# Treatment of Lead-Exposed Children Trial

**PROTOCOL**

**November 4, 1997**

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# 1. PURPOSE AND RATIONALE

## 1.1. Introduction

The adverse effects of exposure to high levels of lead have been known for hundreds of years. Only recently, however, have the effects of relatively low level exposures to lead on development, blood pressure levels, and other health endpoints been recognized. Epidemiologic studies[1], [2] have, for example, reported deficits of three to seven intelligence quotient (IQ) points per 10 micrograms per deciliter (g/dL) increase in average blood lead concentration in cognitive test scores of exposed children tested at ages four to eleven. Primate and human neurodevelopmental research has provided evidence that attention, learning, short-term memory, and executive function may be the selectively deficient domains of cognition that underlie these IQ differences.[3] The Clean Air Science Advisory Committee of the Environmental Protection Agency[4] has recommended 10 g/dL as the maximum safe blood lead concentration for an individual child. The U.S. Centers for Disease Control and Prevention[5] has also recommended 10 g/dL as the blood lead level of concern; values above this level trigger a series of actions including monitoring of exposed children, steps to prevent further exposure, and assessment of the utility of treatment.

Children living in inner cities in the United States, along with those living in older homes with leaded paint, are at highest risk of exposure to lead. The U.S. Agency for Toxic Substances and Disease Registry[6] estimates from 1984 census data that over 12 million children are at risk from leaded paint alone. Unfortunately, little is currently known about the developmental effects of treatment of children with elevated blood lead concentrations. Lead chelation with a variety of agents is known to reduce blood lead concentrations acutely, but the concentration may rebound to as much as 70% of its baseline value within weeks to months after treatment, often requiring repeated courses of treatment. Strategies for treating children with elevated blood lead concentrations and for assessing the developmental effects of those treatments are urgently needed. The Treatment of Lead-Exposed Children (TLC) Trial has been designed to assess the effects of lead chelation with succimer in children aged at least 12 and less than 33 months at the beginning of treatment as measured by developmental status three years after the initiation of treatment.

## 1.2. Study Objectives

### 1.2.1. Primary Objective

To compare the effects of lead chelation with the drug succimer and placebo therapy on developmental status, as measured by full-scale deviation IQ score measured using the Wechsler Preschool and Primary Scales of Intelligence -- Revised (WPPSI-R), three years after initiation of treatment of children initially aged at least 12 and less than 33 months with baseline blood lead concentrations between 20 and 44 g/dL. Residential lead clean-up and nutritional supplementation with multivitamins and minerals will be provided to all study children, irrespective of treatment group.

### 1.2.2. Secondary Objectives

To evaluate the effect of chelation on other measures of developmental status, including the verbal and performance scales of the WPPSI-R, the Child Development Inventory, Conners' Parent Rating Scale, the Woodcock-Johnson Memory for Names, the Stanford-Binet Bead Memory, Kaufman's Magic Window, Diamond's Modified Stroop Task, and the Tower of Hanoi.

To compare the effects of lead chelation and placebo therapy on change in height, weight, and head circumference during the three-year period of treatment and follow-up.

To compare the effects of lead chelation and placebo therapy on change in systolic and diastolic blood pressure levels during the three-year period of treatment and follow-up.

# 2. OVERVIEW OF THE TLC TRIAL

## 2.1. Study Design

The TLC Trial is designed to compare the effect of lead chelation with succimer to placebo therapy in boys and girls who are at least 12 and less than 33 months of age and have blood lead concentrations (PbB) from 20 to 44 g/dL at enrollment in the trial. Children who are referred to TLC-affiliated Clinical Centers with elevated blood lead concentrations will be enrolled in a screening and home evaluation program that includes a minimum of two clinic visits and one home visit. During the screening period, the blood lead levels of referred children will be remeasured by the TLC's central laboratory at the Centers for Disease Control and Prevention (CDC), other eligibility criteria will be checked, and their homes will be visited to determine whether they are amenable to environmental clean-up. Children whose blood lead is confirmed to be in the range of 20 to 44 g/dL by the CDC laboratory and whose home environments meet TLC criteria will be eligible for enrollment in the randomized trial. Upon receipt of informed consent from a parent or legal guardian, eligible children will be randomized to chelation therapy with succimer or placebo. The trial will be conducted as a double-blind, placebo-controlled trial and will enroll both boys and girls equally as mandated by the NIH Revitalization Act. TLC participants will be enrolled without regard to race, but it is expected that the majority will be of African-American descent. Except for the Newark site, where many of the study participants will be Hispanic, enrollment of linguistic minorities will not be possible due to small or non-existent populations at each clinic and due to language capabilities of TLC staff.

Children enrolled in the succimer group will receive one to three rounds of chelation therapy as described subsequently. Blood lead levels will be measured two weeks after the completion of each round of chelation and reported to the Data Coordinating Center. If a child has been randomized to the succimer group and this blood lead measurement is greater than or equal to 15 g/dL, the Clinical Center will be directed to schedule an additional round of succimer treatment. At most three rounds of treatment will be given. To preserve the double blind, the Data Coordinating Center will direct the Clinical Centers to schedule an equal number of rounds of retreatment in the placebo group. Clinical Centers will not have access to blood lead measurements during the treatment period except under special circumstances as described below. The two treatment groups will receive identical vitamin and mineral supplementation and a common lead dust management program which may be supplemented by various Clinical Centers within limitations of budget. Enrolled children will be followed for at least three years, with periodic assessment of their developmental status. The test of the trial's primary hypothesis will be based on developmental status as measured by the Wechsler Preschool and Primary Scale of Intelligence three years after enrollment. A number of additional measures of developmental status will also be considered, particularly measures of learning, short-term memory, attention, and executive function.

## 2.2. Administration

The TLC Trial is sponsored by the National Institute of Environmental Health Sciences (NIEHS) with support from the Office of Research on Minority Health of the National Institutes of Health (ORMH, NIH). The Trial will be conducted at four Clinical Centers: the Children's Hospital of Philadelphia (Philadelphia PA); the Kennedy Krieger Institute, in association with the Johns Hopkins University and the University of Maryland (Baltimore MD); the University of Cincinnati (Cincinnati OH) in conjunction with Columbus Children's Hospital (Columbus OH); and the University of Medicine and Dentistry of New Jersey (Newark NJ). These sites were selected on the basis of technical merit and cost from an open, nationwide competition. They serve inner city communities that are primarily African-American and reflect well the national distribution of lead poisoning. The Harvard School of Public Health (Boston MA) will serve as the Data Coordinating Center, the Centers for Disease Control and Prevention (CDC, Atlanta GA), through its Nutritional Biochemistry Branch, will serve under an Intra-agency Agreement as the Central Laboratory for the Trial, and the Public Health Service Supply Service Center (Perry Point MD) will serve under an Intra-agency Agreement as the Drug Distribution Center.

Central policy for the Trial will be set by a Steering Committee composed of one representative from each of the above-mentioned organizations and the Project Officer (from NIEHS) who will serve *ex officio*, making a total of seven members. Each regular representative will have one vote. The NIEHS Project Officer will vote to resolve ties. The Committee will elect its own Chair. The Steering Committee will be ultimately responsible for the Trial protocol and manual of operations. It will review and approve all requests to undertake ancillary studies that involve TLC subjects or

TLC data as well as all proposals for publications and presentations based on TLC subjects or TLC data. The power to control the budget of the Trial and of the individual contracts rests with NIEHS under the usual federal laws and regulations.

NIEHS has appointed a Data and Safety Monitoring Committee which will be advisory to the Institute. The Committee is composed of the following seven members:

Stephen Gehlbach, Amherst, MA (Chair)

Carol Angle, Omaha, NE

John Faison, Philadelphia, PA

Bernadette Gray-Little, Chapel Hill, NC

Sherman James, Ann Arbor, MI

Lemuel Moyé, Houston, TX

Herbert Needleman, Pittsburgh, PA

Membership was determined by the NIEHS and was limited to people without appointments at the Universities involved in implementing the Trial. Meetings of the Data and Safety Monitoring Committee will be arranged by the Data Coordinating Center. The Project Officer, the Principal Investigator from the Data Coordinating Center, and the Chair of the Steering Committee will commonly attend all or parts of these meetings, but the Data and Safety Monitoring Committee shall have the prerogative of working in executive session without these other individuals. The Data and Safety Monitoring Committee will review and approve the Trial protocol and will monitor the accumulating data and progress of the Trial at least annually. It is anticipated that ordinary recommendations from the Data and Safety Monitoring Committee will be made to the Project Officer, but unusually important findings or opinions of the Committee can be forwarded, at the Committee's discretion, to the Director of NIEHS or to other officials.

A Planning Committee composed of the Steering Committee members and other professional personnel at the various sites will meet as necessary and will be responsible, with assistance from the Data Coordinating Center staff, for writing the Trial protocol and for developing a manual of operations for the Trial. The planning committee will assist with arrangements for the comparable and coordinated implementation of the protocol at the various sites. Meetings of the entire or of partial membership of the Planning Committee may be called by the Steering Committee or by the Project Officer in consultation with the Principal Investigator from the Data Coordinating Center and the Chair of the Steering Committee. The Chair of the Steering Committee will also chair the Planning Committee. The protocol and manual of operations developed by the planning committee will be subject to amendment and approval by the Steering Committee and to approval by the Data and Safety Monitoring Committee.

The work of the Planning Committee will be facilitated by subcommittees with expertise in the several areas related to the Trial. These subcommittees may be established, altered, or abolished as necessary by the Planning Committee. Their membership and responsibilities are subject to review by the Steering Committee. Subcommittees established at the outset of the Trial are: Clinical Issues, Psychometrics, Environmental Issues, Screening and Eligibility, Treatment and Toxicity Monitoring, Community Relations, and Drug Management.

See Appendix 1 for a list of TLC Centers and for committee and subcommittee membership.

## 2.3. Study Population

The planned sample size for the TLC Study is 1,332. Each of four Clinical Centers will enroll 333 children. The racial and ethnic composition of the study sample is expected to reflect the composition of the clinic population at each Clinical Center. However, linguistic minorities will be excluded in all centers except Newark, where Hispanic children make up a sizable portion of the population and will be included.

Table 1 provides estimates in percentages of the racial and ethnic makeup of each Clinical Center's population and of the overall Study population.

**Table 1: Racial and ethnic makeup of study population by clinical center and overall**

| Clinical Center | American Indian or Alaskan Native | Asian or Pacific Islander | Black, not of Hispanic origin | Hispanic | White, not of Hispanic origin | Other or unknown | Total |
|---|---|---|---|---|---|---|---|
| Baltimore, MD | 0% | < 1% | 87% | < 1% | 11% | 1% | 100% |
| Cincinnati & Columbus OH | 0% | < 2% | 79% | < 1% | 19% | 0% | 100% |
| Newark, NJ | 0% | 0% | 71% | 23% | 5% | 1% | 100% |
| Philadelphia, PA | 0% | 5% | 85% | 2% | 8% | 0% | 100% |
| OVERALL | 0% | < 2% | 81% | 6% | 11% | 0% | 100% |

Overall, we estimate that 80 to 85% of TLC subjects will be African-American. Due to physical location and language capabilities at the Clinical Centers, only one Center (Newark, NJ) will have substantial Hispanic representation, at approximately 23% of the Center's population. The Hispanic population is small at the remaining Centers and none of these Centers has the linguistic capability to perform the proposed psychometric testing in Spanish. Asian, Pacific Islander, Alaskan Native and American Indian representation in the TLC population is small at all Clinical Centers and none of the Centers has the linguistic capability to deal with the wide range of languages possible in these racial groups. In addition, the psychometric instruments proposed as outcome measures in this Trial are not available in the appropriate languages and normed for the appropriate cultures. However, since the issue is one of language, not ethnic background, children from these racial groups will be recruited as TLC participants unless the family's primary language is not English.

**Table 2** provides estimates in percentages of the racial and ethnic makeup of the proposed Study sample, given the planned exclusion of linguistic minorities.

**Table 2: Racial and Ethnic Makeup of Proposed Study Sample by Clinical Center and Overall**

| Clinical Center | American Indian or Alaskan Native | Asian or Pacific Islander | Black, not of Hispanic origin | Hispanic | White, not of Hispanic origin | Other or unknown | Total |
|---|---|---|---|---|---|---|---|
| Baltimore, MD | 0% | 0% | 89% | 0% | 11% | 0% | 100% |
| Cincinnati & Columbus, OH | 0% | 0% | 81% | 0% | 19% | 0% | 100% |
| Newark, NJ | 0% | 0% | 72% | 23% | 5% | 0% | 100% |
| Philadelphia, PA | 0% | 0% | 91% | 0% | 9% | 0% | 100% |
| OVERALL | 0% | 0% | 83% | 6% | 11% | 0% | 100% |

## 2.4. Compliance with the NIH Revitalization Act of 1993

The TLC Trial must comply with the NIH Revitalization Act of 1993, which requires that any NIH-funded clinical research include women and minorities as research subjects. In addition, in any trials in which women and minorities are included as subjects, the trial must be designed in a way that will allow for valid sub-group analyses. NIH has completed a set of proposed guidelines for the implementation of the act and these guidelines were published in the Federal Register on March 28, 1994.

The study population will reflect the population known to be at greatest risk due to lead exposure, i.e., low income, urban, African-American children. Consequently, the TLC Trial is primarily a study of a minority population. There is currently no evidence suggesting that there are or are not differences in the effects of lead on cognitive development or of the efficacy of succimer by racial or ethnic group.

The TLC Trial will recruit boys and girls equally as Trial subjects. Research on gender differences in the effects of lead on cognitive development has yielded mixed results.[7] With the expected balanced enrollment by gender, we will be able to perform valid analysis on differences by gender.

We are committed to meeting the spirit as well as the letter of the law with respect to the inclusion of women and minorities in the TLC Trial. A number of leadership positions in the Trial administrative structure are held by women, including the Principal Investigator of the Philadelphia Center and the Chair of the Treatment and Toxicity Subcommittee. Membership on the various TLC committees is well-balanced by gender. With respect to minority representation, the administrative structure of the TLC Trial does not reflect the population to be recruited. However, we are aware of the need for sensitivity to this issue. The proportion of minority membership on the Data and Safety Monitoring Committee is greater than 50%. One of the criteria applied in selecting Clinical Centers was the level of experience of the site in working with inner city communities that are primarily African-American, reflecting the national distribution of lead poisoning. We intend to employ minorities whenever possible in this project, especially as case managers, psychometricians, and other key positions involving interaction with the community. For Spanish-speaking families in the Newark Center, all Informed Consent forms will be translated into Spanish and at least one of the psychometricians will be bilingual to ensure that all neurobehavioral assessments are performed in the preferred language of the children. The Newark Center will also have bilingual members of the environmental assessment team and there will be a translator available for the study as needed.

Every effort will be made to provide courteous and culturally sensitive service to participating TLC families. The training of TLC personnel will cover issues surrounding the need for cultural sensitivity in working with patients, their families, and the larger community. The TLC staff will attempt to provide assistance to the family that goes beyond the confines of the TLC protocol, for example, assistance in obtaining benefits such as supplemental food programs for women and their children (WIC) and food stamps. In addition, the removal of barriers to participation, such as lack of transportation, is crucial to recruitment and retention. Accordingly, TLC will cover the costs of transportation to and from all study visits. Trial-related treatments will be provided free of charge, including drug or placebo, multivitamin and mineral supplements, blood lead tests, developmental assessments, and assessment and clean-up of homes. In addition, the subjects and their families will be given small gifts to establish a sense of camaraderie between TLC families and staff. Such gifts might include small toys for the children and food coupons, diaper coupons, cleaning supplies, and door mats for the families. Participating Centers have found these kinds of gifts to be very welcome to their Clinic families. Such an incentive strategy benefits not only the subjects and their families but is also crucial for a successful Trial, in that incentives tend to encourage long-term follow-up.

Each Clinical Center will develop and implement a plan to educate key individuals and groups in its constituent community about the TLC Trial. The details of these efforts will vary among the Centers, but their general theme will be to inform key individuals about the need and rationale for the trial, about the opportunities that it creates to provide better care to local children with lead poisoning, and about more general issues regarding lead in the environment. Such education will serve to prevent misunderstanding about the randomized, placebo-controlled design of the TLC trial and may assist with recruitment. This educational effort will be carried out primarily through meetings with selected groups and individuals in the respective communities. Limited use of mass media is a possibility. Centers may establish Community Advisory Committees to guide these educational efforts.

# 3. ELIGIBILITY

## 3.1. Pre-randomization Visit 1 (V1)

### 3.1.1. Inclusion Criteria

a. Projected age at randomization (in approximately five weeks) of at least 12 and less than 33 months.

b. Elevated blood lead level per local laboratory.

c. English-speaking family or, in Newark, English or Spanish-speaking family.

d. Willingness of parent or legal guardian to participate as evidenced by first informed consent.

### 3.1.2. Exclusion Criteria

a. Exclusions based on pre-existing medical conditions by parental report and/or physical examination:

(1) Pre-existing significant developmental deficit or disease or syndrome known to be associated with mental retardation, neuromuscular disorder, or sensory deficit, including, but not limited to, phenylketonuria (PKU), Down Syndrome, and Fetal Alcohol Syndrome.

(2) Birth weight under 3 pounds by best available information.

(3) Psychiatric or psychological disorder which would prohibit adequate evaluation, including, but not limited to, autism and reactive attachment disorder.

(4) Known renal or hepatic disease.

(5) Known chronic anemia which is not due to iron deficiency; including, but not limited to, sickle cell disease and thalassemia major.

(6) Cyanotic congenital heart disease.

(7) Known human immunodeficiency virus (HIV) positive.

(8) Allergy to sulfa or mercaptans as evidenced by hives or anaphylactic reaction.

(9) Prior chelation therapy for lead poisoning.

(10) Body surface area greater than 0.713 $m^2$.

b. Any child living in the same household with another child in the treatment phase of the TLC protocol. Housemates may be sequentially entered after six months.

c. Children currently enrolled in any other research drug protocols, other research protocols using psychometric assessments, or other research protocols conflicting with this protocol.

d. Exclusions based on residential history:

(1) The child's current address is outside the defined catchment area of the Center.

(2) The family has definite plans to move from the catchment area of the Center within the foreseeable future.

(3) Family plans for child to be away for three months or more during the first six months of participation.

(4) Child's current residence is too dangerous for TLC personnel to visit.

e. Exclusions based on abnormalities in laboratory values obtained at pre-randomization clinic visit 1 (V1):

(1) PbB < 20 g/dL or PbB > 44 g/dL.

(2) Iron status

(a) Hemoglobin level less than 9 g/dL from any cause.

(b) Hemoglobin level greater than or equal to 9 g/dL and less than 10 g/dL combined with an increased red cell distribution width. Such children will be prescribed three months of therapeutic iron and will return for repeat

testing in one month. If the hemoglobin is greater than or equal to 10 g/dL at repeat testing, the child will be enrolled.

(3) Liver function studies

(a) Alkaline phosphatase greater than twice the upper limit of normal for the local laboratory.

(b) Aspartate aminotransferase (AST) greater than twice the upper limit of normal for the local laboratory.

(c) Alanine aminotransferase (ALT) greater than twice the upper limit of normal for the local laboratory.

(d) Absolute neutrophil count below 800/$mm^3$.

(e) Platelet count below 150,000/$mm^3$.

Children with abnormalities in alkaline phosphatase, AST, ALT absolute neutrophil count, or platelet count will be scheduled for repeat testing of the abnormal laboratory value(s) in two to three weeks. Any further TLC activities will be deferred until the results of this repeat testing are known. If the results are normal, the child will be enrolled.

(4) Other laboratory values

(a) Serum creatinine greater than 1.0 mg/dL.

(b) Proteinuria greater than 2+ on dipstick.

(c) Glucosuria on dipstick.

Children whose serum creatinine is greater than 1.0 mg/dL or with glucosuria or proteinuria will be referred for further work-up of their condition and may be reconsidered for study eligibility if these abnormalities resolve. In such cases, repeat testing of the abnormal laboratory values will be required before any further TLC activities are carried out.

## 3.2. Pre-randomization Visit 2 (V2)

### 3.2.1. Inclusion Criteria

a. Projected age at randomization (in one week) of at least 12 and less than 33 months.

b. Venous blood lead level from CDC of 20 - 44 g/dL.

c. Willingness of parent or legal guardian to participate as evidenced by second informed consent.

### 3.2.2. Exclusion Criteria

a. Inability of family or child to comply with the TLC protocol:

(1) Children missing 50% or more of scheduled visits without extenuating circumstances during the pre-randomization period.

(2) Children at the extremes of multivitamin compliance during the pre-randomization period, i.e., inability to give medication to TLC subject or dispensation of medication to other than TLC subject.

(3) Children or families who, in the best judgment of the clinician, are unable to comply successfully with trial requirements.

b. Exclusions on the basis of the home visual assessment:

(1) Child's current residence is too lead-hazardous to be adequately cleaned and child cannot be relocated in lead-safe housing. The child may be enrolled later if these conditions change.

(2) Child's current residence is too dangerous for TLC personnel to visit.

(3) The child spends significant amounts of time in two or more residences and the TLC Home Assessor is unable to assure that the child's total residential environment will be sufficiently clean to begin chelation therapy.

c. Body surface area less than 0.357 or greater than 0.713 $m^2$.

# 4. CLINICAL INTERVENTION

## 4.1. Pharmacology of Succimer

Succimer (2,3-meso-dimercaptosuccinic acid) is an orally active dithiol compound that is a relatively specific chelating agent for heavy metals, especially lead, arsenic and mercury. The drug undergoes limited absorption in the gastrointestinal tract and then is rapidly metabolized to mixed disulfides which are eliminated in the urine. Blood levels decline slowly with an apparent elimination half-life of about 48 hours in adults.

Succimer has several advantages over other available lead chelating agents. Urinary excretion of essential elements (Ca, Fe, Zn, Cu) is only minimally increased after succimer, in contrast to extensive metalluresis following $CaNa_2EDTA$. Plumburesis appears to be greater following administration of succimer compared to conventional doses of other lead chelating agents. Oral administration of succimer allows for outpatient therapy which is impractical with the parenterally administered $CaNa_2EDTA$. Finally, clinical experience to date has shown succimer to be well-tolerated with minimal toxicity during single or repeated courses of therapy.

To date, reversible adverse effects of succimer include hypersensitivity (incidence about 1-2%) and asymptomatic serum transaminase elevation. Neutropenia and asymptomatic, reversible alkaline phosphatase elevation occasionally have been reported. Other than drug hypersensitivity, these effects have not required discontinuation of succimer therapy.

Disadvantages of succimer relate to the drug's characteristics and pharmacologic information gaps. The "rotten-egg" odor and bad taste may affect compliance as well as produce occasional gastrointestinal upset in children taking the drug. Whether succimer enhances lead absorption is unknown, but it is an important consideration when a child taking the drug continues to reside where lead paint hazards are unabated. Data from animal studies suggest that succimer may produce a redistribution of internal lead stores.

Data from McNeil Laboratories on the stability of succimer in various liquids is presented in Table 3.

**Table 3. Stability of Succimer in Liquid After 15 Minutes**

| Liquid | % Retention of original activity |
|---|---|
| Cranberry juice | 96% |
| Apple juice | 85% |
| Coca Cola | 78% |
| 7-Up | 75% |
| Kool-Aid | 66% |

Food is a difficult matrix for analysis and background interference precluded analysis of chocolate-containing foods. However, McNeil chemists estimate that about 80% of active drug remained 15 minutes after it was mixed with applesauce. It is not believed that succimer bioavailability will be affected by the protein content of any food with which the drug might be mixed.

The optimal dosing regimen and duration of therapy with succimer have yet to be determined.

## 4.2. Treatment Regimen

The treatment dosing in this trial will be based on body surface area (BSA). BSA will be calculated using the following formula, developed by Du Bois and Du Bois.[8]

$$\text{BSA in mm}^2 = (\text{WEIGHT}^{0.425} \times \text{HEIGHT}^{0.725} \times 71.84\ ) / 10{,}000$$

Children randomized to succimer will receive approximately 1050 mg/m$^2$ of succimer in three divided doses per day for seven days, followed by 700 mg/m$^2$ in two divided doses per day for 19 days for a total course of therapy of 26 days.

Children whose body surface area is less than 0.357 or greater than 0.713 will be excluded from the study. Children randomized to placebo will follow a similar BSA-specific regimen. During treatment, children will be seen on days 7, 28, and 42. At each visit, blood will be drawn to measure PbB, complete blood count (CBC), differential, platelet count, AST, ALT, and alkaline phosphatase. Table 4 provides the exact succimer dose by body surface area.

Table 4. Succimer Dose by Body Surface Area

| BSA CLASS | BSA RANGE (m$^2$) | DAYS 1 - 7 | | DAYS 8 - 26 | |
|---|---|---|---|---|---|
| | | DAILY DOSE in mg (# caps/dose) | DOSE DELIVERED (mg/m$^2$/day) | DAILY DOSE in mg (# caps/dose) | DOSE DELIVERED (mg/m$^2$/day) |
| A | 0.357 - 0.428 | 400 (1-1-2) | 1120 - 935 | 300 (1-2) | 840 - 702 |
| B | 0.429 - 0.499 | 500 (2-1-2) | 1167 - 1002 | 300 (1-2) | 700 - 602 |
| C | 0.500 - 0.523 | 500 (2-1-2) | 1000 - 956 | 400 (2-2) | 800 - 765 |
| D | 0.524 - 0.618 | 600 (2-2-2) | 1145 - 971 | 400 (2-2) | 764 - 647 |
| E | 0.619 - 0.642 | 700 (2-2-3) | 1131- 1091 | 400 (2-2) | 646 - 624 |
| F | 0.643 - 0.713 | 700 (2-2-3) | 1089 - 981 | 500 (2-3) | 778 - 701 |

Children whose PbB at day 42 is greater than 15 g/dL will be retreated beginning on day 49. Each child on succimer requiring retreatment will be paired with a placebo child who will follow the same protocol as the retreated child. A maximum of three courses of drug therapy will be administered for up to six months in the treatment phase for children receiving three courses of drug. The protocol for retreatment will be the same as for the initial course of treatment.

In this trial, succimer will be administered using fruit juice or soda. Non-carbonated fruit-flavored beverages will be avoided. If a child refuses to take drug in one of these liquids, the drug will be mixed with approximately one teaspoonful of applesauce, jelly, or vanilla pudding for administration.

## 4.3. Toxicity Monitoring

If the PbB increases to 45 g/dL or greater during the treatment period, the Data Coordinating Center will notify the Clinic to bring the subject in for a repeat blood test within three days. The repeat PbB will be processed by the central laboratory on an urgent basis. If the repeat PbB value from CDC remains above 44 g/dL, the study treatment will be interrupted, and the child will be treated according to the Clinical Center's standards of care for children with lead levels above 44 g/dL. This will include reassessment of the child's environment for potential lead exposure and coordination with the local health department for formal lead assessment as per local requirements. Blinding of treatment assignment will be maintained.

In the unlikely event that the PbB increases to 60 g/dL or greater during the treatment period, the Data Coordinating Center will notify the Clinic immediately, and study treatment will be stopped immediately. The child will be treated according to the Clinical Center's standards of care for children with lead levels 60 g/dL or greater. This will include a reassessment of the child's environment for continuing sources of lead exposure. Repeat blood testing by the CDC laboratory will not be required for treatment; however, a second blood sample will be obtained and sent to the CDC for evaluation. Blinding of treatment assignment will be maintained.

If a child's PbB increases to more than 15 g/dL above her or his baseline (V2) PbB value within six months of randomization, a repeat PbB will be performed as soon as possible. Confirmation of the increase in PbB will trigger environmental reassessment and, where appropriate, further cleanup. Blinding of treatment assignment will be maintained.

Possible toxicities of succimer include elevation of liver function tests and decline in neutrophil counts. Elevations in liver function tests occur in about 5% of children. To maintain blinding, liver function levels will be blinded for both parents and clinic personnel until six months after randomization. Each Clinical Center will identify a physician not having direct subject or guardian contact who will review laboratory results during the period of blinding. The reviewing physician will notify the clinician if transaminase exceeds two times the upper limit of normal, alkaline phosphatase exceeds five times the upper limit of normal, the absolute neutrophil count decreases to less than 800/$mm^3$, the platelet count decreases to less than 150,000/$mm^3$, or the values change in a way which the reviewing physician considers to be of concern. If a value is abnormal, the reviewing physician will order repeat testing. If a second abnormal value is obtained, the reviewing physician may recommend discontinuation of study drug. Blinding of treatment assignment will be maintained.

Suspected or known adverse drug reactions will be reported promptly to the manufacturer, to the Food and Drug Administration, and to the local human subjects committee.

## 4.4. Informed Consent

For all TLC participants, the consent of a parent or legal guardian will be required. The language of the informed consent documents will be that of the parent or legal guardian and will be geared to a 6th grade school educational level. Informed consent will be sought on two occasions. Stage I informed consent will cover the pre-enrollment period and will be obtained at pre-randomization clinic visit 1 (V1). Stage II informed consent will cover enrollment in the randomized protocol and will be obtained either during the visit immediately prior to the initiation of treatment (V2) or the visit at which treatment will be initiated (T0). See Appendix 2 for informed consent forms from each of the Clinical Centers.

## 4.5. Randomization

After Stage II informed consent has been obtained, subjects will be randomized in a 1:1 ratio to either the succimer or placebo treatment group. Treatment assignments will be determined by a permuted blocks randomization scheme with stratification by city (Baltimore, MD, Newark, NJ, Philadelphia, PA, Cincinnati, OH, and Columbus, OH), class of body surface area as defined in Table 4 above, language (English or Spanish), and most recent CDC blood lead level (20 - 24 g/dL and 25 - 44 g/dL). Once treatment has been initiated, a child will be considered to be enrolled in the randomized trial for its duration, regardless of followup status. Children who are taken off the treatment protocol prematurely will continue to be followed according to the TLC schedule. Children will be followed according to study

protocol irrespective of their level of compliance with study treatment, and all available outcome data will be included in the analyses according to the principle of "intent to treat" analysis.

## 4.6. Maintenance of Double-blind

Treatment will be blinded to the fullest extent possible. Both parents and clinic personnel will be blinded to the child's PbB levels during treatment until six months after randomization.

Succimer emits a strong odor of sulfur, while the placebo for succimer emits a smell of alcohol. Therefore, it will not be possible to provide a fully comparable placebo. However, to provide a more sulfur-like smell to the placebo, a vented cylindrical plastic canister, 0.5 inches in diameter and 0.6 inches in length, will be filled with 200 mg of succimer and added to all bottles of study drug (not just those containing succimer). The addition of the canister will change the odor of the placebo to one which is qualitatively similar to, but not as intense as, that of the active drug. Further, every effort will be made to avoid the need for any clinic personnel to open any subject's medication bottle or otherwise deal directly with the study drug. The subjects taking succimer may themselves give off a strong odor; therefore, it may not be possible to blind clinic personnel entirely. For example, parents or caregivers may comment on the smell. Clinic personnel responsible for psychometric assessment, however, will not have contact with subjects or their caregivers during the treatment period.

As discussed above, local laboratory results will be reviewed by a physician who does not have direct subject or guardian contact during the treatment period. If a value is abnormal, the physician will order repeat testing. If a second abnormal value is obtained, the physician may recommend discontinuation of study drug. Blinding of treatment assignment will be maintained.

## 4.7. Compliance Assessment

Because succimer emits a strong odor, the use of pill counts to assess compliance at each Clinic visit will unblind TLC personnel. Several other strategies will be used to quantify compliance with study drug. The parent or caregiver of all subjects will receive a specially designed medication diary. The diary will use pictorial directions in addition to text in English or Spanish. The caregiver will make an entry into the diary when each dose is administered. In addition, they will be instructed to bring the diary and the medication bottle to each treatment visit. At each treatment visit, a member of the clinic staff will review the medication diary and talk with the caregiver about their success in complying with treatment instructions. At the end of each round of treatment, the bottle will be returned to the Drug Distribution Center for pill counting and destruction of left-over study drug. The results of study drug pill counts will be forwarded to the Data Coordinating Center.

Pill counts, while the standard measure of compliance currently in use in most drug trials, have been shown both to overestimate compliance[(9), (10)] and to be unreliable.[(11)] Medication diaries are helpful only when used in conjunction with an objective measure of compliance. Accurate compliance monitoring will help distinguish between the two known reasons for inadequate response to succimer therapy, i.e., continued environmental exposure to lead versus noncompliance with therapy. In the Ohio Center, the Medication Event Monitoring System (MEMS) will be used to provide a more accurate measure of compliance than can be provided by pill counts or medication diaries. The standard MEMS bottle cap contains a special electronic chip which records date and time whenever the bottle is opened. The data gathered in the Ohio Center using the MEMS caps will be used to assess the accuracy of pill counts and medication diaries as measures of compliance.

A relatively new and untested version of the MEMS caps is their "smart cap", which records the number of hours between bottle openings, as well as the date and time of each opening. The "smart" cap can also be programmed to beep when a dose is scheduled to be taken and to display the number of bottle openings that have occurred during each 24-hour interval. In addition to providing an accurate measure of compliance, this new "smart" MEMS cap is hypothesized to assist parents with compliance. The Ohio Center will test the hypothesis that the newer cap enhances compliance by using "smart" caps for half the children and the standard "track" cap for the remainder of the children.

# 5. DEVELOPMENTAL ASSESSMENT

## 5.1. Introduction

Longitudinal studies of the neurobehavioral sequelae of asymptomatic lead toxicity have consistently reported deficits in IQ in lead-exposed children.[12] Thus, the primary hypothesis to be tested in the TLC Trial is that treatment with succimer will lead to improved developmental outcome as evidenced by improved scores on standardized intelligence testing. IQ of study participants will be measured by the Bayley Scales of Infant Development-II (BSID2) at baseline and at the six-month followup visit, by the BSID2 or the Wechsler Preschool and Primary Scales of Intelligence-Revised (WPPSI-R) (depending on the child's age) at the 18-month followup visit, and by the WPPSI-R at the 36-month followup visit.

Using IQ as the sole outcome measure in a study whose population is projected to be 85% African-American would be unacceptable. Controversy has surrounded the assessment of intellectual ability for over a century. Legitimate concerns were raised in the 1960s and 1970s concerning the appropriateness of existing psychological tests for the assessment of minorities, particularly African-Americans.[13] These concerns were focused on potential racial or ethnic bias in standardized measures of intellectual attainment and academic achievement. This has been one of the most emotionally and politically charged controversies in the psychological sciences.[14], [15] Until the last few decades, the instruments used to measure intellectual ability were not subjected to quantitative or qualitative analyses aimed at evaluating racial, ethnic, or gender bias. The more recent psychometric instruments available from the major test publishers are less likely to suffer from these problems.

The assessment of intelligence using norm-referenced tests alone does not provide a complete description of developmental status. The underlying basis for poor intellectual performance (e.g., deficits in attention, organization, impulse control, ability to follow directions, or quality of motor activity) may not be captured by standardized tests of intellectual attainment. Primate and human neurodevelopmental research has provided evidence that the attention, learning, short-term memory, and executive function are the selectively deficient domains of cognition that may underlie IQ differences.[2, 3] Behavioral problems have been found to be associated with lead exposure in some observational studies.[16], [17], [18] In addition, deficits in the fine motor skills important for school work (e.g., the ability to use pencils, crayons, or scissors) have been associated with low to moderate exposure to lead.[19]

Several other measures of developmental status will be obtained. All children will be assessed at approximately 36 months after randomization with the Developmental Neuropsychological Assessment (NEPSY). Designed specifically for use with children, the NEPSY assesses attention and executive function, language, sensorimotor abilities, visuospatial processing, and memory and learning. In addition, the Child Development Inventory (CDI) will be administered to parents at all psychometric visits (baseline, six-, 18-, and 36-month followup visits) and the Conners' Parent Rating Scale - Revised, Short Form (CPRS) will be administered to parents at the 36-month followup visit. The CDI and CPRS utilize parental reports as the principal source of data. Some studies have suggested that the diagnostic utility of standardized tests of cognitive and motor development is improved through the use of maternal reports.[20] Parents are also an important source of information about the child's behavior outside the clinical setting.

