the clinic visit, an outreach worker from the Jersey City Medical Center (JCMC) may ride with the ambulance and assist in contacting and gathering the individual referred participants. When all of the referrals for that day are picked up, the outreach worker may leave and return independently to JCMC.

Each referred participant will be greeted by an EOHCC staff member upon their arrival at EOHCC. They will be led through the completion of a standard EOHCC medical questionnaire, which includes sections on the occupational and medical history of the participant. Information in the questionnaire is necessary for the examining physician, but may not be directly related to the CMSP and will not be made available to the CMSP. A blood pressure reading will be taken and recorded. As described below, urine and blood samples will be taken from each participant. Spirometry examinations will be provided. The questionnaire will be given to the physician, who will review the questionnaire and conduct a physical examination. All physicians will be licensed and experienced in occupational/environmental medicine. If a referral was made on the basis of a physical finding or the follow-up medical evaluation finds ailments potentially due to chromium, the patient will be seen by an occupational dermatologist and/or other specialist.

Clinical Tests

Medical follow-up tests will concentrate on chromium's toxicological effects on the lungs, the kidneys, and the skin. The examining physician will try to determine if a clinical condition in these organs is a result of chromium exposure. Some or all of the following clinical tests will be provided to the participants at UMDNJ:

1) General Physical Examination
2) Urinalysis
3) Blood analysis
4) Spirometry
5) Dermatological Examination
The standard battery of analyses will be performed on urine and blood samples. Analytical results from these tests that are not related to chromium are not discussed in this protocol and will not be made available to the CMSP.

**General Physical Examination**

The participants will receive a thorough physical examination, with focus on the lungs, skin, and nose. The skin will be examined for ulcerations, perforations, or non-specific eczema. Physical exams can help determine the general health status of the participant, which may be useful in the interpretation of a clinical condition or an elevated urine chromium level. Based upon the physical examination, the examining physician may refer the participant to a medical specialist (e.g., otorhinolaryngologist).

**Urinalysis**

Spot urine samples will be collected from all referred participants on the day of the examination. Urine samples will be analyzed both by the NJDOH Laboratory for chromium, creatinine, and specific gravity, and by Metpath Laboratories via standard methodologies for a battery of tests. If the examining physician feels a 24-hour urine collection is clinically indicated and feasible for specific individuals, arrangements for the collection of a 24-hour urine will be made.

The parameters of the urinalysis that will be reported to the NJDOH are chromium, creatinine, specific gravity, ketones, proteins, glucose, blood, and bilirubin. Chromium concentrations will be used to evaluate recent (previous 48 hours) exposure to chromium. The presence and concentrations of low molecular weight proteins, including β₂-microglobulin, will be used as an early indicator of kidney damage.

**Blood Analysis**

A venous blood sample of approximately 12-18 cc will be collected using standard techniques. The blood will be analyzed by Metpath Laboratories via standard methodologies for a battery of tests. The parameters of the blood analysis that will be reported to the NJDOH include the liver enzymes, BUN, and creatinine. At the discretion of the examining physician, additional analyses may be performed on a portion of the blood sample. Damage to the kidneys could be detected by the concentrations of kidney enzymes and the blood pressure of the participants. Blood chromium will not be measured because of the difficulties in obtaining an uncontaminated sample and the lack of adequate background or reference data.

**Spirometry**

Spirometers will be used to evaluate lung capacity and elasticity. Children under seven years old will be excluded from this aspect of the examination. Chromium exposure has been demonstrated to cause respiratory diseases, airway abnormalities, asthma, and interstitial
fibrosis. Spirometry will be obtained by asking patients to breathe into a Collins model instrument at least three times. Specific parameters that will be evaluated are FEV1, FVC, and the FEV1/FVC ratio. Normal spirometry values based upon Knudson Standards1, which account for the patient's sex, age, height, and weight, will be used to identify the presence of an abnormality.

Dermatological Examination

Skin examinations by a dermatologist will only be provided to participants who were referred on the basis of skin conditions observed during the screening physical examination or follow-up physical examination. Examinations and/or tests will be conducted to evaluate whether the skin conditions are or could be due to chromium exposure.

When indicated, patch tests will be performed. Patch tests results will be read by a dermatologist. Patch tests will preferably be performed by a dermatologic nurse in the Department of Dermatology at UMDNJ, but may also be performed at the JCMC. The patch will contain 0.25% potassium dichromate, which will be placed in a Finn Chamber and taped to the patient's back. The patch will be removed from the patient's back after 48 hours. The results of the test will be read and interpreted by a dermatologist 10 minutes after the patch is removed and 24 hours after the patch is removed. Additional readings may be necessary, as determined by the dermatologist.

Notification of Results

Before departing, each participant will receive an oral explanation of any findings made in the clinic. Each participant will be notified by phone and/or mail within one week after the receipt of an abnormal laboratory result. A final letter, containing all results, will be sent to each participant within two weeks after EOHCC's receipt of all the laboratory results. A summary of the final letter will be provided to NJDOH, containing only that information relevant to chromium exposure and chromium's potential health effects. The EOHCC will maintain a clinical record on each participant secured in a locked cabinet. This record will include demographic information, the questionnaire, physical examination information, and laboratory data.

APPENDIX B7

SELECTED PROJECT INSTRUMENTS
PARENTAL CONSENT FORM FOR PARTICIPANTS (aged 2-5) IN THE CHROMIUM STUDY

PLEASE READ, SIGN, AND RETURN THIS FORM IN THE ENVELOPE PROVIDED

I have been informed that the Department of Health is conducting a study of exposure to chromium. This study involves obtaining information about my child's health and activities through my completion of a short questionnaire. My child will be asked to provide a urine sample to be tested for chromium and to have a brief physical examination of the skin and inside the nose.

