Experimental Methodology for the Collection and Analysis of Surrogate and Hand Wipes on CCA-Treated Wood

Definitions

1. Instrument Detection Limit (IDL) - 3 times standard deviation of 10 replicate measurements of reagent blank. The IDLs determined are as follows:
   a. As = 0.01 ppm
2. Method Detection Limit (MDL) - Reagent blank fortified with 2-3 times the IDL. Seven replicate measurements are made. Calculate the MDL as follows:
   MDL = t X S, t =3.14 (99% confidence level for 7 replicates), S = standard deviation
   The MDLs were determined (to the nearest hundredth ppm) to be:
   a. As = 0.02 ppm
3. Laboratory Reagent Blank (LRB) – Polyester wipe or other surrogate material treated with the same extraction procedure as samples. LRB data are used to assess contamination from the laboratory environment.
4. Calibration Blank – Deionized water acidified with nitric acid (10 ml concentrated nitric acid diluted to 100 ml with deionized water).
5. Stock Standard Solution - 1000 ppm solution of analyte purchased from reputable commercial source, used to prepare calibration standards. Replaced before expiration date.
6. Calibration Standards - Solutions containing 0.25, 1, 5, and 10 ppm of As in 10% nitric acid matrix. Calibration standards shall be prepared weekly.
7. Laboratory Performance Check Solution (LPC) – A solution of the analytes of interest used to evaluate the performance and stability of the instrument system. The 5 or 10 ppm calibration standard is generally used.
8. Quality Control Sample (QCS) – A solution of the analytes of interest used to evaluate the performance of the instrument system. QCS is obtained from a commercial source external to the laboratory.
9. Laboratory Fortified Blank (LFB)- Polyester wipe or other material used in wiping experiments to which known quantities of method analytes are added in the laboratory. The LFB is extracted and analyzed exactly like a sample. Its purpose is to determine whether method performance is within acceptable control limits. The LFB will be spiked with 100 μg of As.

Materials: The materials used for sampling are as follows:

1. Polyester – TEXWIPE, TX 1009 Alpha Wipe, 9"x9"
2. High Density Polyethylene (HDPE) – Dupont Tyvek® Envelopes, 9"x12"
3. 1.1 kg steel rubbing disk
4. Vertical Horizontal Wiper
5. Parafilm®

Reagents: Reagents used are as follows:

1. Nitric Acid, Trace Metal Grade
2. Acetic Acid, Trace Metal Grade

Surrogate Sample Collection: The sample collection procedures that CPSC staff follow to collect wipe samples of dislodgeable As on CCA treated wood found in playgrounds, decks, or boards tested in laboratory are as follows:

1. Cover the rubber-coated side of the 1.1 kg steel rubbing disk with a clean piece of Parafilm®. Place the wetted polyester wipe or other designated surrogate wipes over the Parafilm®. The wet polyester surrogate wipes are prepared by wetting a 4.5"x4.5" cut section of polyester with 0.9% saline solution until the weight of the wipe approximately doubles. The dry polyester and HDPE surrogate wipes are prepared by cutting to 4.5"x 4.5" sections. Secure the wipe to the disk with a rubber band, and hose clamp. Ensure that the wipe is smoothly stretched over the disk. See Figure 1 and 2.
2. Attach wipe covered rubbing disk to the lower arm of vertical/horizontal wiper. Secure the wiper to the section of wood to be rubbed. Using c-clamps to attach the wiper to the board can do this. See Figure 3.
3. *Horizontal Sampling:* Place the wipe covered rubbing disk at one end of the wiper. Slide the rubbing disk along tracks of wiper forward and back for 5 strokes. A stroke in this instance is one forward and back movement of the wipe covered disk. Lift the rubbing disk from the board, rotate 90°, and slide disk forward and back 5 more strokes, for a total of 10 strokes, unless otherwise stated in test protocol. The area rubbed is 400 cm^2 (8 cm x 50 cm), unless otherwise stated in test protocol.
4. *Vertical Sampling:* Place the wipe covered rubbing disk at bottom of the wiper. Attach 1.25 kg weight to upper arm of wiper. See Figure 4. The 1.25 kg weight will exert approximately 1.1 kg force on the wipe covered disk in the vertical position. Slide the disk along tracks of wiper forward and back for 5 strokes. Pick the disk from the board, rotate 90°, and slide disk forward and back 5 more strokes, for a total of 10 strokes. The area rubbed is 400 cm^2 (8 cm x 50 cm).
5. Remove the wipe from the disk. Place wipe in a test tube, cover with screw cap, seal with sample label.