Parental IQ will be obtained at the 12-month followup visit using the Wechsler Adult Intelligence Scale -- Revised, Short Form. Maternal IQ is preferred; however, paternal or guardian IQ will be obtained if the biological mother is unavailable for testing.

The schedule for psychometric testing is summarized in Table 5.

**Table 5. Schedule of Psychometric Testing**

| Instrument | Baseline | 6 mos. post randomization | 12 mos. post randomization | 18 mos. post randomization | 36 mos post randomization |
|---|---|---|---|---|---|
| Bayley Scales of Infant Development-II (BSID2) | | | | * | |
| Wechsler Preschool and Primary Scales of Intelligence-Revised (WPPSI-R) | | | | ** | |
| Child Development Inventory (CDI) | | | | | |
| Conners' Parent Rating Scale (CPRS) | | | | | |
| Developmental Neuroopsychological Assessment (NEPSY) | | | | | |
| Wechsler Adult Intelligence Scale -- Revised, Short Form (WAISR-SF) (parental IQ) | | | | | |

* For subjects up to and including 42 months of age at this visit

** For subjects over 42 months of age at this visit

## 5.2. Bayley Scales of Infant Development-II (BSID2)

The BSID2[(21)] is a revision and restandardization of the well-known Bayley Scales of Infant Development.[(22)] It is suitable for infants and young children from one to 42 months of age. The Bayley Scales of Infant Development are the most widely used and precisely constructed of all published infant intelligence tests.

The BSID2 yields a Mental Development Index (MDI) and Psychomotor Development Index (PDI) which are similar to a deviation IQ score with a mean of 100 and a standard deviation of 15. The MDI is designed to evaluate the development of sensory and perceptual acuities and discriminations, acquisition of object constancy, memory, learning, problem solving, vocalization, beginning of complex language, and mathematical concept formation. The PDI is designed to evaluate the development of postural control, coordination of the large muscles, postural imitation, and stereognosis.

The BSID2 includes a Behavior Rating Scale with which the examiner rates the infant's affective, attentional, and motivational behaviors. It consists of thirty separate 5-point items which assess qualitative aspects of the subject's attentional, emotional, and motor behaviors. Previous studies suggest that the regulation of attentional, motor, and emotional behaviors may be perturbed in children with blood PbB concentrations in excess of 20 g/dL.
The BSID2 takes from 45 to 75 minutes to administer.

## 5.3. Wechsler Preschool and Primary Scales of Intelligence - Revised (WPPSI-R)

The WPPSI-R[(23)] is a revision of the original Wechsler Preschool and Primary Scale of Intelligence[(24)] and is suitable for children aged 35 to 87 months. The WPPSI and WPPSI-R possess the best psychometric properties of all published tests of preschool intelligence. Among all preschool IQ tests, the WPPSI-R has been used the most to establish the construct and criterion-based validity of other measures of preschool intellectual attainment.

The WPPSI-R consists of a collection of 12 subtests organized into two scales, a Verbal Scale and a Performance Scale. The Verbal Scales use language-based items while the Performance Scale test uses visual-motor items that are

somewhat less dependent on language. The WPPSI-R yields scale scores for the 12 subtests as well as Verbal, Performance, and Full-Scale deviation IQs which have a mean of 100 and a standard deviation of 15.

The WPPSI-R takes from 60 to 75 minutes to administer.

## 5.4. Wechsler Adult Intelligence Scale - Revised, Short Form (WAISR-SF)

Parental intelligence is one of the most powerful predictors of child IQ. An assessment of parental IQ is included in this clinical trial to serve as a potent covariate as well as a check on the randomization.

Parental IQ will be assessed using the two-subtest short form of the Wechsler Adult Intelligence Scale - Revised[24]. Maternal IQ will be obtained whenever possible. When the maternal IQ cannot be obtained, the clinic will attempt to obtain the paternal IQ or the IQ of the child's primary caregiver. The two-subtest short-form includes the vocabulary and block design subscales. The scoring tables of Silverstein[(25)] will be used. The WAISR-SF will yield a full scale deviation IQ. This particular short form of the full WAIS-R has a higher correlation with full scale IQ based upon the total Wechsler battery than any other subtest dyad (corrected r = 0.90).

The WAISR-SF takes from 20 to 30 minutes to administer.

## 5.5. Child Development Inventory (CDI)

The CDI[(26)] is a revised version of the Minnesota Child Development Inventory (MCDI) and is administered to the parent or caregiver. The 270 items on the CDI are grouped to form several scales. TLC psychometricians will administer only those items which contribute to the scoring of the General Development Scale (GDS). The GDS has a correlation of 0.89 with age in the normative sample. Validity studies using the original MCDI showed that the General Development Scale correlated significantly with various outcome measures, including the Mental and Psychomotor Indices from the Bayley Scales of Infant Development and the General Cognitive Index from the McCarthy Scales of Children's Abilities.[(27), (28), (29), (30)]

The CDI scales were derived rationally, not through factor analysis, and were normed with reference to a sample of 568 children from South St. Paul, Minnesota, a primarily white, working class community. An earlier version of the CDI was shown to have good concurrent validity when applied to a population of minority, high-risk children.[(31)] The CDI is designed to require an eighth-grade reading level for parents to complete it independently. The mean years of parental education for the normative group was approximately 13 years. Interviewers will be available to guide and assist parents in filling out the CDI form. It is anticipated that there will be a significant number of TLC parents and caregivers who will need help filling out the form.

The GDS of the CDI takes approximately 20 minutes to administer.

## 5.6. Conners' Parent Rating Scale (CPRS)

The Conners' Parent Rating Scale - Revised, Short Form[(32)] is a 27-item rating scale administered to the parent or caregiver and used to characterize patterns of child behavior. The items yield standard scores on three sub-scales: Oppositional, Cognitive Problems, and Hyperactivity. The scales were derived in factor analyses using normative data from 2,426 children aged 3 to 17 years. The CPRS has been used extensively in research, and considerable validation data are presented in the test manual.

The CPRS takes approximately 10 minutes to administer.

## 5.7. Developmental Neuropsychological Assessment (NEPSY)

The Developmental Neuropsychological Assessment is the first standardized neuropsychological examination developed specifically for pre-school and primary school children. It is designed to identify underlying neurocognitive deficiencies that interfere with learning. The subtests of the NEPSY are divided into five functional domains: (a)

Executive Functions, including attention, planning, and problem solving; (b) Language and Communication; (c) Sensorimotor Functions; (d) Visuospatial Functions; and (e) Learning and Memory. Deficits in these areas have been associated with lead toxicity in various studies. In the TLC Trial, the NEPSY will be administered at a separate visit approximately 36 months after randomization. At that time, all subjects will be between 48 and 70 months old.

The core battery of the NEPSY takes approximately 1 hour to administer.

## 5.8. Quality Control Procedures

The supervising TLC psychologist at each Clinical Center will train the psychometricians at that Center in all psychometric instruments. In particular, each psychometrician will obtain pilot experience in the assessment of children between the ages of 12 and 72 months using the instruments selected for the trial. On a pilot basis, each trainee will administer the BSID2 to two or three children and the CDI to their parent at ages 12, 18, 24, and 30 months. Training on the WPPSI-R, CPRS, NEPSY will focus on the assessment of preschool children between three and five years of age. Training on the Tower of Hanoi will be performed on children five years of age or older. Pilot children will be sampled from a population similar to that expected to be recruited into the trial at that Center.

Intertester reliability in scoring will be well established prior to formal data collection through the use of video-tape or other means of observation. The performance of psychometricians will be periodically evaluated throughout the study with the use of reliability studies.

Each Center will provide a clean, quiet, and comfortable room large enough to administer all components of the psychometric examinations. To assure optimum performance and standardization among the Centers, children will be scheduled for psychometric examinations during daytime hours, avoiding the child's usual nap time. Care will be taken to ensure that the child is not tired, ill, hungry, or taking any medications which may affect performance when the exam takes place. Children who are ill will be rescheduled for psychometric evaluation.

TLC psychometricians will be required to score each test twice to prevent error resulting from the misreading of raw to scale-score conversion tables. Supervising psychologists will review each test prior to data coding on TLC forms and submission to the Data Coordinating Center.

# 6. ENVIRONMENTAL ASSESSMENT AND CONTROL

## 6.1. Introduction

The environmental intervention in this trial is designed to reduce substantially the subject's exposure to lead attributable to lead-based paint in poor condition and/or to lead-contaminated house-dust. This reduction in exposure is particularly important during the treatment phase, a period of up to six months, and during the period of greatest hand-to-mouth activity for each child, up to approximately 36 months of age. A secondary goal is to reduce exposure to lead for the duration of the trial, a period of up to three years from enrollment. In order to be able to detect any long-term impact of succimer, it is necessary that at least the primary goals be accomplished. Optimally, a child with lead toxicity should be relocated to lead-safe housing; however, this is usually not possible. Lead paint abatement is the next best option but is often difficult and prohibitively expensive, taking many months to complete. The final option, and the one adopted by this trial, is to provide interim control measures aimed at reducing exposure to lead in deteriorating paint and lead dust through in-place management of sources.

This protocol establishes standards of environmental assessment and intervention to be followed by all Clinical Centers. Each Center will meet or exceed applicable local, state, and federal guidelines for the clinical management of children with lead toxicity. See Appendix 3 for copies of the relevant laws, regulations, and guidelines. As resources permit, individual Centers may elect to provide environmental management beyond the common core. TLC efforts are not meant to substitute for lead paint abatement that would be required or encouraged by local health departments. See Appendix 4 for supplemental environmental protocols from the TLC Clinical Centers.

The TLC clean-up protocol does not, and is not intended to, substitute for the legally mandated activities carried out by local or state agencies in each city. TLC activities will be carried out independently of and in addition to municipal or state activities. TLC participation will not relieve anyone of the responsibility to abate. All participants in the Trial will have more clean-up activities done to their homes than they would otherwise have.

## 6.2. Environmental Assessment and Monitoring

### 6.2.1. Initial Home Assessment

At the first clinic visit (V1), environmental assessment will begin with a residential questionnaire designed to help determine eligibility for the trial. Children may be excluded because of the reported quality of current housing, high frequency of changing residences, or extended periods of time spent by the child at two or more secondary residences. In addition, the parent or guardian will be asked several questions related to any lead paint problems in their current dwelling. This information will be of value to the Assessor at the time of the first home visit (H1).

At the first home visit (H1), trained TLC personnel will determine whether the child will be excluded from the Trial based on the condition of the housing, will estimate the amount of work required to clean the residence, and will assess the likelihood that efforts at lead dust suppression will fail within an unacceptably short interval. An assessment will be made of the likely risks of lead exposure based on
(1) condition of painted surfaces

(2) accessibility of non-intact painted surfaces

(3) condition of painted substrates

(4) ease with which surfaces can be cleaned

(5) overall structural integrity of the dwelling, both interior and exterior.

Standardized assessment forms will be used in all Clinical Centers to assess the residential dwelling unit, common areas (such as hallways and stairwells), and porches. Frequency of access by the child to each area will be considered in the environmental assessment and clean-up plan. If the housing unit meets eligibility criteria, the TLC Assessor will sketch a floor plan, record room sizes and number of windows, note the type of flooring with particular attention to carpeting, estimate the amount of time required to prepare and clean the unit, and determine if it will be necessary to contact the building owner or manager prior to any planned clean-up activities.

During the first home visit, the family will be informed as to what will be done, when the cleaning and paint stabilization will be conducted, how long it will take, what they should do in preparation, and what they should do during cleaning and other work. In some cases, a child with an elevated blood lead may be found to live in relatively lead-free housing or to have moved to relatively lead-free housing after the detection of the blood lead elevation and prior to study enrollment. In such cases, the TLC Assessor may elect to implement a less aggressive clean-up plan, if the age and condition of the housing so warrant.

### 6.2.2. Collection of Environmental Lead Monitoring Data

There are several needs for measuring the amount of lead in the child's environment. These data are needed to describe the average level of dust lead exposure across cities. This can be accomplished, for a minimal expenditure of resources, by measuring dust lead levels in a random subset of all study residences in each city. Monitoring data are also needed to assure that the residence has been appropriately cleaned and is relatively lead-safe. This monitoring should be performed as soon as possible following clean-up. Finally, lead measurements may serve as covariates in analyses which attempt to characterize the effectiveness of succimer in reducing blood lead levels. Such data could also be used to explain anomalous responses to succimer therapy and to quantify the extent of residential lead reduction.

Evaluation of contractor performance with respect to the clean-up protocol will be based on post-clean-up visual inspection and a "white glove" test. Since we do not know if our clean-up protocol is adequate to attain Housing and Urban Development (HUD) clearance levels, these guidelines should not be used to monitor clean-up. Similarly, we have no basis for specifying a particular percent reduction in lead loading of dust samples.

To determine and document the effectiveness of the clean-up strategy, pre- and post-clean-up dust wipe samples will be collected from approximately 50 homes in each site. Half of these homes will be evaluated during the first two months of recruitment, analyzed quickly, and reviewed by the Environmental Subcommittee. If the lead loadings increase

following clean-up activities, this information will be used to evaluate the clean-up protocol and the performance of the cleaning crew. The remaining homes will be evaluated over the rest of the year.

A single composite wipe from the floor areas will be collected from each residence approximately three to six months after clean-up. This sample will document the exposure of each study participant following clean-up and treatment. These samples will be archived pending availability of funds to analyze the samples.The measures of lead loading will be obtained by using the HUD wipe method. This is a standard measure which is relatively inexpensive to collect and analyze. It cannot be used on carpets and provides only a measure of loading; however, these constraints are not seen as serious limitations in the context of the TLC Trial.

## 6.3. Lead Dust Suppression Procedures

A TLC cleaning crew will return to the home of each eligible child before randomization to clean that child's house according to a standardized protocol. As resources permit, the family will be provided with plastic bags or cardboard boxes several days prior to cleaning, so that they can pick up items on the floor for easy removal by the cleaning crew.

A strict series of contamination control procedures will be in force throughout the dust suppression process to ensure that contaminated furnishings, cleaning water, and dust are handled appropriately on-site and transported to the designated disposal site as appropriate without loss or spread of material. Vacuum cleaners equipped with high-efficiency particulate accumulator (HEPA) filters will be used to abate interior dust. If the vacuum cleaner bag breaks while a vacuum cleaner is operating or if the vacuum cleaner is operated without a bag, the second stage filter must be changed prior to any further use of the vacuum cleaner.

Each cleaning crew will consist of two or three individuals. This crew will be responsible for the temporary removal of the furnishings and carpeting to other locations within the housing or to a lockable van brought to the housing site for this purpose. Moving the furniture will permit more efficient use of time in cleaning. Removal of all furniture is not necessary; however, furniture remaining in a room during cleaning will be covered in plastic. The crew is also responsible for vacuuming and washing household surfaces including the floors and ledges (e.g., window wells and sills) and restoring the furniture and personal belongings to their original locations.

The first step in cleaning will be the preparation of an area for temporary storage of household belongings from other rooms. This preparation will include an initial one-pass vacuuming. After the temporary storage area has been prepared, the rooms will be cleaned in a sequence which begins with rooms located furthest from the entrance. All ledges (e.g., sills, tops of baseboards) will be washed with a detergent solution. Window wells, if accessible, will be vacuumed to remove paint chips and dust and then wiped clean with a damp sponge. Other dust traps (e.g., venetian blinds, cold air return registers, baseboards) will be inspected and cleaned as appropriate. The family will be encouraged to wash curtains and dispose of old carpets and blinds.

Carpeting will be vacuumed as follows. The carpet will be folded in half and the bottom side of the carpet will be vacuumed and the exposed floor will be vacuumed and damp mopped with the detergent solution. The carpet will then be folded to the opposite side of the room and the same procedures will be carried out on the other half of the carpet and exposed floor. If there is padding beneath the carpet, it will be cleaned in a manner similar to the carpets, if possible. The last step in the cleaning process will be a final vacuuming of the carpet. The carpet will be vacuumed three times at the rate of one minute per square yard each time. Workers will be required to time this vacuuming with a watch. All carpets will be vacuumed with an approved HEPA equipped vacuum and an approved beater bar. In rooms where the carpeting is permanently installed (e.g., wall to wall carpeting), the carpeting will not be folded back and the floor beneath the carpeting will not be cleaned. The carpet will be vacuumed at the rate indicated above. At the completion of the vacuuming, the furniture and personal belongings will be replaced in their original positions.

If there is no carpeting on the floor, the floor will be vacuumed at the rate of one minute per square yard. After the first vacuuming, the floor will be damp mopped with a detergent solution and then vacuumed a second time at the specified rate. This second vacuuming may only be needed in the worst situations where the floor surface is in very poor condition and is therefore likely to retain large quantities of dust.

Badly deteriorated carpets or padding will be permanently removed, if possible. Disposal of the carpet or padding is left to the discretion of the TLC Home Assessor. When disposal or replacement of carpets or padding is indicated, the

existing carpet or padding should be rolled into a tight roll and wrapped with 4 mil polyethylene plastic and taped securely with duct tape or a similarly durable strapping tape prior to removal from the room. If new carpet or padding is to be installed, it should not be installed until all cleaning and paint stabilization in the housing unit has been completed.

Common areas (e.g., hallways, stairs) will be included in the cleaning effort to increase the effectiveness of the dust suppression efforts. Similarly, porches and other exterior entryways will be included in the clean-up program. The limited paint stabilization effort will also be applied to the common areas, porches, and entryways. Particular attention will be given to deteriorated painted surfaces on porches, including ceilings. All surfaces will be vacuumed to remove loose paint.

Door mats at the interior entry to the residential unit will be used to minimize the amount of dust which enters the living space. These mats will be periodically cleaned or replaced to prevent them from becoming a reservoir of lead dust that can contaminate the house. Outdoor mats or indoor-outdoor carpet are recommended. The thickness of indoor mats and their placement must not interfere with the normal opening of the entry door; otherwise, they are likely to be removed by the resident.

A two-bucket system will be used for washing floors. The cleaning solution will be mixed in one bucket; the second bucket will contain rinse water for cleaning the mop head. The water in both buckets will be changed after cleaning approximately every 75 to 100 square feet of floor and after each room is completed. Wash water will be disposed of in the toilet. It will not be disposed of in other places such as sinks, bath tubs, street gutters, or back yards.

## 6.4. Paint Stabilization

It is not the objective of this trial to carry out or oversee comprehensive lead paint abatement activities. However, the interim dust control procedures will be rapidly negated if no attention is given to deteriorated paint surfaces. If the deterioration is extensive and proper paint abatement is not an immediate possibility, then relocation must be sought or the child will be excluded from participation in the trial. If the deterioration is localized to one or two surfaces (e.g., window sills or frames), then in-place management is an appropriate interim option to be carried out under this trial. Loose, peeling paint will be gently brushed with a damp towel or damp sponge to remove the flakes or these can be removed with a vacuum cleaner with an appropriate attachment. Contact paper or a coat of paint may be applied over the deteriorated surface to provide a short term stabilization of the surface. All loose chips must be vacuumed and the surrounding surfaces washed. It is important that the family and landlord understand that this is an emergency measure only. Without adequate preparation of the painted surface, any form of encapsulant will have a short life expectancy. Constant reinspection by the family is required. The family will be instructed to keep children away from the repaired area until more complete abatement can be provided by the owner.

The parent or guardian will be instructed to contact the TLC representative if the surface deteriorates further or if the landlord performs her or his own repairs or repainting. In the latter case, the parent will be instructed to request that the workers clean the area thoroughly by damp mopping and wiping up any dust. The parent should further remove any dust left behind by repair workers.

## 6.5. Followup

Each family will be provided with educational materials and information on lead poisoning and how to minimize its occurrence. As needed and within the constraints of available funds, families will be supplied with cleaning materials, such as a bucket, mop, sponges, and detergent.

Cleaning by TLC personnel beyond the baseline clean-up will occur at a minimum when a subject changes residence. Frequency of recleaning beyond this minimum will be within the constraints of available funds and proportional to the perceived rate of lead dust reaccumulation and rate of deterioration of painted surfaces. The condition of painted surfaces should be assessed periodically. If the temporary stabilization does not appear to be satisfactory, other measures, such as owner-provided abatement or relocation, should be considered.

## 6.6. Quality Control Procedures

To standardize the home visual assessment process, assessors from each city will undergo common training and will use a common assessment form. Photographs of various painted surface conditions with varying degrees of surface degradation will be used.

Training for cleaning and paint-stabilization personnel will include relevant parts of the four-day EPA-approved Lead Abatement Course for Workers, Supervisors, and Contractors or its equivalent as developed specifically for this trial. Prior to the enrollment of the first subject, pilot cleaning will occur in each community in housing selected specifically for this purpose. Workers will be supplied with uniforms to wear during working hours and a facility for changing clothes and cleaning up at the end of the day to eliminate the potential for carrying lead dust into their cars or homes. Work crews will not engage in any paint removal activities unless they have received appropriate training in lead paint abatement procedures and are provided with respirators and other safety equipment and supplies in accordance with local requirements.

# 7. STUDY PROCEDURES

## 7.1. Pre-Randomization Evaluation

### 7.1.1. Introduction

The pre-randomization evaluation schedule includes two pre-randomization clinic visits (V1 and V2) and two home visits (H1 and H2), for a total of four pre-randomization visits. Table 6 summarizes the activities during the pre-randomization period.

Table 6. Visit Schedule for Pre-Randomization Evaluation

| VISIT | V1 | | H1 | V2 | H2 | T0 |
|---|---|---|---|---|---|---|
| WEEK | -6 -5 | -6 -5 | -6 -2 | -2 -1 | -4 -1 | 0 |
| DAY | -42 -35 | -41 -34 | -28 -8 | -14 -7 | -27 0 | 0 |
| Eligibility Checklist | | | | | | |
| Informed Consent | | | | | | |
| PbB | | | | | | * |
| CBC, Differential, Platelet Count | | | | | | |
| Serum Chemistries | | | | | | |
| Creatinine | | | | | | |
| Urine Dip (protein, glucose) | | | | | | |
| Ferritin | | | | ** | | |
| Physical Examination | | | | | | |
| Multivitamin + Minerals + Iron | *** | | | | | Stop |
| 3 mg/kg/day Fe | | **** | | | | Stop |
| Assess Compliance | | | | | | |
| Dispense Drug | | | | | | |
| Psychometric Testing | | | | | | |
| Home Visual Assessment | | | | | | |
| Home Clean-up | | | | | | |

### 7.1.2. Management of Iron Status

Because iron deficiency increases lead absorption and is independently associated with poor developmental outcomes,[33] careful management of the child's iron status is required. Children whose hemoglobin at V1 is less than 9 g/dL from any cause will be excluded from further participation. Children whose hemoglobin at V1 is greater than or equal to 9 g/dL but less than 10 g/dL will be checked for iron deficiency on the basis of the red cell distribution width (RDW). If the RDW is normal, the child will be enrolled. If the RDW is increased, the child will be treated with a therapeutic iron supplement of 3 mg/kg/day and their hemoglobin rechecked in one month. Further TLC activities, such as home visits, will be deferred until the results from the repeat testing are known. If the repeat hemoglobin is 10 g/dL or greater, the child will be enrolled, otherwise, excluded. If a three-month course of therapeutic iron is not completed before study treatment begins, iron supplementation will be interrupted and resumed after the completion of study treatment until a full three months of iron supplementation have been completed. Children whose hemoglobin at V1 is 10 g/dL or greater will be considered to be iron sufficient by virtue of a month or longer course of multivitamin plus iron supplement prior to randomization.

### 7.1.3. Pre-randomization Visit 1 (V1)

Each Clinic will identify potential subjects with elevated blood lead levels whose projected age at enrollment is at least 12 and less than 33 months and whose family's language is English (English or Spanish in the Newark Center). At Pre-randomization Visit 1 (V1) or over the phone prior to V1, the Clinic Coordinator will explain the trial to the family and assess initial eligibility. At V1, informed consent for the pre-randomization evaluation will be sought from the parent or legal guardian of children who satisfy the initial eligibility requirements. See Appendix 2 for Stage I Informed Consent Forms from each of the Clinical Centers. If informed consent is given, a medical history will be obtained and a physical examination performed. Height, weight and head circumference will be measured by standardized procedures. Blood pressure will be obtained. A TLC physician will review and verify the child's eligibility.

Blood will be drawn for determination of blood lead concentration and ferritin by the central laboratory and for local laboratory determination of hemoglobin, red cell distribution width, absolute neutrophil count, platelet count, alkaline phosphatase, ALT, AST, and serum creatinine. A urine dip stick test will be performed in the clinic for proteinuria and glucosuria.

All children will be given a multivitamin with minerals including iron and the caregivers will be instructed as to their administration. A vitamin diary will be provided for parents to record vitamins taken each day. The diary will assist TLC staff in the assessment of compliance. Appointments will be scheduled for the home visual assessment visit (H1) in one to two weeks and for Pre-Randomization Visit 2 (V2) in approximately one month.

Local laboratory results will be available shortly after V1. Children whose hemoglobin is less than 9 g/dL will be excluded from the study. Children whose hemoglobin is equal to or greater than 9 g/dL and less than 10 g/dL and whose red cell distribution width is increased will be provided with three months of supplemental iron therapy and will undergo repeat testing at their next visit (approximately one month). Children who are not iron deficient on the basis of the RDW or whose hemoglobin is greater than or equal to 10 g/dL will be enrolled. Children who show abnormalities on their liver function studies will be brought back to the Clinic for repeat testing of the abnormal values in approximately two to three weeks. If the repeat values are normal, the child may be enrolled. Children whose serum creatinine is greater than 1.0, who show proteinuria of 2+ or greater, or who show glucosuria will be referred for evaluation. If these conditions resolve and the child is otherwise eligible, she or he may be entered in the study at a later time but will be required to repeat the appropriate laboratory tests. In all cases, further TLC activities, such as H1 or V2, will be deferred until the abnormality resolves.

CDC PbB results will be available approximately one week following V1. Children whose PbB from V1 is 45 g/dL or greater will be referred for immediate treatment according to the local standards of care and excluded from the study. Children whose PbB from V1 is less than 20 g/dL will be excluded from the study.

Families of excluded children will be appropriately notified, any scheduled study visits will be cancelled, and they will be provided with appropriate followup based on their lead status.

### 7.1.4. Home Visit 1 (H1): Home Visual Assessment

The Home Visit 1 (H1) will take place as soon as possible after V1 for eligible children. This initial visual assessment will be used to determine whether the child should be excluded from the trial based on poor condition of the housing and to estimate the amount of work required to clean the residence. An assessment will be made of the likely risks of exposure to lead in paint and dust based on the following criteria:

(1) condition of painted surfaces

(2) accessibility of non-intact painted surfaces

(3) condition of painted substrates

(4) ease with which surfaces can be cleaned

(5) overall structural integrity of the dwelling, both interior and exterior.

Attention will be given to the immediate dwelling unit, common areas such as hallways and stairwells, and porches. Frequency of access to the hazardous areas by the child will be considered in the environmental assessment and clean-up plan. An attempt will be made to do visual assessments of secondary residences so that the condition of supplemental residences can be taken into account in determining eligibility.

The assessor will sketch a floor plan, record room sizes and number of windows, note presence and condition of carpeting and other flooring, estimate the amount of time required to prepare the unit for cleaning and determine if it will be necessary to contact the building owner or management prior to any planned clean-up activities.

A Home Visual Assessment Report will be issued and the child's eligibility on the basis of residence reassessed. Families of children who are excluded on the basis of the home visual assessment will be appropriately notified, any scheduled study visits will be cancelled, and they will be provided with appropriate followup based on the child's lead status.

If the child is still eligible, an appointment will be scheduled before the projected date of randomization for Home Visit 2 (H2) for home cleaning.

### 7.1.5. Home Visit 2 (H2): Home Cleanup

If the child's residence(s) meets eligibility criteria, a second home visit will be made for lead dust suppression. This visit will ordinarily take place sometime between H1 and T0. If H2 has not occurred before T0, randomization may proceed with home clean-up to take place as soon as possible after T0. If it is not possible to clean the child's home within one week of initiation of treatment, the child will be excluded.

### 7.1.6. Pre-Randomization Visit 2 (V2)

At Pre-Randomization Visit 2 (V2), eligibility will be reviewed. Ability of the family to attend scheduled study visits and to give study medications will be assessed through compliance with the TLC schedule and with multivitamin supplementation. Families whose children are excluded from the TLC Trial on the basis of compliance will be provided with appropriate followup based on the child's lead status.

If the child remains eligible for the Trial, informed consent for participation in the Trial will be sought. See Appendix 2 for Stage II Informed Consent Forms from each of the Clinical Centers. Demographic information on the subject's family will be obtained. An interim medical history will be obtained and a brief physical examination performed. Height, weight, and blood pressure will be measured by standardized procedures. Blood will again be drawn for central laboratory determination of blood lead level. Children whose ferritin level at V1 was less than 12 ng/dL or who required iron supplementation will also have their ferritin rechecked by the Central Laboratory. If the child's home has not yet been cleaned, an appointment for the home clean-up will be scheduled at the earliest possible date. All eligible children will be scheduled for Treatment Visit 0 (T0) in one week.

## 7.2. Randomization

A few days before T0, eligibility will be reviewed and randomization to treatment group made. Children whose PbB from V1 is 45 g/dL or greater will be referred for immediate treatment according to the local standards of care and excluded from the study. Children whose PbB from V1 is less than 20 g/dL will be excluded from the study. Families will be notified before T0 and provided with appropriate followup.

## 7.3. Treatment

### 7.3.1. Treatment Visit 0 (T0): Initiation of Treatment

Treatment Visit 0 (T0) will be scheduled for approximately one week after V2. If the Data Coordinating Center notifies the Clinical Center that the child is ineligible, then this visit will be cancelled, the parent will be told the blood lead result, and appropriate follow-up will be provided based on the child's lead status. Table 7 shows the activities during the treatment phase.

Table 7. Activities During Treatment Phase

| | CLINIC VISITS | | | | | |
|---|---|---|---|---|---|---|
| All Rounds | T0 / T4 / T8 | | T1 / T5 / T9 | | T2 / T6 / T10 | T3 / T7 / T11 |
| DAY OF DRUG (within course) | 0 | 1 | 7 | 26 | 28 | 42 |
| PbB | | | | | | |
| CBC | | | | | | |
| Chemistries | | | | | | |
| Dispense Study Drug | | | | | | |
| Treatment | | start | | stop | | |
| Brief Physical Exam | | | | | | |
| Psychometric Testing | * | | | | | |
| * Psychometric testing will take place at T0 only (initial round of treatment). | | | | | | |

If not already signed, the second informed consent for randomization and treatment will be obtained at this time. If V2 was more than 14 days earlier, blood will be drawn and shipped to CDC for an additional PbB and the T0 visit will be rescheduled for the following week, when the more recent PbB results become available.

Baseline psychometric testing using the Bayley Scales of Infant Development II and the Minnesota Child Development Index will be performed at T0.

Study drug will be dispensed and dosage reviewed with parent(s). Training in drug administration will be provided to the parent or appropriate caregiver. Using placebo capsules, the TLC nurse will demonstrate how to open the capsule and mix the drug beads with a small amount of fruit juice or soda. After briefly mixing the beads with the liquid, the child will be given the liquid to drink. The parent will be instructed to rinse the medicine cup with additional liquid twice and give to the child to ensure that all beads are administered. If the child refuses to take the drug in a liquid, the beads can be mixed with about one teaspoonful of applesauce or jelly and then given to the child. Before leaving the clinic, the parent will be asked to demonstrate this procedure for the TLC nurse. Parents will be shown how to record doses and any adverse events or problems in the medication diary. Problems in administration and use of diary will be identified and solutions proposed. The parent will be instructed to administer the study drug on an empty stomach. Subjects will begin taking drug on the following morning so that 3 doses can be given that day. Caregivers will be instructed to return with the pill bottle and the medicine diary at each visit.

Parents will be told to stop giving multivitamins and/or iron therapy to the child for the duration of the treatment period. They will also receive an emergency card with a 24-hour phone number to call should emergency unblinding be

necessary. A subject and/or family incentive will be provided. These incentives will be determined by each Clinical Center. Appointments will be made, if possible, for all three Treatment Visits. The parent or guardian will be given a calendar showing scheduled appointments through the end of the treatment course (T1, T2, T3).

### 7.3.2. Treatment Visit 1 (T1)

Treatment Visit 1 (T1) will be scheduled on day 7 of study drug administration. A brief history and physical examination will be performed by the TLC nurse or physician. Any abnormalities will be reviewed by a physician. The TLC nurse will review the medication diary and record study data. Dosing and administration of study drug will be reviewed, problems identified and solutions proposed. In addition, the caregiver will be reminded to reduce the dose starting the following day. Blood will be drawn and sent to the local laboratory for safety monitoring and to CDC for PbB. Monitoring will consist of absolute neutrophil count, platelet count, AST, ALT, and alkaline phosphatase. The appointment for the next visit, in three weeks, will be reviewed. A subject and/or family incentive will be provided.

### 7.3.3. Treatment Visit 2 (T2)

Treatment Visit 2 (T2) will be scheduled on day 28 of the treatment phase. The TLC nurse will review the medication diary and record study data. All pill bottles will be collected and returned to the Drug Distribution Center for pill counts and appropriate disposal. Blood will be drawn and sent to the local laboratory for safety monitoring and to CDC for PbB. Monitoring will consist of absolute neutrophil count, platelet count, AST, ALT, and alkaline phosphatase. The results of the T2 venipuncture are necessary to assess how well the child has tolerated the study drug in anticipation of further courses of treatment, should these be necessary on the basis of the PbB. The appointment for the next visit, in two weeks, will be reviewed. A subject and/or family incentive will be provided.

### 7.3.4. Treatment Visit 3 (T3)

Treatment Visit 3 (T3) will be scheduled for 2 weeks after the end of the treatment period, on day 42 of the treatment phase. A brief history and physical examination will be performed by the TLC nurse or physician. Any abnormalities will be reviewed by a physician. Blood will be drawn and sent to the local laboratory for safety monitoring and to CDC for PbB. Monitoring will consist of absolute neutrophil count, platelet count, AST, ALT, and alkaline phosphatase. The results of the T3 venipuncture are necessary to assess how well the child has tolerated the study drug in anticipation of further courses of treatment, should these be necessary on the basis of the PbB. Results of the PbB measurement obtained at T3 will determine whether a child is retreated or enters follow-up. The appointment for the next visit, in one week, will be reviewed. A subject and/or family incentive will be provided.

The appointment for T4 in one week will be scheduled before the PbB result is available, in anticipation that most children will need more than one course of study drug. If the Data Coordinating Center notifies the clinic that additional therapy is not indicated, the parent will be notified and the appointment will be rescheduled for the first follow-up visit. The family will be instructed to resume multivitamin plus mineral supplements and iron therapy, if prescribed.