I understand that the urine sample will be tested for chromium and for creatinine, a protein used to determine how concentrated the urine is. The urine sample will not be tested for any other substances.

If I find the questions uncomfortable or disagreeable I can refuse to answer or stop participating at any time during the course of the study. I have agreed to take part in this study by providing information and allowing my child to provide a urine sample and to have a brief physical examination with the understanding that:

I understand that all my responses will be kept completely confidential by the New Jersey Department of Health.

My participation is voluntary and I am free to discontinue participation at any time. My refusal will involve no penalty.

The information obtained from all participants will be summarized and a report will be issued. The report will be written in a manner that ensures the confidentiality of individual information. My child's name and identity will not be mentioned.

I understand that all records will be kept in a locked file cabinet by the New Jersey Department of Health. Access to these data will be restricted to those Department of Health employees directly involved in the study. All medical records will be kept completely confidential.

If my child participates, I am aware that I will be notified of the results of the examination and urine analysis.
If I have any questions regarding this study, I may call Barbara Giudici or Patricia Hultmeier of the New Jersey Department of Health at (609) 984-2193.

___ YES, I give permission for my child to participate in the study.

__________________________
Name of Child (please print)

__________________________
Child's Social Security Number

__________________________
Name of Parent or Guardian (please print)

__________________________
Address of Parent or Guardian (please print)

__________________________  Date
Signature of Parent or Guardian

___ NO, I do not give permission for my child to participate in the study.

__________________________
Signature of Parent or Guardian

__________________________  Date

Please return this form with your child tomorrow.

Thank you.
CONSENT FORM FOR WORKER/RESIDENT PARTICIPATION IN THE CHROMIUM STUDY

PLEASE READ, SIGN, AND RETURN THIS FORM IN THE ENVELOPE PROVIDED

I have been informed that the Department of Health is conducting a study of exposure to chromium. This study involves obtaining information about my health and activities. This information will be obtained from me in a short interview lasting about 10 minutes. I will also be asked to provide a urine sample to be tested for chromium and to have a brief physical examination of my skin and inside my nose.

I understand that the urine sample will be tested only for chromium and for creatinine, a protein used to determine how concentrated the urine is. The urine sample will not be tested for any other substances.

If I find the questions uncomfortable or disagreeable I can refuse to answer or stop participating at any time during the course of the study. I have agreed to take part in this study by providing information and a urine sample, and by having a physical examination with the understanding that:

I understand that all my responses will be kept completely confidential by the New Jersey Department of Health.

My participation is voluntary and I am free to discontinue participation at any time. My refusal will involve no penalty.

The information obtained from all participants will be summarized and a report will be issued. The report will be written in a manner that ensures the confidentiality of my individual information. My name and identity will not be mentioned.

I understand that all records will be kept in a locked file cabinet by the New Jersey Department of Health. Access to these data will be restricted to those Department of Health employees directly involved in the study. All medical records will be kept completely confidential.

If I participate, I am aware that I will be notified of the results of the examination and urine analysis.
If I have any questions regarding this study, I may call Barbara Giudici or Patricia Halmeler of the NIDCR at (609) 994-2193.

Yes, I consent to participate in the study.

Name (please print)

Social Security Number

Street Address (Apt. #)  City  Zip Code

Signature  Date

No, I do not wish to participate in the study.

Signature  Date
<table>
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<tr>
<th>Last</th>
<th>First</th>
<th>Personal ID Number</th>
<th>Sample ID Number</th>
<th>Urine Request</th>
<th>Physical Exam</th>
<th>Questionnaire</th>
<th>Completed</th>
<th>Comment</th>
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</table>
Section I:
These questions pertain to your child and where he or she lives.

1. What is the child's name?
(First) __________________________________________
(Last) __________________________________________

2. What is your child's social security number?
_________ - _______ - _______

3. What is the child's present address?
Street Address (Apt. #) ________________________________
City _______________________________________________
   a. Has the child lived at this address for more than 6 months?
      1[ ]Yes  2[ ]No  9[ ]Don't Know

4. Has the child lived at any address in Jersey City, Kearny, or Bayonne (other than his or her present address) in the past 6 months?
   1[ ]Yes  2[ ]No  9[ ]Don't Know
   a. (If Yes:) Please fill in the other address where the child lived.
      Street Address (Apt. #) ________________________________
      City _______________________________________________

5. Has the child ever taken part in a chromium study?
   1[ ]Yes  2[ ]No  9[ ]Don't Know

6. How old is the child?   ________ Years


8. Sex of the child: 1[ ]Male  2[ ]Female

9. What race do you consider the child?
   1[ ]White  3[ ]Hispanic  5[ ]Asian
   2[ ]Black/Afro-American  4[ ]American Indian  6[ ]Other
Questions 10 - 15 are about where the child lives now.

10. When awake, what floor does the child spend the most time on?
   0[ ]Basement  2[ ]Second  9[ ]Don’t Know
   1[ ]First  3[ ]Third or Above

11. When awake, what room of the home does the child spend the most time in?
   0[ ]Basement  3[ ]Bedroom
   1[ ]Kitchen/Dining  4[ ]Other
   2[ ]Living, Den, Family  9[ ]Don’t Know
   a. In that room, what color are the walls painted?
      1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
      2[ ]Other Paint  9[ ]Don’t Know
   b. In that room, what color are the windowsills painted?
      1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
      2[ ]Other Paint  9[ ]Don’t Know

12. What floor does the child sleep on?
   0[ ]Basement  2[ ]Second  9[ ]Don’t Know
   1[ ]First  3[ ]Third or Above

13. What color are the walls painted in the room where the child sleeps?
   1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
   2[ ]Other Paint  9[ ]Don’t Know

14. What color are the windowsills painted in the room where the child sleeps?
   1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
   2[ ]Other Paint  9[ ]Don’t Know

15. Is there wall-to-wall carpeting in any room of the child’s home?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

16. Approximately how many cigarettes are smoked in the child’s home per day?
   __________ Cigarettes Per Day
17. Does the child have a habit of chewing on pencils?
   1[ ]Yes 2[ ]No 9[ ]Don't Know

18. Does the child take any vitamins, mineral supplements or nutritional yeast?
   1[ ]Yes 2[ ]No 9[ ]Don't Know
   a. (If Yes:) What is the brand name?

