

APPENDIX A

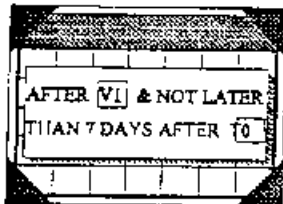
TLC CLEANING PROTOCOL

Home Cleanup (H2)

The purpose of H2 is to reduce risk of environmental exposures attributable to lead-based paint in fair or poor condition and lead-contaminated house dust and to reduce exposure during treatment (up to 6 months). At H2 the Environmental Cleanup Team will clean the housing unit of study participants.

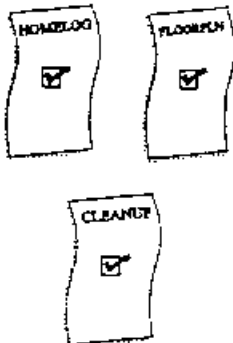
This section of the Manual of Operations covers the minimum activities to be adhered to by all clinical centers. If warranted and resources permit, centers may elect to go beyond these minimums. The TLC cleanup protocols are not substitutes for the legally mandated activities carried out by local or state agencies.

Efforts should be made to use existing Health Department regulations, procedures and resources wherever possible and to the extent that they offer greater risk reduction than procedures recommended in this protocol. It is important that Health Department mandated and/or landlord initiated lead paint abatement activities be carried out in a timely fashion and in a manner that does not increase exposures. Parents are asked to notify the TLC project staff immediately of any paint abatement activities. Thorough cleaning should be carried out immediately after any paint abatement activities. In states where there are no regulations governing lead abatement, Health Departments may do some hazard reduction or hire others to do the work. If this work occurs after TLC hazard reduction, there should be special environmental sampling to assess the quality of that work.



WHEN: After Pre-Randomization Clinic Visit 1 (V1) and before Treatment Visit (T0) plus 7 days. Home cleanup should be completed no later than seven days after first Treatment Visit (T0).

WHO: Environmental Cleanup Team consisting of at least two people who will perform cleanup.



FORMS:

- HOMELOG (Home Assessment Sheet) from the H1 inspection
- FLOORPLN (Floor Plan) from the H1 inspection
- CLEANUP (Home Cleanup Report)

EQUIPMENT:

- Vacuum cleaners-- must be equipped with a HEPA filter.
Approved vacuum cleaners include:
 - a. Nilfisk GS80
 - b. Wap 767
 - c. Other HEPA-equipped vacuum cleaners
- Vacuum Cleaner Accessories:
 - for woodwork (ledges): a round brush with combination rubber holder
 - for non-carpeted floors: the standard floor tool
 - for crevices: a narrow crevice tool
 - spare secondary filters
 - spare vacuum cleaner bags
- Beater Bar for Vacuum Cleaner
 - Kenmore Model #116 or any other electrically driven beater bar
- Detergent
 - high phosphate detergent (tri-sodium phosphate (TSP))
 - equivalent non-TSP cleaning substance
 - other cleaning agents developed specifically for removing lead
- Floor Mop
 - must be equipped with a replaceable cellulose sponge cleaning head (with optional towel) and a wringing device.
- Cellulose sponge cleaning heads for mops
 - Some centers may choose to use towels wrapped around mop heads in place of sponge cleaning heads. Towels should be discarded after use. The sponge cleaning or towel head should be replaced after each room.*
- 4 mil polyethylene bags
- 6 mil plastic sheet (for deteriorated carpet disposal)
- #1 pencils
- Watch

- Duct tape
- Towel (for brushing loose paint)
- Contact paper (optional)
- Cleaning sponges (must be cellulose-type sponge)
- 2nd stage HEPA filters (replacement)
- Many vacuum cleaner bags
- Spray bottles
- 2 or more sponge buckets (1 for wash, 1 for rinse)
- 2 or more mop buckets (1 for wash, 1 for rinse)
- Brushes
- Waterproof gloves (for using TSP wash)
- Eye protection
- Portable eyewash kit
- Uniforms for Environmental Cleanup Team to wear during working hours and a facility for changing clothes and shoes and cleaning-up at the end of the day to negate the possibility of carrying lead dust into their cars and/or home.
- Name tags and other identification
- Respirators and other safety equipment and supplies, as appropriate.