Extraction/Digestion: The laboratory staff shall acidify and start extraction procedure within 72 hours of receiving wipe samples. The procedure is as follows:

1. Heat water bath to 60°C.
2. Add 15 ml of 10% nitric acid to test tubes containing rubbed wipes. Cover securely to minimize evaporation.
3. Place tubes in heated shaker bath overnight (approximately 22 hours). Remove test tubes from water bath, and let cool to room temperature (>15C). An LRB and LFB shall be put through extraction analysis process with each batch of samples.
4. Vortex test tubes prior to analysis to ensure mixing. The wiping material remains in the test tube throughout the extraction and analysis process.

Hand Wipe Sample Collection: The sample collection procedures that CPSC staff followed to collect hand wipe samples in Hand Study 3 and further studies are as follows:

1. Prior to each hand rub, the volunteer washes their hands with soap and water.
2. Rinse the hand used for the rubbing with 100 ml of deionized water. Collect the deionized water as the pre-rub rinse sample.
3. The volunteer rubs the 700 cm^2 (14 cm x 50 cm) designated board section for 10 strokes. The volunteer shall place the 1.1 kg disk on top of the hand during the rubbing in order to maintain a constant force. The hand should be oriented diagonally across the width of the board so that the whole surface area of the palm of the hand covers the board.
4. After the rubbing rinse the hand with 100 ml of 5% acetic acid, wipe with a polyester wipe that has been wetted with 5% acetic acid, rinse again with 100 ml of 5% acetic acid. Combine the rinse, wipe, and second rinse as one sample. Repeat the rinse wipe rinse procedure a second time and combine all 3 as a second sample.
5. Transfer the samples from the hand rubs to beakers, and evaporate to dryness at room temperature (>15C) in a fume hood.
6. Transfer the dry wipes to a test tube, rinse the beakers with 5 ml of 10% nitric acid and transfer to the same test tube as the sample wipe. Repeat the rinse procedure of the beaker 3 times until the final volume transferred to the test tube is 20 ml.
7. Heat the test tubes containing the wipes and 20 ml of 10% nitric acid to 60°C overnight (approximately 22 hours).
8. Vortex test tubes prior to analysis to ensure mixing. The wiping material remains in the test tube throughout the analysis process.

ICP Operating Procedures and Quality Control Measures

Analysis

1. Perform wavelength calibration daily. This can be done prior to igniting plasma. An internal mercury source lamp is used for the wavelength calibration.
2. Ignite plasma. Set conditions as follows:
   a. R.F. power = 1150 watts
   b. Auxiliary flow = 15 liters/minute
   c. Nebulizer flow = 30.06 psi
   d. Pump rate = 100 rpm
   e. Purge time = 10 seconds
3. Allow the instrument to become thermally stable before beginning. This requires at least 30 minutes of operation prior to doing peak search for the analytes of interest.
4. Open the CCA method. Ensure following elements and wavelengths (nm) are selected:
   a. As 189.042, and 193.759
5. Perform peak search using 10 ppm standard to ensure optimum setting.