19. Does the child attend school or day care?
   1[ ]Yes 2[ ]No 9[ ]Don't Know
   a. (If Yes:) What is the name of the school or day care the child attends?

   b. (If Yes:) What is the address?
     Street Address __________________________
     City __________________________

Section II:
For the parent or guardian completing this questionnaire: These questions refer to you and your relationship to this child.

20. What is your name?
   (First) __________________________
   (Last) __________________________

21. What is your mailing address?
   Street Address (Apt. #) __________________________
   City __________________________ Zip Code ______

22. What is your telephone number?
   (_____ _____) _______-

23. What is your relationship to the child taking part in this study?
   1[ ]Parent 2[ ]Sibling 3[ ]Grandparent 4[ ]Other

---

Sample ID No.: ____ ____ ____ ____

Page 3 of 6 Pages.
Section III:
The following questions refer to your child's health.

24. Has your child ever been diagnosed by a physician to have:
   a. Diabetes?
      1[ ] Yes  2[ ] No  9[ ] Don't Know

   b. Asthma?
      1[ ] Yes  2[ ] No  9[ ] Don't Know

   c. A hole through the middle of the nose
      (a nasal septum perforation)?
      1[ ] Yes  2[ ] No  9[ ] Don't Know

   d. A skin problem?
      1[ ] Yes  2[ ] No  9[ ] Don't Know
      24d.  

      (1) (If Yes:) What kind?

   e. Kidney disease?
      1[ ] Yes  2[ ] No  9[ ] Don't Know

   f. Cancer?
      1[ ] Yes  2[ ] No  9[ ] Don't Know
      24f.  

      (1) (If Yes:) What kind?

25. If the results of your child's urine test are abnormal, would you like a physician to receive them?
   1[ ] Yes  2[ ] No  9[ ] Don't Know

   a. (If Yes:)
      Physician Name ________________________________
      Street Address ________________________________
      City __________________________ Zip Code _______

STOP HERE!

The remaining questions are attached for your information
and will be asked at the time of the interview.

EHS-
AUG 91

Page 4 of 6 Pages.
Section IV:
The following questions refer to the activities of the child who is participating in this study and where he or she spent the past two days.

26. In the past 48 hours, how much time did you [your child] spend in the following places:
   a. Inside your [his or her] house, including sleeping time?
      1[ ]None        3[ ]8-16 Hours
      2[ ]Less Than 8 Hours  4[ ]More Than 16 Hours
      26a. ___
   b. At school?
      1[ ]None        3[ ]8-16 Hours
      2[ ]Less Than 8 Hours  4[ ]More Than 16 Hours
      26b. ___
   c. Outside near your [his or her] home?
      1[ ]None        3[ ]8-16 Hours
      2[ ]Less Than 8 Hours  4[ ]More Than 16 Hours
      26c. ___

27. Have you [Has your child] spent more than 4 of the past 48 hours in any one location (other than those listed above)?
   1[ ]Yes        2[ ]No        9[ ]Don't Know
   27. ___
   If NO, go to Question 28.
   If YES, please list where you were [your child was]:
   a. Street Address ____________________________
      City ____________________________
      (1) How much time did you [your child] spend here?
         2[ ]Less Than 8 Hours
         3[ ]8 - 16 Hours
         4[ ]More Than 16 Hours
         27a1. ___
   b. Street Address ____________________________
      City ____________________________
      (1) How much time did you [your child] spend here?
         2[ ]Less Than 8 Hours
         3[ ]8 - 16 Hours
         4[ ]More Than 16 Hours
         27b1. ___
28. In the past two days, when you were [your child was] at home did you [he or she] do or help with any of the following activities:
   a. Sweep, vacuum or dust inside the house?
      1[ ]Yes  2[ ]No  9[ ]Don't Know
   28a. [___]
   b. Clean attic, garage or basement?
      1[ ]Yes  2[ ]No  9[ ]Don't Know
   28b. [___]
   c. Clean, weed or plant in the yard?
      1[ ]Yes  2[ ]No  9[ ]Don't Know
   28c. [___]
29. During the past two days did you [your child] do or help with any hobbies or jobs that involved pressure-treated wood, boilers, refrigeration equipment, welding, metal working, fabric dyes, tanning leather, cement, plating, ceramics, laboratory chemicals or glass making?
   1[ ]Yes  2[ ]No  9[ ]Don't Know
   29. [___]
   a. (If Yes:) Please describe the hobby or job that was done:

30. Have you [was your child] taken any vitamins, mineral supplements or nutritional yeast in the past two days?
   1[ ]Yes  2[ ]No  9[ ]Don't Know
   30. [___]

To be completed by Interviewer:

Interviewer Initials: [___]
Date of Interview: [____]/[____]/[____]
Date Urine Collected: [____]/[____]/[____]

To be completed by New Jersey State Department of Health Staff:

DEP Number: [____]
DCH Number: [____] [____]
Block Number: [____] [____] [____]
# CHROMIUM QUESTIONNAIRE

(For Ages 11 and Over)

Sample ID No.: |          |          |          |          |

<table>
<thead>
<tr>
<th>Section I:</th>
<th>DO NOT WRITE IN THIS COLUMN</th>
</tr>
</thead>
<tbody>
<tr>
<td>These questions pertain to yourself and where you have lived in the past 6 months. When choices are given, check one choice. Please fill in ALL blanks with information.</td>
<td></td>
</tr>
</tbody>
</table>