### 7.3.5. Subsequent Treatment Visits

If the PbB measurement obtained at T3 or T7 is 15 g/dL or greater, drug treatment will be readministered. Subsequent treatment visits (T4, T5, T6 and T7 for the second course of treatment, and T8, T9, T10 and T11 for the third course of treatment) will follow the schedule of the initial treatment phase, excluding psychometric testing. Except for psychometric testing, which will be administered at T0 only, the protocol for retreatment will be the same as for the initial course of treatment. No more than three courses of treatment will be given to any child.

### 7.3.6. Off Protocol

Children may be taken off the TLC treatment protocol for a number of different reasons, as discussed above. Such children will remain enrolled in the TLC Trial. In particular, followup and psychometric visits will occur on the originally projected schedule.

## 7.4. Followup Schedule

Once treatment has been completed, children will resume taking nutritional supplementation for the duration of the trial. Children who were found to be iron deficient during the enrollment phase will resume iron therapy, for a total of three months of supplementation.

The followup schedule will be timed with reference to randomization, rather than to end of treatment. This will keep the followup schedule in synch with the timing of psychometric followup. All children will be seen every three months through the 24-month post-randomization visit. After that visit, followup visits will occur every four months. In cases where the six-month post-randomization date occurs later than three months following the end of treatment, an additional followup visit will be scheduled between the end of treatment and the six-month post-randomization date. In particular, children who require only one round of treatment will have their first followup visit scheduled for one month after day 42 (T3). Any children who, for whatever reason, do not follow the standard TLC treatment schedule will still follow this schedule for followup, i.e., they will be seen at six months post-randomization regardless of their treatment status.

Children will be followed until the age of 72 months or the end of the study. A reminder call will be made or a card mailed to the family one week prior to each scheduled visit.

At each followup visit, a brief history and physical examination will be performed by the TLC nurse or physician. Any abnormalities will be reviewed by a physician. The subject will be given an adequate supply of multivitamins and the parent will be instructed to continue their administration. Blood will be drawn and sent to CDC for determination of PbB. A subject and/or family incentive will be provided. An appointment will be made for the next visit.

# 8. LABORATORY PROCEDURES

## 8.1. Introduction

Blood samples for blood lead and serum ferritin determination will be shipped to the Nutritional Biochemistry Branch, CDC, in Atlanta, which will serve as the Central Laboratory for the trial. All other blood work will be done locally, following local protocols. Samples for blood lead and ferritin analysis will be collected by venipuncture by personnel trained and experienced in pediatric venipuncture using proper sterile technique and following universal precautions and CDC guidelines.

Samples will be shipped to the CDC the same day they are collected. During the treatment phase of the trial, blood sample will be shipped via overnight delivery. During the followup phase of the trial, shipping need not be shipped overnight. Routine turn-around time, i.e., the time from the receipt of the sample at CDC to the reporting of results to the Data Coordinating Center, will be five working days (i.e., one week). The shipping and reporting system will include a means of identifying and expediting samples requiring analysis on an urgent or STAT basis. Urgent samples will be processed so that results are available no less than two days before the next visit; these will include PbB samples at V1, V2, and T3. STAT samples will be processed so that results are available within 24 hours of receipt of sample; these will include confirmation of PbBs greater than 44 g/dL or confirmation of increase in PbB greater than 15 g/dL.

All analytical results will be reviewed by both the study analyst and the study laboratory supervisor at the central laboratory. All quality control materials will be reviewed by the laboratory supervisor. Data will be transmitted to the Data Coordinating Center via Internet on a daily basis as needed. Data will also be recorded onto floppy disks and optical disks for archiving.

Residual TLC blood samples will be stored at CDC for a minimum of one year following publication of trial results.

## 8.2. Blood Lead Analysis

Lead will be measured in blood by atomic absorption spectrometry based on the method described by Miller *et al*.[34] The lead content will be determined by using a Perkin-Elmer Model 4100-ZL graphite furnace atomic absorption spectrophotometer with Zeeman-effect background correction. Lead contamination must be carefully avoided throughout all procedures. All materials used for collecting and processing specimens will be pre-screened for possible lead contamination. All laboratory processing work will be performed under clean conditions, including laminar flow hoods.

## 8.3. Ferritin Analysis

Ferritin, like hemoglobin, is a major iron storage protein. Circulating plasma ferritin is most like the L-isoferritin. Serum ferritin provides a much more sensitive indicator of iron body stores than a traditional serum iron assay. Serum ferritin is increased in iron overload, aging, infection, inflammation, liver disease, juvenile rheumatoid arthritis, leukemia, and Hodgkin's disease. Serum ferritin is reduced in iron deficiency.

Ferritin will be measured by using the Bio-Rad Laboratories "Quantimmune Ferritin IRMA" kit which is a single-incubation two-site $^{125}$I-immunoradiometric assay (IRMA) based on the general principles of assays as described by Addison *et al*.[35] and Miles[36] and modified by Jeong *et al*[37].

## 8.4. Quality Control Procedures

### 8.4.1. Lot Testing of Supplies for Lead Contamination

Lot testing for lead contamination is a critical part of the accurate evaluation of lead in whole blood. Lead may contaminate most commercial blood collection devices (e.g., "Vacutainers") from a variety of sources, including the container materials themselves (glass, stainless steel, rubber, or plastic) and the anticoagulants used. EDTA is a particularly common source. To assure that blood lead values obtained are accurate and not falsely elevated from contamination, CDC will undertake a screening program to evaluate the lead levels in Vacutainer tubes for the TLC Trial and any and all devices that contact the TLC blood specimens, including disposable syringes, stainless steel needles, skin cleaning devices or solvents (such as isopropanol in alcohol pads).

### 8.4.2. Laboratory Analyses

Estimates of imprecision will be generated from long-term quality control pool results. A quality control system of "bench" quality control specimens will be inserted by the analyst in each analytical run (a set of consecutive assays performed without interruption) so that judgements may be made on the day of analysis. All levels of blood lead concentration are assessed by taking these samples through the complete analytical process. The data from these materials will then be used in estimating methodological imprecision and in assessing the magnitude of any time-associated trends.

The "bench" quality control pools are prepared in sufficient quantity to last the duration of the trial. The levels chosen are in the low range (approximately 20 g/dL) as well as elevated range (approximately 40-44 g/dL) so as not to be obvious to the analyst. In every batch of 20 specimens analyzed, either one low or high concentration quality control pool will be randomly inserted. Limits will be established for new pools after 20 runs.

If, after reviewing the analytical and quality control data, the system is declared "out of control" by the supervisor, the entire run will be repeated. If the "out-of-control" condition still exists for ferritin, a new kit will be used and the autodiluter evaluated for pipetting precision and accuracy. If the "out-of-control" condition exists for blood lead, all instrumental parameters will be reverified, and matrix modifier and all other reagents will be checked for possible contamination. National Institute of Standards and Technologies (NIST) Standard Reference Material (SRM) 955a "Lead In Blood" materials[38] will be analyzed in addition to normal bench quality control pools in order to confirm accuracy and precision has been reestablished. Specimens for any analytical run held in question will be reassayed after the system has been reverified to be "in control."

*8.4.2.1. Blood Lead Analysis*

The blood lead analysis method to be used in the TLC Trial has been used for several years in the Nutritional Biochemistry Branch, CDC, for environmental and occupational health studies, as well as for the Third National Health and Nutrition Examination Survey (NHANES III). The method has proven to be accurate, precise, and reliable. The primary standard used is a NIST SRM lead nitrate, and the NIST SRM 955a "Lead In Blood" materials will also be used as external standards. Bench quality control materials are prepared by CDC as EDTA-whole blood from lead-dosed cows.

*8.4.2.2. Serum Ferritin Analysis*

The serum ferritin method has also been used in the Nutritional Biochemistry Branch for a number of years, including the NHANES III Study. The method has been proven to be highly comparable to the International Committee for Standardization in Hematology (ICSH) reference enzyme immunoassay method. The ICSH International Reference Ferritin Standard from the National Institute of Biologicals, Standards, and Chemicals, U.K., is used as the external validation material for accuracy and precision.

Because of reliability and availability, four levels of Bio-Rad Laboratories ECS Division "Lyphochek" lyophilized human serum controls will be used as bench quality control materials for ferritin analysis. Approximate values will be 5, 50, 150, and 400 ng/mL. Bench quality control pools as well as blind quality control pools may also be made from filter-sterilized fasting human serum.

# 9. DRUG DISTRIBUTION

## 9.1. Trial Medications

As described in Section 4.2, children will be randomly assigned to active drug or placebo. The dosing regimen will be based on six categories of body surface area. The total number of bottles needed is projected to be 1,332 bottles of active drug and 1,332 bottles of placebo, based on the assumption that each participant will need an average of two treatments (two bottles per participant). An additional 30 bottles each of succimer and placebo will be retained by the Drug Distribution Center for quality assurance samples. Study drug, both active and placebo, will be packaged in bottles of 95 and 130.

All trial medication, both active and placebo, will be provided by the manufacturer, McNeil Consumer Products Company, to the Drug Distribution Center. The Drug Distribution Center will receive, inspect, store, repackage and ship all trial medications.

### 9.1.1. Repackaging of Trial Medications

The Drug Distribution Center will repackage the medications in amber color glass unit-of-use containers, with child-resistant safety caps and a tamper-evident seal. The Drug Distribution Center will prepare two-thirds of the projected drug requirements before enrollment begins. When half of the projected total has been dispensed, the Drug Distribution Center will repackage the remaining one-third of the drug in proportions to be specified by the Data Coordinating Center based on actual trial experience.

In order to provide placebo with an odor comparable to that of succimer, the Drug Distribution Center will place a small canister containing 200 mg of active drug into each bottle of placebo drug. A canister containing 200 mg of placebo will be placed inside each bottle of succimer so that all bottles will appear the same.

Each bottle of drug will be assigned a unique number in random sequence at the Drug Distribution Center. Equal numbers of active and placebo drug will be placed in sequential order in shipping cartons. Each shipping carton will be assigned a unique identifying number. The Drug Distribution Center will provide to the Data Coordinating Center a database containing the bottle number, the carton number, and a code indicating whether active or placebo. This database will be used with a randomization algorithm different from that which was used at the Drug Distribution Center to further randomize drug assignments for trial participants.

### 9.1.2. Labelling of Trial Medications

The Drug Distribution Center will label all repackaged bottles of trial medications according to a double-blinded design. Neither the clinic nor the patient will know the contents of any bottle. The primary label affixed by the Drug Distribution Center will state that the bottle may contain succimer or placebo; will include a detachable, tamper-evident sealed packet containing identification of the drug in the bottle which can be used in cases of emergencies which require unblinding of the patient; and will include a standard, detachable bar-code with the unique Control Number of the bottle of drug. This bar code will be transferred to the patient record after the bottle of drug is assigned.

The Drug Distribution Center will provide each clinic with secondary labels that conform to local regulations. Clinic personnel will complete the label with the requisite dosing information when dispensing the drug. The secondary label will provide space for the date dispensed, dosing directions, Principal Investigator's name, address and emergency phone number. Secondary labels will be available in Spanish as required for individual patients. Clinical Centers will be responsible for providing the information on local regulations for the secondary label.

## 9.2. Vitamins and Mineral Supplements

Each child will receive a supply of multivitamins plus mineral supplements to be taken throughout the study except during treatment. Estimated total multivitamins plus mineral supplements is 1,391,366 tablets. This total assumes a 7% attrition rate each year of followup to treatment.

The Drug Distribution Center will purchase in bulk 1.5 million daily doses of multivitamins plus mineral supplements for the Trial. The Drug Distribution Center will receive, inspect, store, and ship containers of multivitamins plus mineral supplements to the Clinics. The Data Coordinating Center will recommend which vitamins to purchase.

Multivitamins plus mineral supplements will be repackaged in unit-of-use bottles.

## 9.3. Storage, Shipping and Inventory Control

The Drug Distribution Center will store all containers of trial medication and multivitamins plus mineral supplements for shipment and will maintain computerized inventory records of all available quantities of trial medication. The Data Coordinating Center will also maintain records of available drug in all clinics and at the Drug Distribution Center.

The Drug Distribution Center will ship the study drug and multivitamins plus mineral supplements to the clinics as needed. Copies of shipping invoices will be given to the Data Coordinating Center.

The Drug Distribution Center will distribute all orders for trial medication and multivitamins plus mineral supplements to the clinical sites using a delivery service that tracks shipments. Trial medication will be shipped to the Clinical Centers on an as-needed basis, upon request from the Coordinating Center, within two business days of request. Shipments of multivitamins plus mineral supplements will be sent to the Clinical Centers when requested by Clinical Centers and within five business days of request.

Trial drug and multivitamins plus mineral supplements will be dispensed at six clinics in four Clinical Centers: Baltimore (2 clinics), Newark (1 clinic), Ohio (2 clinics), and Philadelphia (1 clinic).

## 9.4. Documentation

The Drug Distribution Center will provide the Data Coordinating Center with:

- A statement of methods to be used for maintaining accurate and complete records of drugs dispensed.
- Assurance of proper storage and inventory control of drugs.
- A statement that dispensing and labelling of drugs and multivitamins plus mineral supplements are handled in accordance with local regulatory requirement for each Clinical Center.

- A listing on paper and 3½" disk in ASCII format, specifying for each bottle of drug or placebo:
  - Control Number
  - whether drug is active or placebo
  - carton number.
- Invoices and packing slips for each study medication shipment specifying the Control Numbers of all bottles shipped.
- Invoices and packing slips for multivitamins plus mineral supplements shipped.
- Specification of method used for generating Control Numbers, e.g. the name of the software used to randomly assign numbers and copies of relevant pages from the software manual describing the random sequence generator.
- The name and telephone number of a contact person with whom the Data Coordinating Center can work.

## 9.5. Return and Disposal of Unused Medication

The Clinical Centers will return all used and unused bottles of study drug to the Drug Distribution Center. Unused capsules will be counted and the counts reported to the Data Coordinating Center. The Drug Distribution Center will account for and dispose of all unused active drug and placebo capsules and bottles.

# 10. STATISTICAL METHODS

## 10.1. Power Calculations

The primary hypothesis of the TLC trial is that succimer treatment of children with elevated levels of blood lead will improve developmental status three years after treatment begins. Although the primary hypothesis will be tested by an analysis of covariance (see below), we assume for the purposes of the sample size calculation that the hypothesis will be tested by an unadjusted comparison of the mean developmental status at the three-year followup visit in the succimer and placebo groups. We assume that the standard deviation of the standardized WPPSI-R test scores in the study sample will be 15 and that 1,040 randomized children (78% of those enrolled) will complete the three-year followup visit successfully. The variance assumption should be conservative, both because test scores in the study sample may have lower variance than that in the normative population and because adjustment for baseline developmental status through analysis of covariance will reduce the error variance.

Study power with respect to the WPPSI-R can be calculated as a function of the difference in mean test scores between treatment groups. Assuming a Type I Error rate of 0.05 (two-sided) and a sample size of 1,040 evaluable children, Figure 1 shows the power of the study as a function of the difference. In particular, a difference of three IQ points implies a power of 90% for a standard deviation of test scores of 15 (solid line). This power improves to 98% if we assume a standard deviation of 12 (dashed line).

Relatively little is known about the potential effects of chelation on other measures of developmental status (CDI, CPRS, Neuropsychological Battery), height and weight. The power of the study to detect differences in mean values of these outcome variables between treatment groups can, however, be described in a generic way. Table 8 presents the smallest detectable difference for a standardized test score for a fixed sample size of 1,040 as a function of power and standard deviation of the test score. For example, for a score with a standard deviation of 10, the study will detect a mean difference in score of 1.7 with a power of 80%.

| Table 8. Smallest detectable difference for standardized test scores. | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Standard Deviation | | | | | | |
| Power | 4 | 6 | 8 | 10 | 12 | 14 | 16 |
| 20% | 0.3 | 0.4 | 0.6 | 0.7 | 0.8 | 1.0 | 1.1 |
| 30% | 0.4 | 0.5 | 0.7 | 0.9 | 1.1 | 1.2 | 1.4 |
| 40% | 0.4 | 0.6 | 0.8 | 1.1 | 1.3 | 1.5 | 1.7 |
| 50% | 0.5 | 0.7 | 1.0 | 1.2 | 1.5 | 1.7 | 1.9 |
| 60% | 0.5 | 0.8 | 1.1 | 1.4 | 1.6 | 1.9 | 2.2 |
| 70% | 0.6 | 0.9 | 1.2 | 1.5 | 1.8 | 2.2 | 2.5 |
| 80% | 0.7 | 1.0 | 1.4 | 1.7 | 2.1 | 2.4 | 2.8 |
| 90% | 0.8 | 1.2 | 1.6 | 2.0 | 2.4 | 2.8 | 3.2 |

Although the primary hypothesis of this study concerns the effects of chelation therapy in the study sample as a whole, questions about differential effects of chelation by race and gender are of scientific interest. Because approximately 85% or more of study participants are expected to be African American heritage, the study will provide little information about differential effects by race. The study will, however, provide some information about differential effects by gender. This question will be investigated by first testing for an interaction between gender and treatment in the analysis of covariance model. If a statistically significant interaction is detected, it will be necessary to estimate the treatment effect separately for boys and girls. If the test for interaction does not achieve statistical significance, the effect in each subgroup should be estimated by the overall estimate of the effect.

Because the sample must be divided into four subgroups for a test for interaction, the variance of the estimated difference in effect between boys and girls will have variance four times larger than the estimate of the overall effect. Figure 2 presents the power of the study to detect a gender by treatment interaction as a function of the size of that difference.

If we assume that test scores have a between-child standard deviation of 15 points, a test for interaction at the 0.05 level of significance will have power of approximately 76% to detect a difference in effect sizes between boys and girls of 5 points. With a standard deviation of 12, approximately the same power is achieved for differences of 4 IQ points. Given that the study is designed to detect an overall difference of 3 IQ points between treatment groups, it seems implausible that chelation therapy would have differential effects of that magnitude in boys and girls. The study will have power of 50% or less to detect interactions of 3 points or less.

## 10.2. Baseline Comparisons

Following standard practice in the analysis of parallel group randomized clinical trials, the analysis will begin with an assessment of the comparability of the two treatment groups at baseline. The Bayley scales of Infant Development II (BSID II) and the Child Development Inventory (CDI) will provide baseline measures of developmental status. Although randomization will ensure that any differences in the distribution of baseline characteristics are due to chance, exact and Student's t-tests will be used to compute p-values testing the equality of distributions and mean values for categorical and continuous variables, respectively. These p-values will be helpful in screening the baseline distributions for comparability.

## 10.3. Evaluation of Efficacy

### 10.3.1. Test of Primary Hypothesis

The primary hypothesis of the TLC Trial is that chelation with succimer will result in an increase in the mean IQ at three-year followup, as measured by the WPPSI-R full-scale deviation IQ. This hypothesis will be tested by an analysis of covariance. The dependent variable for this analysis will be WPPSI-R score at the three-year followup visit when that measurement is obtained, and WPPSI-R score at the 18-month followup visit when it is available and the three-year assessment is not. Independent variables will include indicator variables for clinic, treatment group, body surface area group, language group, baseline blood lead level group, and baseline scores on the BSID II. Irrespective of compliance, each study participant for whom a WPPSI-R score is available will be included in the analysis according to their treatment assignment (an "intent-to-treat" analysis).

### 10.3.2. Tests of Secondary Hypotheses

Secondary outcome variables to be assessed in the TLC Trial include the other developmental measures described in Section 5, as well as height, weight, head circumference, systolic blood pressure, and diastolic blood pressure, as measured at the three-year followup examination. The hypotheses that chelation has a beneficial effect on these outcome variables will also be tested by analyses of covariance. Each ANCOVA will included clinic, treatment group, body surface area group, baseline blood lead level group, and baseline measures of developmental status, height, or weight most appropriate for and highly correlated with the dependent variable. These analyses will also employ the intent-to-treat principle.

### 10.3.3. Analysis of Repeated Measures

Height, weight, and the CDI will be measured at each regular examination, and IQ (using either the BSID II or the WPPSI-R) will be measured at baseline, six, 18, and 36 months. Longitudinal methods will be used to compare the rates of change in these outcome variables during the three-year followup period. Specifically, linear models with unrestricted covariance structures[39] will be used to test the hypothesis of equality of rates of change in the two treatment groups. These hypotheses will be tested by fitting models of the form

$$yij = a + b1 * tij + b2 * groupi + eij$$

where $y_{ij}$ is the developmental score for the ith child at the jth followup visit, $t_{ij}$ is the elapsed time from baseline at this visit, "$group_i$" represents the child's treatment group, and $e_{ij}$ is the error term.

Two considerations lead to the decision to use longitudinal analyses as secondary rather than primary analyses. First, two different measures of IQ will be obtained in this study, the BSID II and the WPPSI-R, raising concerns about changes in measure in a repeated measures analysis. The second and most important consideration, however, is that the comparison of greatest interest in this trial is that at the three-year followup examination. Previous studies suggest that the beneficial effect of chelation may be largest at this examination, and developmental status at this examination is also most relevant to the long-term effect of chelation on development. The analysis of covariance of the WPPSI-R at the three-year examination, adjusting for baseline BSID II score, will retrieve most of the information about trend that would be available from longitudinal analysis of the three followup examinations.

### 10.3.4. Other Analyses

Additional analyses will be performed to compare blood lead levels during and after treatment in the two treatment groups, investigate the relation between blood lead level and developmental status at the three-year followup examination, investigate the relation between change in blood lead level and development status at the three-year followup examination, and evaluate the association between compliance-adjusted measures of treatment and developmental outcome.

## 10.4. Monitoring for Efficacy and Safety

All TLC participants will have completed the treatment phase of the TLC trial before any participants begin the three-year follow-up visits at which the primary outcome variable, the full-scale IQ, will be measured by the WPPSI - R. Thus, it will not be necessary to develop formal sequential monitoring procedures for early termination of the enrollment and treatment phase of the trial on the basis of demonstrated efficacy. The investigators, the NIEHS Project Office, and the Data and Safety Monitoring Committee (DSMC) will nevertheless be responsible for monitoring the progress of the study closely for evidence of both efficacy and possible adverse effects of treatment.

Food and Drug Administration (FDA) regulations for investigational new drugs include specific requirements for reporting of adverse drug experiences (ADEs). All serious ADEs will require an immediate telephone call by the TLC physician to the Data Coordinating Center (DCC), the FDA, the Project Office, and other TLC physicians. FDA notification must occur within three days of recognition of a possible serious ADE. Any death or hospitalization will be considered a serious ADE. In addition, the DCC will routinely gather data on all possible ADEs for regular reporting to the DSMC and the FDA.

All available information on efficacy and safety will be presented to the DSMC as part of the DCC report prepared for each Committee meeting, and annual reports will be prepared for submission to the FDA as required by the Investigational New Drug authorization. Because no single endpoint will be specified in advance as a primary endpoint for assessment of toxicity, no formal statistical stopping rules will be established for monitoring toxicity. The DCC will prepare, as part of its regular statistical report to the DSMC, an interpretation of any statistically significant finding regarding possible side effects of active treatment.

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## APPENDIX 1: Committee and Subcommittee Membership

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## APPENDIX 2: Core Consent Forms

## Pre-Enrollment Informed Consent

Your child has been exposed to a moderate amount of lead. This amount of lead does not make your child sick, but it may be enough to harm your child's development, thinking and learning as the child gets older. Children get exposed to lead mostly from dust and chipped paint in their homes. It is important to keep lead dust and chipped paint away from children. We do not know if giving a child medicine to get rid of some of the lead in their bodies will keep the lead from harming them. We do know that medicines that take lead out of the body have side effects, like all medicines.

Your child may be eligible for our study -- the Treatment of Lead-Exposed Children study. We call it TLC for short. We want to see whether a medicine prevents lead in children's bodies from harming them as they grow older. This medicine is called succimer, and it gets rid of some of the lead in children's bodies. It is now used for children who have more lead in their bodies than your child has.

All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint, will get vitamins and minerals, will get regular checkups and blood tests from a doctor, and will get tests of their thinking, learning and development. The parent or parents, usually the mother, will also have a short intelligence quotient, or IQ test, which is a test of their thinking and reasoning skills, but will not get check-ups or blood tests.

Half the children in the TLC study will get capsules that have succimer in them. Succimer should remove some of the lead from these children's bodies, but it has some side effects. The other half of the children in the TLC study will get capsules that look the same, but have no succimer in them. These capsules will not remove lead from these children's bodies, and have no side effects.

Children with amounts of lead in their bodies like your child's usually do not get medicine to help them get rid of the lead. Succimer is not recommended for children with amounts of lead in their bodies like your child has unless they are in a study. Succimer has been approved for treating children who have more lead in their bodies than your child does.

We do not know whether it is better for children like yours to get the succimer or not. To help find this out, we will put half of the children in the TLC study into a group that gets succimer and half of the children into a group that gets capsules without succimer. We will decide which group your child will be in at random, like tossing a coin. Every child will be in one group or the other. Unless there is a problem, you and the TLC doctor who takes care of your child will never know which group your child is in. There will be another doctor at the hospital who does know your child's group in case of problems. Children will be in this study for 3 years, but they will not take capsules for longer than one year. There is no charge for the study.

Today, we are asking your permission to find out whether your child is eligible to be in the TLC study. Participation is completely voluntary. If you agree to participate, then this is what will happen:

### 1. Clinic visits and blood tests

Your child will have a blood test and check up today. You will get another appointment to come back to the clinic in about one month for a second check up and blood test. We will look for several things with the blood tests. We will measure the amount of lead. We will make sure that there is not something about the way that your child's liver or kidneys work that would keep us from giving succimer to them.

We will make sure that the cells in their blood are normal and that they have enough iron. If your child has so little iron that he or she is anemic or has low blood, then we will give you iron for him or her and check him or her again after taking it to see if he or she is eligible.

The blood is usually taken with a needle from the vein in the child's arm, and the amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. Very rarely, a child gets a blood clot or infection. If anything unexpected happens, a doctor from the study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

### 2. Home visits and Cleanup

We will send someone to your home to see if they can find out where the lead came from, and if it can be cleaned up. If your child spends much time at another home, we will also want to look at it. If we can tell that your child will probably be eligible for the study, then specially trained cleaners, who know about lead, will come to your home and clean up any dust and chipped paint. If there is another home where your child spends much time, then we will clean that home too.

### 3. Vitamins and minerals

We will give you vitamins with minerals tablets, and ask that you give one to your child every day. We will give you a vitamin diary and ask you to write down the times that you give your child the vitamins.

Even if you agree now to do these things, you can stop anytime for any reason. If you do stop, your child cannot be in the study, but it will not change the regular medical care of your child, or change any other benefits outside the TLC study that your family gets. Regular medical care for children like yours includes blood tests for lead. The xxx city health department is responsible for inspecting homes of children whose blood tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. Whatever the city does will not be changed if your child is eligible for this study, or if you decide to be in the TLC study.

Not every child will be eligible for the TLC study. Most of the time, we can tell if a child is eligible by the second clinic appointment, in about one month, but sometimes it will take longer. If your child is eligible, then we will ask for your consent again before your child is treated. We will give you a copy of the consent form for the treatment part of the study to take home with you today.

The results of the TLC study will help doctors know how to treat other children like yours who have been exposed to lead. Your child will not benefit from the TLC study's results, because the results will not be ready in time to help treat your child. The benefits to your child of letting us find out if they are eligible for the TLC study are that we will look carefully at your home for lead dust and chipped paint and tell you about it, clean-up the lead if it looks like your child is eligible, give you vitamins and minerals for your child, have a doctor examine your child, and check the amount of lead in your child's body carefully. There is no charge to you for any of this. Some of the things, like the check ups and blood tests, are often done anyway to children who have been exposed to lead, and some insurance pays for them. We may ask your insurance to pay, but if they do not pay we will not charge you.

We need your help if your child is going to participate in the TLC study. It is important that you give your child the vitamins and keep the vitamin diary, that you keep the appointment to have your home checked for lead, and that you keep the appointment in the clinic next month. Only families that can keep most appointments and give their children vitamins regularly can be in the study.

The TLC study records are confidential, and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study.

## Enrollment Informed Consent

Your child has been exposed to a moderate amount of lead. This amount of lead does not make your child sick, but it may be enough to harm your child's development, thinking and learning as they get older. Children get exposed to lead mostly from dust and chipped paint in their homes. It is important to keep lead dust and chipped paint away from

children. We do not know if giving a child medicine to get rid of some of the lead in their bodies will keep the lead from harming them. We do know that medicines that take lead out of the body have side effects, like all medicines.

Your child is eligible for our study, which is called the Treatment of Lead-Exposed Children study, or TLC for short. We want to see whether a medicine prevents lead in children's bodies from harming them as they grow older. This medicine is called succimer, and it gets rid of some of the lead in children's bodies. It is now used for children who have more lead in their bodies than your child has.

All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint, will get vitamins and minerals, will get regular check ups and blood tests, and will get tests of their thinking, learning and development. The parent or parents, usually the mother, will also have a short intelligence quotient, or IQ test, which is a test of their thinking and reasoning skills, but will not get check-ups or blood tests.

Half the children in the TLC study will get capsules that have succimer in them. The other half of the children in this study will get capsules that look the same, but have no succimer in them. Children will be in this study for 3 years, but they will not get study capsules for longer than a year. There is no charge for the study.

Now that we know that your child is eligible, we are asking your permission for them to be in the treatment part of the study. Participation is completely voluntary. If you agree to participate, then this is what will happen:

## 1. Medicine and medicine diaries

We will give you enough capsules to give to your child for 26 days, Taking capsules for 26 days is called a course of therapy, or just a course. Since the capsules are too big for your child to take, we will show you how to open them and sprinkle the beads of medicine that are inside into some food or drink. We will give you a diary and ask you to write down when you have given the capsule, and whether your child is sick. Some people find the capsules smelly; this does not mean that they are spoiled or that they will make your child sick.

The medicine used in this study, succimer, is now used for children with more lead in their bodies than your child has. In this study, we are giving higher doses of succimer than are used in those children, and we are giving succimer for a week longer than it is given to those children. We are doing this because we have to get enough lead out of your child's body to make a difference. Many children have to take more than one course of succimer to get enough lead out of their bodies, and we think that using the succimer the way we are using it will cut down the number of children who need more than one course.

Half the children in this study will get capsules that have succimer in them. Succimer should remove some of the lead from children's bodies, but has some side effects. Side effects from succimer happen in about 10% to 20% of children. The most common side effects are rashes, upset stomach, changes in blood tests that measure how children's livers are working, lower numbers of white cells (the cells that fight infection) in the children's blood, and lower numbers of platelets (the cells that help blood clot) in the children's blood. So far, there have been very few serious side effects with succimer, and they have gone away when the succimer was stopped. Few children have had to stop succimer because of side effects. If your child has severe or too many side effects, we will stop the medicine. We will ask you about any illness that your child has had when you come to clinic, and we will look for side effects with blood tests.

The other half of the children in this study will get capsules that look exactly the same, including the beads inside, but have no succimer. These capsules will not remove lead from children's bodies, and have no side effects.

Since we do not know whether it is better for children like yours to get succimer or not, we will put the children into these two groups at random, like tossing a coin. You and the TLC doctor who takes care of your child will never know which group your child is in, unless there is a problem. There will be another doctor at the clinic who does know in case of problems.

It is important that you tell us if your child gets sick while taking the capsules, and we will give you phone numbers to use for calling us. We also ask you to write down in a medicine diary if your child gets sick while taking the TLC capsules. It is also important to tell us if your child is taking any other medicines while they are taking capsules. A doctor from the TLC study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

We will ask you to come back to the clinic in one week after your child starts taking capsules and we will check your

child and do a blood test for lead and for any side effects. The blood is usually taken with a needle from the vein in the child's arm, and the amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. Very rarely, a child gets a blood clot or infection. We will look at the medicine diary with you to see how many of the capsules your child took, and we will ask you if your child was sick.

We will ask you to come back to the clinic again one month from now, and have the same things done. If the lead in your child's body has not gone down enough, then we will ask you to come back to clinic and give you enough capsules for another 26 day course to give to your child. We think that about half to three quarters of the children in the study will get a second course. The chance will be the same whether your child got the capsules with succimer or the capsules without. If your child gets a second course, then we will ask you to come in for blood tests and a check up at one week and one month after the course starts, and to keep a medicine diary, the same as the first course. A few children, about 10%, who still have too much lead will get a third course of capsules, which will be the same as the first two courses.

## 2. Blood lead results

You and the TLC doctor taking care of your child will not know the results of the blood lead tests done during the first six months after your child starts taking capsules, but another doctor will know in case there is a problem. If your child is still taking capsules after six months, then you will not know the results of the blood lead tests done during treatment, and for three months after your child is finished taking capsules. You may have the blood lead results after these treatment periods if you want them.

## 3. Followup visits and vitamins

Once your child finishes taking the capsules, we will ask you to come back about every three to four months for a blood lead test until you have been in the study for about three years. We will give you vitamins at these clinic checkup visits, and ask that you give one to your child every day. You will not need to keep a diary anymore, but we think it is important for your child to take the vitamins every day.

## 4. Thinking, reasoning, and development tests

We will test your child's thinking, reasoning and development three times: at six months, 18 months, and three years after they begin taking capsules. These tests take about 2 hours or less in the younger children, and about 2 hours and 30 minutes in the oldest children. The tests have the child play with toys and mazes and solve simple problems. Most children enjoy these tests, but they have to be feeling well to do them. Sometimes the tests have to be re-scheduled if your child is sick or not feeling well.

When your child is three, we will give a parent, usually the mother, a short version of an IQ test, which involves reading and solving problems and takes about 45 minutes. We will also ask the parent questions about the child's behavior. There are no risks from any of these tests.

## 5. Damage at home or moving to a different home

It is important for you to tell us if you move, or if a plumbing leak or anything else damages the walls or ceilings in your home, because we will need to come out and inspect and clean up the way we did at the beginning of the study. If the doctor who sees the results of the blood lead tests finds that the amount of lead in your child's body has gone up too much, we may want to come and inspect or clean your home again. Very rarely, a child's lead might go up so high during the study enough so that they are no longer eligible for the TLC study. This usually happens because something happened at their home, such as sanding paint, or they visited a home where there was chipped paint or dust with lead

in it. If this happens, the child will get the usual care for children with larger amounts of lead in their bodies, which my include succimer. The TLC study will not pay for or provide that care.

Even if you agree now to do these things, you can stop any time for any reason. If you do stop, it will not change the regular medical care of your child, or change any other benefits outside the TLC study that your family gets. Even if you stop being in the study in the early part, we will still invite you to come in later for the blood tests and the tests of your child's thinking, reasoning and development.

Regular medical care for children like yours includes blood tests for lead. The xxx city health department is responsible for inspecting homes of children whose blood tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. All of the inspections and clean-ups in the study are additions to what the city would do, and the city's actions will not be changed.

Children with amounts of lead in their bodies like your child's usually do not get medicine to help them get rid of the lead. Succimer is not recommended for children with amounts of lead in their bodies like yours unless they are in a study. Succimer has been approved for treating children who have more lead in their bodies than your child does.

If anything unexpected happens, a doctor from the TLC study will help take care of any immediate need, but the study can not give you care or pay for care for a problem that takes a long time to resolve.

The results of the study will help other children because better decisions will be made about their treatment. Your child will not benefit from the study's results, because they will not be ready in time to help us in treating your child.

The benefits to your child are:

We will look carefully at your home for lead dust and chipped paint and tell you about it.

We will clean-up the lead dust in your home.

We will give you vitamins and minerals for your child.

A TLC doctor will examine your child regularly.

We will check the amount of lead in your child's body carefully and regularly.

We will regularly test your child's thinking and development.