6. Perform calibration using the calibration blank and standards. Calibration shall be performed a minimum of once a day when used for analysis, or each time the instrument is set up. Results for each standard shall be within 5% of the true value. If the values do not fall within this range, recalibration is necessary.
7. Analyze the QCS immediately after calibration. The analyzed value of each analyte should be within ±10% of the expected value. If analyte values are outside the ±10% limit, recalibration is required.
8. Analyze the LPC following QCS analysis, after every tenth sample, and at the end of the sample run. The analyzed value of each analyte should be within ±10% of its expected value. If an analyte value is outside the interval reanalyze the LPC. If the analyte is again outside the ± 10% limit, recalibrate the instrument, and all samples following the last acceptable LPC solution should be reanalyzed.
9. Potential spectral interferences for As are detected by observing the scans during analysis and by analyzing 2 emission lines for each element. If results for the two emission lines for a particular element differ by more than 10%, spectral interferences should be suspected. Observe the wavelength scans for each emission line. If peak overlap or high background is observed for one element emission line and not the other, spectral interference should be suspected for that emission line. Use results for the emission line that does not show peak overlap or high background.
10. At least one LRB must be analyzed with each sample set. If an analyte value in the LRB exceeds 2 times its determined MDL, then laboratory or reagent contamination should be suspected. The source of the contamination should be identified and resolved before continuing analyses.
11. At least one LFB will be analyzed with each batch of samples. Calculate accuracy as percent recovery. Analyte recoveries should be within ±20%. If recoveries are outside this limit, source of the problem should be identified and resolved before continuing analyses.
12. Dilute any samples that have analyte values exceeding 1.5 times the high calibration standard, or 15 ppm. Reanalyze.

Calculation

Average results for the two element emission lines for every sample in which results are within the 10% differential limit. If spectral interferences are observed, then calculate results in accordance with paragraph 9 of the above section "Analysis". Results will be reported as total µg and are calculated as follows:

c= concentration of analyte found in extract, ppm (µg/ml)
v= volume extract
d = dilution factor
Total analyte, as µg = 100cvd.

Hand Results

The results of the 2 rinse/wipe/rinse samples for each board section shall be combined and reported as total dislodgeable As.