1. What is your name?
   (First) __________________________________________________________
   (Last) __________________________________________________________

2. What is your social security number?
   _______ - _______ - _______

3. What is your telephone number?
   ( _______ ) _______ - _______

4. What is your present address?
   Street Address (Apt. #) __________________________________________
   City ______________________ Zip Code ___________________________
   a. Have you lived at this address for more than 6 months?
      1[ ]Yes 2[ ]No 9[ ]Don't Know

5. Have you lived at any address in Jersey City, Kearny, or Bayonne (other than your present address) in the past 6 months?
   1[ ]Yes 2[ ]No 9[ ]Don't Know
   a. (If Yes:) Please fill in the other address where you lived.
      Street Address (Apt. #) __________________________________________
      City ___________________________________________________________

6. Have you ever taken part in any chromium study?
   1[ ]Yes 2[ ]No 9[ ]Don't Know

7. How old are you? ________ Years


9. Sex: 1[ ]Male 2[ ]Female

10. What race do you consider yourself?
    1[ ]White 2[ ]Black/Afro-American 3[ ]Hispanic 4[ ]American Indian 5[ ]Asian 6[ ]Other 10[ ]

BAS- AUG 91

Page 1 of 9 Pages.

B - 47
Questions 11-15 are about where you live now.

11. When awake, what floor do you spend the most time on?
   0[ ]Basement  2[ ]Second  9[ ]Don't Know
   1[ ]First     3[ ]Third or Above

12. When awake, what room of your home do you spend the most time in?
   0[ ]Basement  3[ ]Bedroom
   1[ ]Kitchen/Dining  4[ ]Other
   2[ ]Living, Den, Family  9[ ]Don't Know

   a. In that room, what color are the walls painted?
      1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
      2[ ]Other Paint                     9[ ]Don't Know

   b. In that room, what color are the windowills painted?
      1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
      2[ ]Other Paint                     9[ ]Don't Know

13. What floor do you sleep on?
   0[ ]Basement  2[ ]Second  9[ ]Don't Know
   1[ ]First     3[ ]Third or Above

14. What color are the walls painted in the room where you sleep?
   1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
   2[ ]Other Paint                     9[ ]Don't Know

15. What color are the windowills painted in the room where you sleep?
   1[ ]Yellow, Orange or Green Paint  3[ ]Not Painted
   2[ ]Other Paint                     9[ ]Don't Know

16. Is there wall-to-wall carpeting in any room of your home?
   1[ ]Yes  2[ ]No  9[ ]Don't Know

17. Approximately how many cigarettes are smoked in your home per day?

   __________ Cigarettes Per Day

18. Do you have a habit of chewing on pencils?
   1[ ]Yes  2[ ]No  9[ ]Don't Know
19. Do you take any vitamins, mineral supplements or nutritional yeast?
   1[ ] Yes  2[ ] No  9[ ] Don't Know
   a. (If Yes:) What is the brand name?

20. Do you attend school?
   1[ ] Yes  2[ ] No  9[ ] Don't Know
   a. (If Yes:) What is the name of the school you attend?
      __________________________
   b. (If Yes:) What is the address of the school?
      Street Address __________________________
      City __________________________

Section II:
The following questions are about your jobs if you are working now.

21. Are you currently employed?
   1[ ] Yes  2[ ] No  9[ ] Don't Know
   If NO, go to Question 23.
   a. (If Yes:) What is the name of your main workplace?
      __________________________
   (1) Where is this workplace located?
      Street Address __________________________
      City __________________________
   (2) How many hours a week do you usually work there?
      ________ Hours Per Week
   (3) What is your job title?
      __________________________

EHS-
AUG 91
22. Do you have a second or part-time job?
   1[ ]Yes  2[ ]No  3[ ]Don’t Know
   a. (If Yes:) What is the name of this other workplace?
      __________________________________________________________
      (1) Where is this workplace located?
          Street Address _________________________________________
          City _________________________________________________
      (2) How many hours a week do you usually work there?
          ________ Hours Per Week
      (3) What is your job title?
          ____________________________________________________
Section III:
The following questions refer to your health.

23. Has a physician ever told you that you have:

a. Diabetes?
1[ ]Yes 2[ ]No 9[ ]Don't Know

b. Asthma?
1[ ]Yes 2[ ]No 9[ ]Don't Know

c. A hole through the middle of the nose (a nasal septum perforation)?
1[ ]Yes 2[ ]No 9[ ]Don't Know

d. A skin problem?
1[ ]Yes 2[ ]No 9[ ]Don't Know

(1) (If Yes:) What kind?

23a. ___

23b. ___

23c. ___

23d. ___

23e. ___

23f. ___

23g. ___

23h. ___

23i. ___

23j. ___

23k. ___

23l. ___

23m. ___

23n. ___

23o. ___

23p. ___

23q. ___

23r. ___

23s. ___

23t. ___

23u. ___

23v. ___

23w. ___

23x. ___

23y. ___

23z. ___

24. If the results of your urine test are abnormal, would you like a physician to receive these results?

1[ ]Yes 2[ ]No 9[ ]Don't Know

24a. *

24b. *

a. (If Yes:)

Physician Name ________________________________

Street Address ________________________________

City ______________________ Zip Code ________

STOP HERE!

The remaining questions will be asked by an interviewer.
Section IV:
The following questions refer to your activities in the past two days.

25. In the past 48 hours, how much time did you spend in the following places:
   
a. Inside your house, including sleeping time?
   
   1[ ] None
   2[ ] Less Than 8 Hours
   3[ ] 8-16 Hours
   4[ ] More Than 16 Hours

b. At work?
   
   (1) Main workplace?
   