We believe that children in the study will get equal or better care than children outside the study, and that their homes will have less lead in them sooner than if they were not in the study. There is no charge to you for any of this. Some of the things, like the check ups and blood tests, are often done to children who have been exposed to lead, and some insurance pays for them. We may ask your insurance to pay, but if they do not pay we will not charge you.

The TLC study records are confidential, and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study.

## APPENDIX 3: Regulation of Environmental Lead

## CDC Guidelines

The following material is excerpted from *Preventing Lead Poisoning in Young Children: a Statement by the Centers for Disease Control* [(40)]

Page 3:

| Table 1-1. Interpretation of blood lead test results and followup activities: class of child based on blood lead concentration. |
|---|

| Class | Blood Lead Class Concentration (g/dL) | Comment |
|---|---|---|
| I | 9 | A child in Class I is not considered to be lead-poisoned. |
| IIA | 10-14 | Many children (or a large proportion of children) with blood lead levels in this range should trigger communitywide childhood lead poisoning prevention activities. Children in this range may need to be rescreened more frequently. |
| IIB | 15-19 | A child in Class IIB should receive nutritional and educational interventions and more frequent screening. If the blood lead level persists in this range, environmental investigation and intervention should be done. |
| III | 20-44 | A child in Class III should receive environmental evaluation and remediation and a medical evaluation. Such a child may need pharmacologic treatment of lead poisoning. |
| IV | 45-69 | A child in Class IV will need both medical and environmental interventions, including chelation therapy. |
| V | 70 | A child with Class V lead poisoning is a medical emergency. Medical and environmental management must begin immediately. |

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Blood lead level 20-69 g/dL. Children with venous blood lead levels in this range should have a full medical evaluation. This includes a detailed environmental and behavioral history (asking about reading or other learning disabilities, language development, pica, etc.), a physical examination, and tests for iron deficiency. Particularly for children needing urgent medical followup (that is, for blood lead level 45 g/dL), pediatric health-care providers with limited experience in treating lead poisoning should consider referring such children to a clinic with experience in managing childhood lead poisoning. These children should also have complete environmental investigations so that lead hazards can be reduced. The local public childhood lead poisoning prevention programs will often work as a team with the pediatric health-care provider and the child's family to ensure appropriate environmental followup.

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Followup of children with blood lead levels 20 g/dL

If the blood lead level is 20 g/dL, the child should be given a repeat test for confirmation. If the venous blood lead level is confirmed to be 20 g/dL, the child should be referred for medical evaluation and followup . . . Such children should continue to receive blood lead tests every 3-4 months or more often if indicated. Children with blood lead levels 45 g/dL must receive urgent medical and environmental followup, preferably at a clinic with a staff experienced in dealing with this disease. Symptomatic lead poisoning or a venous blood lead concentration 70 g/dL is a medical emergency, requiring immediate inpatient chelation therapy . . .

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| Table 6-3. Class of child and recommended action according to blood lead measurement | | |
|---|---|---|
| Class | Blood Lead Concentration | Action |
| I | 9 | Low risk for high-dose exposure: rescreen as described in text.<br>High risk for high-dose exposure: rescreen as described in text. |
| IIA | 10-14 | Rescreen as described in text. If many children in the community have blood lead levels 10, community interventions (primary prevention activities) should be considered by appropriate agencies. |
| IIB | 15-19 | Rescreen as described in text.<br>Take a history to assess possible high-dose sources of lead. |

| | | |
|---|---|---|
| | | Educate parents about diet, cleaning, etc. Test for iron deficiency. Consider environmental investigation and lead hazard abatement if levels persist. |
| III | 20-44* | Conduct a complete medical evaluation. Identify and eliminate environmental lead sources. |
| IV | 45-69* | Begin medical treatment and environmental assessment and remediation within 48 hours. |
| V | 70* | Begin medical treatment and environmental assessment and remediation IMMEDIATELY. |
| *Based on confirmatory blood lead level. | | |

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| Table 6-4. Suggested timetable for confirming capillary blood lead results with a venous blood lead measurement | |
|---|---|
| Blood Lead Level (g/dL) | Time Within Which Blood Lead Level Should Be Obtained |
| <10 | Not applicable |
| 10-14 | Not applicable |
| 15-19 | Within 1 month |
| 20-44 | Within 1 week |
| 45-69 | Within 48 hours |
| 70 | Immediately |

Pages 52-55:

EVALUATION OF THE CHILD WITH A BLOOD LEAD LEVEL 20 g/dL

History and Physical Examination

A child with a blood lead level 20 g/dL should have a pediatric evaluation, whether or not symptoms are present.

Special attention should be given to:

1. A detailed history, including the presence or absence of clinical symptoms, child's mouthing activities, the existence of pica, nutritional status (especially iron and calcium intake), dietary habits, family history of lead poisoning, potential sources of lead exposure (including exposure due to home renovation), and previous blood lead measurements.

2. Detailed environmental and occupational histories of adults in the household or other places the child spends a lot of time.

3. The physical examination, with particular attention to the neurologic examination and psychosocial and language development. A neurobehavioral assessment may be useful in children receiving chelation therapy both at the time of diagnosis and as the child approaches school age. Findings of language delay or other problems can prompt referral to appropriate programs.

4. Evaluation of iron status using measurement of iron and total iron binding capacity or of ferritin.

IRON STATUS AND SPECIAL TESTS

Tests for Iron Deficiency

Because iron deficiency can enhance lead absorption and toxicity and often coexists with it, all children with blood lead level 20 g/dL should be tested for iron deficiency. Measurements of hemoglobin, hematocrit, and reticulocytes are not adequately sensitive, and erythrocyte protoporphyrin (EP) is not specific enough to diagnose iron deficiency (although EP can be used to screen for iron deficiency).

Serum iron and iron binding capacity (transferrin saturation) and ferritin are the most sensitive indicators of iron status. An abnormally low ratio of serum iron to iron binding capacity (transferrin saturation) of 0.2 is consistent with iron deficiency. The serum ferritin level, however, is the most definitive and accurate indication of overall iron status,

although it is an acute phase reactant and may be falsely elevated in sick children; a value 12 g/dL [sic] indicates iron deficiency. Although all iron deficient children should receive treatment for this condition, the treatment should not be started until after chelation is completed in children receiving dimercaprol (BAL).

Edetate Disodium Calcium ($CaNa_2EDTA$) Provocative Chelation Test

The mobilization test is used to determine whether a child with an initial confirmatory blood lead level of 25 to 44 g/dL will respond to chelation therapy with a brisk lead diuresis (Piomelli *et al*., 1984; Markowitz and Rosen, 1991). Because of the cost and staff time needed for quantitative urine collection, this test is used only in selected medical centers where large numbers of lead-poisoned children are treated. Children whose blood lead levels are 45 g/dL should not receive a provocative chelation test; they should be referred for appropriate chelation therapy immediately . . .

Radiologic Examination of the Abdomen

Radiologic examination of the abdomen (flat plate) may show radiopaque foreign material if the material has been ingested during the preceding 24 to 36 hours. Neither negative nor positive xray results are diagnostic or definitive. A flat plate of the abdomen may, however, provide information about the source of lead if paint chips or other lead objects are found.

Radiologic Examination of the Long Bones

X-rays of the long bones are unreliable for diagnosing acute lead poisoning, and they should not be obtained on a routine basis. They may provide some indication of whether lead poisoning has occurred in the past or has been ongoing for a length of time, and this may occasionally be important. Lines of increased density in the metaphyseal plate of the distal femur, proximal tibia, and fibula may be caused by lead which has disrupted the metabolism of bone matrix. Although these lines are sometimes called lead lines, they are areas of increased mineralization or calcification and not xray shadows of deposited lead.

Pages 60-62:

Medical Management of Asymptomatic Lead Poisoning

Clinical management of asymptomatic lead-poisoned children with blood lead levels high enough to require chelation is similar to that of symptomatic children. Focus on reducing the child's exposure to lead and decreasing the child's body burden of lead.

Although succimer has been approved for chelation of children with blood lead levels >45 g/dL, experience with this drug is limited. Therefore, the treatment regimen discussed here uses $CaNa_2EDTA$ and BAL ...

Blood lead level 70 g/dL. Children with blood lead levels 70 g/dL (with or without symptoms) represent an acute medical emergency. If the blood lead level is 70 g/dL, give both BAL and $CaNa_2EDTA$ in the same doses and using the guidelines as for treatment of symptomatic lead poisoning. A second course of chelation therapy with $CaNa_2EDTA$ alone may be required if the blood lead concentration rebounds to a value 45 g/dL within 5 to 7 days after treatment. In general allow at least 5 to 7 days before beginning a second course of $CaNa_2EDTA$. Some practitioners give a second course of chelation after a 3-day rest period if the immediate post-treatment blood lead level is >35 g/dL (J. Chisolm, personal communication).

Blood lead level 45 to 69 g/dL. If the blood lead value is between 45 and 69 g/dL, chelation treatment should be limited to $CaNa_2EDTA$ only. $CaNa_2EDTA$ is given for 5 days at a dose of 1,000 $mg/m^2$/day intravenously by continuous infusion or in divided doses, as described on Page 56. During treatment, evaluate renal and hepatic function and serum electrolyte levels regularly. Do not continue $CaNa_2EDTA$ treatment for more than 5 days (Piomelli *et al*., 1984).

A second course of chelation therapy with $CaNa_2EDTA$ alone may be required if the blood lead level rebounds to 45 g/dL within 7 to 14 days after treatment. Allow 5 to 7 days before beginning a second course of $CaNa_2EDTA$.

Blood lead level 25 to 44 g/dL. For this blood lead range, the effectiveness of chelation therapy in decreasing the adverse effects of lead on children's intelligence has not been shown. Treatment regimens vary from clinic to clinic.

Some practitioners treat children with lead levels in this range pharmacologically. (Although it is not approved for this use, some use D-penicillamine for children in this blood lead range.) The minimum medical management for children with these blood lead levels is to decrease the children's exposure to all sources of lead, to correct any iron deficiency and maintain an adequate calcium intake, and to test frequently to ensure that the child's blood lead levels are decreasing. Many experienced practitioners decide whether to use chelation therapy on the basis of the results of carefully performed $CaNa_2EDTA$ mobilization tests.

Blood lead level 20 to 24 g/dL. Only very minimal data exists about chelating children with blood lead levels below 25 g/dL, and such children should not be chelated except in the context of approved clinical trials. A child with a confirmed blood lead level of 20 to 24 g/dL will require individual case management by a pediatric health-care provider. The child should have an evaluation with a special attention to nutritional and iron status. The parents should be taught about 1) the causes and effects of lead poisoning, 2) the need for more routine blood lead testing, 3) possible sources of lead intake and how to reduce them, 4) the importance of adequate nutrition and of foods high in iron and calcium, and 5) resources for further information. . . Sequential measurements of blood lead levels along with review of the child's clinical status should be done at least every 3 months. Iron deficiency should be treated promptly. Children with blood lead levels in this range should be referred for environmental investigation and management. Identifying and eradicating all sources of excessive lead exposure is the most important intervention for decreasing blood lead levels.

POST-CHELATION FOLLOWUP

At the end of each treatment cycle, the blood lead concentration usually declines to <25 g/dL. Within a few days, however, reequilibration among body lead compartments takes place and may result in a rebound; thus, the blood lead level must be rechecked 7 to 21 days after treatment to determine whether retreatment is necessary (Piomelli *et al.*, 1984; Chisolm *et al*., 1985).

Children who undergo chelation treatment require long-term followup preferably from pediatric health-care providers, nutritionists, environmental specialists, and community out-reach workers. Community outreach workers provide a critical bridge between hospital-based or clinic-based (outpatient) medical care, health advocacy education, and environmental remediation outside the hospital. Children should never be discharged from the hospital until they can go to a lead-free environment (CDC, 1985; Piomelli *et al*., 1984). Lead-free safe housing (with friends, relatives, or in designated transitional housing), in which a treated child can live during the entire abatement process through the post-abatement clean-up, must be arranged. With appropriately carried-out public health measures, complete and safe abatement should be achieved during the treatment period (CDC, 1985).

Once a child is discharged to a safe environment, frequent followup is mandatory. In general, depending on the initial blood lead value, most children who require chelation therapy must be followed closely for at least one year or more. All children undergoing chelation treatment should be seen every other week for 6-8 weeks, then once a month for 4-6 months. A child treated with BAL and $CaNa_2EDTA$ should be followed more closely: weekly for 4 to 6 weeks, then monthly for 12 months.

At each clinic visit, housing information should be updated. If history suggests that exposure is increasing or if blood lead levels are rising, the dwelling must be reinspected to evaluate the possibility of new sources of environmental lead, inadequate abatement, or unsound structures in buildings (for example, poor plumbing with leaks) that cause further chipping or breakdown of a previously repaired dwelling (Piomelli *et al*., 1984).

Page 66-70:

ENVIRONMENTAL CASE MANAGEMENT

Time Frames for Investigations and Interventions

The following guidelines describe the maximum time within which environmental interventions should be implemented. All children with blood lead levels 20 g/dL should have environmental interventions conducted as quickly as possible. Children with blood lead levels 45 g/dL require prompt chelation therapy. The homes of these children must be remediated before they are allowed to return.

Blood lead levels between 45 and 69 g/dL. These children can be given a slightly lower intervention priority than the children classified as medical emergencies. Environmental investigation and intervention should begin within 5

working days and should include the same components as for children with higher blood lead levels. The homes of these children must be remediated before they are allowed to return.

Blood lead levels between 20 and 44 g/dL. Environmental investigation and intervention should begin within 10 working days. Since many of these children will not be hospitalized and since allowing exposures to continue might lead to further increases in blood lead levels, environmental interventions for these children should be conducted as quickly as possible.

Investigating the Environment and Communicating the Results

The technical aspects of inspecting a home for lead-based paint are discussed below. In general, an investigation of the environment of a lead poisoned child should include the following steps:

1. Determine the most likely sources of high-dose exposure to lead.

2. Investigate the child's home to identify possible sources of lead. Include both the interior and exterior environment and give special attention to painted surfaces, dust, soil, and water. (Details on how to test for lead-based paint are in the next section.)

3. Advise parents and caretakers about identified and potential sources of lead and ways to reduce exposure.

4. In cases in which the parent does not own the home, notify the property owner immediately that a child residing on the property has lead poisoning. Discuss the results of the environmental investigation and the abatement interventions required with the property owner. Emphasize the importance of prompt abatement. When a child with a medical emergency from lead poisoning is identified, an immediate, face-to-face meeting with the property owner may best demonstrate the need for emergency intervention.

5. Advise parents and property owners that no residents or personal belongings should remain in the home during abatement.

6. Monitor the effectiveness and timeliness of abatement procedures closely.

7. Coordinate environmental activities with those of other professionals, including the health-care providers and persons responsible for public health and social management. A team approach to intervention will help provide a timely and effective followup.

Emergency Measures to Reduce Lead Exposure

The first phase of environmental intervention may be to use short-term emergency interventions to temporarily reduce lead hazards. As soon as a blood lead level 20 g/dL (or, if resources permit, 15 g/dL) is confirmed, parents should be advised of the hazards of lead-based paint and lead dust. They should be told not to attempt abatement themselves -- improper abatement will most likely increase lead dust levels in the home and create additional, more severe exposure for the child. The temporary nature of interventions other than abatement should be emphasized.

When the source of lead is paint and paint-contaminated dust, parents can be instructed to stabilize the paint, wet-mop all floors, and wet-clean window sills and window wells at least twice per week. Cleaners high in phosphates appear to work particularly well. Sponges and rags used in this cleaning should be used for no other purpose. In particular, they should not be used to wash dishes or clean eating- or food-preparation surfaces, since dangerous contamination could result. Children's hands should be washed regularly, particularly before eating. Toys and pacifiers that are mouthed should be washed at least daily. Cribs and playpens should be moved away from chipping or peeling paint; furniture can be placed in front of areas that are not intact to make them less accessible. Dry sweeping of dust should be avoided, because it will stir up and spread the dust.

Long-Term Measures to Reduce Lead Exposure

The next phase of environmental intervention involves long-term hazard reduction. If the source of lead is paint and paint-contaminated dust, the lead hazards are permanently abated only when all lead-based paint is completely removed or otherwise made permanently inaccessible. Less extensive practices, which are commonly used by childhood lead poisoning prevention programs, may be called "long term abatement." Certain maintenance procedures (for example, frequent cleaning and keeping walls freshly painted) may be classified as "preventive maintenance," but in general these procedures offer no absolute assurance of safety. In cases other than "permanent abatement," how long the hazard will remain under control depends on such factors as the quality of the workmanship, the thoroughness of the procedure, the soundness of the underlying structure, and the condition of the plumbing and roof. Moisture from leaky

pipes or roofs can quickly cause paint that was smooth and intact to blister and scale, generating hazardous levels of lead dust. Except in unusual situations (such as in the case of housing that is not likely to be viable for more than a couple of years or when no alternative housing is available), temporary measures to reduce exposure should not be a substitute for abatement or an excuse for delaying abatement.

Evaluating Intervention Activities

The effectiveness of any intervention for a lead-poisoned child should be evaluated by its impact on the child's blood lead level. Measurement of environmental lead levels may also be helpful.

Assessing the Lead Problem in the Child's Community

If a number of children are identified as being lead-poisoned in a community, communitywide interventions . . . should be considered.

Baltimore Guidelines

LEAD POISONING PREVENTION PROGRAM

PILOT

Guidelines For Response To A Child

With Elevated Blood Lead Level

Baltimore City Health Department December 1, 1991

Introduction

In the Spring of 1991, the Baltimore City Health Department began development of a pilot project to improve services under the Lead Poisoning Prevention Program. The enclosed guidelines will govern implementation of the pilot project. The pilot is anticipated to begin in the Fall of 1991 and to last one year. A comprehensive evaluation will be conducted. The evaluation will be designed in conjunction with an evaluation subcommittee of the Mayor's Task Force on Lead Poisoning Prevention. A grant has already been awarded by the CDC for evaluation.

The pilot has been developed with the intention of correcting major difficulties in the existing system of response to lead poisoned children, including: a large percentage of uncompleted abatements; abandoned properties; high costs and financial hardships; and displacements of families.

Goals of the pilot project are as follows:

. Responsiveness to needs of child and family

. Emphasis on family support and education

. Efficient assessment of hazard

. Practical, low cost strategy

. Minimal displacement

. Prompt cleanup

. Prompt abatement

. 100% compliance

The pilot project will include interventions for all children who have blood lead of >= 20 g/dl who are referred to the Baltimore City Health Department through the Maryland Department of the Environment Childhood Lead Registry. Currently there are 400-500 new cases per year identified through the Registry. Health Department encouragement of increased blood lead testing during the coming year and the lowering of the blood lead to which we are responding will result in a substantial increase in caseload.

The pilot will be implemented by the Baltimore City Health Department with ongoing assistance from the Department of Housing and Community Development. Within the Health Department, the Lead Poisoning Prevention Program will staff the pilot project. Personnel include a nursing supervisor; 3 community health nurses, 4 (clinical) outreach investigators; a social worker; 9 environmental sanitarians; 4 office assistants; and 2 lab employees. Plans are underway to recruit additional staff with housing/abatement expertise. The staff is headed by the Lead Program Director. Ultimate responsibility for the pilot will rest with the Health Commissioner's office.

Guidelines for the pilot cover the entire series of steps to be taken by the Health Department, Parent or caretaker of the child and the property owner once a child is identified as poisoned. Sections include: initial communications when a child is identified; investigation of causes of poisoning; education and counselling for families with poisoned children; additional support services for families; required environmental remedies in residences if hazards are identified through inspection; required procedures for abatement of hazards; clearance standards for abated properties; monitoring of abated properties; and sanctions for lack of compliance with guidelines or regulations.

Property owners must understand that the pilot calls for environmental remedies that are still being evaluated. There are no guarantees that additional remedies won't be required to pass a clearance test or during the abatement monitoring period.

LEAD POISONING PREVENTION PROGRAM

PILOT

Guidelines For Response To A Child

With Elevated Blood Lead Level

1. Initial Communication By the Lead Poisoning Prevention Program (all cases of elevated blood lead)

Goal: To ensure the child's family and the property owner are alerted to the lead problem and the Health Department's role in resolving it.

1.1. Upon identifying a child with elevated blood lead through the Maryland Department of the Environment Childhood Lead Registry, the Lead Poisoning Prevention Program (LPPP) will notify in writing the parent or caretaker of the poisoned child and the property owner of the child's primary residence.

1.2. Written notification to the parent or caretaker will include information about the Health Department's knowledge of the child's medical problem; steps which will need to be taken for the child and the residence; the role of the LPPP will play in assisting the family; and information concerning the LPPP intent to cause minimal disruption to the family's living situation and promote maximum cooperation between tenant and property owner.

1.3. Written notification to the property owner will include information that a child residing in the property is poisoned; information concerning the nature of lead poisoning and likely sources; steps which will need to be taken regarding the property; and information concerning the LPPP intent to cause minimal disruption and promote maximum cooperation between tenant and property owner.

2. Investigation of Sources of Poisoning (all cases of elevated blood lead)

Goal: To ensure that the LPPP thoroughly understands the child's circumstances and likely causes of poisoning and that a thorough record documenting the situation is created.

2.1. Investigation will be conducted by clinical and environmental staff of the LPPP.

2.2. Clinical investigation will consist of consultation with the child's medical provider as needed, and consultation with the child's parents or caretaker. Documentation will be made regarding family history and household situation, child's condition and behavior problems, child's whereabouts and possible risk factors, etc. Visual inspection of the child's primary and secondary residences can confirm impressions of environmental staff in its investigation.

2.3. Environmental investigation will consist of visual inspection of primary and secondary residences, in addition to dust testing, testing of and selected paint samples and XRF testing. Protocols for the environmental inspection will be set forth in a separate document. Protocols will be based on approved COMAR thresholds for hazardous levels of lead in dust. Lead dust testing results of floors, window sills, and window wells will be a primary indicator of lead hazards in residences frequented by the child. Other primary indicators will include overall condition of the home, condition of the substrates, defective paint, and presence or absence of lead-based paint.

3. Education and counselling (all cases of elevated blood lead)

Goal: To ensure the family of the poisoned child has a thorough understanding of the problem of lead poisoning and how to respond to it.

3.1. Education and counselling for the family of a poisoned child will include written materials as well as explanation and demonstration by LPPP staff at the residences of the child.

3.2. At least three meetings with the parent or caretaker will take place while the child is on active caseload, the first to introduce basic information, the additional two to reinforce it.

3.3. Topics will include sources of hazards within the residences; means avoiding exposure; importance of child's supervision, observance of child's behavior and availability of age appropriate toys; proper preventive diet; appropriate cleaning technique and schedules; areas to be cleaned; and importance of ongoing testing and followup treatment of the child.

3.4. Education and counselling may be conducted by clinical staff, environmental staff or a combination of the two to maximize use of staff time.

IV. Additional Health and Social Interventions

Goal: To ensure that the poisoned child is adequately monitored and treated, and that the family avails itself of all resources available through the Health Department and other public agencies.

A. Clinical staff will follow CDC guidelines for medical monitoring and management of poisoned children. Children will remain on active caseload according to CDC guidelines.

B. If additional family problems are observed during education and counseling meetings, LPPP staff will make referrals for assistance to other Health Department programs, social work staff, or other city and state agencies.

C. LPPP and HCD staff will provide assistance and encouragement on matters relating to temporary or permanent relocation of the family or family members. Staff will assist in identifying housing through HCD, or other providers of housing, including private property owners who may have vacancies. Staff will make every effort to maintain ongoing contact during the abatement process with the parent or caretaker during the period of relocation.

Any relocation problem preventing timely abatement which cannot be resolved by LPPP staff will be resolved by the Commissioner of his designee.

V. Environmental Interventions (primary and secondary residences with hazards identified through the investigation and inspection of the property).

Goal: To ensure that tenant and property owner thoroughly understand the results of investigation and the entire process to be followed bases on the investigation. To ensure that LPPP and the property owner agree to the prescribed alternative procedure for abatement for the property, and that abatement is adequately completed in a timely fashion.

A. Requirement for Conference

If hazards are identified through dust testing or paint testing upon inspection of the child's residence, the LPPP staff will schedule a conference with tenant and property owner in a timely fashion at the residence of the poisoned child.

B. Procedure for Conference

At the conference, LPPP staff will review the following: 1) the testing process and hazards identified; 2) orders for immediate cleanup; 3) orders to remedy specific hazards; 4) the appropriate methods for abatement under the lead regulation; 5) contractors approved for abatement work; 6) relocation services available and obligations of tenant and property owner regarding relocation; 7) deadlines for compliance with the abatement order; 8) sanctions for non-compliance r inadequate compliance; and 9) intent by the Health Department to promote a cooperative spirit throughout the process, to accomplish a prompt abatement, and to avoid displacement of the family.

The tenant and property owner may discuss changes in orders for abatement with LPPP staff and requirements may be modified on the basis of that discussion. A formal appeal process will be established by the Commissioner.

Detailed Procedures for the conference, discussion of remedies, and appeals shall be set forth in a separate protocol for the conference.

C. Orders for Alternative Procedures for Abatement

1) Immediate Cleanup: Within 10 days of the conference, the property owner will be responsible for a cleanup of the child's residence to eliminate the most immediate hazards for the child. (Proof of cleanup must be provided).

The cleanup will consist of hepa vacuuming, and phosphate washing of woodwork, trim, walls, ceilings, windows and wells, floors, carpets, porches, basements in use, and, if possible, household furnishings.

A property owner who has begun abatement with suitable relocation of tenants within 10 days may forego this initial cleanup process (However, the property owner will still be responsible for appropriate cleaning and preparation of all intact surfaces which will require repainting as part of the abatement requirement).

2) Abatement: Within 45 days of the conference, or 60 days if negotiated for adequate reason, the property owner will be responsible for complying with an order to abate the lead hazards. The abatement may include, but not be limited to the following:

a) elimination of code violations contributing significantly to lead hazards, including not limited to roof and plumbing leaks, interior and exterior chipping and peeling paint, holes in walls and floors, loose and deteriorating materials, etc.

b) window treatments, including: complete replacement according to spec; or modification according to spec to eliminate all abrasion of leaded surfaces.

c) treatment of doors and frames according to spec to eliminate abrasion of leaded surfaces.

d) treatment of floors and stairs according to spec to create cleanable surfaces and reduce wear and friction. (Elimination of all carpeting and rugs where possible).

e) repainting of all corrected interior and exterior chipping and peeling surfaces with approved paints.

f) Thorough post-abatement cleanup as required under COMAR 26. 02. 07. 08. A-H.

The order to abate will include a workplan for property indicating the specific remedies required. The order will indicate to the property owner that the abatement workplan under this pilot is experimental and that completion of the workplan will not necessarily result in meeting clearance standards. The property owner may still be responsible for additional abatement ordered by the Health Department.

Abatement specifications will be detailed in a separate protocol.

3) Prohibitions: All abatement methods prohibited under COMAR 26.02.07.3A. are also prohibited under these guidelines.

4) Safety/Containment: Persons performing abatement must comply with provisions of COMAR 26.02.07.04, 26.02.07.05, 26.02.07.07, and 26.02.07.11.

5) Waste Disposal: Persons performing abatement must comply with provisions of COMAR 26.02.07.09.

D. Relocation of Occupants During Abatement

Pregnant women and children should not (except under circumstances indicated below) be on the premises during the abatement process, day or night. LPPP staff will play an active role in temporarily relocating at risk family members. Assistance will include advice on packing or safely storing possessions, identification of available alternative housing, and coordination with the property owner to minimize the period of relocation.

Under certain circumstances, if the property owner and contractor can adequately demonstrate that abatement can be performed without risk to the occupants, the Commissioner may allow residents to remain on the premises.

The Commissioner will not in any case allow occupancy by a child with a blood lead of 30 ug/dl or greater or under a year old while interior abatement is taking place.

3.5. Post Abatement Inspection

Inspection procedures and clearance standards will be consistent with COMAR 26.02.07.12. the inspection will be a two step process. The first step will be a visual inspection to determine that encapsulation and replacement under the workplan has been properly completed and that all surfaces which need repainting are properly patch tested, cleaned and prepared. The second step, after repainting, will be a visual and dust sampling inspection.

3.6. Properties Which Fail Post-Abatement Clearance Tests

If the property fails post-abatement inspection either through visual inspection or dust sampling, LPPP staff may request recleaning and minor adjustments to the abatement workplan. However, if the property fails again after additional efforts to clean up, LPPP staff may order additional abatement. The time allowed to perform additional abatement may be negotiated based on cost, volume of work required, etc. LPPP staff may recommend permanent relocation of at-risk occupants if work will not be completed in a timely fashion. Final resolution of any disagreements regarding post-abatement clearance and additional requirements will rest the Commissioner.

3.7. Ongoing Monitoring of Properties

For a period of two years subsequent to clearance under COMAR 26.02.07.12 the LPPP staff will periodically reinspect the property through visual examination and dust sampling to determine whether clearance standards are still met. Additional cleanup measures or physical improvements to the property may be required if lead levels in dust are not below clearance standards or surfaces have not remained intact during this monitoring period.

The Commissioner will develop protocols and specific schedules for post abatement monitoring.

3.8. Non-compliance or Inadequate Compliance

Failure by the property owner to comply completely with any portion of these guidelines including procedures, deadlines, standards or abatement requirements, will make the property owner subject to any all penalties of the Baltimore City Housing code.

VI. Houses in Uncorrectable Condition

Goal: To ensure timely relocation of a family when it is clear abatement will not be accomplished in a seriously substandard property.

If in the opinion of the Health Commissioner, investigation and inspection indicate that a house will not realistically be abated because of extremely low market value, structural unsoundness, multiple code violations, extremely high dust levels and high XRF readings, LPPP staff will take the following actions:

A. Confer with the tenant and property owner explaining testing results and assessment of the property.

B. Order cleanup to the extent possible as long as the property remains occupied.

C. Coordinate with HCD to relocate the family as soon as possible to a lead safe environment.

D. Consult with HCD to take appropriate actions to board the property.

Inspection Protocol

In response to a child with elevated blood lead, Lead Poisoning Prevention Program (LPPP) staff will conduct the inspection in the primary residence of the child and other residences or premises frequented by the child.

Inspection shall consist of: 1) a visual examination of the premises, including assessment of housekeeping and assessment of the degree of deterioration of the property; 2) paint sampling and XRF analysis; and 3) dust sampling. The inspector shall make a detailed record of all findings on inspection forms designed for the pilot.

Visual Inspection

Visual inspection shall include a rating of housekeeping; notation of all plumbing/water leak problems; notation of all areas of interior and exterior chipping and peeling paint; notation of all seriously damaged interior and exterior chipping and peeling paint; notation of all seriously damaged interior and exterior painted surfaces; notation of abrading painted surfaces; and notation of window condition. (Windows should be raised and lowered in order to fully note chipping and peeling conditions).

Paint Sampling and XRF Analysis

The inspector will utilize XRF analysis and paint chip sampling, as needed, to further confirm the existence of a lead hazard on interior and exterior surfaces. Specifically, the inspector will test for lead on deteriorated, abrading, or chipping and peeling painted surfaces. The inspector may test only a representative sample of deteriorated, abrading, and chipping and peeling surfaces in any given room in order to assess the hazard.

Dust Sampling

The inspector will take a sample of a minimum of 9 dust wipes in a two-story row home as follows:

Location #

window wells 3

window sills 3

floors 3

9 total

The sample should include the kitchen, a room often used as child's play area, and child's bedroom.

Methods for XRF analysis, chip, and dust sampling shall be in accordance with procedures approved by MDE and the LPPP.

Grounds For ordering Cleaning and Abatement

The following will be grounds for the Commissioner to order cleaning and abatement by the property owner:

1) Any dust wipe with a level of

200 ug/sq. ft. floor

500 ug/sq. ft. window sill

800 ug/sq. ft. window well

2) Any deteriorating, abrading, or chipping and peeling surface testing positive for lead.

3) Any code violation related to lead hazards found in conjunction with hazardous conditions which are grounds under 1) or 2) above.

Conference Protocol

The conference among tenant, property owner and LPPP staff will be scheduled as soon as possible after inspection of a property. The conference may be scheduled through phone contact, with written confirmation if possible. The conference should take place at the property to be abated.

Attendees should include but not be limited to the property owner or representative with authority and parent or caretaker of the child.

The LPPP should be represented by the sanitarian who inspected the property, but additional staff or supervisors may also participate.

If the property owner is very familiar with the process or if for good reason cannot attend or have a representative at a conference, the property owner may receive information by mail and telephone. However, any appeal will likely require an on-site meeting. Failure of a property owner to cooperate in the process may result in penalties. A work order will be sent to the owner, who will still be required to complete abatement.

At the conference, LPPP staff will first present a summary of the steps which have taken place up to the conference, including inspection procedures and results.

LPPP staff will then present a work order and work plan for the house, which will include a clear list of specific surfaces or building components which must be addressed and how to address them.

LPPP staff will also provide the parent or caretaker with information regarding expectations of the parents or caretaker to house clean routinely once abatement completed.

The parent, property owner or their representative may discuss specifics of the workplan and suggest modification of the work order. Agreement by LPPP staff to alter the workplan will depend upon general condition of the property, dust levels from the inspection and blood lead level of the child.

The least negotiable changes to the order should be the most hazardous conditions (e,g., severely deteriorated surfaces, windows).

LPPP staff also needs to make clear that despite agreement to make changes to workplan, final clearance standards will remain the same. The most likely way to meet clearance standards is to follow original workplan.

Any questions which cannot be resolved on site at the conference may be further reviewed by the supervisory staff with final workplan issued to the property owner within five days of the conference.

A parent, caretaker, or property owner may request an appeal to the workplan within five days of receipt. The LPPP will assign an appeal officer to handle all appeals. Appeals should be resolved within five days.

Materials and information to be distributed at the conference include but are not limited to:

- A workplan indicating acceptable treatment methods for various surfaces which need to be addressed;
- A copy of regulations specifying worker safety and containment rules during abatement;
- A list of relocation options and contact persons and a contact person within the LPPP who
- can be of further assistance in coordinating the relocation process;
- A copy of the protocol explaining the post-abatement monitoring process.
- A list of contractors trained to do effective

Post Abatement Monitoring Protocol

Once a property owner has complied with orders to abate a property and the property has met clearance standards (visual and dust test) for post-abatement inspection, the property will be considered safe for reoccupancy.

However, the property will be subject to reinspection (visual and dust test) for a period of two years from the date clearance is indicated.

Reinspection will occur at approximately 6 months, one year, and two years.

Visual Inspection

LPPP staff will document that surfaces remain intact and that no significant chipping and peeling paint problems have developed.

Dust Sampling

LPPP staff shall collect a minimum of 9 dust wipes as follows:

3 floors

3 sills

3 wells

The samples should include an entranceway, the kitchen, and a young child's bedroom (specifically that of the poisoned child if that child still resides in the property).

If hazards are identified through visual inspection or dust sampling, the LPPP staff will order additional cleanup or abatement, reinspect, and extend ongoing monitoring for at least one year beyond the failed inspection.

Decisions Concerning Additional Cleaning or Improvement

Condition of Dust Status of Action

Property Levels Children

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Intact surfaces Moderate No reelevation Recleaning required within

no chipping and elevation or new elevated 20 days. Reinspect within 3

peeling paint (within 1000 blood lead months. ug/sq. ft.) Continued elevated dust (moderate) levels will require further stabilization, encapsulation or replacement of leaded surfaces.