BEFORE HOME CLEANUP (H2):

Coordinator schedules visit with residents. Family is reminded that they will be asked to prepare living unit for cleanup, including packing of small items; that all children should be moved to another location outside the housing unit during cleanup; that a responsible adult should be in unit during cleanup. A letter is mailed to the parent or legal guardian confirming the date and time and requesting that the home is properly prepared. Here is a suggested letter:

Dear _____

Since you are a part of the _____ TLC (Treatment of Lead-Exposed Children) Trial, your home will receive a professional cleanup in an effort to reduce lead dust and paint hazards.

My name is _____ and I work for the _____ TLC Program.

This is a reminder that on _____ at _____ our contractor will be coming to your home to do the work that we discussed. It is important that you prepare your home so that the cleaning team can do the work quickly and completely.

- Pack up any small articles in the boxes or bags that we will give you so that all the furniture can be moved for cleaning. We will bring boxes or bags to your home on _____.
- Pick up any small things from the floor so that the floor can be cleaned well.
- Be sure to put all valuable and breakable items away to a safe place.
- Empty kitchen sink or bathtub of all items so that our workers can easily get water.
- Be finished with the kitchen and bathroom by _____ a.m. so that our workers can start on time.
- Use the attached check list to make sure your home is ready for clean up.

If you have any questions, please call me at _____.

Please help us help your children. Thank you!

Here is a checklist you might want to send with the letter...

Cleanup CHECKLIST		
To Prepare for Lead Cleanup in Your Home		
House ID _____	Address _____	
Date of Cleanup _____	Time Begin _____	Total # Rooms _____
WINDOWS:		
_____	Remove plants	
_____	Remove fans	
FURNITURE:		
_____	Clear small items off tops so that furniture can be moved	
CLOTHES, TOYS, SMALL ITEMS, PICTURES, AND OTHER BREAKABLE THINGS:		
_____	Pack in boxes or bags and put on sofas or beds, if possible	
_____	Clear off as much floor surface as possible	
_____	All objects you can more should betaken off the floor (examples are toys, clothes, shoes, boxes, etc.)	
_____	Put away valuable things.	
WALLS:		
_____	Remove items/pictures/mirrors off walls, if possible.	
ROOMS:		
_____	Empty all sinks and bathtub.	

One business day before cleanup, coordinator calls family to remind them of scheduled cleanup and to remind them to have children out of unit, small articles packed, and windows cleared. Name of designated adult who will be present during the cleanup is confirmed if known or obtained.

Provide Environmental Cleanup Team with directions to unit, names and phone numbers of responsible family member, plus copy of FLOORPLN, HOMELOG, and specifications of work to be performed.

AT HOME CLEANUP (H2):

Identify yourself by name as the contractor or staff for the TLC Trial who will be doing the cleanup. Show identification.

Ask to speak to designated adult whose name has been given. Review with this adult what will be done during cleanup.

Verify that arrangements have been made for all children to be out of living unit during cleanup, if possible. If this is not possible, ask that all children be relocated into one room until at least one of the rooms is cleaned and the children use that room.

Initial Steps

Videotaping of all rooms and contents prior to start of cleanup is optional depending on clinic funds. If the cleaning crew will be videotaping resident belongings, this should be done before the cleaning starts. The crew should ask permission of the adult present before beginning videotaping.

If feasible, all furniture and personal belongings should be moved from areas to be cleaned.

Rooms to which furniture is moved, should be given one pass by the vacuum to minimize tracking lead dust into them.

Order of Cleaning

The Environmental Cleanup Team should review FLOORPLN and HOMELOG before the visit to determine best method and order of cleaning.

Cleaning of rooms should be sequenced to avoid passing through rooms already cleaned, and should proceed so that common areas and the entryway to the dwelling are cleaned last.

Cleaning within each room should begin on the ceilings and end on the floors.

Cleaning Procedures

The HEPA/Wet Wash/HEPA Cycle

The cleaning cycle is called the HEPA/Wet Wash/HEPA cycle and is applied to each area as follows:

- first, the area is HEPA-vacuumed;
- next, the area is washed down;
- after drying, the area is HEPA-vacuumed again;

The third HEPA vacuuming can be omitted when floors are smooth and intact.