   1[ ] None
   2[ ] Less Than 8 Hours
   3[ ] 8-16 Hours
   4[ ] More Than 16 Hours

   (2) Secondary workplace?
   
   1[ ] None
   2[ ] Less Than 8 Hours
   3[ ] 8-16 Hours
   4[ ] More Than 16 Hours

c. At school?
   
   1[ ] None
   2[ ] Less Than 8 Hours
   3[ ] 8-16 Hours
   4[ ] More Than 16 Hours

d. Outside near your home?
   
   1[ ] None
   2[ ] Less Than 8 Hours
   3[ ] 8-16 Hours
   4[ ] More Than 16 Hours

26. Have you spent more than 4 of the past 48 hours in any one location (other than those listed above)?
   
   1[ ] Yes
   2[ ] No
   9[ ] Don't Know

If NO, go to Question 27.

If YES, please list where you were:

a. Street Address

   City

(1) How much time did you spend here?

   2[ ] Less Than 8 Hours
   3[ ] 8 - 16 Hours
   4[ ] More Than 16 Hours
b. Street Address

City

(1) How much time did you spend here?

2[ ] Less Than 8 Hours
3[ ] 8 - 16 Hours
4[ ] More Than 16 Hours

26b. [*] *

26b. [__]

26b1. [__]

27. In the past two days, did you do any of the following activities at your house:

a. Sweep, vacuum or dust inside the house?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

b. Clean attic, garage or basement?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

c. Clean, weed or plant in the yard?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

27a. [__]

27b. [__]

27c. [__]

28. In the past two days, did you do any of the following activities at your main workplace:

a. Sweep or clean inside the workplace?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

b. Work in a dusty indoor or outdoor (unpaved trucking area, etc.) setting?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

c. Work with outdoor soil at the workplace (digging, raking, laying pipe, etc.)?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

d. Wash equipment or vehicles at the workplace?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

28a. [__]

28b. [__]

28c. [__]

28d. [__]

29. In the past two days, did you do any of the following activities at your secondary workplace:

a. Sweep or clean inside the workplace?
   1[ ] Yes 2[ ] No 9[ ] Don't Know

29a. [__]
b. Work in a dusty indoor or outdoor (unpaved trucking area, etc.) setting?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

c. Work with outdoor soil at the workplace (digging, raking, laying pipe, etc.)?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

d. Wash equipment or vehicles at the workplace?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

30. During the past two days, did you do any hobbies or jobs that involved pressure-treated wood, boilers, refrigeration equipment, welding, metal working, fabric dyes, tanning leather, cement, plastering, ceramics, laboratory chemicals or glass making?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

a. (If Yes:) Please describe the hobby or job that was done:

31. During the past two days, did you take part in any strenuous athletic activity, which continued for 1 hour or more?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

a. (If Yes:) Please describe what you did:

32. Have you taken any vitamins, mineral supplements or nutritional yeast in the past two days?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

33. Have you smoked cigarettes in the past two days?
   1[ ]Yes  2[ ]No  9[ ]Don’t Know

a. (If Yes:) How many cigarettes in the past two days?
   ________ Cigarettes (a pack has 20 cigarettes)
34. Did you drink beer or wine in the past two days?
   1[ ]Yes  2[ ]No  9[ ]Don't Know

   a. (If Yes:) How many cans (12 oz) of beer in the past two days?
      ________ Cans of Beer

   b. (If Yes:) How many glasses (4 oz) of wine in the past two days?
      ________ Glasses of Wine

To be completed by Interviewer:

   Interviewer Initials:  ________
   Date of Interview:    ________/______/______
   Date Urine Collected  ________/______/______

To be completed by New Jersey State Department of Health Staff:

   DEP Number            ________
   DOH Number            ________/______
   Block Number          ________/______
REQUEST FOR SAMPLE ANALYSIS
HUDSON COUNTY CHROMIUM PROJECTS
URINE SAMPLE for STANDARD ANALYSES
(CHROMIUM, CREATININE and SPECIFIC GRAVITY)

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**COLLECTION DATE:**

(ONLY ONE DATE PER BATCH)

**PROGRAM CONTACT:**

**PHONE:**

**COMMENTS:**

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# Sample Chain of Custody Record

**Name and Address of Submitting Agency:**

**Date and Time Samples Collected:**
- **DATE:**
- **TIME:**

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**Submitting Agency Representative (Print):** __________

**Signature:**

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<th>Field Number</th>
<th>Relinquished By</th>
<th>Received By</th>
<th>Time</th>
<th>Date</th>
<th>Reason for Change of Custodian</th>
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**CHEM-41**

**DISTRIBUTION:**
- White and Canary - Chemical Laboratory
- Pink - Submitter

**B - 50**
**I. PATIENT INFORMATION**

1. Name: (First) __________________ (Last) __________________

2. Social Security Number: ______ ______ ______ ______

3. Address: (Street) __________________ (City) __________________

4. Height: ______ Ft. ______ In.

5. How does the patient rate his/her health compared to others that he/she knows?
   - [ ] Better  [ ] Same  [ ] Worse

   Does the patient have a history of any of the following that is temporally related to his/her potential chromium exposure?