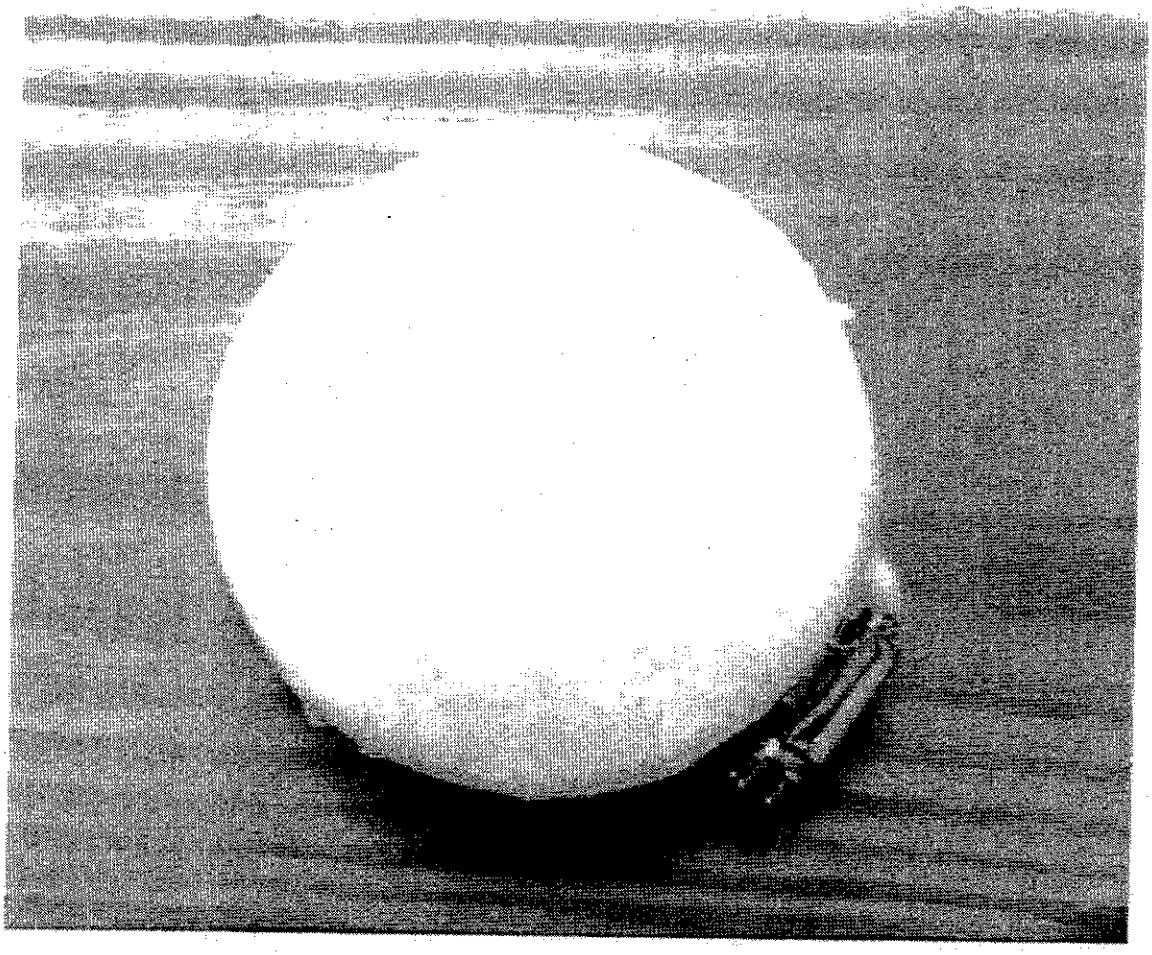
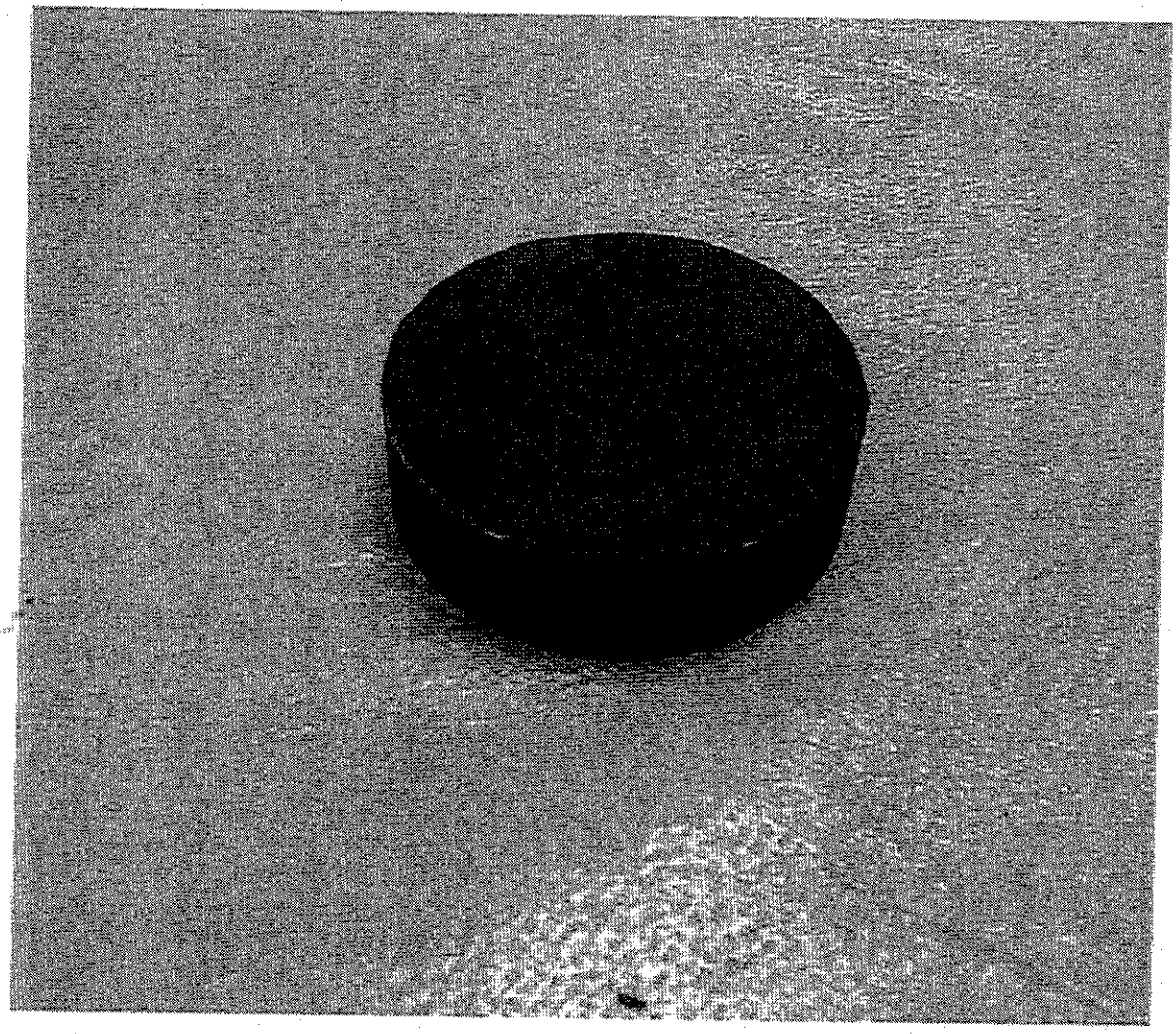