The rationale for this three pass system is as follows:

- the purpose of the first pass HEPA vacuum is to remove all dust and remaining debris that is available to the vacuum;
- the wet wash works to further dislodge dust from surfaces, but the mopping or washing process may not pick up all the dislodged dust particles;
- the final HEPA cycle removes any remaining particles dislodged but not removed by the wet wash. This is optional if floor is smooth and intact (e.g. linoleum, vinyl, tile). Wooden floors, while they may be smooth and intact, may have large cracks in the tongue and groove that trap particles. Such floors *should* get a final HEPA cycle.

HEPA Vacuuming Procedures

Surfaces to be cleaned include horizontal surfaces except ceilings (for example, floors, window sills and wells). Areas of loose or peeling paint, such as those on floors, ceilings, walls, windows and doors, will also be cleaned. Other items -- HVAC equipment (such as heating diffusers, radiators, pipes, vents), fixtures of any kind (light, bathroom, kitchen), built-in cabinets, appliances and other dust traps -- should be vacuumed. The Home Assessment Inspector when doing the H1 inspection visit should note in the comments section on HOMELOG which particular parts of the home need to be carefully cleaned.

When vacuuming carpets, the HEPA vacuum must be equipped with an electrically driven beater bar (agitator head) fixed to the cleaning head to aid in dislodging and collecting deep dust and lead. This bar should be used on all passes on the carpet face during dry vacuuming.



EMPTYING THE HEPA VACUUM -- Operators should use extreme caution when opening the HEPA vacuum for filter replacement or debris or vacuum bag removal, due to the high potential for accidental release of accumulated dust into the environment. For example, this can occur if the vacuum's seal has been broken and the vacuum's bag is disturbed. HEPA vacuum filter replacement should be performed in an area to prevent contamination of dwelling unit or off site, and care should be taken that the dust does not spread. If the vacuum cleaner bag breaks while a vacuum cleaner is operating or if a vacuum cleaner is operated without a bag, the second stage filter must be changed prior to any further use of the vacuum cleaner.

Wet Detergent Wash

Several types of detergents have been used to remove leaded dust. Detergents with a high-phosphate content (containing at least 5% tri-sodium phosphate, also known as TSP) have been found to be effective when used as part of the final cleaning process. Some TSP detergents can damage existing surface finishes.

Proper procedures for using high phosphate detergents also apply to most other types of detergents and include the following steps:

Manufacturer's Dilution Instructions

Users of high-phosphate detergents should follow the specific manufacturer's instructions for the proper use of the product, especially the recommended dilution ration. Even diluted, tri-sodium phosphate is very irritating to the skin and should be used only with water-proof gloves. Eye protection should be worn; portable eyewash facilities should be available.

Appropriate Cleaning Equipment

Since the high-phosphate detergent mixture is used to wash down a variety of surfaces, several kinds of application equipment are needed, including cleaning solution spray bottles, sponge buckets, mops, variously sized hand sponges, brushes and towels. Using the proper equipment on each surface is essential to the quality of the wash process.

Proper Wet Cleaning Procedures

At the conclusion of the first HEPA vacuuming, all surfaces that were HEPA vacuumed should be thoroughly and completely washed with a high-phosphate solution or other cleaning agents and rinsed. As is the case for HEPA vacuuming, work should proceed from top to bottom and sequenced to avoid passing through rooms already cleaned.

Changing Cleaning Mixture

Many manufacturers of cleaners will indicate the surface area that their cleaning mixture will cover. To avoid recontaminating the area by using overly dirty water, users should follow the surface area limits provided by the manufacturer. **Regardless of manufacturer recommendation, the cleaning mixture should be changed after each room.**



Dirty water should be disposed in the toilet and then flushed.

Specific Cleaning Instructions

Walls and Frames

Loose, peeling paint can be gently brushed with a damp towel or damp sponge to remove the flakes or removed with a vacuum cleaner with an appropriate attachment. Work crews should not engage in any paint removal activities such as scraping or sanding. Contact paper, duct tape or a coat of paint can 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 with the detergent solution.