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Intact surfaces High elevation No reelevation Recleaning required. Further dust

no chipping and (above or new elevated or XRF testing of selected surfaces.

peeling paint 1000 ug/sq. blood lead Further visual assessment.

ft. beyond Additional stabilization,

clearance) encapsulation or replacement of

suspected hazards. Reinspection within 3 months.

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Deteriorated Moderate to No reelevation Further stabilization, encapsulation

surfaces; or high or new elevated or replacement of leaded surfaces.

or chipping elevation blood lead Recleaning Reinspection within 3

and peeling months.

paint

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Any Any *Reelevation or Further encapsulation or replacement

new elevation of leaded surfaces. Recleaning.

of blood lead. Reinspection within 3 months.

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*Must be reasonably related to occupancy of the property being monitored. (The child must be living in the property for a reasonable length of time at least 2 months.)

ABATEMENT REGULATIONS FOR LEAD PAINT

City of Baltimore

Kurt L. Schmoke, Mayor

July 1, 1987

RULES AND REGULATIONS GOVERNING HOUSING

Pursuant to the power conferred upon the Committee composed of the Commissioner of Housing and Community Development, the Chief of the Fire Department, the Commissioner of Health, and a member of the City Council by Sections 401 and 402 of Article 13 of the Baltimore City Code (1983, Replacement Volume) the following rule and regulation is deemed proper and necessary for the enforcement of Sections 101 and 104 of Article 11 of the Baltimore City Code and "The Housing Code of Baltimore City" (Baltimore City Code, 1983 Replacement Volume) and for the protection of the health of the inhabitants of the City of Baltimore, and is hereby adopted:

Regulation 5. Lead-Based Paint Abatement

4. Definitions

In the regulation, certain words, terms and phrases, and their derivatives shall be construed and given the meaning specified below:

1) abate/abatement - shall mean the appropriate reduction of, removal of, or encapsulation of lead followed by thorough clean-up and post clean-up treatment of the surfaces and sources that promote exposure resulting in the possibility of lead toxicity or poisoning.

2) child/children - shall mean a person under age six (6).

3) Commissioner - shall mean the Commissioner of the Baltimore City Health department or his/her designee.

4) Department - shall mean the Baltimore City Health Department.

5) elevated blood lead (EBL) - shall mean excessive absorption of lead in the blood in concentrations defined as an elevated blood lead level in children by the Centers for Disease Control (CDC) of the United States Department of Health and Human Services, as that definition may be revised in the future by the CDC.

6) environmental inspection - shall mean a survey of a property, conducted by the Commissioner or Department, to determine the presence of any or certain health hazards.

7) health hazard - shall mean a condition, as determined by the Commissioner, posing a threat to the welfare, safety and health of any individual, the general public or certain populations thereof.

8) lead-based paint - shall mean paint, varnish, shellac or similar coating containing more than 0.06% of lead in the final dried solid.

9) lead-based paint violation - shall mean (a) the violation of any state or local law regulation concerning lead-based paint, or (b) the presence of lead-based paint on the interior or exterior surfaces of any property or on any toy, appliance, item of furniture or other household item that is easily accessible to a child; or that is cracking, peeling, chipping, blistering, or flaking or is in an otherwise deteriorated condition; or that is chalking so that the lead dust generated therefrom is determined by the Commissioner to pose a health hazard; or that is present on surfaces defined as woodwork or woodtrim.

10) lead dust - shall mean dust containing lead, generated by the deterioration of lead-based paint or by environmental factors.

11) owner - shall mean any person, firm, corporation, guardian, conservator, receiver, trustee, executor, or other judicial officer, who, alone or jointly or severally with others, owns, holds, or controls the whole, or any part, of the freehold or leasehold title to any property, with or without accompanying actual possession thereof, and shall include in addition to the holder of legal title, any vendee in possession thereof, but shall not include a mortgagee or an owner of a reversionary interest under a ground rent lease. In the case of a toy, appliance, item of furniture or other household item which is the property of a tenant, the term "owner" shall mean tenant for the sole propose of the abatement of a lead-based paint violation existing thereon.

12) secondary residence - shall mean a caretaker's home, day care center, or other dwelling, institution or property frequented by an EBL child.

13) surface that is easily accessible to a child - shall mean the interior, exterior or other surface of a dwelling or secondary residence that presents a potential biting surface (up to 4 feet in height and 4 inches in depth) to a child.

14) woodwork or woodtrim - shall mean all wooden or metal interior fittings or ornamentation, such as moldings, doors, staircases and window sashes and trim; and all such exterior surfaces easily accessible to a child.

5. Procedures related to the identification of an EBL child

5.1. In the event a child has been identified as having an elevated blood lead (EBL) level, the Commissioner shall request the Department to conduct an environmental inspection of the child's dwelling and/or secondary residence. If a lead-based paint violation is found, the Commissioner shall issue a notice requiring the abatement of the violation by the owner in conformance with this regulation.

6. Procedures related to the issuance of an order to abate

6.1. In the event the Commissioner determines the existence of a lead-based paint violation, the Commissioner shall notify the owner of the property of the existence of the lead-based paint violation and order the abatement of such violation within a specified time of the receipt of the notice, not to exceed 30 days unless otherwise ordered by the Commissioner. Such violations shall be abated in conformance with the standards set forth in Section IV below.

6.2. To determine the existence of a lead-based paint violation, the Commissioner shall request the Department to conduct an environmental inspection of the property, to include common areas of multi-family dwellings. A rebuttable presumption of the presence of lead-based paint shall be based on one or more of the following:

1) readings of the X-RF analyzer taken during the environmental inspection which indicate a lead content greater than 0.7 $mg/cm^2$;

2) analysis of paint samples taken during the environmental inspection indicating more than 0.5% lead;

3) analysis of dust samples taken during the environmental inspection which indicate the existence of a health hazard as determined by the Commissioner.

6.3. In the event the environmental inspection results in the determination that lead dust is present in any dwelling or secondary residence, but that a lead-based paint violation does not exist, the Commissioner may require that the dwelling or secondary residence be cleaned in conformance with Section IV, Subsection B.6. below.

7. Standards for abatement

The minimum mandatory standards for every abatement of a lead-based paint violation, whether or not that abatement is being carried out in response to a notice issued by the Commissioner, an agency of government, a court, or voluntarily, are as follows:

7.1. Posting of dwelling or secondary residence under abatement

7.1.1. A person engaged in the abatement of a lead-based paint violation shall post 20 inch by 14 inch caution signs immediately inside the entrances and exits of a dwelling or secondary residence under abatement. Such signs shall be conspicuously placed and shall inform persons entering or exiting the property that an abatement of a lead-based paint violation will be or is being performed.

7.1.2. Except in emergency situations, signs shall be posted at least three days in advance of commencing the abatement project.

7.1.3. Such signs shall remain posted until the Department issues a written notice in conformance with Section V, Subsection C below to the owner.

7.2. Methods of Abatement

Abatement of a lead-based paint violation includes all of the following: removal of lead-based paint, encapsulation of lead-based paint, or replacement of surfaces containing lead-based paint; thorough clean-up; and post clean-up treatment of surfaces (including floors). Abatement must be carried out in conformance with the following:

7.2.1. **General**

a. If the surface requiring abatement is subject to a Baltimore City Code violation or is found to be in violation of the Baltimore City Code, the violation must be corrected prior to the abatement of the lead-based paint violation, unless the Commissioner determines that the correction of the violation is more appropriate after the abatement process.

b. Work shall be done in progression through the dwelling or secondary residence beginning with the area farthest from the entrance. In a multi-story dwelling or secondary residence, work shall begin on the uppermost floor in the area farthest from the stairway.

c. Furnishings, including wall-to-wall carpeting, must be removed from each room or area as it is prepared for abatement. Those furnishings that cannot be moved (e.g., built-in furniture) must be covered with plastic at least 6 mils. thick and sealed with tape. Furnishings should be thoroughly cleaned to remove lead dust before returning them to a room that has undergone abatement.

d. Each area that is to be abated shall be sealed with plastic at least 6 mils. thick and tape prior to abatement in order to contain the lead dust and abatement residue.

e. Sanding and use of an open flame torch and chemical strippers containing methylene chloride are prohibited abatement techniques. Methylene chloride based strippers may be used, if necessary, in small quantities as a final touch-up method.

f. All cabinets, closets and drawers must be sealed with tape so as to prevent contamination by lead dust and/or lead particles.

g. In the case of a rental property, the tenant is responsible for the removal of all ingestibles from any room or area under abatement prior to the commencement of the abatement.

h. The entire floor of the work area shall be covered with plastic at least 6 mils. thick, and all seams and edges secured with tape or staples.

i. All abated surfaces must be inspected by the Department prior to the painting or coating of said surfaces. Such inspections will be completed within a reasonable timeframe.

7.2.2. Walls/ceilings

a. If the defective area of a wall or ceiling surface is localized, only the defective area should be scraped and repaired to create a smooth surface. The entire wall or ceiling (not simply the defective area) must then be repainted with a paint containing less than 0.06% lead in the final dried state, after (1) a Departmental inspection in conformance with Subsection 1.i. above, and (2) performing a cleanup in conformance with Subsection 6 below.

b. If the wall or ceiling condition is determined by the Department to be unsuitable for repainting, covering with fiberglass, vinyl, sheetrock and/or any type of paneling or other covering which seals the seams and edges will be satisfactory.

7.2.3. Woodwork and woodtrim

a. Approved methods are replacement, covering with new wood with sealed or caulked seams, and/or paint removal using a heatgun or chemical trippers not containing methylene chloride. Methylene chloride based strippers may be used, if necessary, in small quantities as a final touch-up method. Off-site chemical stripping of woodwork or woodtrim is also acceptable.

b. All abated surfaces must be repainted with paint containing less than 0.06% lead in the final dried state, after (1) a Departmental inspection in conformance with Subsection 1.i. above, and (2) performing a clean-up in conformance with Subsection 6 below.

7.2.4. **Windows**

a. Acceptable methods are replacement window units and/or removal of lead-based paint by use of heatgun or chemical strippers not containing methylene chloride. Methylene chloride based strippers may be used, if necessary, in small quantities as a final touch-up method. Replacement window slides may be used on sides of the existing frame.

b. Windows must be completely abated, including inside, outside, and sides of sashes; window frames must be abated to the outside edge of the frame, including slides, sash guides and window wells.

c. All abated surfaces must be repainted with paint containing less than 0.06% lead in the final dried state, after (1) a Departmental inspection in conformance with Subsection 1.i. above, and (2) performing a clean-up in conformance with Subsection 6 below.

7.2.5. **Floors**

a. Floors coated with lead-based paint must be encapsulated using vinyl tile or linoleum flooring. Upon written request from the owner, the Commissioner may consider other appropriate means of abating floor surfaces.

b. After clean-up of the entire work area in conformance with Subsection 6 below, all floors, stair treads and risers must be sealed using polyurethane, deck enamel or the equivalent. As an alternative, vinyl tile, linoleum flooring, or the equivalent may be used.

c. Floors, already covered with intact vinyl tile, linoleum flooring, or the equivalent need only be cleaned in conformance with Subsection 6 below.

7.2.6. **Clean-up**

a. At the end of each workday, rooms or areas in which abatement is incomplete shall be thoroughly cleaned in conformance with this subsection, or properly sealed from the remainder of the dwelling or secondary residence.

b. Before unsealing each room or area, it should be thoroughly cleaned, inspected by the Department within a reasonable timeframe, surfaces recoated, and then cleaned again. Once a room or area has received clean-up, it should not be re-entered by workmen.

c. At a minimum, the first clean-up should consist of a thorough High Efficiency Particle Accumulator (HEPA) vacuuming of all surfaces, including woodwork and woodtrim, walls, ceilings, windows and window wells, and floors, followed by a high phosphate wash and a second HEPA vacuuming. After repainting or coating walls, woodwork and woodtrim, ceilings, windows, and floors, the clean-up process should be repeated.

d. In the absence of a HEPA vacuum, two thorough wet washings with a high phosphate wash, with frequent changes of water, each followed by a wet vacuuming while surfaces are still wet followed by two additional such treatments after repainting or coating, will be considered satisfactory.

e. Use of an ordinary household vacuum for clean-up of abatement debris is prohibited. Sweeping should be limited to preliminary cleanings only.

f. All sponges, rags, mop heads and other materials used in clean-up must be properly disposed of along with other abatement debris.

7.3. Presence of occupants during abatement

7.3.1. The Commissioner shall exercise his/her best efforts to instruct the occupants of the dwelling or secondary residence of the health hazards associated with the abatement procedures. All occupants must be out of the work area while abatement is underway.

7.3.2. Children and pregnant women are specifically prohibited from entering and/or remaining in a dwelling or secondary residence at any time during the abatement process, including times when work is not in progress. These persons should not return to the dwelling or secondary residence until such time as the Commissioner determines that abatement has been completed in a satisfactory manner.

7.4. Safety of workers

7.4.1. Persons carrying out abatement activities must comply with all applicable federal, state, and local laws and/or regulations related to safety in the workplace.

7.5. Disposal of abatement waste

7.5.1. Disposal of waste generated in the course of the abatement process shall be in compliance with Hazardous Waste Small Quantity Generators regulations as required by COMAR 10.51.03. Lead waste subject to COMAR 10.51.03 shall be removed from the site not later than seven days after completing the abatement. Lead waste not subject to COMAR 10.51.03 shall be removed from the site not later than twenty-four hours after completing the abatement.

7.5.2. Lead abatement waste shall be transported and disposed of in a manner to prevent lead from becoming airborne.

7.5.3. If disposal of lead waste is within the State of Maryland, disposal facilities authorized for that purpose shall be used.

7.5.4. In no event shall such waste be disposed of through regular residential or commercial trash collection.

7.6. Exemptions

7.6.1. The Commissioner may, on a case-by-case basis, approve an alternative procedure for abatement of a lead-based paint violation, provided that the owner submits a written description of the alternative procedure to the Commissioner and demonstrates to the satisfaction of the Commissioner that compliance with this regulation is not practical or feasible, or that the proposed alternative procedure provides the equivalent control and removal. The Commissioner, following his/her review, may approve an alternative procedure if he/she determines that it will minimize the emissions of lead into the environment.

8. Procedures related to inspection of the abatement

8.1. The Commissioner may inspect any dwelling or secondary residence at any time during the abatement to determine compliance with abatement standards.

8.2. When the abatement has been completed, the Commissioner shall perform a followup environmental inspection to determine if the abatement has been completed in conformance with this regulation. This determination shall be made based on one or more of the following:

1) reading of the X-RF analyzer;

2) dust sample analysis;

3) analysis of paint samples.

If a visual inspection of the property by a bonafide employed inspector of the Department discloses that the abatement was not carried out in conformance with this regulation, further abatement action may be required.

8.3. If abatement is determined to have been in compliance with any notice to abate and in conformance with this regulation, the Commissioner shall issue a written statement to the owner that the lead-based paint violation notice has been abated. Such statement shall not preclude the Commissioner from issuing future notices of lead-based paint violations against the same dwelling or secondary residence. The owner has a continuing obligation to maintain the dwelling or secondary residence in accordance with this regulation.

8.4. At the conclusion of an abatement performed under proper permit from the City of Baltimore, the final sign-off of the permit by the proper authority shall indicate that, to the best of the Department's ability to determine, the abatement was performed in conformance with this regulation.

9. Liability of the Department

9.1. The issuance of a statement by the Commissioner to an owner that a lead-based paint violation notice has been abated does not subject the Commissioner or the Department to any claims for liability if the issuance of the statement was made in good faith.

10. Penalties

10.1. Any violation of this regulation shall be deemed a violation of the Baltimore City Housing Code and violators shall be subject to any and all penalties set forth therein.

11. Severability

11.1. The provisions of this regulation are hereby declared severable. If any word, phrase, clause, sentence, paragraph, section or part in or of this regulation or the application thereof to any person, circumstance or thing is declared invalid for any reason whatsoever, the remaining provisions and the application of such provisions to other persons, circumstances or things shall not be affected thereby but shall remain in full force and effect, the Committee hereby declaring that it would have ordained the remaining provisions of this regulation without the word, phrase, clause, sentence, paragraph, section or part, or the application thereof, so held invalid.

MARYLAND DEPARTMENT OF THE ENVIRONMENT
CHILDHOOD LEAD REGISTRY

BACKGROUND

In accordance with Section 6-303 of the Environmental Article, Annotated Code of Maryland (COMAR 26.02.0) a statewide Childhood Lead Registry (CLR) was established in 1988 based on mandatory reporting by laboratories. The law requires that laboratories submit a report to the Maryland Department of the Environment (MDE) for all blood tests to screen for lead poisoning performed on children 0-18 years of age. The current method to test children for lead poisoning is a direct blood lead test either by capillary or venous method.

Lead screening of children is not legally mandated in Maryland. The Department of Health and Mental Hygiene (DHMH) and MDE are working together to implement the recommendations of the Centers for Disease Control (CDC) contained within the guidelines published in the October 1991 statement **PREVENTING LEAD POISONING IN YOUNG CHILDREN,** on a statewide basis. To date, the majority of lead screening has been through the Healthy Kids Program (EPSDT) for Medical Assistance insured children.

The new action level for lead poisoning awareness is 10 g/dl and the level for full public health intervention, environmental investigation and community health nursing (CHN) case management, has been lowered from 25g/dl to 20/dl.

REPORTING

The Childhood Lead Registry is an in-house, PC-based computerized system in dBASE III+. The Maryland State Laboratory and two private labs report electronically via modem to the Registry; other private laboratories continue to report using hard copy. All processing laboratories FAX or phone elevated results to the CLR to ensure prompt case management. Telephone and mail contact with private laboratories and health care providers is frequently required to obtain demographic information for proper referral and case management.

The CLR publishes an annual report on lead screening in Maryland. To date, the majority of Maryland children age 0 - 6 years have **not** been tested for lead. In 1991, the results of 27,484 blood lead test, representing 22,800 children, were reported to the Registry.

The Registry also maintains a data base for identified poisoned children in dBASE III+. Starting in 1992, data on cases will be entered into CDC's Stellar program.

Followup

All new cases [children with blood leads level 20g/dl] are referred to the local health department for CHN intervention and referral to a sanitarian for an environmental investigation. Locally, the CHN is the case manager. At the State level, the CLR manager provides oversight for case management of poisoned children. MDE also provides technical environmental assistance including on site inspections as indicated.

A 100-200% increase in the number of new cases is expected to result from increased awareness and screening and improved reporting. In addition, over one half of all Maryland children screened in 1990, using the blood lead test, had lead levels in excess of 10g/dl.

Title 26
DEPARTMENT OF THE ENVIRONMENT

Subtitle 02 OCCUPATIONAL, INDUSTRIAL, AND RESIDENTIAL HAZARDS

Chapter 07 Procedures for Abating Lead Containing Substances from Buildings

Authority: Environment Article §§1-104 and 7-206 -- 7-208
Annotated Code of Maryland

.01 Scope

These regulations establish appropriate techniques for abatement of lead-containing substances from interior and certain exterior areas in group day care centers, in all residential property including owner-occupied residential property, and in buildings appurtenant to group day care centers and residential properties.

.02 Definitions

A. The following terms have the meanings indicated.

B. Terms Defined.

(1) "Abate" or "abatement" means the elimination of exposure to lead-based substances that may result in lead toxicity or poisoning, by the removal or encapsulation of lead-containing substances, by thorough cleanup procedures, and by post-cleanup treatment of surfaces.

(2) "Business entity" means a partnership, firm, association, corporation, sole proprietorship, or other business unit and any employee of it.

(3) "Child" means a person under the age of 6.

(4) "Contractor" means any business entity, public unit, or person performing the actual abatement for a lead abatement project.

(5) "Department" means the Maryland Department of the Environment.

(6) "Encapsulate" or "encapsulation" means to resurface or cover surfaces and to seal or caulk seams with durable material, so as to prevent or control chalking, flaking lead-containing substances from becoming part of house dust or accessible to children.

(7) "HEPA" or "high efficiency particle air" means a filter capable of filtering out particles of 0.3 microns or greater from a body of air at 99.97 percent efficiency or greater.

(8) "Lead abatement project" means any work performed in order to abate the presence of a lead-containing substance.

(9) "Lead-containing substance" means any paint, plaster or other surface coating material containing more than 0.50 percent lead by weight calculated as lead metal in the dried solid, or more than 0.7 milligrams per square centimeter by the X-ray fluorescence analyzer.

(10) "Owner" means a person, firm, corporation, guardian, conservator, receiver, trustee, executor, or other judicial officer, who, alone or jointly or severally with others, owns, holds, or controls the whole of any part of the freehold or leasehold title to any property, with or without accompanying actual possession of it, and shall include in addition to the holder of legal title, any vendee in possession of it, but may not include a mortgagee or an owner of a reversionary interest under a ground rent lease.

(11) "Public unit" means"

(a) Any agency, bureau, department, or instrumentality of State government;

(b) Any agency, bureau, department, or instrumentality of federal or local government;

(c) Any public, quasi-public, or municipal corporation.

(12) "Woodwork" means all wooden or metal interior or exterior fittings or ornamentation, such as moldings, doors, staircases, and window sashes and trim.

(13) Work Area.

(a) "Interior work area" means a hallway, room or group of rooms in which abatement takes place on the inside of a residential property, or group day care center.

(b) "Exterior work area" means an outdoor porch, stairway, or other element of woodwork on the exterior of a residential property, a group day care center, or a building appurtenant to a residential property or group day care center, on which abatement takes place.

.03 Methods of Abatement

A. A person performing abatement of lead-containing substances may not use the following methods:

(1) Open flame burning;

(2) Dry sanding, except as allowed in §B(2);

(3) Open abrasive blasting, except as allowed in §B(2);

(4) Uncontained hydro-blasting;

(5) Methylene chloride for interior use except that methylene chloride may be used in interior work areas for localized touch-up; or

(6) Dry scraping.

B. A person performing abatement of lead-containing substances shall only use the following methods:

(1) Replacement. Any component part of a building may be abated by replacement with a part free of lead-containing substances.

(2) Removal.

(a) Unless replaced, encapsulated, or reversed, woodwork and floors may only be abated by using the following techniques:

(i) Offsite chemical stripping;

(ii) Heat gun;

(iii) Non-flammable chemical strippers which do not contain methylene chloride, except that chemical strippers containing methylene chloride may be used for localized touch-up;

(iv) Sander equipped with HEPA vacuum;

(v) Vacuum-blasting in exterior work areas only; or

(vi) Contained hydro-blasting in exterior work areas only.

(b) Unless replaced or encapsulated, walls or ceilings may only be abated by using the following techniques:

(i) Wet-scraping of loose material if scraping is followed by encapsulation;

(ii) Vacuum-blasting in exterior work areas only; or

(iii) Contained hydro-blasting in exterior work areas only.

(3) Encapsulation

(a) A wall or ceiling surface may be abated by encapsulation using only the following materials:

(i) Gypsum board;

(ii) Fiberglass mats;

(iii) Canvas backed vinyl wall coverings;

(iv) Formica;

(v) Tile;

(vi) Paneling; or

(vii) Other durable material that does not readily tear, chip or peel.

(b) A floor surface may be abated by encapsulation using only the following materials:

(i) Tile;

(ii) Vinyl flooring;

(iii) Wood; or

(iv) Stone.

(c) A woodwork surface may be abated by encapsulation using only the following materials:

(i) Plastic;

(ii) Metal; or

(iii) Wood.

(4) Reversal. A woodwork surface may be abated by reversal of its component parts so long as no lead-containing surface remains exposed at the completion of the process, and all seams are caulked and sealed.

(5) Windows Generally. Windows, when abated, shall be completely treated, including inside, outside and sides of sashes. Window frames shall be abated to the outside edge of the frame, including slides, sash guides and window wells.

C. Alternative Procedures.

(1) The Department may, on a case-by-case basis, allow an alternative procedure for abatement of a lead paint hazard, provided that the owner of contractor who uses this procedure shall submit a written description of the alternative procedure to the Department which demonstrates to the satisfaction of the Department that the proposed alternative procedure provides the equivalent control and removal.

(2) In all cases in which the Department allows the use of an alternative procedure under §C(1), the owner and resident shall, for a 1-year period after completion of the lead abatement project, permit the Department to enter the area where the abatement occurred in order to inspect the property for the purpose of determining the effectiveness and durability of the allowed alternative procedure. Before conducting such an inspection the Department shall give written notice to the owner and resident of the property.

.04 Personal Protection

A. A business entity or public unit shall ensure that its employees are protected in accordance with all applicable federal, State, and local standards, in particular those set forth in the Maryland Occupational Safety and Health (MOSH) regulations governing Occupational Exposure to Lead in Construction (COMAR 09.12.32).

B. All persons not covered by COMAR 09.12.32 and working on a lead abatement project shall, when present in the work site, wear disposable clothing, shoe covers and, if a heat gun or sander equipped with HEPA vacuum is being used for abatement, a half-mask air purifying respirator equipped with high efficiency filters.

.05 Control of Access.

A. Except as provided in §D, a person or pet may not enter or remain in the work area of a group day care center, residential property, or building appurtenant to a group day care center or residential property, until the Department determines that the lead abatement project has been completed in a satisfactory manner under Regulation .12J, unless that person is:

(1) The owner of the building or the owner's designee;

(2) The contractor engaged for the lead abatement project and his employees;

(3) A State, county, or local enforcement official or his designee;

(4) An inspector who represents a lender with a security interest in the building which is being abated; or

(5) A federal, State, or local official, or his designee, engaged in research on lead buildings.

B. Exemption. If a renovation process is not reasonably expected to break or disturb any lead based substance, then the requirements of §A do not apply.

C. Except as provided in §D, all persons entering a work area during a lead abatement project which involves the removal of lead paint shall wear:

(1) Disposable shoe covers which shall be removed when leaving the work area; and

(2) A half-mask air purifying respirator equipped with high efficiency filters during or after the use of a heat-gun or sander equipped with HEPA vacuum.

D. Multiple Family Dwellings. At all times when a lead abatement project is being conducted in a common area of a dwelling occupied by three or more households:

(1) Residents and pets shall use alternative entrances and exits which do not require passage through the work area, if such an entrance and exit exists;

(2) The contractor shall use all reasonable efforts to create an uncontaminated passage for entrance and egress of all building occupants; and

(3) If the entrance and egress to a building can only be through the work area, abatement in common areas shall be conducted between the hours of 9 a.m. to 3 p.m. only, and the work area shall be cleaned with a HEPA vacuum at the end of each working day until all surfaces are free of visible dust and debris.

.06 Removable Objects

A. Except in an emergency, at least 7 days, but not more than 30 days before a contractor may commence a lead abatement project, the owner of the building where the lead abatement project is to take place shall notify all residents of:

(1) The area which is to be abated;

(2) The date abatement is to commence; and

(3) The residents' obligation under §B to place all personal items in a box or other closed, easily handled container.

B. Every resident of an area, which is to be abated, who has received a notice under §A, shall be responsible for placing all personal items in boxes or other closed, easily handled containers, and shall pay the reasonable costs of packing and storage of any loose personal items remaining in the work area at the time designated for commencement of abatement in the notice issued under §A.

C. Before a contractor may commence a lead abatement project, the owner of the building where the lead abatement project is to take place shall remove all furniture and packed personal items from the work area and store them in a secure place.

.07 Control of Emissions and Dust

A. Caution Signs.

(1) At each separate work area, the contractor performing an abatement shall display a caution sign in the following manner wherever the treatment process is reasonably expected to break or disturb any lead-containing substances:

(a) At least 3 days before removing or encapsulating lead paint, the contractor shall post signs immediately outside all entrances and exits to the work area except that, in emergency situations, posting shall be done as soon as possible;

(b) The contractor shall keep the signs posted until the Department issues the written notice of completion and compliance under Regulation .12J; and

(c) The contractor shall ensure that the sign required by §A(1) meets the following description:

(i) The sign is at least 20" by 14", and states the date and place of the lead abatement project,

(ii) Except as provided in §A(1)(c)(iii), the sign includes the phrase "Caution Lead Hazard, Keep Out" in bold lettering at least 2 inches high, and

(iii) In dwellings occupied by 3 or more households where common areas are to be abated the sign includes the phrase "Caution Lead Hazard, Do Not Remain in Work Area Unless Authorized" in bold lettering at least 2 inches high.

(2) Multiple Family Dwellings.

(a) In dwellings occupied by 3 or more households where common areas are to be abated, the contractor shall post a notice meeting the description in §A(2)(b) on the door of each apartment in the building at least 3 days before a lead abatement project commences.

(b) The notice required in §A(2)(a) shall contain:

(i) The date of commencement of abatement and the area to be abated; and

(ii) The statement "Please observe caution signs, instruct children not to remain in work area."

B. Containment.

(1) Interior Containment. Before beginning to abate a lead-containing substance in an interior work area, the contractor performing an abatement shall:

(a) Check to make sure that all movable objects have been removed from the work area as required by Regulation .06;

(b) If the work area is a room or group of rooms within a building, seal the work area from all other portions of the building with plastic sheeting at least 6 mils thick, waterproof tape, and industrial staples;

(c) Seal opening seams of all kitchen cabinets and refrigerators individually with tape;

(d) Cover all non-movable objects, such as radiators, refrigerators, stoves, kitchen cabinets, built-in furniture, and bookcases, with plastic sheeting at least 6 mils thick taped securely in place;

(e) Cover floors in the work area with plastic sheeting at least 6 mils thick sealed with tape and staples;

(f) Shut down all forced air ventilation in the work area and seal exhaust and intake points in the work area; and

(g) Remove for professional cleaning, or replace, all carpeting present before abatement.

(2) Exterior Containment. Before beginning to abate a lead-containing substance in an exterior work area, the contractor performing the abatement shall use the following procedures:

(a) Liquid Waste Produced by Abatement Technique.

(i) For all situations, when liquid waste is produced by any abatement technique used, the contractor shall place plastic sheeting at least 6 mils thick on the ground as close as possible to the building foundation, or on the floor when applicable.

(ii) When sheeting is placed on the ground, it shall be raised at its edge and extend a sufficient distance to contain the liquid waste. Plastic sheeting may not be required to extend beyond the edge of the nearest sidewalk.

(iii) When sheeting is placed on an exterior floor, it shall cover the entire exterior floor.

(b) Non-liquid Waste Produced by Abatement Technique

(i) For all situations, when non-liquid waste is produced by any abatement technique used, the contractor shall place plastic sheeting at least 6 mils thick on the ground as close as possible to the building foundation, or on the floor when applicable.

(ii) When sheeting is placed on the ground, it shall extend out from the foundation 3 feet per story being abated, with a minimum of 5 feet and a maximum of 20 feet. Plastic may not be required to extend beyond the edge of the nearest sidewalk.

(iii) When sheeting is placed on an exterior floor, it shall cover the entire exterior floor.

(iv) The contractor shall weight the sheeting at the foundations, and along all edges and seams.

(v) If the constant wind speed is over 15 mph, exterior abatement producing dry waste may not be performed unless vertical shrouds are erected.

(3) For all sealing and covering the contractor shall use:

(a) Plastic sheeting, at least 6 mils thick or equivalent;

(b) Duct tape or equivalent waterproof tape;

(c) Staples of industrial size; and

(d) Other additional appropriate work practices to contain particulate lead or lead-containing liquids.

(4) Exception. A surface or object may not be covered of sealed while that surface itself is actively being abated.

(5) Alternative Procedures. The Department may, on a case-by-case basis, allow an alternative procedure for containment of lead within a work area, provided that the owner or contractor who uses this procedure shall submit a written description of the alternative procedure to the Department which demonstrates to the satisfaction of the Department that the proposed alternative procedure provides the equivalent containment.

.08 Cleanup of Work Area

A. Interior Cleanup. After completion of the removal, replacement, encapsulation, or reversal involved in an abatement project, the contractor shall:

(1) Deposit all lead waste, including sealing tape, plastic sheeting, mop heads, sponges, filters, and disposable clothing in double plastic bags of at least 4 mils thick, or single bags 6 mils thick, and seal the bags;

(2) Before washing as required in §A(3), vacuum-clean all surfaces in the work area including woodwork, walls, windows, window wells, and floors with a HEPA vacuum.

(3) After vacuum-cleaning as required in §A(2), wet wash all surfaces in the work area including woodwork, walls, windows, window wells, ceilings and floors with a solution containing at least 1 ounce of 5 percent trisodium phosphate to each gallon of water; and

(4) After washing as required by §A(3), vacuum-clean all surfaces, after they have dried, as described in §A(2), with a HEPA vacuum until no visible residue remains.

B. Exterior Cleanup. After completion of the replacement, removal, encapsulation, or reversal involved in an exterior abatement project, the contractor shall:

(1) Recover all visible debris from all exterior areas;

(2) Vacuum all porches treated;

(3) Wet wash all surfaces in the work area, including woodwork, windows, window wells, and floors with a solution containing at least 1 ounce of 5 percent trisodium phosphate to each gallon of water.

C. Except as provided in §F, after the cleaning outlined in §§A and B, after a satisfactory inspection under Regulation .12B, every contractor shall repaint with a paint containing not more than 0.06 percent lead in the dried solid, or recoat all surfaces treated, except those encapsulated surfaces which have smooth easily cleanable factory-finished surfaces.

D. Before repainting or recoating under §C, each contractor shall notify the Department that the cleanup required under §§A and B is completed, and shall undergo any inspection required by Regulation .12B.

E. After painting or coating as required under §C, the contractor shall repeat the cleaning process set forth in §A in all interior work areas.

F. After completion of the cleaning required under §E, the contractor shall seal all floors in interior work areas with:

(1) Polyurethane;

(2) Gloss deck enamel;

(3) A tight fitting vinyl floor covering; or

(4) An equivalent impermeable material, if a smooth, cleanable surface is not already present.

G. In owner-occupied dwellings in which a lead abatement project is being done by the owner and not by a hired contractor, after completion of the replacement, removal, encapsulation, or reversal involved in a lead abatement project, the owner may, instead of following the cleanup procedures set forth in §A: (1) Deposit all waste, including sealing tape, plastic sheeting, mop heads, sponges, filters, and disposable clothing, in double plastic bags at least 4 mils thick, or single plastic bags at least 6 mils thick, and seal the bags;

(2) Wet wash all surfaces in the work area, including woodwork, walls, windows, window wells, and floors with a solution containing at least 1 ounce of 5 percent trisodium phosphate to each gallon of water, twice; and

(3) Wet vacuum-clean all surfaces in the work area, including woodwork, walls, windows, window wells, and floors while surfaces are still wet.

H. Alternative Procedures. The Department may on a case-by-case basis allow an alternative procedure for cleanup of a lead abatement project, provided that the owner or contractor who uses this procedure shall submit to the Department a written description of the alternative procedure which demonstrates to the satisfaction of the Department that the proposed alternative procedure provides the equivalent degree of dust removal.

.09 Waste Disposal

A. Each owner or contractor engaged in a lead abatement project shall:

(1) Remove lead waste from the site of a lead abatement project not later then 48 hours after completing the cleanup; and

(2) Comply with applicable hazardous waste regulations.

B. Transport and Disposal. Each owner and contractor engaged in a lead abatement project shall transport and dispose of lead waste in a manner to prevent lead from becoming airborne.

.10 Records

A. Each business entity and public unit shall make a record of the following information for every lead abatement project which it performs:

(1) Name and address of the contractor responsible for the project;

(2) The location and description of the of lead-based substances within the work area which was abated;

(3) Starting and completion dates of the lead abatement project; and

(4) Summary of abatement techniques used to comply with Regulations .04 - .08.

B. Each business entity and public unit shall:

(1) Retain the record required to be made under §A for 6 years from the date of the completion of the lead abatement project; and

(2) Make this record available to the Department upon request.