Figure 1 Polyester Covered Disk

Figure 2. Rubber Coated 1.1 kg disk



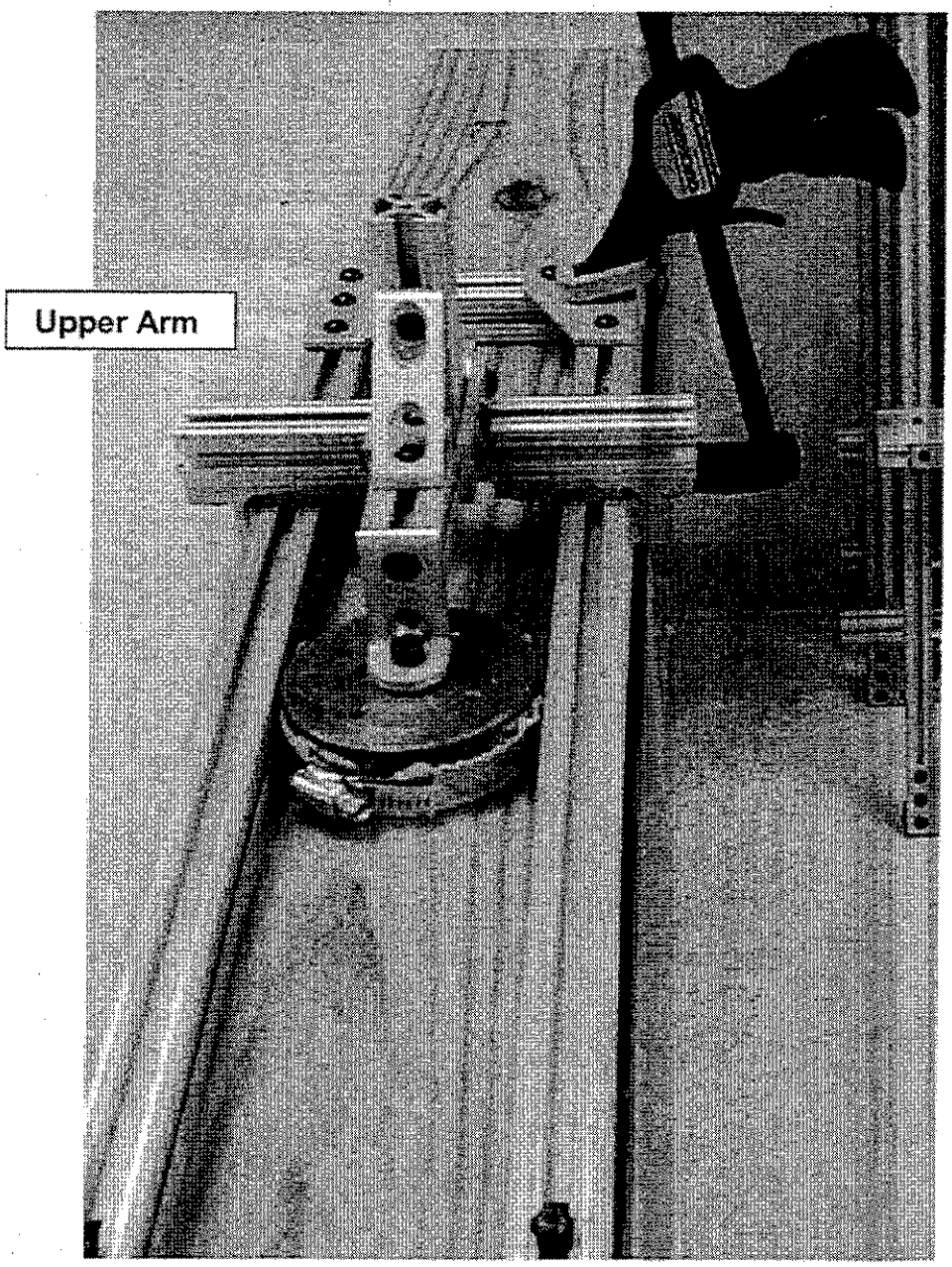
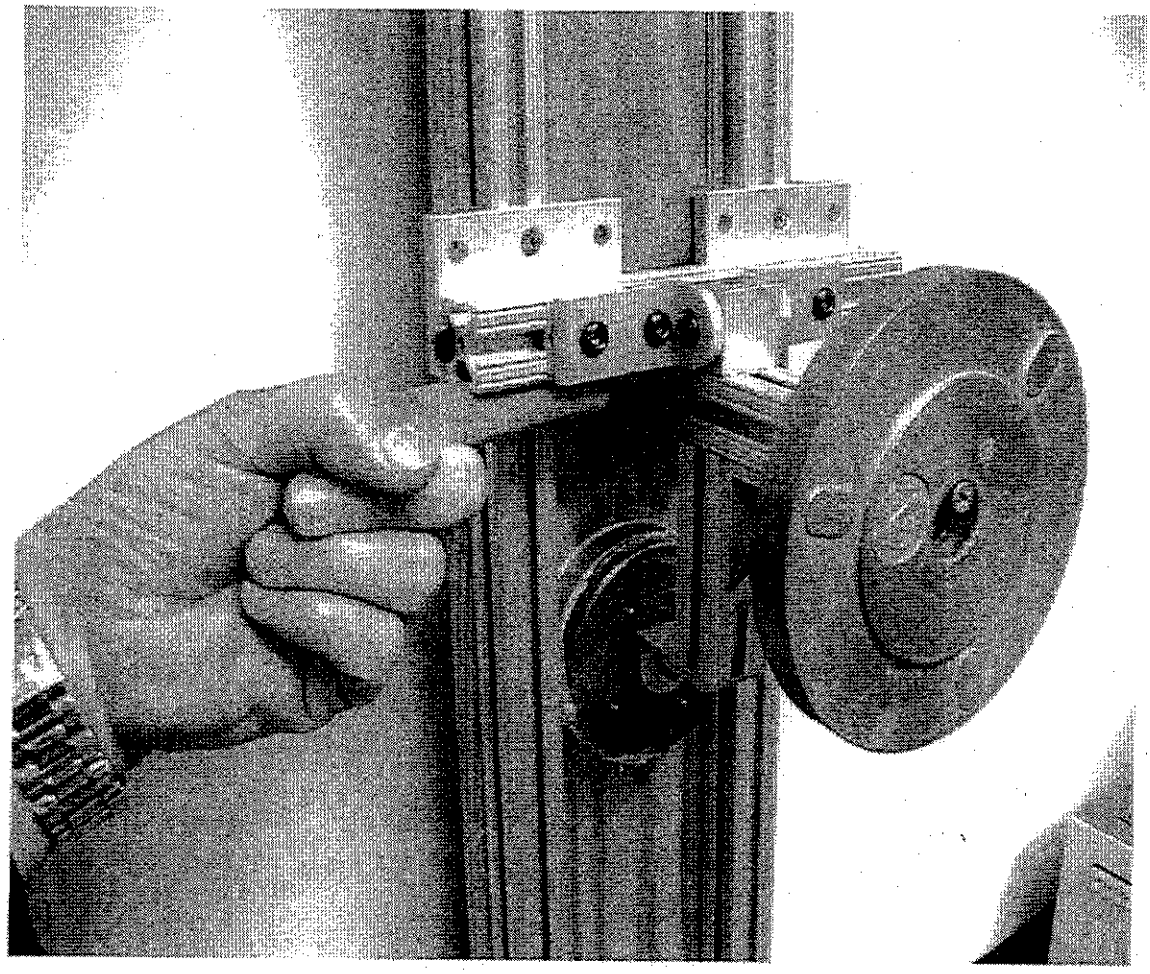