6. Asthma  [ ] Yes  [ ] No  [ ] DK

7. Chronic Unrelenting Allergies  [ ] Yes  [ ] No  [ ] DK

8. Skin Ulceration  [ ] Yes  [ ] No  [ ] DK

9. Chronic Dermatitis  [ ] Yes  [ ] No  [ ] DK

10. Nasal Ulceration  [ ] Yes  [ ] No  [ ] DK

11. Nasal Septal Perforation  [ ] Yes  [ ] No  [ ] DK

**II. PHYSICAL EXAMINATION**

12. Did you find any skin abnormalities?
   - [ ] Yes  [ ] No

   Please draw location of skin abnormality:

   a. (If yes:) Was it a skin ulcer?
   - [ ] Yes  [ ] No

   b. (If yes:) Was it dermatitis?
   - [ ] Yes  [ ] No

   c. (If yes:) Was it another skin abnormality?
   - [ ] Yes  [ ] No

   Please describe skin abnormality:

13. Did you find any nasal or pharyngeal abnormalities?
   - [ ] Yes  [ ] No

   Please draw location of nasal or pharyngeal abnormality:

   a. (If yes:) Was it a nasal ulceration?
   - [ ] Yes  [ ] No

   b. (If yes:) Was it nasal-septal perforation?
   - [ ] Yes  [ ] No

   c. (If yes:) Was it tonsillar inflammation?
   - [ ] Yes  [ ] No

   d. (If yes:) Was it another nasal/pharyngeal abnormality?
   - [ ] Yes  [ ] No

   Please describe nasal or pharyngeal abnormality:

**III. REFERRAL**

14. Was a referral made on the basis of possible exposure to chromium?
   - [ ] Yes  [ ] No
New Jersey State Department of Health  
Chromium Medical Surveillance Project  

PATIENT INFORMATION: SCREENING EXAMINATION

<table>
<thead>
<tr>
<th>Name of Patient</th>
<th>Patient SSN</th>
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<tr>
<td>Name of Physician</td>
<td>Date of Examination</td>
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I am the physician working with the New Jersey State Department of Health to determine if you had any medical conditions that could be caused by exposure to chromium. When I examined you:

- [ ] I did not find any abnormalities of your skin, nose, or throat. This means that it is unlikely that you have been exposed to large amounts of chromium.

- [ ] I found
  on physical examination of your skin, nose, and throat, which is:

- [ ] You have a history of

- [ ] This condition is unlikely to be related to exposure to chromium, therefore we recommend:

- [ ] I found
  on physical examination of your skin, nose, and throat, which is:

- [ ] You have a history of

- [ ] This condition is possibly related to exposure to chromium. We would like to schedule you for additional testing. There would be no charge for this testing and we will be happy to assist you with transportation if you should need it. You will be contacted within the next two weeks to schedule the follow-up evaluation.

You should continue to avoid chromium in the ways that we discussed. You should see your personal physician for any other medical problems or conditions that you may have because the evaluation done today was only for chromium-related health.

If you have any questions about these results or about chromium-related health effects, please call the New Jersey State Department of Health at 609-984-2193, during the hours of 8:30 AM to 4:30 PM, Monday to Friday.

Signature of Physician | Date
--- | ---
BHS-12 | Nov 91

Distribution: White-Patient, Canary-NJSDH, Pink-Clinic

B - 60
THANK YOU
for taking part in the New Jersey Department of Health’s Chromium Screening Program.

- The doctor who examined you has already told you of his or her findings. You have received the written information about your examination.

- Your urine sample will be tested for chromium. The results of that test will tell us if you had been exposed to an unusual amount of chromium in the past few days. These results will be mailed to your home address. You will be scheduled for more detailed follow-up if there is any evidence of excess chromium exposure.

- There are some things you can do that may decrease your risk of future health problems related to chromium exposure:

  ☐ STAY AWAY FROM KNOWN CHROMIUM WASTE SITES.
  ☐ DO NOT TOUCH OR TRY TO CLEAN UP ANYTHING THAT LOOKS LIKE CHROMIUM WASTE.

  Chromium waste is usually in the form of reddish-brown pebbles. Chromium-contaminated water is yellow in color. Wherever this contaminated water dries (on outdoor soil, basement walls, etc.), yellow-green crystals may form. Call the New Jersey Department of Environmental Protection and Energy [NJDEPE] if you see any chromium water, crystals or waste.

  ☐ IF YOU COME IN CONTACT WITH CHROMIUM, WASH YOUR SKIN WITH COOL WATER.
  ☐ USE A DAMP CLOTH TO DUST INSIDE YOUR HOME AT LEAST ONCE A WEEK.
  ☐ DAMP-MOP FLOORS AT LEAST ONCE A WEEK.
  ☐ SHARE THIS INFORMATION WITH FAMILY, NEIGHBORS & FRIENDS.

If you need any further information about chromium and your health, you may call the New Jersey Department of Health, Environmental Health Service at (609)884-2193. For information regarding the location and clean-up of chromium-contaminated sites, you may contact George Tomaccio of the NJDEPE, Bureau of Community Relations at (609)884-3081.
DEAR !NAME!

Thank you for your recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of your urine sample collected on !URINEDATE!. If you received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in your urine sample was !CHROMIUM! micrograms per liter. The laboratory analysis shows that you may have been exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether you were exposed to excess chromium at other times.

Your level of chromium was higher than that of most people screened. We do not know if an elevated amount of chromium in the urine is related to adverse health effects. For this reason we have referred you to the University of Medicine and Dentistry of New Jersey (UMDNJ) for further evaluation. Staff from UMDNJ will be contacting you to arrange for an appointment and transportation to the UMDNJ Clinic, if needed, and to arrange for dust sampling for chromium inside your home.

If you have any questions regarding this information, please contact Patricia Haltmeier of the New Jersey Department of Health at (609) 984-2193 between 8:00 A.M. and 4:00 P.M.

Sincerely,

Jerald A. Fagliano, M.P.H.
Program Manager
Environmental Health Service
Date to be stamped

[fill in name]

DEAR [fill in name]:

Thank you for your recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of your urine sample collected on [fill in date]. If you received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in your urine sample was [fill in micrograms per liter]. Considering your age, activities and urine diluteness, the analysis shows that you were not exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether you were exposed to excess chromium at other times.

If you have any questions regarding this information, please contact Patricia Halmeyer of the New Jersey Department of Health at (609) 984-2193 between 8:00 A.M. and 4:00 P.M.