C. This regulation does not apply to owner-occupied dwellings in which abatement is being done by the owner.

.11 Health and Safety Training

A. Within the 5 years immediately before beginning work on a lead abatement project, all inspectors involved in the enforcement of these regulations and all workers involved in a lead abatement project shall have taken a qualifying training course which meets the requirements set out in §B, and have received a certificate of completion.

B. Qualifying Training Course. A training course in lead abatement shall:

(1) Receive approval from the Department;

(2) Provide at least 6 hours of instruction reflecting state of the art information on the following topics:

(a) Health effects of lead exposure;

(b) Work practices necessary to minimize lead dust concentration, including work area preparation, work area decontamination, and waste disposal;

(c) Requirements of regulation and standards established by the:

(i) Maryland Department of the Environment; and

(ii) Maryland Occupational Safety and Health Act; and

(d) Worker protection, including respiratory protection, protective clothing, safety equipment, medical surveillance, and personal hygiene;

(3) Require trainees to demonstrate proficiency in the skills necessary to perform lead abatement projects, before issuing a certificate under §B(4); and

(4) Issue a certificate of completion of training.

C. An inspector involved in the enforcement of these regulations and any worker involved in a lead abatement project shall make this certificate available to the Department upon request.

D. Every instructor at a qualifying lead abatement training course shall be an:

(1) Industrial hygienist certified by the American Board of Industrial Hygiene;

(2) Industrial hygienist in training designated by the American Board of Industrial Hygiene; or

(3) Individual with equivalent education or experience as determined by the Department.

E. Instructors at all qualifying lead abatement training courses shall:

(1) Maintain a list of students who have completed a training course in lead abatement and the dates on which training occurred;

(2) Make this list available to the Department upon request; and

(3) Retain this list for at least 5 years.

.12 Procedures for Determining Compliance

A. The Department may inspect a work area at any time during a lead abatement project to determine compliance with this regulation.

B. After receipt of notice of completed cleanup required by Regulation .08D the Department shall, within 24 hours, notify the contractor or owner of the time and date on which an initial inspection will take place, if one is to be made. If the contractor or owner is not reachable by telephone, notice shall be sent by first class mail. Any inspection performed under this subsection shall be completed within 2 working days of giving telephone notice to the contractor or owner. Notice by mail will require an additional 5 working days for completion of the inspection.

C. The inspection performed under §B shall be a visual inspection to determine whether surfaces requiring abatement have been abated.

D. The inspector shall immediately notify the contractor or owner, if either is present, of the results of the inspection under §B, and shall point out and describe any area with inadequate treatment. If the contractor or owner is not present during the inspection under §B, the inspector shall notify the contractor and owner of the results of the inspection, and

shall include the locations and characteristics of surfaces with inadequate treatment, by letter mailed within 24 hours of the inspection, by first class mail.

E. Before repainting or recoating under Regulation .08C, the contractor shall receive notice of:

(1) A satisfactory inspection under §B; or

(2) The decision not to conduct an inspection under §B.

F. Upon completion of all requirements of Regulations .08 and .09, a contractor shall notify the Department of readiness for final inspection.

G. Within 24 hours of receipt of notice under §F, the Department shall notify the contractor or owner of the time and date on which an inspection will take place, if one is to be made. If the contractor or owner is not reachable by telephone, notice shall be sent by first class mail. Any inspection performed under this section shall be completed within 2 working days of giving this notice to the contractor and owner. Notice by mail will require an additional 5 working days for completion of the inspection.

H. Every inspection performed under §G shall include at least:

(1) Dust sampling to be followed by analysis in accordance with §I; and

(2) Visual inspection.

I. All dust samples collected under §H shall be analyzed for extractable lead by:

(1) The Maryland Department of Health and Mental Hygiene, State Laboratories Administration; or

(2) A laboratory approved by the Maryland Department of the Environment to perform the analysis.

J. The Department shall notify the owner and the contractor in writing, sent by first class mail, of the results of the final inspection within 24 hours of receiving the results of lead dust analysis conducted under §I. If the results of the lead dust analysis conducted under §I do not meet the standards set out in §K, the contractor shall perform a further cleanup as described in Regulation .08H. If results of the lead dust analysis meet the standards set out in §K, the Departmental notice shall state that the lead abatement project has been completed and complies with the standards set out in §K. A statement of completion and compliance may not preclude the Department from taking any future enforcement action against the same group day care center, residential property, or building appurtenant to a group day care center or residential property.

K. A lead abatement project shall be deemed to be in compliance with these regulation if:

(1) Floor lead dust levels are below 200 micrograms per square foot;

(2) Windowsill lead dust levels are below 500 micrograms per square foot;

(3) Window well lead dust levels are below 800 micrograms per square foot; and

(4) All abated surfaces and all floors have been treated to provide smooth and easily cleanable surfaces.

I. This regulation does not apply to abatement projects conducted in owner-occupied dwellings by the owner, unless the abatement is ordered by the Department, a local government unit, or a court of competent jurisdiction.

.13 Liability of Department

The issuance of a statement of completion and compliance under Regulation .12J by the Department to an owner or contractor does not subject the Department to any claims for liability if the issuance of the statement was made in good faith.

.14 Enforcement

A person who violates any provision of this chapter shall be subject to all equitable, legal and administrative remedies set forth in Environment Article, §§7-258 -- 7-268, inclusive, Annotated Code of Maryland.

Administrative History

Effective date: August 8, 1988 (15:16 Md R 1918)

CHANGES TO REGULATIONS

Changes frequently occur to regulation published in the Code of Maryland Regulations (COMAR). These changes are always printed in the *Maryland Register*, COMAR's bi-weekly supplement. Consult the "Cumulative Table of COMAR Regulations Adopted, Amended, or Repealed" in the most recent issue of the *Maryland Register*.

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Newark Guidelines

NEW JERSEY STATUES

ANNOTATED

Official Classification

Title 24

Food and Drugs

1989

Cumulative Annual Pocket Part

[For Use In 1989-1990]

Replacing 1988 Pocket Part in back of volume

INCLUDING LAWS

through the

1988 First Annual Session

Section



Last additions in text indicated by underline; deletions by

WESTLAW Electronic Research

See WESTLAW Electronic Research Guide following the Preface.

24:14A-1. Use on toys, furniture or accessible surfaces of dwelling; prohibition

No person shall apply lead paint to toys, furniture or the exposed interior surfaces of any dwelling as defined in this act. or to any exterior surface that is readily accessible to children. .

L.1971. c.366, § 1. Amended by L.1976, c. 116, § 1. eff Nov. 16, 1976.

Historical Note

Section 13 of L.1971. c. 366, approved Dec. 28, 1971, provided:

"This shall take effect on the first day of the month following enactment."

Title of Act:

An Act prohibiting the use of lead paint under certain circumstances, providing remedies and penalties for violations thereof, and supplementing Title 24 of the Revised Statues. L. 1971. c. 366.

Cross References

Testing of children for lead poisoning. see § 26:2 - 130 et seq.

24:14A-2. Toys or Furniture; sale or transfer for profit or knowingly transfer or exchange: prohibition

No person shall sell or transfer for profit or offer to sell or transfer for profit toys or furniture to which lead paint has been applied. and no person shall knowingly transfer or exchange or offer to transfer or exchange toys or furniture to which lead paint has been applied and which will be readily accessible to children.

L.1971. c. 366 § 2. Amended by L.1976. c. 116, § 2, eff. Nov. 16, 1976.

**Historical Note** C.J.S. Agriculture §§ 95 to 98, 100.

Effective date, see note under § 24:14A-1. C.J.S. Poisons § 2 et seq.

24:14A-3. Violations: disorderly persons

Any person violating the provisions of this act shall be a disorderly person.

L.1971, c. 366, § 3.

Historical Note Cross References

Effective date, see note under § 24:14A-1. General penalty, disorderly persons. see § 2A:169

24:14A. Definitions

For purposes of this act:

a. "Approved" means satisfactory compliance as determined and recorded by the Department of Health.

b. "Department" means the State Department of Health.

c. "Lead paint" means any pigmented, liquid substance applied to surfaces by brush, roller, spray, or other means in which the total nonvolatile ingredients contain more than 1% of lead, by weight, calculated as metallic lead.

d. "Dwelling" means any building or structure or portion thereof which is occupied in whole or in part as the home, residence, or sleeping quarters of one or more persons and includes any dwelling unit, rooming house or rooming unit, and any facility occupied or used by children.

e. "Board" means local board of health, regional health commission or other locally constituted health agency having primary jurisdiction to enforce this act.

f. "Interior surfaces" and "exterior surfaces" shall include but shall not be limited to window sills, window frames, doors, door frames, walls, ceilings, stair rails and spindles or other appurtenances, including equipment on the premises of dwellings as defined herein.

L.1971, c. 366, § 4. Amended by L.1976. c. 116, § 3, eff. Nov. 16, 1976.

**Historical Note** C.J.S. Agriculture §§ 95 to 98, 100.

Effective date, see note under § 24:14A-1. C.J.S. Poisons § 2 et seq.

Words and Phrases (Perm. Ed.)

24:14A-5. Lead paint upon interior of building or exterior of surface accessible to children: public nuisance

The presence of lead paint upon the interior of any dwelling, or upon any exterior surface that is readily accessible to children causing a hazard to the occupants or anyone coming in contact with such surfaces is hereby declared to be a public nuisance.

L.1971. c. 366 § 5. Amended by L.1976, c. 116 § 4, eff. Nov. 16, 1976.

Historical Note

Effective date, see note under § 24:14A-1. C.J.S. Nuisances § 20 et seq.

24:14A-6. Duties of boards; investigation of violations; enforcement of act; reports

The board in each municipality or other area of jurisdiction, shall have the primary responsibility for investigation of violations under this act and the enforcement of this act, and shall make reports of all such violations and enforcement procedures to the State Department of Health.

L.1971, c. 366, § 6.

**Historical Note** C.J.S. Health § 13 et seq.

Effective date, see note under § 24:14A-6.

24:14A-7. Lead paint upon interior of dwelling or exterior surface accessible to children; order of removal and disposition

When the board of health having primary jurisdiction under this act finds that there is lead paint on the interior walls, ceilings, doors, floors, baseboards, or window sills and frames of any dwelling, or any exterior surface that is really accessible to children it may order the removal and appropriate disposition of such lead paint, under such safety conditions as it may specify, and as shall be approved by the department.

L.1971, c. 366, § 7. Amended by L.1976, c. 116, § 5 eff. Nov. 16, 1976.

**Historical Note** C.J.S. Health §§ 28 to 36, 52.

Effective date, see note under: § 24:14A-7

24:14A-8. Occupants of dwelling with lead poisoning or high risk of lead intoxication; notice to owner of public nuisance; order to abate

When the board of health having primary jurisdiction hereunder finds that there is lead paint on the interior walls, ceilings, doors, floors, baseboards, or windows sills and frames of any dwelling or any exterior surface that is readily accessible to children and further finds a person occupying or using such dwelling is an unequivocal case of lead poisoning at high risk of lead intoxication as defined by department regulation it shall at once notify the owner that he is maintaining a public nuisance and order him to abate the nuisance and refinish such interior surface of the dwelling or exterior surface that is readily available to children within 10 days in accordance with regulations specified by the commissioner, and dispose of any lead paint residues in an approved area. In lieu of removal of the lead paint the accessible surface may be covered by such a durable material and in a manner approved by the department. Repainting a surface with a nonleaded paint without complete removal of the existing lead paint shall not be deemed to be satisfactory compliance with this act.

A duplicate of the notice shall be left with one or more of the tenants or occupants of the dwelling. If the owner resides out of the State or cannot be so notified speedily, a notice left at the house or premises shall suffice.

L.1971, c. 366 § 8. Amended by L. 1976, c. 116, § 6, eff Nov. 16, 1976.

**Historical Note** C.J.S. Nuisances § 108.

Effective date, see note under § 24:14A-1.

24:14A-8.1. Eviction of occupants to avoid corrective maintenance

No person found to be in violation of the law shall evict, or cause to be evicted occupants for the purpose of avoiding corrective maintenance ordered by the local board of health to eliminate hazardous lead exposure.

L.1976, c. 116, § 7, eff. Nov. 16, 1976.

24:14A-9. Failure of owner to obey notice or order to abate; removal of nuisance; payment of expenses by owner; action to collect: lien

If the owner so notified shall not comply with the notice or order of the board of health having primary jurisdiction hereunder within the time specified, the board shall proceed to remove the nuisance and make the necessary repairs, bill the owner, therefor, and, if necessary, to recover the expense in a civil action against the owner. The unpaid expense of the board shall become a lien on the real property immediately upon removal of the nuisance and completion of necessary repairs.

L.1971, c. 366, § 9.

Historical Note Cross References

Effective date, see note under § 24:14A-1. Funds for loans under this section, see § 26:2- 136.

24:14A-10. Nonenforcement by board; enforcement by department

If the department finds that any board having primary jurisdiction under this act is not enforcing the provisions of this act or any rules and regulations promulgated thereunder, the department may cause a disorderly person's complaint to the made against persons violating the provisions of this act, or may bring action requiring such board to show cause why it is not enforcing this act.

L.1971, c. 366, § 10.

**Historical Note** C.J.S. Disorderly Conduct § 4.

Effective date, see note under § 24:14A-1.

24:14A-11. Rules and regulations by department

The commissioner of the department shall have the power to prescribe rules and regulations establishing criteria for the identification of areas and conditions involving high risk of lead poisoning or intoxication, specifying methods of detection of lead in dwellings, and standards for the repair of premises containing lead paint, and other rules and regulations necessary to effectuate the purposes of this act.

L.1971, c. 366, § 11. Amended by L.1976, c. 116 § 8, eff. Nov. 16, 1976.

**Historical Note** C.J.S. Health § 13.

Effective date, see note under § 24:14A-1.

24:14A-12. Repealed by L.1985. c. 84. § 10, eff. March 25, 1985

Historical Note
The repealed section, providing for a program to control lead poisoning, was added by L.1971, c. 366 § 12

See. now § 26:2-132
Statement: committee statement to Senate. No. 150 L.1985, c. 84, § 26:2-130

Last additions in text indicated by underline; deletions by

NEW JERSEY STATUTES
ANNOTATED

Title 26

HEALTH AND VITAL STATISTICS

26:2-130. Legislative findings

The Legislature finds and declares that:

a. Exposure to lead and lead poisoning lead to morbidity, mortality, mental retardation, and learning disability in young children, the monetary and social costs of which far exceed the costs of monitoring and preventing lead poisoning.

b. The New Jersey Department of Health estimates that 44 of every 1000 children are at risk of lead poisoning and that the rate of lead poisoning among children at risk now exceeds the rate of paralytic polio at the height of the epidemic of the 1950's; however, the department has the resources to test and follow up on only 16% of the 220,000 children it estimates are at risk of lead poisoning.

c. Very few health departments have the resources to comply fully with the minimum standard of performance for local boards of health and Chapter XIII of the State Sanitary Code concerning control of lead poisoning in children due to the costs of the required testing, followup and abatement.

L.1985, c. 84 § 1, eff. March 25, 1985.

Historical Note

Title of Act:

An Act to mandate testing of certain children one through five years of age for lead poising, supplementing Title

26 of the Revised Statues, repealing section 12 of P.L.1971, c. 366 and making an appropriation. L.1985, c. 84.

Cross References

Containers containing lead for food or beverages, see § 24:15A-1 et seq.
Paint containing lead, see § 24:14A-1 et seq.

26:2-131. Definitions

As used in this act:

a. "Child" means a person one through five years of age;

b. "Commissioner" means the Commissioner of Health;

c. "Department" means the Department of Health;

d. "Lead poisoning" means a concentration of lead as defined in chapter XIII of the State Sanitary Code established pursuant to section 7 of P.L.1947, c. 177 (C. 26:1A-7).

L.1985, c. 84, § 2, eff. March 25, 1985.

26:2-132. Lead poisoning abatement and control program

The department, within the limits of funds appropriated for this purpose, has the responsibility for the development, implementation and coordination of a program to control lead poisoning and abate identified lead hazards by:

a. Identifying areas where there is a high risk of the presence of lead paint in a dwelling;

b. Establishing testing procedures for the detection of the presence of lead in persons and dwellings; and

c. Stimulating professional and public education concerning the need to test, detect and control lead poisoning and to abate identified lead hazards.

L.1985, c. 84, § 3, eff. March 25, 1985.

Historical Note

**Prior Laws:** C. 24:14A-12 (L.1971, c. 366, § 12).

26:2-133. Testing for lead poisoning

a. Within the limits of funds appropriated pursuant to this act, every child determined to be at high risk of lead poisoning according to criteria established by the Department of Health shall be tested for lead poisoning. The department shall adopt regulations for the testing pursuant to the "Administrative Procedure Act,"

P.L.1968, c. 410 (C. 52:14B-1 et seq.), which are consistent with accepted public health practice and specify the periodicity for, and methods of testing and followup for lead poisoning.

b. The commissioner may require that testing for lead poisoning take place through institutions, agencies, and programs that serve children, including but not limited to municipal and county health departments, hospitals, clinics, physicians' offices, special supplemental food programs for women, infants and children, early and periodic screening, diagnostic and treatment services, day-care centers, Head Start programs and pre-schools.

c. The institution, agency or program which conducts the testing shall notify, in writing, parents or guardian of children who have been tested as to the results of the testing with an explanation in plain language of the significance of lead poisoning, the importance of treating it at an early age, and the public services available for treatment.

d. The commissioner may exempt a child from the lead poisoning testing provisions of this act if the parent or guardian of the child objects to the testing in writing on the grounds that the testing conflicts with his religious tenets or practices.

L.1985, c. 84, § 4, eff. March 25, 1985.

26:2-134. Lead poisoning control plan

Within six months of the effective date of this act, the commissioner shall prepare a comprehensive plan to control lead poisoning in the State. The commissioner shall submit the plan to the Governor and the Legislature.

L.1985, c. 84, § 5, eff. March 25, 1985.

26:2-135. Reports

The commissioner shall issue an annual report to the Governor and the Legislature by October 1 of each year. The report shall include a summary of lead poisoning testing and abatement program activities in the State during the preceding fiscal year and any recommendations or suggestions for legislative consideration.

L.1985, c. 84, § 6, March 25, 1985.

26:2-136. Loans to local health boards

The department may set aside up to 10% of the funds appropriated pursuant to this act for the purpose of providing loans to local boards of health to abate lead paint nuisances pursuant to section 9 of P.L.1971, c. 366 (C. 24:14A-9). The department shall establish criteria for making the loans and procedures for repayment of the loans to the department.

L.1985, c. 84, § 7, eff. March 25, 1985.

HUMAN BLOOD, ETC.

26:2-137. Regulations

The commissioner shall, pursuant to the provision of the "Administrative Procedure Act," P.L.1968, c. 410 (C.52:14B-1 et seq.), adopt regulations necessary to effectuate the provisions of this act.

L.1985, c. 84, § 8, eff. March 25, 1985.

NEW JERSEY STATE
DEPARTMENT OF HEALTH
CN 364
TRENTON, NJ 08625-0364

Chapter XIII
Childhood Lead Poisoning

Chapter 51
Childhood Lead Poisoning
State Sanitary Code Chapter XIII

Subchapter 1. General Provisions

8:51-1.1 Scope

The rules in this chapter shall apply to children age one through five years, who are considered at high risk of lead poisoning, screening agencies, laboratories and individuals responsible for property in which high risk children reside. Although not yet required by law, the Department of Health recommends that children between nine months and six years of age be screened in accordance with CDC recommendations.

8:51-1.2 Purpose

The purpose of this chapter is to protect at risk children from the toxic effect of lead exposure.

8:51-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Child" means a person one through five years of age.

"Commissioner" means the Commissioner of the New Jersey Department of Health.

"Department" means the New Jersey Department of Health.

"Diagnosis" means the categorization of a child who has an elevated blood lead level or has another medically accepted indicator of lead toxicity.

"Elevated blood lead level" means an abnormal level of lead in the blood stream at the level as defined in the latest revision of the Centers for Disease Control Statement--- "Preventing Lead Poisoning in Young Children", available from the Centers for Disease Control, Atlanta, Georgia 30333.

"Elevated erythrocyte protoporphyrin (EP)" means an abnormal level of hemoglobin precursors at a level defined in the latest revision of the Centers for Disease Control Statement, "Preventing Lead Poisoning in Young Children".

"EPA" means the U.S. Environmental Protection Agency.

"HEPA" means a high efficient filter which is able to filter out fine particles.

"High risk of lead intoxication" means in a child a blood lead level equal to or greater than 40 micrograms per 100 milliliters whole blood and an erythrocyte protoporphyrin determination equal to or greater than 110 micrograms per 100 milliliters whole blood, or a confirmed concentration of lead in whole blood equal to or greater than 40 micrograms per 100 milliliters if no erythrocyte protoporphyrin determination is available.

"High risk neighborhood" means those areas whose high degree of risk has been identified by the local board of health, using methodology pursuant to N.J.A.C. 8:51-8.

"Lead toxicity" means a significantly elevated blood lead level, as defined in the latest revision of the Centers for Disease Control Statement, "Preventing Lead Poisoning in Young Children".

"NHANES II" means the second National Health and Nutrition Examination Survey, CDC National Center for Health Statistics.

"NIOSH" means the National Institute for Occupational Safety and Health.

"OSHA" means the Occupational Safety and Health Administration.

"Priority I" means any municipality designated pursuant to N.J.A.C. 8:51-8 at the highest risk for lead poisoning among its children.

"Priority II" means any municipality designated pursuant to N.J.A.C. 8:51-8 at a moderate risk for lead poisoning among its children.

"Priority III" means any municipality designated pursuant to N.J.A.C. 8:51-8.3 at a low risk for lead poisoning among its children.

"Screening" means applying detection technique to large numbers of presumably asymptomatic children to determine if they have been exposed to lead and, if so, what the risks of continued exposure are.

"Suspect room or area" means those locations which are accessible to a child which may be a source of lead exposure.

"Tight lead paint" means leaded paint which is firmly affixed to the surface upon which it is applied.

"WIC" means the Special Supplemental Food Program for Women, Infants and Children.

## Subchapter 2. Screening

### 8:51-2.1 Target population and screening schedule

(a) Children who live in communities designated "Priority I" as determined by the Department of Health and set out in Appendix I of this chapter, incorporated herein by reference, are at high risk for lead poisoning.

(b) Children who live i communities designated "Priority II" as determined by the Department of Health and set out in Appendix II of this chapter, incorporated herein by reference, and who are in the following categories, are at high risk for lead poisoning:

1. The child is a Medicaid recipient;

2. The child's family income qualifies them for the WIC Program; and

3. The child is living in an identified high risk neighborhood.

(c) Each community designated Priority I or Priority II in accordance with this chapter, shall develop a screening schedule. It is recommended that any program screening high risk or other children for lead poisoning comply with the latest revision of "Preventing Lead Poisoning in Young Children", (Centers for Disease Control, Atlanta, Georgia 30333) which is incorporated herein by reference, in establishing screening schedules and intervals.

### 8:51-2.2 Screening methods

Venous or capillary blood shall be used for screening tests. Sampling methods used in the field shall be compatible with laboratory capabilities. It is recommended that agencies comply with the recommendations found in the latest revision of "Preventing Lead Poisoning in Young Children" (Centers for Disease Control, Atlanta, Georgia 30333), which is incorporated herein by reference, in selecting a screening method.

### 8:51-2.3 Medical intervention

Local boards of health shall insure that any institution, agency or program providing lead screening services shall arrange for a diagnostic evaluation of any child who is found at screening to have lead toxicity. If the screening test was done on capillary blood, a venous blood lead level should be determined. Medical intervention, including follow up testing, shall be tailored individually for each child. Other children living in the same dwelling shall be referred for testing, diagnosis and treatment, if necessary.

### 8:51-2.4 Notification and counseling

The institution, agency or program which conducts a screening program shall notify, in writing, parents or guardians of children who have been tested of the results of testing, accompanied by an explanation in plain language of the significance of lead toxicity, the importance of treating the toxicity at an early age and the public services available for

treatment. The family of the child shall also be notified that a hazard may exist in the dwelling and counseled on preventive measures.

## Subchapter 3: Environmental Intervention

### 8:51-3.1 Investigation of elevated lead or lead toxicity cases

Whenever a child is determined to have an elevated blood lead level or lead toxicity, the local board of health shall conduct an epidemiologic investigation to identify lead sources in the child's environment. If the results of the epidemiologic investigation reveal any loose paint, including cracked, chipped, blistered, peeling or flaking paint, a determination of lead content of the painted surface in the suspect areas shall be made. If the paint is found to be leaded, the procedures found in N.J.A.C. 8:51-5, Standards for Repair on Premises Containing Lead Paint, shall be implemented. Other children in the suspect dwelling should be referred for screening and follow up in accordance with N.J.A.C. 8:51-2.

### 8:51-3.2 Investigation of high risk of lead intoxication cases.

When a child is determined to have a high risk of lead intoxication as defined in N.J.A.C. 8:51-1.3, the local board of health shall conduct shall conduct an epidemiologic investigation. Dwelling units shall be inspected and tested to determine whether the presence of lead paint is in excess of 1.0 percent by dry weight or one milligram or higher per square centimeter. If levels of lead paint in excess of one milligram or higher per square centimeter are found, N.J.A.C. 8:51-5, Standards for Repair on Premises Containing Lead Paint shall be implemented. Other children in the suspect dwelling should be referred for screening and follow up in accordance with N.J.A.C. 8:51-2.

## Subchapter 4: Determination of Lead In Dwelling Units

### 8:51-4.1 Methods of determination of lead in surface coverings

(a) The methods of determination of lead in surface covering shall be specified in (b) or (c) below.

(b) The chemical determination of the lead content in paint shall be made by laboratory analysis, using quantitative measurements of samples of surface coverings. Lead content in paint in excess of 1.0 percent by dry weight shall be prohibited.

(c) The physical determination of the lead content in paint may be made by non-destructive measurements using X-ray fluorescence analyzers (X-R-F) or other instruments approved by the New Jersey State Department of Health, Accident Prevention and Poison Control Program. A lead content in paint of one milligram or higher per square centimeter of paint surface, when tested by this method, shall be prohibited.

### 8:51-4.2 Sampling and/or X-ray fluorescence analyzer

(a) Paint samples shall be collected and/or X-ray fluorescence analyzer readings shall be obtained from each suspect room and shall include both interior and exterior surfaces of a windowsill, door and door frame. In addition, paint samples and/or analyzer readings should be obtained from such other highly suspect areas as crib railings, play pen

railings, toys, stairs, or banisters and surfaces with loose paint. The preferred sampling locations shall include surfaces which have been or are accessible to being chewed or areas which are peeling or flaking.

(b) All paint samples should generally be limited to that part of the surface which may eventually be required to be removed.

## Subchapter 5: Standards for Repair on Premises Containing Lead Paint

### 8:51-5.1 Exterior surfaces

Lead paint on any exterior surface that is readily accessible to children and is determined by the local board of health to be causing a hazard to the occupants or anyone coming in contact with such surfaces shall be removed to the base surface or covered with a durable material approved by the Department pursuant to N.J.A.C. 8:51-5.5

### 8:51-5.2 Interior surfaces

Loose lead paint on any interior surface, including cracked, chipped, blistered, peeling or flaking paint, shall be removed to the base surface wherever found.

### 8:51-5.3 Removal of tight lead paint

(a) Tight lead paint shall be removed to the base surface in the following areas, as indicated:

1. Windowsills: complete removal;
2. Windows and frames below the four-foot level: complete removal on exposed surfaces;
3. Doors below four-foot level: removal four inches back on hinge and latch edges and other sharp edges;
4. Door frames below four-foot level: complete removal;
5. Handrails: complete removal;
6. Spindles ("Balusters"): removal on surfaces adjacent to walking areas;
7. Stair treads: removal four inches back from lip on top of tread and from lip to riser on bottom side; and
8. Any other chewable surface below the four foot level: removal four inches back from edge.

### 8:51-5.4 Removal not required

(a) Removal may be performed, but is not required, on the following surfaces;

1. Walls in good condition without broken areas;
2. Baseboards;
3. Skirtboards on staircases;
4. Step risers; or
5. Any surface below the four-foot level which does not present a chewable surface.

### 8:51-5.5 Covering

If paint is not removed as required in this subchapter, surfaces shall be covered with plasterboard, wallboard, wood paneling or similar durable material approved by the New Jersey State Department of Health, Accident Prevention and Poison Control Program, to a height of at least four feet above the floor. Any construction permit required pursuant to the Uniform Construction Code Act (N.J.S.A. 52:23-119 et seq.) and the Uniform Construction Code, N.J.A.C. 5:23 shall be obtained from the agency having jurisdiction.

8:51-5.6 Other repairs

Any condition, such as moisture or water damage, which causes peeling of paint, loosening of plaster or other structural deterioration shall be repaired prior to any repairs required by this subchapter.

8:51-5.7 Access to areas being corrected

(a) No pregnant women or children under 12 years of age shall be allowed in the dwelling unit while paint removal is in progress.

(b) Areas being corrected shall be completely cleaned, vacuumed and damp mopped at the end of each work day so that children and/or pregnant women may return to the dwelling unit in safety.

8:51-5.8 Reinspection

(a) Upon completion of repair and prior to repainting, an inspection shall be made by the local board of health to determine if the hazard has been satisfactorily eliminated.

(b) All repairs may be finished with a suitable non-lead paint or other hard non-lead surface.

8:51-5.9 Safety standard for owner

When an owner has been notified to comply with this subchapter, the local board of health shall provide the owner of such dwelling units with a copy of N.J.A.C. 8:51-7 to be used when removing the lead paint.

Subchapter 6. Reporting

8.51-6.1 Laboratories

(a) All laboratories shall immediately and completely report, on forms provided by the State Department of Health, results of laboratory examinations which indicate blood lead levels in children equal to or greater than an elevated level as defined in the latest revision of the Centers for Disease Control Statement "Preventing Lead Poisoning in Young Children" to:

1. The State Department of Health;

2. The local board of health; and

3. The physician submitting the specimen.

8:51-6.2 Monthly status report

Local boards of health shall report monthly to the Department all violations of this chapter and the status of enforcement procedures against owners of properties designated as a public nuisance pursuant to N.J.S.A. 24:14A-8.

8:51-6.3 Monthly statistical report

Local boards of health not using the laboratory services provided by the State Department of Health for blood lead, erythrocyte protoporphyrin or paint analysis shall provide the State Department of Health with a monthly statistical tabulation of analytic results.

8:51-6.4 Confidentiality of records

All records collected by the State Department of Health which identify individual patients, address information and laboratory tests results shall be confidential, and shall not be released without parental consent.

Subchapter 7. Removal of Lead Paint

8:51-7.1 Methods permitted in the reduction of lead paints hazards

(a) The following methods shall be permitted in the reduction of lead paint hazards:

1. Replacement;

2. Covering (least costly) including, but not limited to:

i. Plastic or metal "L"-shaped moldings;

ii. Plasterboard;

iii. Wallboard;

iv. Wood paneling; or

v. Similar durable material;

3. Scraping;

4. Use of heat (infrared lamps or electric heat guns); and

5. Chemical paint removers except chemical paint removers containing methylene chloride, which may be used only for localized touch-up work.

(b) The Uniform Construction Code (N.J.S.A. 52:23-119 et. seq.) and the State Uniform Fire Safety Act (N.J.S.A. 52:27D-192 et. seq.) should be reviewed for restrictions on the use of materials.

8:51-7.2 Methods prohibited in the reduction of lead paint hazards

(a) The following methods are prohibited in the reduction of lead paint hazards:

1. Sanding;

2. Gas fired torch; and

3. Abrasive or sand blasting.

(b) A waiver for the use of abrasive or sand blasting may be obtained on a determination of the local board of health for individual work sites.

8:51-7.3 Safety standards for the removal of lead paint

(a) The methods used in the removal of lead paint shall not present a hazard to health from fumes, dust, vapors or liquids by inhalation or absorption through the skin or the mucous membranes, either from removal materials or from the lead paint being removed.

(b) Scraping presents a danger of lead dust and/or particles in the eyes. To protect the eyes from dust, chips and flakes of paint, safety goggles should be worn. Scraping also presents a danger of inhalation or swallowing of lead dust and/or particles. To protect against such inhalation or swallowing, a NIOSH approved respirator for toxic dusts, equipped with a HEPA filter cartridge (color coded purple) should be used.

(c) The use of chemical paint removers presents a health hazard from the inhalation of vapors. To protect against such inhalation when working with solvents which evaporate readily, a NIOSH approved respirator for organic solvents in combination with a HEPA filter cartridge should be used. Adequate ventilation should be provided by open windows or fans when using chemical paint removers. The use of chemical paint removers also presents a health hazard from the absorption of solvents and paint removers through the skin. To protect against such absorption, impervious gloves should be worn.

(d) The use of heat presents a health hazard from the inhalation of toxic lead fumes in concentrated amounts or in small concentrations over a period of time. To protect against such inhalation, a NIOSH approved respirator for toxic dusts equipped with a HEPA filter cartridge (color coded purple) should be used.

(e) WARNING: Respirators are a poor substitution for controlling or preventing exposures with abatement methods which have lower lead exposure. Using an inappropriate respirator or one not properly fitted can be extremely hazardous. The paper dust mask available at hardware stores may not be adequate. Not only is protection inadequate, but the user may have a false sense of security.

8:51-7.4 Preparation for the removal of lead paint

(a) Workers and occupants of buildings where removal of lead paint is being undertaken shall be notified of the health hazards, using the following, or similar statement:

"Lead is a heavy metal which is toxic to humans. Lead poisoning affects every cell of the body, but especially the blood, kidneys, and nervous system. The effects on the nervous system are serious, with the severity depending on the amount and the length of time of exposure. Adults and children are at high-risk of lead poisoning when lead dust or fumes are present and are most often poisoned by inhaling the lead dust or fumes.

The effects on adults include: persistent headaches, nausea, vomiting, visual disturbances, dizziness, poor appetite, loss of weight, cramps or constipation. If you have any or all of these symptoms, consult your physician at once.

Children are more susceptible to lead poisoning than adults. Children do not usually have easily identifiable symptoms, even when they have high blood lead levels. If symptoms do develop, brain damage has already occurred. Symptoms include: pallor or paleness, fatigue or tiredness, irritability, malaise, behavior changes and regression to a younger ability level. More serious symptoms include: weakness, clumsiness, abdominal pain, constipation, persistent vomiting and changes in consciousness. If you child has been exposed to lead, take the child to your physician or local health department for a blood sample which will be tested to show whether or not there is reason to be concerned."

(b) The worker shall select a deleading method that will produce the least amount of lead dust and/or fumes.

(c) The worker shall delead interior surfaces one room at a time, to minimize dispersion of lead.

(d) When deleading exterior surfaces, drop cloths shall be used to catch all wastes. Shrubs and trees shall be covered and dust and chips shall be removed from the ground promptly.

(e) Plastic sheets or impervious drop cloths shall be used to cover all floors, carpets, furniture, heat and/or air conditioning ducts, vents, grates and equipment in the work area.

(f) The work area shall be sealed off from the remainder of the dwelling by taping doors and/or using plastic sheets until both work and clean up activities are complete. All plastic used shall be at least six mil thick and all tape shall be waterproof.

8:51-7.5 General Safety precautions for the removal of lead paint

(a) In accordance with N.J.A.C. 8:51-5.7, children and pregnant women shall not be permitted to remain in the dwelling unit while deleading is in process.

(b) All electrical connections shall be checked for proper grounding.