Carpets

The surface of the carpet should be vacuumed as follows: The carpet is folded in half and the bottom side of the carpet is vacuumed, along with the floor which was exposed. The carpet is then folded to the opposite side of the room and the other half of the floor and the other half of the bottom of the carpet is vacuumed. The carpet is replaced to its original position. If there is padding beneath the carpet, it should be cleaned in a manner similar to the carpets if possible. Cleaning or disposal of the carpet and/or pad is at the discretion of the Home Assessment Inspector, and always with the permission of the adult owner. The last step in the cleaning process will be the final vacuuming of the carpet. The carpet should be vacuumed a **total of three times at the rate of three minutes per square yard each time** (required). Calculate area of rugs in room to nearest square yard to determine the amount of vacuuming required. Workers should have a watch in their possession to monitor the amount of vacuuming. At the completion of the vacuuming, the furniture and personal belongings will be replaced in their original positions. All carpets should be vacuumed with an approved HEPA equipped vacuum and an approved beater bar.

Badly deteriorated carpets should be permanently removed if possible. When disposal or replacement of carpets is indicated, the existing carpet should be rolled into a tight roll and wrapped with 6 mil polyethylene plastic and taped securely with duct tape or

a similar durable strapping tape prior to removal from the room. If new carpet is to be installed, it should not be installed until all cleaning and paint stabilization in the housing unit have been completed.

In rooms where the carpeting is permanently installed, as in wall-to-wall carpeting, the carpeting will not be folded back and the floor will not be cleaned underneath the carpeting. It should, however, still be vacuumed at the rate indicated above.

Wood, Tile, Vinyl and Linoleum Floors

If there is no carpeting on the floor, the floor is vacuumed at the rate of **one minute per square yard**. After the first vacuuming, the floor should be damp mopped with a detergent solution, and then vacuumed a second time at the same rate. The second vacuuming may be omitted if the floor surface is intact and smooth.

For washing floors, a two bucket system is recommended. The cleaning solution should be mixed in one bucket. Rinse water for cleaning the mop head is in the second bucket. Water in the rinse bucket should be changed whenever dirty. The cleaning solution bucket and rinse bucket should be changed after cleaning approximately every 75-100 square feet (8-10 square yards) of floor and after each room is completed.

A cellulose sponge mop head should be used for washing floors. The sponge may be covered with a rag. The rag (or sponge, if one was used) will be changed after each room. The cellulose sponge will be changed after each house. Sponges and rags should not be discarded at the subject's house.

Other Areas

All ledges e.g. sills, tops of baseboards, etc. should be washed with a sponge and the detergent solution.

Window wells, if accessible to Environmental Cleanup Team, should be vacuumed to remove paint chips and dust and then washed with a damp sponge and detergent solution.

Other dust traps such as venetian blinds, cold air return registers, forced air heating registers, radiators, and base boards must be inspected and cleaned. These dust traps should be noted on HOMELOG by the Home Assessment Inspector when at H1.

Any duct work with visible accumulation of dust should be vacuumed if covering can be easily removed.

The family should be encouraged to wash curtains and dispose of old carpets and blinds.

Abatement Procedures

- It is not the objective of the TLC 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 painted surfaces. If the deterioration is extensive and proper paint abatement not an immediate possibility, then relocation must be sought. If the deterioration is localized to one or two surfaces, such as on window sills or frames, then in-place management is an appropriate interim option to be carried out under this study if resources permit.
- If funds permit, other encapsulation procedures may be employed.
- Door mats at the interior entry to housing units can be used to minimize the amount of dust that enters the living space. They need to be periodically cleaned or replaced to prevent them from becoming a reservoir of lead-dust that can contaminate the house. Outdoor mats, e.g. indoor-outdoor carpet are recommended. The thickness of indoor mats and their placement must not interfere with the normal opening of the entry door. If otherwise, they likely will be removed by the resident. Some sites will offer new doormats as replacements. If this is the case, try to get the old one disposed

Completion of Cleanup

- All carpets and furniture should be put back in place. Boxes or bags of small articles should be returned to appropriate rooms, although occupants should be asked to unpack.
- Wipe smooth surfaces of furniture before they are returned to cleaned rooms.