Figure 3. Vertical/Horizontal Wiper Attached to Board with C-Clamp

Figure 4. Vertical/Horizontal Wiper in vertical mode with weights attached. The disk is moved across board by pushing t-bar as demonstrated above.



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: Jan 2003

TO : Patricia Bittner, M.S., Project Manager for CCA-Treated Wood in Playground Equipment

Through : Andrew G. Stadnik, P.E., Associate Executive Director
Directorate of Laboratory Sciences
Warren Porter, Division Director, Division of Chemistry
Directorate of Laboratory Sciences

FROM : David Cobb, Chemist, Division of Chemistry
Dwayne Davis, Chemist, Division of Chemistry

SUBJECT : CCA-Treated Wood Field Study – Phases III and IV

BACKGROUND

Chromated copper arsenate (CCA) treated wood is being used for some children's playground equipment. There has been growing concern about the potential chemical exposure to arsenic (As) from the surface of the wood. In order to characterize CCA-treated wood and assess possible health hazards of As from treated wood, studies have been conducted to measure the amount of dislodgeable As obtained by rubbing CCA-treated boards. Previous studies involved using various surrogate materials to rub boards and determine dislodgeable As[1]. A number of hand studies have also been conducted by United States Consumer Product Safety Commission (CPSC) staff[1], but these were mainly conducted on new boards and were designed to evaluate hand loading. New CCA-treated wood was used in the previous study because it was readily available from local suppliers, and could be brought into the laboratory for testing during winter months. New wood is used by consumers to build playground and deck structures either from kits or from their own plans.

This memorandum describes a recently completed study of decks and playgrounds built with CCA-treated wood. In phase III the wood on decks was sampled by having adult human volunteers rub the boards with their bare hands. The same boards were also rubbed with various surrogate materials. A correlation between the hands and surrogates was established, and in phase IV playgrounds were sampled using only the surrogates.

PURPOSE

The objectives of this study were to: 1) Estimate the amount of As that the bare hand can pick up by rubbing actual boards of various ages and conditions that are found in the field; 2) Establish a correlation between surrogate materials and the hand over the range of boards in the field, to enable use of a surrogate material in a larger field study or in a mitigation study; 3) Explore the rate of hand loading of dislodgeable As as a function of the number of hand rubs for in-use wood; 4) Obtain data on the dislodgeable As found on actual playgrounds in use.

MATERIALS

The materials used for sampling are described in attachment (B)

METHODS

Samples, Phase III - Decks:

Eight CCA-treated wood decks were sampled. Four of the structures had been treated with some form of water sealer during the lifetime of the structure. Information on the structures is contained in Table 1. Pictures of each structure are contained in Figures 1 through 8 of attachment (A).