(c) All workers shall wear coveralls, gloves, shoe covers or separate work shoes, hat and goggles. All street clothes shall be kept in a clean area, separate from work clothes. All work clothes shall be removed before eating and after cleaning up the work area.

(d) Eating, drinking, smoking and chewing tobacco or gum shall be prohibited in areas where deleading is taking place. Storage of food and drink shall be prohibited in areas where deleading is taking place. Prior to eating, all persons shall wash their hands, arms and face with soap and warm water and shall rinse their mouths thoroughly.

(e) All persons entering the work area shall wear properly functioning NIOSH approved respirator which is appropriate for the lead removal method to be used. The respirator face piece shall be washed at the end of each day and stored in a clean area.

(f) Any construction permit required pursuant to the Uniform Construction Code Act (N.J.S.A. 52:23-119 et. seq.) and the Uniform Construction Code, N.J.A.C. 5:23 shall be obtained from the agency having jurisdiction.

8:51-7.6 Clean up after the removal of lead paint

(a) The clean up process is a critical element of the deleading process. Workers shall begin the daily clean up process by vacuuming all paint chips and dust, using an industrial vacuum cleaner equipped with HEPA filters which meet or exceed OSHA and EPA safety standards for the control of lead and other toxic dusts.

(b) Workers shall damp mop or sponge all surfaces within the work area daily, after the removal of lead paint.

(c) All waste products shall be placed in plastic bags and sealed at the end of each work day.

(d) After the completion of the deleading process, non-pregnant adult occupants shall wash down all surfaces within the deleaded area daily until no further dust is visible.

8:51-7.7 Disposal of waste products after

the removal of lead paint

All combined waste containing lead concentration averaging 5.0 milligrams/liter or higher shall be disposed of in an Environmental Protection Agency hazardous waste landfill or lead smelter pursuant to N.J.A.C. 7:26-8.12.

Subchapter 8. Methodology for Determination of Community Prioritization for Lead Poisoning

8:51-8.1 Screening criteria; Priority I

(a) Any municipality which has children at risk, as classified by NHANES II data, and whose sum of the standard scores is greater than one Standard Deviation (5.3841) above the State mean (0.000), shall be considered Priority I (see Appendix I, incorporated herein by reference).

(b) Every child who lives in the communities listed in Appendix I shall be tested for lead poisoning at least once per year within the limits of funds appropriated. Screening should be conducted in accordance with census tract ranking. Communities shall prioritize their census tracts from the highest to the lowest, based on potential hazard score derived from the factors enumerated in Appendix IV, which is incorporated herein by reference.

(c) Case findings efforts by annual blood test should be conducted in settings, which include, but are not limited to, the following:

1. Child health conferences;

2. WIC clinics

3. Day care centers

4. Nursery schools; and

5. Door to door in high risk neighborhoods.

(d) A community shall be reclassified as Priority II if all children have been tested during the year and no child has an elevated blood lead level as defined in the latest revision of the Centers for Disease Control Statement "Preventing Lead Poisoning in Young Children", available from the Centers for Disease Control, Atlanta, Georgia 30333 and the New Jersey State Department of Health, Accident Prevention and Poison Control Program, 363 West State Street, Trenton, New Jersey 08625-0364.

8:51-8.2 Screening criteria; Priority II

(a) Any municipality which has children at risk, as classified by NHANES II data and census data, and whose sum of the standard scores is less than one Standard Deviation above the State mean shall be considered Priority II (see Appendix II, incorporated herein by reference).

(b) Every child who lives in the communities listed in Appendix II shall be tested for lead poisoning at least once per year within the limits of the funds appropriated, if any of the following conditions are met:

1. The child is a Medicaid recipient;

2. The child's family income qualifies them for the WIC Program;

3. The child is living in an identified high risk neighborhood.

(c) Screening should be conducted in accordance with census tract ranking. Communities shall prioritize their census tracts from the highest to the lowest based on the potential hazard derived from the factors enumerated in Appendix IV, which is incorporated herein by reference.

(d) Case finding efforts by annual blood test should be conducted in settings, which include, but are not limited to, the following:

1. Child health conference;

2. WIC clinics;

3. Day care centers;

4. Nursery schools; and

5. Door to door in

high risk neighborhoods.

8:51-8.3 Screening criteria; Priority III

(a) Any municipality which has no children at risk as classified by NHANES II data and census data, or which has no children under the age of five per the most recent census data, shall be considered Priority III (see Appendix III, incorporated herein by reference).

(b) Screening upon request should be made available through the local health department, although it is not required.

P.L.1993, CHAPTER 288, approved December 16,1993

Assembly Substitute for

1992 Senate No. 1135 and Assembly Nos. 1732 and 1350 (ACS)

*AN ACT* requiring the certification of persons and business firms performing lead evaluation and lead abatement, supplementing Titles 26 and 52 of the Revised Statutes and making an appropriation thereof.

BE IT ENACTED by the Senate and general Assembly of the State of New Jersey:

1. The Legislature finds and declares that:

Lead poisoning is the most prevalent environmental health problem facing children in New Jersey today; the Department of Health estimates that over 177,000 children under the age of five in New Jersey are at high risk of lead poisoning, and the effects of lead poisoning in children include learning disabilities, mental retardation, behavioral disorders, hyper-irritability, lack of coordination, loss of appetite, vomiting, abdominal pain, convulsions, permanent brain damage and death; even low levels of lead exposure can cause subtle neurological changes, reduced concentration and attentiveness, reduced IQ scores, behavioral problems, and learning disabilities; these problems persist and can adversely affect the child's chances for success in school and life; lead poisoning is caused by environmental exposure to lead and the most significant sources are lead-based paint in older housing and lead-laden dust and soil; and the Department of Health estimates that approximately 65% of New Jersey's housing stock may contain lead-based paint, representing a potential public health hazard of alarming magnitude.

The Legislature further finds and declares that:

Persons performing lead evaluation and lead abatement work must receive appropriate training and certification to ensure that lead evaluations and abatements are reliable, thorough, and safe; persons performing lead evaluation, without proper training, may fail to detect lead-contaminated surfaces; an abatement work plan that is based on an improper evaluation will be inadequate to rid a dwelling of a lead hazard; persons performing lead abatement, without proper training, may cause the contamination of an entire home with dangerous levels of lead; and a certification program for lead abatement is essential to ensure the safety of the occupants and the safety of the workers and is also necessary to protect consumers from fraud, abuse, and shoddy work practices.

2. As used in sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill):

"Commissioner" means the Commissioner of Health.

"Department" means the Department of Health.

"Lead Abatement" means a process designed either to mitigate or to eliminate permanently lead-based paint hazards on a premises and includes, but is not limited to: the removal of lead-based paint and lead-contaminated dust; the containment or encapsulation of lead-based paint; the replacement of lead-painted surfaces or fixtures; the removal or covering of lead-contaminated soil; and all preparation, cleanup, disposal and post-abatement clearance testing activities associated with such measures.

"Lead evaluation" means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report explaining the results of the investigation.

"Lead-based paint" means paint or other surface coating material that contains lead in excess of 1.0 milligrams per centimeter squared or in excess of 0.5% by weight, or such other level as may be established by federal law.

"Lead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust or soil or lead-contaminated paint that is deteriorated or present in surfaces, that would result in adverse human health effects.

"Surface" means an area such as an interior or exterior wall, ceiling, floor, door, door frame, window sill, window frame, porch, stair, handrail and spindle, or other abradable surface, soil, furniture, a carpet, a radiator or a water pipe.

3. a. A person shall not perform a lead evaluation or lead abatement work unless the person is certified by the department pursuant to this act.

b. The commissioner shall establish a certification program to assure the competency of persons to perform lead evaluations or lead abatement work in a safe and reliable manner. The commissioner may establish different classes of certification reflecting the different types and complexities of lead evaluation and abatement activities.

c. The commissioner shall certify a person who satisfactorily completes the certification training course required pursuant to this act, passes an examination prescribed by the department and meets any other requirements for certification that may be established by the commissioner or by federal law.

d. The certification shall be in writing with a photo identification, signed and dated by the commissioner. It shall be carried upon the person while performing evaluation or abatement services.

e. Notwithstanding the provisions of subsection a. of this section to the contrary, a person who is certified to conduct lead evaluations or perform lead abatement work in a jurisdiction outside of New Jersey is entitled to receive a New Jersey certification from the department if the person demonstrates successful completion of a training and certification program in that jurisdiction that is at least as rigorous and comprehensive as the State training and certification program.

f. Lead evaluation and lead abatement certifications shall be for a period not to exceed two years and shall be non-transferable. A person may apply for recertification during the 90-day period before the certification expiration date or the 90-day period after the certification expiration date; except that if a person applies after the certification expiration date, he shall not perform any services for which certification is required until the certification is renewed. If a certification has expired for more than 90 days, the person is required to obtain a new certification.

g. Nothing in this section shall be construed to restrict or otherwise affect the right of any person to engage in painting, woodworking, structural renovation or other indoor or outdoor contracting services that may result in the disturbance of paint, but a person shall not hold himself out as certified by the department or otherwise represent that he has specialized competency to perform lead evaluation or abatement work, unless he has been certified or otherwise specifically authorized pursuant to section 1 through 13 of P.L., c, (C. )(pending before the Legislature as this bill).

4. a. The department shall develop, offer, or accredit training courses which shall be required for certification. These training courses shall include instruction in safe and effective evaluation and abatement methods. The training courses shall be developed in accordance with regulations adopted by the Department of Community Affairs pursuant to sections 14 through 23 of P.L., c. (C. )(pending before the Legislature as this bill) and the "State Uniform Construction Code Act," P.L.1975, c.217 (C.52:27D-119 et seq.).

b. The training course for persons performing lead evaluation shall include, but not be limited to, instruction in:

(1) safe and effective techniques and methods to test for lead hazards and assess lead hazards on premises before, during and after abatement of lead hazards;

(2) risk assessment of the dangers posed by lead hazards on a premises and the effectiveness of various abatement techniques and methods and hazard reduction measures to reduce the risk posed by the presence of lead;

(3) safe work practices, including determining whether occupants must be relocated during lead abatement;

(4) practices to prevent contamination of the premises; and

(5) applicable State and federal requirements.

c. The training course for persons performing lead abatement shall include, but not be limited to, instruction concerning:

(1) safe and effective abatement techniques to remove, cover, encapsulate, or otherwise mitigate lead-based paint and lead-contaminated dust and soil;

(2) possible routes of exposure during abatement of lead hazards;

(3) safe work practices, including determining whether occupants must be relocated during lead abatement;

(4) proper cleanup of lead-contaminated waste generated on the premises during and after lead abatement;

(5) safe and lawful handling, transport and disposal of lead-contaminated waste; and

(6) applicable State and federal requirements.

d. The commissioner is authorized to adopt any applicable federal requirements or guidelines established by federal law, including any requirements or guidelines that apply to homeowners or other property owners, notwithstanding that the requirements or guidelines may be inconsistent with the provisions of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill).

e. The department may establish continuing education requirements for recertification.

f. A person shall not hold himself out as accredited by the department or otherwise represent that he is competent to offer training unless he has been accredited to provide training pursuant to this section.

5. a. The department may deny, suspend, impose conditions upon, revoke, or refuse to renew a certification for good cause, including but not limited to, the department's finding that:

(1) a person has obtained a certification based upon a misrepresentation or fraud;

(2) a person performed work without a certification as required in section 3 of P.L., c. (C. )(pending before the Legislature as this bill);

(3) a person engaged in unsafe work practices, violated the rules promulgated by the Department of Community Affairs pursuant to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill), failed to obtain a permit pursuant to the Uniform Construction Code, M.J.A.C.5:23-1.1 et seq. or acted in a manner which posed a health risk to others;

(4) the quality of the person's performance is below standards set by the department and remedial measures such as consultation and training are not accepted or do not result in improvement to a level of acceptable proficiency;

(5) a person made false reports or reports not based on work done;

(6) a person knowingly authorized or permitted the use of the name of a certified person to an uncertified person;

(7) a person falsely represented his certification credentials; or

(8) a person has violated any provision of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill).

b. An applicant or certificate holder whose application or certification is denied, suspended, conditionally issued, revoked or not renewed is entitled to a hearing pursuant to the provisions of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).

c. Denial of, suspension of, imposition of conditions upon, revocation of, or refusal to renew a certification shall not limit the department from pursuing against the applicant or certificate holder any other lawful remedy available to the department.

d. Any person whose certification has been revoked shall be ineligible to apply for certification for three years from the date of revocation.

6. If the department has reason to believe that a person who: is not certified pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill) is engaging in lead evaluation or lead abatement work or is soliciting another person to engage, employ or retain him to perform lead evaluation or lead abatement work, for pecuniary gain; or is either certified or not certified pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill) and is causing an imminent threat to the public health, safety or welfare, the department may initiate a civil action in a court of competent jurisdiction for injunctive relief to enforce or prevent a violation of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill). The court may proceed in the action in a summary manner.

7. A person who knowingly or purposely:

a. hinders or delays the department in the enforcement of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill);

b. fails to obtain the certification required by section 3 of P.L., c. (C. )(pending before the Legislature as this bill) and engages in lead evaluation or lead abatement work for pecuniary gain;

c. solicits another person to engage, employ or retain him to perform a lead evaluation or lead abatement work, for pecuniary gain, when he is not certified pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill);

d. holds himself out as accredited by the department or otherwise represents that he is competent to offer training when he is not accredited to provide training pursuant to section 4 of P.L., c. (C. )(pending before the Legislature as this bill); or

e. otherwise violates any provision of sections 1 through 13 of P.L., c. (C )(pending before the Legislature as this bill); is guilty of a disorderly persons offense.

8. As an alternative, or in addition to the provisions of section 7 of P.L., c. (C. )(pending before the Legislature as this bill), the commissioner may, subject to notice and hearing, impose an administrative civil penalty for a violation set forth in this section not to exceed $1,000 for the first offense and $5,000 for each subsequent offense. If the violation is of a continuing nature, each day it continues constitutes an additional and separate violation.

The penalty may be sued for recovered by and in the name of the commissioner in a civil action in court of competent jurisdiction by a summary preceding under "the penalty enforcement law," N.J.S.2A:58-1 et seq. For the purpose of this act, the Superior Court and the municipal court shall have jurisdiction to enforce the provisions of "the penalty law."

The department may compromise and settle a claim for a penalty under this section in such amount as the department determines to be appropriate and equitable.

As used in this section, a violation shall include the:

a. obstructing, hindering, delaying or interfering by force or otherwise with the commissioner in the exercise of any power or the discharge of any function or duty pursuant to the provisions of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill);

b. preparing, uttering or rendering of any false statements, reports, documents, plans or specifications permitted or required pursuant to sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill); or

c. refusal or failure to comply with a ruling, action, order or notice of the commissioner pursuant to section 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill).

9. The department shall assess fees from persons for certification and recertification and from training providers for training course or continuing education course that it accredits. The fees shall be used to support the certification and accreditation programs.

10. The provisions of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill) shall not apply to a property owner who personally performs his own lead abatement in a dwelling unit that he occupies as his primary place of residence.

11. Sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill) shall be enforced by the commissioner or his representative, who shall have the right of entry to all premises at which the department has reason to believe that lead abatement or evaluation activities have taken place or are taking place, or to any premises occupied or used by a business firm subject to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill); and the right to review any records for the purpose of inspection or investigation.

12. The department, in consultation with the Department of Community Affairs, shall adopt rules and regulations pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) to carry out the provisions of sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill).

13. There is appropriated to the Department of Health $90,000 from the General Fund to establish and implement the certification and training program established pursuant to sections 1 through 13 of P.L., c. (C. )(pending before the Legislature as this bill).

14. As used in sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill):

"Business firm" means and includes any corporation, company, association, society, firm, partnership or joint stock company, or any sole proprietor, engaged in, advertising, or holding itself out to be in the business of lead evaluation or lead abatement.

"Commissioner" means the Commissioner of Community Affairs.

"Department" means the Department of Community Affairs.

"Lead abatement" means a process designed either to mitigate or to eliminate permanently lead-based paint hazards on a premises and includes, but is not limited to: the removal of lead-based paint and lead-contaminated dust; the containment or encapsulation of lead-based paint; the replacement of lead-painted surfaces or fixtures; the removal or

covering of lead-contaminated soil; and all preparation, cleanup, disposal and post-abatement clearance testing activities associated with such measures.

"Lead evaluation" means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report explaining the results of the investigation.

"Lead-based paint" means paint or other surface coating material that contains lead in excess of 1.0 milligrams per centimeter squared or in excess of 0.5% by weight, or such other level as may be established by federal law.

"Lead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust or soil or lead-contaminated paint that is deteriorated or present in surfaces, that would result in adverse human health effects.

"Surface" means an area such as an interior or exterior wall, ceiling, floor, door, door frame, window sill, window frame, porch, stair, handrail and spindle, or other abradable surface, soil, furniture, a carpet, a radiator or a water pipe.

15. a. A business firm shall neither directly nor indirectly perform lead evaluation or abatement work without first obtaining certification from the department. Certification may be issued to perform lead evaluation or abatement work if the business firm employs or will employ sufficient numbers and types of personnel certified by the Department of Health pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill) to perform lead abatement work and meets all other requirements that the commissioner may establish pursuant to section 23 of P.L., c. (C. )(pending before the Legislature as this bill). The certification shall be in writing, shall contain an expiration date, and shall be signed by the commissioner.

b. A person or business firm shall not undertake a project involving lead abatement work without first obtaining a construction permit for that project pursuant to section 12 of P.L. 1975, c.217 (C.52:27d-130). No permit shall be issued for lead abatement work, except to:

(1) an owner undertaking work on his own premises using his own employees, if those employees are certified by the Department of Health pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill);

(2) a homeowner proposing to perform lead abatement work himself on a dwelling unit that he owns and occupies as a primary place of residence; or

(3) a business firm certified pursuant to this section to perform such work.

The issuance of a construction permit to an individual homeowner proposing to perform lead abatement work on a dwelling unit that he owns and occupies as a primary place of residence shall be accompanied by written information developed by the department explaining the dangers of improper lead abatement, procedures for conducting safe lead abatement, and the availability of certified lead abatement contractors, or of any available training for homeowners.

c. Nothing in this section shall be construed to restrict or otherwise affect the right of any business firm to engage in painting, woodworking, structural renovation or other indoor or outdoor contracting services that may result in the disturbance of paint, but a business firm shall not hold itself out as certified by the department or otherwise represent that it has specialized competency to perform lead evaluation or abatement work unless it has been certified or otherwise specifically authorized pursuant to this section.

16. The certification required pursuant to section 15 of P.L., c. (C. )(pending before the Legislature as this bill) shall be for a period not to exceed two years and shall not be transferable. A business firm may apply for recertification during the 90-day period before the certification expiration date, or the 90day period after certification expiration date; except that if a business firm applies after the certification expiration date, the firm shall not perform any services for which certification is required until the certification is renewed. If a certification has expired for more than 90 days, the business firm is required to obtain a new certification.

A copy of the certification shall be conspicuously displayed for public review in the business office of a business firm engaged in the business of abating lead-based paint hazards or conduction lead evaluations. Additionally, the certification number shall be displayed on all business vehicles and at all lead abatement or lead evaluation jobs in progress.

A certification or recertification shall not be issued until a certification fee has been paid in full to the department. The commissioner shall establish application and certification fees by regulation pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), in an amount sufficient to cover costs to the department of administering and enforcing the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill).

17. The commissioner may adopt regulations, including amendments to the Uniform Construction Code, N.J.A.C.5:23-1.1 et seq., prescribing standards, including appropriate training and certification requirements, governing safe practices for construction work that, although not a lead abatement, may create a lead hazard to an occupant of a building or structure. In addition, the commissioner may adopt any applicable requirements or guidelines established by federal law or regulation.

18. Sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill) shall be enforced by the commissioner or his representative who shall have the right of entry to all premises at which the department has reason to believe that lead abatement or evaluation activities may have taken place or are taking place or to any premises used or occupied by a business firm subject to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill); and the right to review any records for the purposes of inspection or investigation.

19. a. The department may deny, suspend, impose conditions upon, revoke, or refuse to renew a certification for good cause, including:

(1) violating, or abetting another to commit a violation of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill);

(2) making a false statement on an application for certification, or in providing other information required by the department;

(3) misrepresentation of qualifications, or fraudulently obtaining certification;

(4) engaging in practices during lead abatement work contrary to safe procedures established therefor; and

(5) employing persons to perform lead abatement or lead evaluation work who are not certified pursuant to section 3 of P.L., c. (C. )(pending before the Legislature as this bill) to perform such work.

b. A business firm whose application or certification is denied, suspended, conditionally issued, revoked, or not renewed is entitled to a hearing pursuant to the provisions of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).

c. Denial of, suspension of, the imposition of conditions upon, revocation of, or refusal to renew a certification shall not limit the department from pursuing against the applicant or certificate holder any other lawful remedy available to the department.

d. A business firm whose certification has been revoked shall be ineligible to apply for certification for three years from the date of revocation. This ineligibility shall extend to any other business firm having any proprietor, officer, director, general partner, or shareholder or limited partner with at least a 10% interest, in common with the business firm whose certification was revoked.

20. If the department has reason to believe that a condition exists that poses an imminent threat to the public health, safety or welfare, the department may initiate a civil action in a court of competent jurisdiction for injunctive relief to enforce or prevent a violation of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill). The court may proceed in the action in a summary manner.

21. Any person who knowingly or purposely:

a. hinders or delays the department in the enforcement of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill);

b. fails to obtain certification required by sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill);

c. refuses to make his certification accessible to the commissioner; or

d. otherwise violates any provision of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill); is guilty of a disorderly persons offense. If the person is a corporation, all officers, directors, and shareholders owning at least a 10% interest in the corporation may be held liable for any violation by the corporation pursuant to this section.

22. As an alternative, or in addition to the provisions of section 21 of P.L., c. (C. )(pending before the Legislature as this bill), the commissioner may, subject to notice and hearing, impose an administrative civil penalty for a violation set forth in this section not to exceed $1,000 for the first offense and $5,000 for each subsequent offense. If the violation is of a continuing nature, each day it continues constitutes an additional and separate violation.

The penalty may be sued for and recovered by and in the name of the commissioner in a civil action in a court of competent jurisdiction by a summary proceeding under "the penalty enforcement law," N.J.S.2A:58-1 et seq. For the purposes of this act, the Superior Court and the municipal court shall have jurisdiction to enforce the provisions of "the penalty enforcement law."

The department may comprise and settle a claim for a penalty under this section in such amount as the department determines to be appropriate and equitable.

a. As used in this section, a violation shall include the:

(1) obstruction hindering, delaying or interfering by force or otherwise with the commissioner in the exercise of any power or the discharge of any function or duty pursuant to the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill);

(2) preparing, uttering or rendering of any false statements, reports, documents, plans or specifications permitted or required pursuant to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill); or

(3) refusal or failure to comply with a ruling, action, order or notice of the commissioner pursuant to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill).

b. A person shall be deemed to have violated or caused to be violated the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill) if an officer, agent or employee under his control has violated or caused to be violated any provision of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill).

c. If a person subject to sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill) is a corporation, all officers, directors and shareholders having at least 10% interest shall be jointly and individually liable for any violation by the corporation.

23. The department, in consultation with the Department of Health, shall adopt regulations pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) to implement the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill), including regulations prescribing standards for the performance of lead abatement work. Additionally, the commissioner may adopt any applicable requirements or guidelines established by federal law or regulation, including any requirements or guidelines that apply to homeowners or other property owners, notwithstanding that the requirements or guidelines may be inconsistent with the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill).

24. The department shall delegate, by rule or by interagency agreement pursuant to R.S. 52:14-4, to the Department of Labor, its administrative and enforcement duties and functions pursuant to the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill) relating to the certification of business firms to perform lead evaluation or abatement work on public buildings, commercial buildings, bridges or any other buildings or structures that do not contain dwelling units. When the Department of Labor receives such a delegation, the Department of Labor shall be reimbursed by the department in an amount that is sufficient to cover the costs incurred by the Department of Labor in administering and enforcing the provisions of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill). The costs incurred by the Department of Labor in administering and enforcing this act shall be annually certified by the Director of the Office of Management and Budget in the Department of the Treasury. The Department of Community Affairs shall have ultimate responsibility for ensuring that lead evaluation and abatement work on all buildings and structures conforms to the requirements of sections 14 through 24 of P.L., c. (C. )(pending before the Legislature as this bill).

25. This act shall take effect 18 months after the date of enactment; except that sections 12 and 23 of this act shall take effect immediately and sections 3, 4 and 15 shall take effect six months after the date of enactment.

STATEMENT

Sections 1 through 13 of this Assembly Substitute direct the Commissioner of Health to establish a certification program to assure the competency of persons to perform lead evaluations or lead abatement work in a safe and reliable

manner. The commissioner may establish different classes of certification reflecting the different types and complexities of lead evaluation and abatement activities.

The substitute provides that the commissioner shall certify a person who satisfactorily completes the required certification training course, passes an examination prescribed by the Department of Health (DOH) and meets any other requirements for certification that may be established by the commissioner or by federal law.

The substitute provides, however, that the certification requirements shall not be construed to restrict or otherwise affect the right of any person to engage in painting, woodworking, structural renovation or other indoor or outdoor contracting services that may result in the disturbance of paint; but a person shall not hold himself out as certified by the department or otherwise represent that he has specialized competency to perform lead evaluation or abatement work, unless he has been certified or otherwise specifically authorized pursuant to the substitute.

The substitute also directs the DOH to develop, offer, or accredit training courses which shall be required for certification.

Sections 14 through 24 of this substitute would require that a business firm obtain certification from the Department of Community Affairs (DCA) before performing lead evaluation or abatement work. Certification, for a period not to exceed two years, may be issued if the business firm employs sufficient numbers and types of personnel certified by the DOH to perform lead abatement work, and meets all other requirements that the Commissioner of Community Affairs adopts by regulation. The substitute sets forth the procedures for obtaining certification and requires that a business firm conspicuously display its certification for public review.

The substitute also requires that a person or business firm obtain a construction permit prior to undertaking any project involving lead abatement. A construction permit for lead abatement work would be issued only to: the owner of the premises using his own DOH-certified employees, a homeowner doing the abatement himself, or a business firm certified pursuant to the substitute. The substitute expressly excludes from its provisions any painting, woodworking or other contractual services that may result in the disturbance of paint.

The substitute provides that a person or business firm is guilty of a disorderly persons offense if it knowingly or intentionally:

a. hinders or delays the DOH or DCA in the enforcement of the substitute;

b. fails to obtain the required certification and engages in lead evaluation or lead abatement work;

c. in the case of individuals, solicits another person to engage, employ or retain him to perform a lead evaluation or lead abatement work when he is not certified;

d. in the case of training programs, holds itself out as accredited by the department or otherwise represents that it is competent to offer training when it is not accredited to provide training;

e. in the case of business firms, refuses to make its certification accessible to the commissioner of Community Affairs; or

f. otherwise violates any provision of the substitute.

The respective departments are authorized to deny, suspend, impose conditions on, revoke or refuse to renew a certification for good cause, as outlined in the substitute.

The substitute also authorizes the Commissioner of Health and Community Affairs, respectively, to impose civil penalties of $1,000 for the first offense and $5,000 for each subsequent offense.

The substitute provides that the Commissioners of Health and Community Affairs shall assess fees for certification and accreditation of training programs, which fees shall be used to support the departments' respective certification and accreditation programs. The substitute also appropriates $90,000 to the DOH to begin implementation of the program.

The DCA is mandated to delegate its administrative and enforcement duties to the Department of Labor for buildings or structures that do not contain dwelling units.

Finally, the substitute takes effect 18 months after enactment, but the respective commissioners shall begin certification of individuals and business firms six months from the date of enactment.

Requires certification of persons and business firms performing lead evaluation and lead abatement by DOH and DCA, respectively; appropriates $90,000.

Subtitle 3. Lead-Based Paint

§ 6-303. Blood lead reporting.

(a) Report by medical laboratory. A medical laboratory shall report to the Department the results of all blood lead or erythrocyte protoporphyrin tests performed on any child 18 years and under.

(b) Report by Department. The Department shall report the results of blood lead or erythrocyte protoporphyrin tests indicating an elevated blood lead level, as defined by regulation, to:

(1) The local health department in the jurisdiction where the child resides; and

(2) The Department of Health and Mental Hygiene.

(c) Regulations. The Department shall adopt regulations to:

(1) Govern the reporting requirements of laboratories to the Department under subsection (a) of this section; and

(2) Provide for the reporting of information by the Department to local health departments and the Department of Health and Mental Hygiene.

(1985, ch. 308; 1987, ch. 306, § 3; 1990, ch. 136.)

Effect of amendment. The 1990 amendment, effective July 1, 1990, rewrote the section.

Bill review letter. Chapter 136, Acts 1990 (House Bill 223) was approved for constitutionality and legal sufficiency

as it was determined that a discrepancy between the title of the bill and the body of the bill was not of constitutional significance. (Letter of Attorney General dated Apr. 19, 1990).

Ordinance

of the

City of Newark, N.J.

AN ORDINANCE TO AMEND TITLE 14, HEALTH AND SANITATION, CHAPTER 2A. LEAD POISONING OF THE REVISED ORDINANCES OF THE CITY OF NEWARK, NEW JERSEY, 1966, AS AMENDED AND SUPPLEMENTED TO INSURE THAT THE LEAD POISONING ORDINANCE CONFORMS TO THE STATE REGULATIONS PERTAINING TO LEAD POISONING

**WHEREAS**, the City of Newark has heretofore established regulations for the purpose of investigating cases of elevated blood lead levels by the health officer of the City of Newark; and

**WHEREAS**, the New Jersey State Department of Health and the Legislature have adopted new regulations pertaining to such cases; and

**WHEREAS**, the Director of Health and Human Services of the City of Newark is desirous of adopting regulations concerning lead poisoning cases to conform to state regulations and provide standards for the investigation of cases of elevated blood lead levels to be made part of Title 14 of the Revised Ordinances of the City of Newark.

NOW, THEREFORE, BE IT ORDAINED BY THE MUNICIPAL COUNCIL OF THE CITY OF NEWARK, NEW JERSEY THAT:

**SECTION 1:** That Title 14, Health and Sanitation; Chapter 2A, Lead Poisoning; in its entirety be amended and supplemented to read as follows:

CHAPTER 2A. LEAD POISONING:

Article 1. DEFINITIONS

14:2A-1. Definitions:

For the purposes of this ordinance [chapter]:

**Chewable surface** shall mean any surface that is less than 4 inches back from a wall, furniture, houseware or equipment edge offering a biting surface to a child.

**Child** means a person six (6) months through five (5) years of age.

**Dwelling** shall mean a building or structure or part thereof containing one or more dwelling units.

**Elevated blood lead level** means an abnormal level of lead in the bloodstream at the level as defined in the latest revision of the Center for Disease Control's statement "Preventing Lead Poisoning in Young Children" available from Atlanta, Georgia 30333.

**Elevated erythrocyte protoporphyrin (EP)** means an abnormal level of hemoglobin precursors at a level defined in the latest revision of the Center for Disease Control's Statement, "Prevention Lead Poisoning in Young Children".

**Dwelling Unit** shall mean any room or groups of rooms or any part thereof located within a building and forming a single habitable unit with facilities which are used or designed to be used for living, sleeping, cooking, eating or bathing.

**Department** shall mean the Department of Health and Human Services of the City Newark, New Jersey.

**High risk of lead neighborhood** means those areas whose high degree of risk has been identified by the local board of health, using methodology pursuant to N.J.A.C. 8:51-8.

**Initial inspection** shall mean the first investigation or survey or examination of the dwelling unit within a building that is inhabited or occupied by a child who has a blood level of 20 micrograms per 100 milliliters or higher.

**Lead toxicity** means a significantly elevated blood lead level, as defined in the latest revision of the Center for Disease Control's Statement, "Preventing Lead Poisoning In Young Children".

**Lead paint** shall mean any pigmented liquid substance applied to a surface by brush, roller or spray or other means in which the total non-volatile ingredients contain more than 1% of lead, by weight, calculated as metallic lead.

**Occupant** shall mean a person or persons in actual possession of and living in the building or dwelling unit.

**Owner** means any person who has legal title to any dwelling, with or without accompanying actual possession thereof; or, who has equitable title and is either in actual possession or collects rents therefrom; or, who is executor, executrix, trustee, guardian, or receiver of the estate of the owner, or as mortgagee or as vendee in possession either by virtue of a court order or by agreement or voluntary surrender of the premises by the person holding the legal title, or as collector of rents has charge, care or control of any dwelling or rooming house. Any person who is a lessee or assignee subletting or assigning any part or all of any dwelling shall have joint responsibility over the portion of the premises sublet or assigned.

Article 2. INVESTIGATIONS OF CERTAIN DWELLING UNITS

14:2A-2. Dwelling of a child with high blood lead level, inspection.

When it has determined that a child has elevated blood lead level as defined in the Center for Disease Control's Statement "Preventing Lead Poisoning in Young Children", within 2 days after such findings have been reported to the health officer, the dwelling unit in which the child resides may be inspected by a representative of the Department and a minimum of 2 paint samples of chewable surfaces and sidewalls below a 4 foot level may be collected from each room and submitted to a laboratory certified by the New Jersey State Department of Health to ascertain the lead content by weight calculated as metallic lead.

The physical determination of the lead content of paint may also be made by non-destructive measurements using radio isotope x-ray fluorescent analyzers (X-R-F) or other instruments approved by the State Department of Health. Lead content in paint in excess of 1.0 mgs. per square centimeter of paint surface when tested by this method shall be in violation.

14:2A-3. Declaration of health hazard.

If any of the aforementioned surfaces are found to contain lead paint, then they shall be declared a health hazard.

14:2A-4. Removal of lead paint; covering surface.

Within the dwelling unit, all lead paint shall be removed to the base or bare surface from all chewable surfaces and sidewalls that are below a 4 foot level and these surfaces shall be made impervious, durable, nonabsorbent, tight and in good repair; also, these surfaces shall be finished with a suitable non-lead paint thereby rendering these surfaces clean and washable. In lieu of removing lead paint from chewable surfaces and sidewalls below a 4 foot level, these surfaces may be covered up to a level of at least 4 feet, by an impervious, durable, nonabsorbent, tight material that is in good repair and does not contain more than 1% lead by weight, calculated as metallic lead, and is approved by the Department, thereby rendering the surface clean and washable. Repainting a chewable surface or a sidewall below a 4 foot level with a non-lead paint without completely removing all the existing lead paint to the base or bare surface shall not be deemed to be in satisfactory compliance with this ordinance.

14:2A-5. Condition of surfaces.

All other surfaces shall be impervious, durable, nonabsorbent, tight and in good repair, and, if painted, finished with a non-lead paint.

14:2A-6. Removal of tight lead paint.

(a) Tight lead paint shall be removed to the base surface in the following areas, as indicated:

1. Window sills: complete removal;

2. Windows and frames below the four-foot level: complete removal on exposed surfaces;

3. Doors below four-foot level: removal four inches back on hinge and latch edges and other sharp edges;

4. Door frames below four-foot level: complete removal;

5. Handrails: complete removal;

6. Spindles ("balusters"): removal on surfaces adjacent to walking areas;

7. Stair treads: removal four inches back from lip on top of tread and from lip to riser on bottom side; and

8. Any other chewable surface below the four foot level: removal four inches back from edge.

14:2A-6.1 Removal not required.