Damage to Occupant's Property/Liability

- For TLC sites who are employing a cleaning contractor, the contract should address the issue of breakage. It is obvious that the Environmental Cleanup Team will need to move occupant's belongings during the course of the cleaning work. Every attempt will be made on the part of the TLC staff to encourage the families to consolidate their belongings so that movement by the Environmental Cleanup Team is kept to a minimum.
- Continued compliance on the part of the families is of paramount importance to the TLC Trial. In this regard, the Environmental Cleanup Team needs to be extremely careful in performing work at the work site. If any item is obviously broken during cleanup, it needs to be replaced immediately, the same day if possible. Other claims should be handled on a

case-by-case basis. Each sites is required to write reimbursement procedures including who is responsible for reimbursement.

Safety and Health

- A strict series of contamination control procedures must be in force throughout the dust abatement process to ensure that cleaning materials and removed from the site to a designated disposal site without loss or spread of contaminated materials.
- Any dirt or dust removed from the work site, including bags from the vacuum cleaners, must be placed immediately in plastic trash bags, a minimum of 4 mil in thickness, of sufficient size to allow the bag top to be twisted and sealed securely with a locking device. These bags must be securely anchored in the transport vehicle to prevent any spillage as the workers travel from work site to work site or to a dump site.
- All cleaning equipment, especially cellulose sponge mop heads, rags and towels, must be removed from the home when the cleaning crew leaves in order that the resident is not tempted to use these possibly lead contaminated materials for regular household chores.
- All vacuum cleaning attachments and other cleaning tools should be wiped before leaving site.
- To prevent any contamination of work sites, all vacuum cleaners will be emptied and fitted with a new bag prior to entering a work site.
- Carpeting removed from a work site may not be left unattended on the street curb, especially overnight. After removal from the work site, it must be guarded or secured to prevent loss until it is transported to the designated dump site. This is not hazardous waste and does not have to be transported to a secured land fill, but it must be removed from the site. We are trying to prevent people from "helping themselves" to lead-contaminated materials.
- Wash water (both detergent solution and rinse water) should be disposed of in the toilet. It should not be disposed of in other places such as sinks, bath tubs, street gutters, or back yards.
- Crew should clean up any mess or spills created during cleanup or disposal of materials.

Cleanup Monitoring

- Environmental Cleanup Team performance should be monitored by a post-cleanup visual inspection by the Home Assessment Inspector. The first 25 housing units and every 10th home thereafter will be inspected. The inspection process can take place concurrently with the Post-Cleanup Wipe Sampling as part of the Monitoring Residential Lead Dust.

- It is not known if this cleanup protocol is adequate to attain HUD clearance levels. HUD guidelines, therefore should not be used to monitor contractor performance. In addition there is no basis for specifying a particular percent reduction in lead loading. Therefore, lead measurements in the home should not be used to monitor contract compliance unless the lead loadings are seen to increase following cleanup activities.

Here is a suggested checklist for centers who wish to monitor the work of the Environmental Cleanup Team:

LEAD CLEANING CHECKLIST

(This section filled out by the Environmental Cleanup Team.)

House ID _____ Address _____

Date _____ Total # Rooms _____

Preparation of Areas to be Cleaned

- Remove pictures, etc. from walls, if possible.
- Quick vacuum of entire unit.

Ceiling

- Vacuum loose paint chips.

Walls

- Vacuum loose paint chips.

Baseboards

- Use vacuum then wipe with damp cloth to remove dust.

Windows

- Use vacuum to clean tops of window, ledge and trim.
- Use vacuum to clean inside wells and sills.
- Wipe sills, ledges, trim and glass with damp cloth and cleanser.

Doors

- Use vacuum to clean top of door trim.
- Wipe door trim with damp cloth and cleanser.

Radiator or Air Return Registers

- Use vacuum to clean radiator or register.
- Wipe with damp cloth.

Surfaces

- Wipe all horizontal surfaces with damp cloth.

Cleaning Procedures

- Water changed frequently and flushed down toilet.

Floors

- Vacuum all floor surfaces.
- Vacuum carpeted areas four times in varying directions.
- Wet mop all hard floor surfaces.

Final Cleanup

- Pack up cleaning equipment; check for all items.
- Seal cleaning debris and remove from premises.
- Return furniture to original positions.

LEAD CLEANING CHECKLIST (continued)

(This section filled out by Environmental Cleanup Team and signed by the adult present.)