Sincerely,

Jerald A. Fagliano, M.P.H.
Program Manager
Environmental Health Service
Date to be stamped

Dear [NAME]:

Thank you for your recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of your urine sample collected on [URINEDATE]. If you received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in the urine sample which you provided was less than 0.20 micrograms per liter, the lowest level that can be found by laboratory methods. This analysis shows that you were not exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether you were exposed to excess chromium at other times.

If you have any questions regarding this information, please contact Patricia Halmeyer of the New Jersey Department of Health at (609) 984-2193 between 8:00 A.M. and 4:00 P.M.

Sincerely,

Jerald A. Pagliano, M.P.H.
Program Manager
Environmental Health Service
Date to be stamped

RE: !FNAME! !LNAME!

DEAR !FNAME! !LNAME!:

Thank you for your child's recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of !FNAME!'s urine sample collected on !URINEDATE!. If your child received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in !FNAME!'s urine sample was !CHROMIUM! micrograms per liter. The laboratory analysis shows that your child may have been exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether your child was exposed to excess chromium at other times.

!FNAME!'s level of chromium was higher than that of most children screened. We do not know if an elevated amount of chromium in the urine is related to adverse health effects. For this reason we have referred !FNAME! to the University of Medicine and Dentistry of New Jersey (UMDNJ) for further evaluation. Staff from UMDNJ will be contacting you to arrange for an appointment and transportation to the UMDNJ Clinic, if needed, and to arrange for dust sampling for chromium inside your home.

If you have any questions regarding this information, please contact Patricia Haltmeier of the New Jersey Department of Health at (609) 984-2193 between 8:00 A.M. and 4:00 P.M.

Sincerely,

Jerald A. Fagliano, M.P.H.
Program Manager
Environmental Health Service

B - 66
Date to be stamped

DEAR !PARFNAME! !PARLNAME!:

Thank you for your child's recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of !FNAME!'s urine sample collected on !URINEDATE!. If your child received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in !FNAME!'s urine sample was !CHROMIUM! micrograms per liter. Considering your child's age, activities and urine diluteness, the analysis shows that your child was not exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether your child was exposed to excess chromium at other times.

If you have any questions regarding this information, please contact Patricia Haltmeier of the New Jersey Department of Health at (609) 984-2193 between 8:00 A.M. and 4:00 P.M.

Sincerely,

Jerald A. Fagliano, M.P.H.
Program Manager
Environmental Health Service
Date to be stamped

RE: !FNAME! !LNAME!:

Dear !FNAME! !LNAME!:

Thank you for your child's recent participation in the New Jersey Department of Health Chromium Medical Surveillance Project. This letter contains the results of the chromium test of !FNAME!'s urine sample collected on !URINEDATE!. If your child received a physical examination on that day, you were notified of the examination results at that time.

A small amount of chromium is found in all people and is essential for good health.

The concentration of chromium in !FNAME!'s urine sample was less than 0.20 micrograms per liter, the lowest level that can be found by laboratory methods. This analysis shows that your child was not exposed to an excess of chromium in the days immediately before the urine sample was collected. This test does not indicate whether your child was exposed to excess chromium at other times.

If you have any questions regarding this information, please contact Patricia Haltmeier of the New Jersey Department of Health at (609) 984-2193.

Sincerely,

Jerald A. Fagliano, M.P.H.
Program Manager
Environmental Health Service
To: Chromium Medical Surveillance Project
   Environmental Health Service
   New Jersey Department of Health

From: Iris Udasin, MD

Date:

Re: Summary of Follow-up Medical Examination Findings

Patient Name: ________________________________

Examination Date(s) ________________________________

Examining Physician(s) ________________________________

Findings of the General Physical Examination:
Were there any abnormal conditions identified upon examination of:

   lungs? _______ skin? _______ nose? _______

Were any findings likely to be related to chromium exposure? [Yes / No ]

If yes, please elaborate: ________________________________

Urine Analysis: Analysis of the urine sample yielded the following results:

   Beta-2-microglobulin ______ Ketones ______ Proteins ______
   Glucose ______ Blood ______ Bilirubin ______

A 24-hour urine sample [ was / was not ] requested. If a 24-hour sample was requested, the participant provided a [ complete / partial / no ] sample.

The urine analysis [ did / did not ] indicate chromium-related effects.

If it did, please elaborate: ________________________________
**Blood Analysis:** Analysis of the blood sample yielded the following results:

BUN _______ Creatinine _______

All liver enzymes concentrations [ were / were not ] within the normal range.

If not, please elaborate__________________________

The blood analysis [ did / did not ] reveal chromium-related effects.

If it did, please elaborate:________________________

**Spirometry:** Spirometry testing yielded the following values:

FEV1 _______ FEC _______ FEV1/FEC Ratio _______

All spirometry values [ were / were not ] within the normal ranges.

Spirometry [ did / did not ] reveal chromium-related effects.

If it did, please elaborate _______________________

**Examination by Dermatologist:** The patient [ was / was not ] examined by a dermatologist. If yes, please elaborate on supplemental page.

**Conclusions of Follow-up Medical Examination:**

The follow-up medical examination [ did / did not ] reveal chromium-related health problems. If it did, please elaborate:

__________________________

__________________________

__________________________

If applicable, the following recommendations and/or referrals were provided to the participant:

__________________________

__________________________

__________________________
Supplemental Page: Follow-up Examination Report
Examination by Dermatologist

<table>
<thead>
<tr>
<th>Patient Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatologist Name</td>
<td></td>
</tr>
<tr>
<td>Date of Examination</td>
<td></td>
</tr>
</tbody>
</table>

**Findings of Examination by Dermatologist:**

Did the examination reveal any dermatological conditions? [ yes / no ]

If yes, please elaborate:

<p>| |</p>
<table>
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<tr>
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</thead>
</table>

Were these conditions likely to be related to chromium exposure? [ yes / no ]

If yes, please elaborate:

<p>| |</p>
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<tr>
<th></th>
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</thead>
</table>

A patch test [ was / was not ] offered to the patient.