(a) Removal may be performed, but is not required, on the following surfaces:

1. Walls in good condition without broken areas;

2. Baseboards;

3. Skirtboards on staircases;

4. Step risers; or

5. Any surface below the four-foot level which does not present a chewable surface.

14:2A-6.2 **Covering.**

If paint is not removed as required in this subchapter surfaces shall be covered with plasterboard, wallboard, wood paneling or similar durable material approved by the New Jersey State Department of Health, Accident Prevention and Poison Control Program, to a height of at least four feet above the floor. Any construction permit required pursuant to the Uniform Construction Code Act (N.J.S.A. 52:23-119 et. seq.) and the Uniform Construction Code, N.J.A.C. 5:23 shall be obtained from the agency having jurisdiction.

14:2A-7. Service of notice.

When it has been determined that a lead painted surface exists below a 4 foot level, or that surfaces are not impervious, durable, nonabsorbent, tight and in good repair a notice or order shall be served to the owner.

Article 3. INVESTIGATION OF OTHER PORTIONS OF DWELLINGS.

14:2A-8. Correction of Violations.

Recorded violations shall be corrected within ten (10) days after the notice or order has been served. Extensions from this order or notice shall not be granted by any health officer.

14:2A-9. Failure to Correct Violations, Fine

Failure to correct the recorded violations within ten (10) days after the notice or order has been served may result in a fine of up to $1,000.00 for each violation for each day that the violation(s) exist beyond the prescribed period of time.

If the Court determines that violation(s) exist, the Court shall not consider reducing the total amount of the penalties referred to herein until the Court has been satisfied that the violations are abated.

14:2A-10. Inspection after positive report.

All other portions of the dwellings, including all other dwelling units, shall be inspected within 45 days of the initial inspection by a representative of the Department, provided that a report of the samples collected during the initial

inspection, from a laboratory that is certified by the New Jersey Department of Health, reveals that a surface below a 4 foot level indicates the presence of lead paint.

14:2A-11. Surface rectified.

All surfaces that are not impervious, durable, nonabsorbent, tight and in good repair shall be rectified in a manner approved of by the Department.

14:2A-12. Notice served.

When it has been determined that any surface is not impervious, durable, nonabsorbent, tight and in a good repair a notice or order shall be served to the owner.

14:2A-13. Violations (s) Corrected.

Recorded violations (s) shall be corrected within ten (10) days after the notice or order has been served. Extension from this notice shall not be granted by any health officer.

14:2A-14. Fine for Uncorrected Violations (s).

Failure to correct the recorded violations (s) within ten (10) days after the notice or order has been served may result in a fine of up to $1,000.00 for each violations for each day that the violations (s) exist beyond the prescribed period of time.

If the Court determines that violations (s) exist, the Court shall not consider reducing the total amount of the penalties referred to herein until the Court has been satisfied that the violations (s) are abated.

Article 4. DETERMINATION OF PRESENCE OF LEAD.

14:2A-15. **Sampling.**

A minimum of 2 paint samples may be collected from each suspect room which should include a windowsill and door or door frame. In addition, samples may also be collected from other highly-suspected areas, such as crib railings, playpen railings, stairs or banisters and surfaces with loose paint. Preferred locations to be sampled may include

surfaces which have been chewed or eaten, suspected of having been chewed or eaten or areas which are peeling or flaking. All interior sampling should generally be limited to that part of the surface which may eventually be required to be removed.

14:2A-16. Methods of determination.

(a) The chemical determination of the lead content in paint by quantitative measurements of samples of surface coverings may be made in laboratories certified by the New Jersey State Department of Health. Lead content in paint in excess of 1.0 percent by dry weight shall be in violation.

(b) The physical determination of the lead content of paint may be made by non-destructive measurements using radioisotope X-ray Fluorescent analyzers (X-R-F) or other instruments approved by the State Department of Health. Lead content in paint in excess of 1.0 mgs. per square centimeter of paint surface when tested by this method shall be in violations.

Article 5. REPAIRS BEFORE REFINISHING

14:2A-17. Causative conditions removed.

All plumbings leaks or any other existing violations or conditions that cause the peeling of paint or loosening of plaster shall be repaired before any surfaces are refinished or covered.

14:2A-18. Inspection after repairs; finished surfaced.

Upon completion of repair and prior to repainting an inspection shall be made to determined if the hazard has been satisfactorily eliminated. All repairs may be finished with a suitable non-lead paint or other hard non-lead surface.

Article 6. DECLARATION OF HEALTH HAZARD

14:2A-19. Accessible lead painted surfaces as health hazards.

Whenever a representative of Department determines that a lead painted surface is accessible to children it may be declared a health hazard.

**SECTION 2:** All prior ordinances or parts thereof inconsistent with this ordinance are hereby repeated.

**SECTION 3:** This ordinance shall become effective upon passage and publication in accordance with the law.

STATEMENT

This ordinance will ensure that the standards used by the local Health Officers are the same as the standards used by the State to Control Lead Paint. In addition, this ordinance will remove the administrative hearing process in order to increase the speed of prosecuting violators of the ordinance.

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Philadelphia Guidelines

CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH

REGULATIONS RELATING TO LABELING, APPLICATION,
AND REMOVAL OF LEAD PAINT

Approved:
BOARD OF HEALTH April 26, 1966
(Amended November 16, 1977)

LAW DEPARTMENT June 22, 1966
(Amended November 22, 1977

RECORDS DEPARTMENT July 27, 1966
(Amended December 26, 1977)

55-A-2162

# REGULATIONS RELATING TO LABELING, APPLICATION, DISPOSAL AND REMOVAL OF LEAD BASED COATING

Pursuant to Section 5301(b) of the Home Rule Charter and Section 6403 of the Philadelphia Code, the following regulation are promulgated by the Board of Health and issued by the Department of Public Health.

## 1. DEFINITIONS

In these regulations, the following definitions apply:

(a) Approved. Satisfactory compliance with this section of the Philadelphia Code as determined and certified by the Department of Public Health.

(b) Dwelling, dwelling units, rooming unit and institution or similar type facility. A building structure which is wholly or partly used or intended to be used for living, sleeping, or cooking, by human occupants.

(c) Lead Based Coating. Any paint, lacquer or other applied liquid surface coating, and putty or caulking or other sealing compound except those allowed by Federal Law or Regulation which contains a quantity of lead more than sixhundredths of one percent (0.06 of 1%) by weight of its nonvolatile content as determined by laboratory analysis or which in dried film has a lead content of 0.7 milligrams or more per square centimeter (0.7 $mg/cm^2$) as determined through the use of instrumentation approved by the Department.

## 2. PROHIBITED USE OF LEAD BASED COATING

No person shall apply or cause to be applied any lead based coating to toys, furniture, food utensils, household products, or the interior or exterior surfaces, fixtures or appurtenances of any dwelling, rooming house, fixtures or appurtenances of any dwelling, rooming house, dwelling unit, rooming unit, institution or similar type facility except as allowed by Federal Law or Regulation. Such interior or exterior surfaces include all areas accessible to the height of five (5') feet and any other area where existing surface coating is not intact.

## 3. PROHIBITED SALE, TRANSFER OR DELIVERY OF TOYS, FURNITURE, FOOD UTENSILS OR HOUSEHOLD PRODUCTS TO WHICH LEAD BASED COATING HAS BEEN APPLIED

No person shall sell, transfer or deliver toys, furniture, food utensils or household products to which lead based coating has been applied.

4. LABELING OF LEAD BASED COATING

No person shall store, sell or transfer for retail purposes a lead based coating unless the container used in retail trade bears a label in conformance with federal law or regulation. In the absence of a federal labeling requirement, such container shall bear a conspicuous warning statement printed in letters which are legible and in contrast with other printing appearing on the container and shall further conform in wording, type, style and size as shown herein and state as follows:

WARNING!
CONTAINS TOXIC AMOUNTS OF LEADHARMFUL
IF TAKEN INTERNALLY.

Do not apply on toys, furniture, food utensils, household products or interior or exterior surfaces of any dwelling or facility which may be occupied or used by children. Avoid prolonged contact with skin and breathing of vapors or spray mist. Close container after each use.

Use with adequate ventilation.
KEEP OUT OF THE REACH
OF CHILDREN
This warning shall also be required on accompanying literature including direction for use, where appropriate. Where tinting or coloring added to coating at the point of sale produces a final coating product with more than 0.06% lead, the labeling requirements of this section shall apply.

Labels on containers of lead based coating manufactured prior to the effective date of this regulation shall be made to conform with the above labeling requirements by the application of a separate warning label which shall be affixed directly upon the existing label, provided that after one year from the effective date of these regulations the warning shall be an integral part of the label on the container.

5. REMOVAL OF LEAD BASED COATING

Where the Department determines that the presence of lead based coating on any toy, furniture, food utensil, household product, or the interior or exterior surfaces, fixtures or appurtenances of any dwelling, rooming house, dwelling unit, rooming unit, institution or similar type facility creates a health hazard to children, it shall issue an order to the owner,

his agent or occupant to eliminate the hazard. Lead based coating shall be completely removed from any surface which can be chewed or ingested by children. Cracked, chipped, blistered or peeling lead based coating shall be completely removed.

The lead based coating ordered to be removed shall be completely removed to the base surface under such safety conditions as may be approved by the Department. In lieu of removal of the lead based coating, the accessible surface, up to the height of five (5') feet, shall be covered with an approved durable material. Repainting a surface without the complete removal of the existing lead based coating shall not be deemed to be satisfactory compliance with this section.

The methods used for the removal to lead based coating shall not present a hazard to health from fumes, dust or vapors by inhalation or absorption through the skin and mucous membranes and shall be in accordance with all applicable laws, ordinances, regulations and safety standards and practices of the City, state and federal agencies.

6. DISPOSAL OF LEAD BASED COATINGS

Any lead based coating offered for sale, stored or transferred for retail purposes in violation of these regulations shall be disposed of by returning unopened containers to the manufacturer and demonstrating to the Department by credit receipt the date and amount returned, or by disposal in accordance with the Pennsylvania Solid Waste Management Act, the Philadelphia Air Management Code, other applicable municipal, state, and federal codes, or by any other means acceptable to the Department.

Section 6103 PENALTIES

(1) In addition to any other sanction or remedial procedure provided in the Health Code, any person who shall violate any provision of this Title, and Regulation adopted under it, any order of the Department issued thereunder, or any condition of any license required thereunder and any person who knowingly participates in any such violation by any other person or who has reason to know that his participation will materially contribute to any such violation by another person, shall be subject to a fine of not less than $25.00 and not more than $150.00 for the first violation and not less than $50.00 and not more than $300.00 for the second and each subsequent violation together with imprisonment not exceeding 90 days if the fine and costs are not paid within 10 days. Continuous violation of the same provisions shall be a separate violation for each day.

Effective date for these Regulation: February 28, 1978.

***NOTE:** The provisions of Section 6103 apply to all violations of the Health Code. They are printed here, in part, for information only.

(Bill No. 704)

Explanation:

{Brackets} indicate matter deleted.

*Italics* indicate new matter added.

AN ORDINANCE

Amending Sections 6-403 and 5-502 of The Philadelphia Code relating, respectively, to Residential and Occupancy Hygiene and Orders of the Department of Public Health by enlarging upon certain prohibited conduct, by authorizing the Department of Public Health to abate certain health hazards caused by the presence of lead based coating and by providing that orders issued by the Department shall be complied with within a reasonable period of time.

The Council of the City of Philadelphia hereby ordains:

Section 1. Section 6-403 of the Philadelphia Code is amended to read as follows:

§6-403. Residential and Occupancy Hygiene.

(1) Definition.

[(a) Lead Paint. Any pigmented, liquid substance applied to surfaces by brush, roller or spray in which the total non-volatile ingredients contain more than one percent (1%) of lead, by weight, calculated as metallic lead.]

(a) Lead Based Coating. Any paint, lacquer or other applied liquid surface coating, and putty or caulking or other sealing compound which contains a quantity of lead in excess of that amount allowed by Federal Law or Regulation pertaining to lead based paint.

(2) Prohibited Conduct.

(a) No person shall apply *or cause to be applied any* lead [paint] *based coating* to toys, furniture, *food utensils, household products* or the interior or *exterior* surfaces, *fixtures or appurtenances* of any dwelling, rooming house, dwelling unit, rooming unit, *institution* or *similar type* facility, {occupied or used by children} *except at those locations permitted by Federal Law or Regulation.*

(b) No person shall sell, transfer or deliver toys, [or] furniture, *food utensils or household products* to which lead [paint] *based coating* has been applied.

(c) No person shall store, sell, or transfer for retail purposes any lead based coating, except where permitted by Federal Law or Regulations. Any lead based coating stored, sold or transferred in violation of this provision shall be disposed of in accordance with regulations adopted by the Board of Health.

(d) No person shall sell permit lead based coating to remain any toy, furniture, food utensil, household product or the exterior or interior surfaces, fixtures or appurtenances of any dwelling, rooming house, dwelling unit, rooming unit, institution or similar type facility where the surface may be readily accessible to children under the age of six years and where the Department determines that the presence of Lead based coating creates a health hazard to children under the age of six.

(3) Labeling.

(a) Containers in which lead [paint] *based coating* is stored, sold or transferred for retail purposes, *as permitted by Federal Law or Regulation*, shall be labeled in accordance with regulations adopted by the Department.

(4) Hazardous Conditions.

(a) The Department of Public Health, upon application by any owner or person in control of a premises, shall test or cause to be tested said premises to determine the presence of lead [paint] *based coating*. The Department shall make such additional determinations as to enable the Department to issue a certificate that the premises is or is not in compliance with this section of The Philadelphia Code.

[(c)] (.1) The fee for aforesaid examination and certificate shall be [fifteen ($15.00)] *twenty ($20.00)* dollars.

[(b) Where the Department determines that the presence of lead paint upon any premises creates a health hazard to children, it shall issue an order to the owner or occupants to eliminate the hazard in accordance with methods prescribed by regulations issued by the Department.]

(b) Where analysis, through the use of instrumentation approved by the Department or made in a laboratory, reveals the presence of lead based coating on any toy, furniture, food utensil, household product or any interior or exterior surface, fixture or appurtenance in violation of §6-403 (2) (d), the Department shall issue an order to the owner, his agent or occupant to eliminate the health hazard in accordance with methods prescribed by regulations issued by the Department.

(.1) Abatement of Violations.

(.a) If the person upon whom the order is served does not comply with the order of the Department to correct the condition creating the health hazard within the prescribed time period the Department may, itself or by contract, correct the condition by eliminating the hazard, charge the costs thereof to the owner, and, with the approval of the Law Department, collect the costs by lien or otherwise.

Section 2. Section 6-502 of The Philadelphia Code, relating to Orders of the Department of Public Health, is amended to read as follows:

§6-502. Orders.

* * *

(3) Any person to whom such an order is directed or from whom any action, forbearance, or compliance is in any way required shall comply with such order within [thirty days of receipt of the order] *such reasonable period of time as the Department shall specify in such order.*

* * *

Explanation:

[Brackets] indicate matter deleted.

*Italics* indicate new matter added.

SPECIFICATIONS FOR THE REMOVAL OF LEAD HAZARDS

City of Philadelphia

Department of Public Health

Environmental Health Services

Childhood Lead Poisoning Prevention Program

321 University Ave

Philadelphia, PA 19104

Lead paint creating a health hazard to children shall be eliminated in accordance with the "Regulations Relating to Labeling, Application and Removal of Lead Paint". These procedures will assist you in complying with the regulations and the letter ordering removal of lead-based paint, or the Paint Evaluation Report

Acceptable Lead Hazard Abatement Methods:

1. Removal (to bare wood/surface) of lead paint as specified under hazard reduction procedures.

2. Cover the lead painted area with an approved tight, permanent cover (i.e. panelling, wall board, etc.) or an approved encapsulant.

3. Removal of lead-painted item from the premises for off-site paint removal at a commercial stripping facility.

4. Removal of the leaded item from the dwelling unit, and proper disposal.

Remember: All loose, peeling, chipping, flaking paint must be completely removed from the areas designated on the Lead Paint Order Certification. If the area is identified as MBA, which means "Must Be Abated", then the area must be treated as having positive readings for leaded paint.

Read the Lead Paint Order Certification / Paint Evaluation Report to identify the room or location where lead must be removed and the specific areas at each location.

Removal Procedures:

1. Partial Removal

a. Areas with chipping and peeling lead paint must be thoroughly moistened and then scraped down to the bare wood or other surface so that all edges are flush and smooth with the bare wood/surface and until no paint can be pried loose with a fingernail.

b. For interior tracks and wells of windows below five (5) feet, if there is any peeling, chipping or flaking - completely remove all paint.

c. If lead paint has been applied over wallpaper or other surface coverings on walls, ceilings or woodwork, then the paint and the surface covering must be tight and flush to the surface, or it must be removed.

2. Total Removal

a. Areas must be thoroughly moistened and then scraped to the bare wood/surface from the floor to a height of five (5) feet, until all edges are flush and smooth with the bare wood or surface.

b. For window sills and aprons, frames, or interior tracks (window wells) at a height of five feet or less from the floor - completely remove paint.

c. For doors and door frames at a height of 5 feet or less from the floor - remove from edge back four (4) inches on both hinge and latch edges of door, and completely remove all paint on frame.

d. For all handrails, spindles and banisters - completely remove paint.

e. For stair treads - remove paint four (4) inches back from lip of tread and from lip to riser on bottom of lip; all loose paint shall be removed from riser.

f. All other chewable surfaces (i.e. baseboard lips, radiators and covers, etc.) at a height of five (5) feet or less - remove paint four (4) inches back from edge.

g. If lead paint has been applied over wallpaper or other surface coverings on walls, ceilings or woodwork, then the paint and the surface covering must be removed.

3. Methods of Abatement by Encapsulization:

Effective 7/1/92 the Philadelphia Department of Public Health will accept the application of liquid encapsulant materials to lead painted surface in lieu of paint removal, based on the following criteria:

a. The encapsulant must be of the elastomeric or multipart epoxy or acrylic type and it must be manufactured specifically for the encapsulation of lead based paint.

b. The encapsulant must be applied in accordance with the 1990 HUD guidelines for lead paint removal in Public and Indian Housing. That is:

- The encapsulant may be applied to non-impact stationary surfaces such as walls, window frames or baseboards.

- For application to high wear surfaces such as window sills the encapsulant must contain glass fibers or similar material.

- All encapsulated areas must be completely covered to a uniform thickness as specified by the manufacturer. The manufacturer's application instructions and proof of the type and quantity of the materials used must be available to the inspector upon request.

- High impact surfaces such as contact or friction areas in door frames, window sash tracks or window wells may not be encapsulated by this method.

c. Evidence of substrate failure such as cracking, peeling or delamination, or failure of the encapsulant to adhere to the surface will be grounds for rejecting the abatement job.

Regulations governing the labeling and removal of lead based paint promulgated under 6-403 of the Philadelphia Code allow acceptance of an encapsulant in lieu of the removal of lead based paint. Spreadable liquid encapsulants have been tested by HUD and while their long term effectiveness has not yet been established due to the recent development of these products, they have been accepted as an alternative to lead paint removal on a performance criteria basis for Public and Indian Housing. Accordingly, the use of approved encapsulants will be accepted by the Philadelphia Department of Public Health only when used in conformance with the above criteria.

4. Methods of Abatement by Encasement:

Where applicable, covering a lead painted surface with an approved, tight, durable covering such as paneling or wall board, metal or tile will be accepted in lieu of paint removal.

5. Requirements for Orders to Remove Lead Items: (Furniture, dishware, etc.)

Locate the item identified on the Order Letter & remove the item from the property and dispose of the item properly; OR remove the item from the property and completely remove all lead or leaded coatings from the item. (ex.: sending furniture or woodwork out to be chemically stripped)

General Procedures / Safety Precautions:

1. No children or any woman of childbearing age should be allowed in the property at any time while abatement activities are being conducted. Any adults who are not engaged in abatement activities should also be out of the building or on another floor with the doors closed and windows open for ventilation.

2. Do not allow any person back into the property until all surfaces have been properly cleaned.

3. Prior to and during abatement activities, the worker should:

a. Open all windows in the room where he is working.

b. Wear a face mask or proper respirator fitted with HEPA filters.

c. Wear washable protective clothing or disposable coveralls.

d. Wear work gloves, safety goggles, hair and foot coverings.

e. Neither have nor consume any food or drink nor smoke in the work area.

f. Wash hands and face before eating, drinking or smoking. (Should also remove work clothes)

g. Keep a fire extinguisher in the work area, if using heat to soften paint.

h. When all work and clean-up are done for the day, remove and dispose of work garb; if non-disposable, wash separately from any other laundry. Bathe to remove any lead dust from your person.

4. To conduct lead paint abatement correctly:

a. Remove all furniture, rugs, curtains or other items from work area or cover thoroughly with drop clothes.

b. Follow all safety requirements and precautions.

c. Use a paint scraper and a spray water bottle to "mist scrape" the loose paint - (first spraying an area with water then scraping the paint off.) When doing a total removal, heat the paint with a hot air gun until it just starts to bubble, then scrape it off with the scraper. Don't heat the paint too long or it will start to smoke and burn. Most masks will not protect you against the fumes released. Do not use an open flame (torch).

Paint Removers and Solvents may be used; but manufacturer's safety precautions should be followed (i.e. respirator for organic vapors, no skin contact, adequate ventilation, etc.)

Lead Paint Removal: Clean-Up Instructions

a. All paint chips, flakes and dust must be removed from all painted surfaces, walls and ceilings, carpets, furniture and any other areas or household items.

b. All clean-up must be done with an HEPA (High Efficiency Particulate Accumulator) vacuum cleaner to prevent contamination with fine lead-paint dust.

c. All surfaces in the work area must be vacuumed, washed with water and a high-phosphate detergent, vacuumed and washed again, to remove all dirt and dust. All debris, paint chips, vacuum cleaner bags, wash rags/sponges, drop cloths, must be folded into and sealed in 6 mil thick plastic sheets or bags and disposed of properly.

Repainting:

Once all abatement work has been completed **and the Department has certified that the work has been done properly;** all surfaces where paint was removed and all horizontal wooden surfaces not covered with formica, tile, linoleum or similar cleanable substances must be covered with two coats of any interior non-leaded paint or varnish.

Ohio Guidelines: Cincinnati OH

CITY OF CINCINNATI

BOARD OF HEALTH

GENERAL SANITATION REGULATION

00053

NOVEMBER, 1992 REVISION
8/25/93 VERSION

00053 - 15. REGULATING THE SALE AND USE OF PAINT CONTAINING MORE THAN 1 PERCENT OF METALLIC LEAD.

(A) Labeling.

No person shall sell, hold for sale, transport, or give away a hazardous substance, unless properly labeled. When a hazardous substance is labeled in compliance with applicable state or federal law, this section shall not apply except that if the commissioner finds that the labeling of the substance is inadequate to protect the public health, the labeling of the substance shall, upon the order of the commissioner and written notice to the manufacturer or distributor, contain such additional matter as may be required.

(B) Lead Paint.

1. No person shall possess, sell, hold for sale, give away or leave in any place paint containing more than five-tenths percent of metallic lead, based upon total non-volatile content of the paint, unless the labeling bears the following

statement: "Contains lead. Harmful if eaten. Do not apply on toys, furniture, interior or exterior surfaces which might be accessible to children." This sub-section does not apply to marine paints, roof cements and coatings, automotive finishes which are not sold at retail, or to paints in residential building-other than paints for toys, children's furniture, interior or exterior surfaces which might be accessible to children--which are sold for purposes other than resale, to the city or state or federal government, or a manufacturer, an industrial plant, a public utility or metal structural contractor.

2. No person shall manufacture, sell or hold for sale children's toys or children's furniture which have a paint containing more than five-tenths of metallic lead based on the non-volatile content of the paint.

3. No person shall use paint containing more than five-tenths percent of metallic lead based on the non-volatile content of the paint on the exterior or interior surfaces of any property accessible to small children.

4. When the department finds that there is paint or other material containing more than five-tenths percent of metallic lead based on the non-volatile content of the paint on the exterior or interior surfaces of any property, including items other than those with painted surfaces, it may order the removal of the paint or removal of the property, under such safety conditions as it may specify, and the refinishing of the exterior or interior surfaces with a suitable finish which is not in violation of this section.

(C)

1. Loose and flaking paint containing lead in excess of five-tenths percent on interior or exterior surfaces of any property accessible to small children shall be removed or made inaccessible and/or the surfaces recovered with paint or other covering. If paint is used, it shall not contain lead in excess of five-tenths percent.

2. Interior and exterior surfaces of property found to have coatings which contain lead in excess of the five-tenths percent limit, when said coatings are identified as the probable source of undue lead absorption or lead poisoning in human beings, shall have the coatings removed, covered or made inaccessible to small children. When panelling or other covering is used, it shall cover the wall at least four feet above floor level.

00053 - 17 SEPARABILITY CLAUSE

Should any section, paragraph, sentence, clause, or phrase of this Regulation be declared unconstitutional or invalid for any reason, the remainder of said Regulation shall not be affected thereby.

00053 - 19 PENALTY

Any person who shall violate any provision of this regulation shall be subject to the penalties provided by ordinance enacted by Cincinnati City Council. Each and every violation of the provisions of this regulation shall constitute a separate offense. This resolution shall take effect and be in force from and after the earliest period allowed by law.

Ohio Guidelines: Columbus, OH

CHAPTER 4527

Lead Based Coatings and Lead Bearing Substances



Cross References

Lead Poisoning - see Ohio R.C. Ch. 4125

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4527.01 Definitions.

For purposes of this chapter the following definitions shall apply:

(a) "Lead-based coatings" shall mean any paint, lacquer, or other applied liquid surface coating or putty which contains a quantity of lead more than five-tenths of 1 per centum (0.5 of 1%) lead by weight, calculated as lead metal, in the total nonvolatile content of liquid paints, or such standard, not to exceed five-tenths of 1 per centum (0.5 of 1%) in coatings as may hereafter be established by Federal law or regulation.

(b) "Lead-bearing substance" shall mean any structural substance or material which contains 0.3 milligram per square centimeter or more of metallic lead, based upon the total nonvolatile content of the substance.

(c) "Surface" shall mean the outermost layer or superficial area of the interior or exterior of a dwelling or dwelling unit including but not limited to the walls, ceilings, floors, stairs, windows, window sills, window frames, baseboards, decks, porches, railings, woodwork, metal work, trim and fixtures of a dwelling or dwelling unit.

(Ord. 356-75.)

4527.02 Lead-based coatings.

No person shall sell, use or apply lead-based coatings which may be inhaled, ingested or absorbed and which are intended for use:

(a) In or upon any exposed surface of any dwelling or dwelling unit readily accessible or hazardous to children.

(b) In or upon fixtures or objects used, installed or located upon exposed surfaces of any dwelling or dwelling unit readily accessible or hazardous to children.

(c) In or upon furniture, toys, playground equipment, cooking, eating or drinking utensils or food or liquid containers. (Ord. 356-75.)

4527.03 Other lead-bearing substances.

No person shall sell or manufacture the following lead-bearing items:

(a) Fixtures, objects, toys or furniture which may be chewed or eaten by children.

(b) Cooking, eating or drinking utensils or containers for food or liquid which may be chewed or eaten by children. (Ord. 356-75.)

4527.04 Warning statement.

(a) Within 30 days of the effective date of this chapter, all lead-based coatings existing in dealer or manufacturer inventories, or any coating to be manufactured for sale to the general public within the City within 30 days after this chapter becomes effective shall be required to be marked with the following stick-on-label:

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WARNING

CONTAINS LEAD

DRY FILM OF THIS PAINT MAY

BE HARMFUL IF EATEN OR CHEWED

Do not apply on toys and other children's articles, furniture, or interior surface of any dwelling which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units, such as windows sills, porches, stairs or railings to which children may be commonly exposed.

KEEP OUT OF REACH OF CHILDREN

(b) All lead-based coating for sale to the general public manufactured more than 30 days after the effective date of this chapter must bear identical labeling to that found in part (a) of this section. However, the following part of the warning statement must appear on the principal display panel:

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WARNING

CONTAINS LEAD

DRY FILM OF THIS PAINT MAY

BE HARMFUL IF EATEN FOR CHEWED

See other cautions of

(Side or Back) Panel.

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The remainder of the warning label may appear on the side or back panel of the lead-based coating container.

(c) All lead-based coatings manufactured more than 30 days after the effective date of this chapter for sale other than to the general public must be labeled in the following manner.

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WARNING
CONTAINS LEAD COMPOUND

Do not apply to toys, furniture or other surfaces which might be chewed by children.

Wash hands thoroughly after using and before eating or smoking.

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(Ord. 356-75.)

4527.05 Public nuisance.

Any dwelling or dwelling unit in which interior or exterior surfaces readily accessible or hazardous to children contain loose, chipped, peeling or flaking paint or plaster containing 0.3 milligram per square centimeter or more of metallic lead is hereby declared to be a public nuisance.

(Ord. 356-75.)

4527.06 Inspection and notice.

The division shall inspect dwellings or dwelling units for the presence of lead-based coatings contained in loose, chipped, peeling or flaking paint or plaster or lead-bearing substances upon its own initiative or upon complaint. It may remove samples necessary for laboratory analysis.

Upon determination of the presence of metallic lead in a quantity of 0.3 milligram per square centimeter or more in the paint or plaster notice shall be given to the owner and all occupants by certified mail, return receipt requested, and shall be posted in a conspicuous place upon the dwelling or dwelling unit.

Upon determination of the presence of metallic lead in a quantity of 0.3 milligram per square centimeter or more in said paint or plaster, the Division shall notify the Health Commissioner of the names and addresses of all occupants of the dwelling or dwelling unit and the names and addresses of the owners of the dwelling or dwelling unit. Occupant families with children six years of age or younger shall be informed by the Division of the lead poisoning testing and treatment program available through the Columbus Department of Health. All physicians, nurses or public health officials who diagnose or suspect lead poisoning in any person shall report such findings to the Columbus Health Commissioner. The Commissioner of Health shall report such findings to the division. (Ord. 525-84)

4527.07 Enforcement; Division my perform work.

(a) When the Division determines the presence of loose, chipped, peeled, or flaking paint or plaster which contains more than 0.3 milligram per square centimeter or more of lead-bearing substances upon any interior or exterior surface or fixture, the Division shall order the owner or owners to remove or permanently cover such paint or plaster in a manner approved by the Columbus Health Commissioner. The process of removal shall be accomplished in a manner which is not dangerous to the health of human beings and shall provide for the elimination and safe disposal of all flakes, chips and debris containing lead-bearing substances.

(b) If, after ten (10) days following the date of notification to the owner, the removal of lead-bearing substances has not begun and the owner of the dwelling or dwelling unit has not requested a hearing as provided by Section 4509.02, the Division may contract to have the work done. The Division shall cause the cost of such repair to be charged against the land on which the building exists as a municipal lien or to be recovered in a civil suit against the owner.

(c) There is hereby established a fund to treat surfaces containing 0.3 milligram per square centimeter or more of metallic lead if the owner or owners of the dwelling or dwelling unit fail to comply with the order of the Division made

pursuant to Section 4527.07(a). The fund shall be reimbursed from the costs recovered pursuant to (b) above. (Ord. 525-84.)

4527.08 Retaliatory eviction prohibited.

No owner of any dwelling or dwelling unit, after receiving notice of an inspection under this chapter, shall engage in retaliatory action against an occupant of the affected dwelling. It is presumed any such retaliatory action by the owner is in violation of Section 4509.07. (Ord. 356-75.)

APPENDIX 4: Supplemental Environmental Protocols

Baltimore

The Baltimore Clinical Center is negotiating with the State of Maryland Department of Housing and Community Development (DHCD) for funds to perform supplemental environmental interventions in the houses of children enrolled in the TLC trial. These funds would enable enrollment of children living in a wider spectrum of housing conditions and would likely increase the effectiveness of the environmental protocols in the short-term (i.e. during drug treatment) and the longer term (i.e. during the preschool years when the risk of lead toxicity is greatest, and throughout the entire period of follow-up). The primary supplemental protocol described below is referred to as the Repair & Maintenance (R&M) Level II protocol. Also described below is the R&M Level I protocol for houses requiring less intensive R&M work. The Baltimore Clinical Center has experience with both R&M protocols as part of ongoing studies of interventions to reduce exposure to lead in residential paint and dust.

R&M Level II work is expected to take 1-2 working days per house to complete. In addition to the in-common, minimum requirements of the TLC environmental protocol, R&M Level II work will entail enhanced treatments of floors, stairways, trim components and windows, with special attention to friction points. To the extent possible in a furnished dwelling, floors and stair treads will be treated to make them smooth and easily cleanable by the work crews and the occupants over time. Depending on their initial conditions, floors, stair treads and stair risers will be sealed or covered. Lead-painted windows will receive an in-place treatment including stabilization of the paint on the exterior trim, installation of new aluminum or vinyl sash guides and new aluminum caps on the window wells, and sealing of the interior sills with a non-flat paint or encapsulant. Deteriorated windows or window components would be replaced as needed. Lead-painted doors will be rehung as needed to reduce friction. Damaged areas of lead-painted walls will be required and/or encapsulated (e.g. by the use of drywall or fiberglass mat material).

Houses that require less R&M work, on the basis of visual inspection, will receive R&M Level I treatments that can generally be performed in one working day per house. In addition to the common minimum requirements of the TLC protocol, windows will receive a less intensive in-place window treatment consisting of the aluminum window well caps and the stabilization of the painted rim on the exterior of the windows. Surfaces and components that require removal of peeling or flaking paint would be repainted (e.g. doors, window trim, baseboards).

The frequency of recleaning beyond the above supplemental environmental intervention will be within the constrains of available funds and proportional to the perceived rate of lead dust re-accumulation and rate of deterioration of painted surfaces. The condition of painted surfaces will be assessed periodically. If the temporary stabilization does not appear to be satisfactory, other measures, such as owner-provided abatement or relocation will be considered.

Newark

Pre- and post-cleanup dust samples will be collected in 100 rather than only 50 homes in New Jersey. In addition, as specified in the main protocol, dust samples will be collected from all homes 3-6 months after randomization. At these follow-up visits, not only will samples be collected by the HUD method, but also approximately five other wipe samples will be collected from each home using tare-weighted filters that will allow separate estimates of the amount of dust accumulated and the concentration of lead within the dust. In addition, vacuum samples will be collected from all major carpets left in the home. The additional samples will be analyzed locally within New Jersey.

After the completion of recruitment, homes of study children will be cleaned every six months and will undergo an assessment of dust lead concentrations annually. If a family moves into a new home, cleaning will be undertaken as soon as possible and will be followed by an assessment of dust lead in the new environment.

Philadelphia

As funds permit, a second cleaning by TLC protocol will occur at year 1. Households will also receive a recleaning after moving, if the child experiences a rise in blood lead of 15 g/dL or greater over baseline, of if significant environmental events occur at the household. Such events would be: renovation, remodeling, collapse of ceiling, *etc.*

All families participating in the TLC trial will receive a cleaning package consisting of a bucket, mop, and cleaning detergent.

Ohio

In addition to the clean-up of dwelling units at the time of enrollment, the Ohio Consortium intends to re-clean each unit at 6-month intervals following enrollment. The protocol for these supplemental cleanings will be essentially the same as the initial clean-up. These supplemental cleanings, which are intended to minimize the impact of recontamination, will continue throughout the three year follow-up period, provided that the family does not move.

In the event that the family relocates, the new residence will be cleaned as soon as possible following the move and at 6 month intervals thereafter. Following each clean-up, the families will be provided with cleaning supplies (soap, sponge mop, bucket and sponges) and cleaning instructions to assist them in maintaining a healthy environment for their children.