The TLC Environmental Cleanup Team cleaned this home on (date)_____. The following repairs were done:

The following items were thrown away:

Comments:

Signed _____

Date _____

AFTER HOME CLEANUP (H2):

- Environmental Cleanup Team completes form CLEANUP with a #1 pencil and returns it to clinic coordinator.

CLEANUP is a data form. No identifying information, other than the child's Study ID Number, should appear on the form. A copy is made for the child's file and the original is mailed to the Data Coordinating Center.

- Environmental Cleanup Team returns forms HOMELOG and FLOORPLN to coordinator for clinic files.
- Coordinator makes copy of CLEANUP for clinic files and sends original to Data Coordinating Center.

Post-Cleanup Wipe Sampling: Monitoring Residential Lead Dust

- Post-cleanup wipe samples will be collected from each of the homes inspected for contractor monitoring, that is, the first 25 housing units plus every 10th home thereafter. These are the same homes with Lead Dust samples from the Home Assessment. For more information, see the section on "Monitoring Residential Lead Dust" in the *Manual of Operations*.

APPENDIX C

Geometric Means Dust Lead Loadings (Fg/ft²) by Surface Type and by Group Based on the Earlier EPA-funded Study (Farfel, 1997a) ^a

Surface Type	Group	Pre-Intervention Fg/ft ² (no. Houses)	Post-Intervention Fg/ft ² (no. Houses)	6-12 Months Fg/ft ² (no. Houses)
Floor	Professional Clean A	26 (97)	16 (91)	21 (58)
	Professional Clean B	92 (62)	31 (62)	43 (19)
	Minor Repair ^b	129 (47)	76 (47)	75 (6)
	Major Repair ^c	117 (13)	24 (37)	24 (14)
Window Sill	Professional Clean A	107 (97)	35 (91)	54 (58)
	Professional Clean B	535 (62)	164 (62)	197 (19)
	Minor Repair	1,706 (47)	126 (47)	585 (6)
	Major Repair	444 (13)	18 (37)	75 (14)
Window Well	Professional Clean A	962 (97)	91 (91)	320 (58)
	Professional Clean B	13,759 (62)	452 (62)	2,111 (19)
	Minor Repair	29,648 (47)	1,258 (47)	16,199 (6)
	Major Repair	4,153 (13)	44 (37)	296 (14)

a These data are not limited to study houses sampled at 24 months.

b This type of intervention was introduced later in the project and consequently a small number of houses were available for 6 to 12 month sampling during the study period.

c The number of houses at post-intervention is larger because some major repair interventions were performed as the second intervention, and pre-intervention wipes were generally not collected for the second intervention.

**Median Dust Lead Loadings (Fg/ft²) by Surface Type and by Group
Based on the Earlier EPA-funded Study (Farfel, 1997a) ^a**

Surface Type	Group	Pre-Intervention Fg/ft² (no. Houses)	Post-Intervention Fg/ft² (no. Houses)	6-12 Months Fg/ft² (no. Houses)
Floor	Professional Clean A	29 (97)	17 (91)	45 (58)
	Professional Clean B	165 (62)	39 (62)	60 (19)
	Minor Repair ^b	324 (47)	180 (47)	127 (6)
	Major Repair ^c	328 (13)	43 (37)	39 (14)
Window Sill	Professional Clean A	109 (97)	21 (91)	73 (58)
	Professional Clean B	538 (62)	147 (62)	227 (19)
	Minor Repair	2,074 (47)	159 (47)	1,152 (6)
	Major Repair	490 (13)	19 (37)	77 (14)
Window Well	Professional Clean A	1,165 (97)	57 (91)	216 (58)
	Professional Clean B	34,879 (62)	1,391 (62)	6,662 (19)
	Minor Repair	105,655 (47)	2,668 (47)	26,229 (6)
	Major Repair	6,710 (13)	50 (37)	479 (14)

a These data are not limited to study houses sampled at 24 months.

b This type of intervention was introduced later in the project and consequently a small number of houses were available for 6 to 12 month sampling during the study period.

c The number of houses at post-intervention is larger because some major repair interventions were performed as the second intervention, and pre-intervention wipes were generally not collected for the second intervention.