Date patch applied  

Dates patch read  

**Findings:**

<p>| |</p>
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<tr>
<th></th>
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</thead>
</table>

The patch test [ did / did not ] reveal allergic reaction to chromium.
Supplemental Page: Follow-up Examination Report
Examination by Dermatologist

Patient Name ____________________________

Dermatologist Name ________________________

Date of Examination ______________________

Findings of Examination by Dermatologist:

Did the examination reveal any dermatological conditions? [yes / no]

If yes, please elaborate:

________________________________________

________________________________________

________________________________________

Were these conditions likely to be related to chromium exposure? [yes / no]

If yes, please elaborate:

________________________________________

________________________________________

A patch test [was / was not] offered to the patient.

Date patch applied ________________________

Dates patch read __________________________

Findings: __________________________________

________________________________________

________________________________________

The patch test [did / did not] reveal allergic reaction to chromium.
APPENDIX C

Comparison of Urine Chromium Decision-making Methods
APPENDIX C

Comparison of Urine Chromium Decision-making Methods

Introduction

As described in section 3.2.9 and Appendix B of this report, a decision had to be made on whether the urine chromium concentration in each screened individual was high. The CMSP used a decision-making method in which an "excess" concentration would be computed for each participant, which is the difference between the observed concentration and an expected level (taking into account relevant personal, behavioral, environmental and sample characteristics). If a screened participant's excess was more than 0.5 µg/l (representing the 98th percentile excess level among the baseline population), the participant was referred for follow-up evaluation.

As a check on the judgments made by this method, two other decision-making methods were examined and tested periodically during the screening project. Individual decisions were made based on:

1) comparison of the unadjusted urine chromium concentrations of the screened persons with the 98th percentile level of this concentration in the baseline population (1.06 µg/l), or

2) comparison of the chromium/creatinine ratios of the screened persons with the 98th percentile level of this ratio in the baseline population (2.56 µg/g creatinine).

At the end of the screening project, decisions based on the excess method (which used information from the baseline survey only) were compared to decisions that might have been made based on urine chromium models developed after all data were analyzed. These decisions is comparison was based on:

3) comparison of the adjusted urine chromium concentrations of the screened persons with the 98th percentile level of this concentration in the baseline population (0.75 µg/l), computed as described in section 3.4.2, using the model including participants of all ages.

Methods

The 98th percentiles of the unadjusted urine chromium, chromium/creatinine ratio, and adjusted urine chromium concentration in the baseline population were computed. Alternative referral decisions for screened participants were made based on these values. The proportion referred by each method was calculated.

Examination of the referral proportions alone, however, do not indicate the degree to which the methods agree on an individual basis. Decisions made by each of these methods were cross-tabulated with decisions made by the excess method employed in the CMSP.
Percent agreement (the proportion of participants whose decisions were the same by both methods) and the kappa statistic (a measure of agreement between two methods that corrects for concordance due to chance alone). Values of kappa exceeding 0.75 are considered to represent excellent agreement between methods, while values below 0.40 reflect poor agreement (Fleiss, 1981).

Results

Referral proportions for each method are found in Table C-1. Of the decision-making methods tested, the excess method resulted in the highest overall referral proportions, while the ratio method resulted in the lowest. Referral proportions were higher in females in all methods, but especially with the ratio method.

The percent agreement and kappa statistic for each method in comparison to the excess method are found in Table C-2. The agreement was good to excellent between the excess method and the unadjusted and adjusted methods, according to the kappa statistic values. However, the agreement between the excess and ratio methods was poor, as indicated by the low kappa values. In general, agreement statistics were slightly better among females than males.

The poor agreement between the ratio and excess method is attributable to the inflation of the ratio among individuals with low creatinine levels. When screened individuals whose creatinine levels were below 0.70 g/l were excluded from the computation of the agreement statistics, as suggested by Berode et al. (1991) and Stern et al. (1992), the kappa values rise to 0.65, 0.66 and 0.65 for all participants, males and females, respectively. The 98th percentile of the ratio in the baseline population, among those with creatinine greater than 0.70 g/l, dropped to 0.72 μg/g, indicating that persons with low creatinine were over-represented in the high end of the ratio distribution.

References


Table C-1. Referral proportions of screened participants, by decision-making method.

<table>
<thead>
<tr>
<th>Decision-making Method*</th>
<th>Referral Proportion</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>Males</td>
<td>Females</td>
</tr>
<tr>
<td>Excess</td>
<td>9.9%</td>
<td>9.1%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>6.2%</td>
<td>6.1%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Ratio</td>
<td>5.6%</td>
<td>4.0%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Adjusted</td>
<td>8.6%</td>
<td>8.2%</td>
<td>9.2%</td>
</tr>
</tbody>
</table>

* Decisions based on exceeding the 98th percentile level in the baseline population.

Table C-2. Percent agreement and kappa statistic, comparing individual decisions with those made by the excess method.

<table>
<thead>
<tr>
<th>Decision-making Method*</th>
<th>Percent Agreement (Kappa Statistic)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>Males</td>
<td>Females</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>96% (0.75)</td>
<td>95% (0.72)</td>
<td>97% (0.79)</td>
</tr>
<tr>
<td>Ratio</td>
<td>87% (0.13)</td>
<td>84% (0.09)</td>
<td>90% (0.17)</td>
</tr>
<tr>
<td>Adjusted</td>
<td>96% (0.75)</td>
<td>95% (0.73)</td>
<td>97% (0.78)</td>
</tr>
</tbody>
</table>

* Decisions based on exceeding 98th percentile level in the baseline population.