Samples, Phase IV - Playgrounds:

LS staff found 15 playgrounds in the local Washington Metropolitan area including Virginia and Maryland. Twelve of the playgrounds were constructed from kits and non-kit designs using CCA-treated lumber. The playgrounds included both playsets where consumers supplied the lumber and play sets where the manufacturer supplied the lumber. Information on the structures is shown in Table 2. The playground structures were labeled S9 through S23. Photographs of each structure are shown in figures 9 through 23 of attachment (A).

Table 1. Structure Identification, Phase III.

ID	Description	Age	Sealer Treatment	Location
1	Deck near ground. Southern exposure, large shade tree nearby. Spots with algae or moss. Slightly warped boards. Well weathered, even wear, brown appearance	15 years	No finish. Cleaned 1 or 2 times with chlorine bleach and water	Bethesda, MD
2	2nd level deck. Southern exposure. No trees. Yellow with green tint	5 months	No	Frederick, MD
3	Deck, western exposure. No shade trees. Well weathered, brown appearance	14 years	No	Centreville, VA
4	Deck, raised off ground. Northern exposure, shade from house. No wear or weathering. Varying green tint	New	Wood manufactured with water repellant	Bethesda, MD
5	Deck, raised off ground. Northern exposure. Shade from house. No wear or weathering. Redwood color from stain	12-14 years	Water repellent preservative applied 2-3 years ago	Oak Hill, VA
6	Deck, raised off ground. Northern exposure. Shade from house and trees. Cracks and splinters	15-18 years	Stain applied 6-7 years ago. Water repellent sealer applied 2 years ago	Bethesda, MD
7	Deck, raised off ground. Southeast exposure. Some shadow from trees. Gray brown. Smooth	5 years	Yes, but unknown	Vienna, VA
8	Deck, raised off ground. Southern exposure. No trees. Gray/brown weathered	8 months	Wood manufactured with water repellant	Oak Hill, VA

Table 2. Playground Structure Information, Phase IV.

I.D.	Description	Age	Lumber Supplied by kit Manufacturer	Sealer	Location
9	Boards are gray, weathered, and cracking	10 years	Yes	Water repellent preservative applied approximately 10 years ago	Washington, DC
10	Good condition	5 months	No	No	Frederick, MD
S11	Good condition. Board surfaces smooth. Green algae in some places. Structure likely shaded most of day because of trees.	Approx. 8yrs	NO	Semitransparent, 7 yrs ago	Rockville, MD
S12	Boards are gray. Pretty smooth. No green areas. Structure likely shaded most of day because of trees.	Over 6yrs	NO - NC	NO - NAS - Gray	Rockville, MD
S13	Boards are gray with smooth surfaces.	Unknown	NO - NC	NO - NAS - Gray	Silver Spring, MD
S14	Boards green from algae. Exposed to sun; no shade.	11yrs	Yes	NO - NAS - Gray	Oak Hill, VA
S15	Good condition, smooth boards; not weathered.	18yrs	Unknown	Unknown	Oak Hill, VA
S16	Good condition; not weathered. Exposed to sun.	6mon	Yes	Yes - Original finish - 6 months old	Oak Hill, VA
S17	Good condition. Receives partial sun exposure.	5yrs	Unknown.	Yes - Power washed & stained approx. one year prior.	Oak Hill, VA
S18	Gray, splitting and weathered boards. Exposed to sun. Set doesn't appear to be constructed from a kit.	7 yrs	NO	NO - NAS - Gray	Gaithersburg, MD
S19	Good condition, smooth boards. Exposed to sun.	Approx. 7yrs	Yes	Yes - Finished 1-2 years prior. Boards inside clubhouse appear unfinished.	Gaithersburg, MD
S20*	Good condition, smooth boards. Exposed to sun.	4yrs	Yes	Yes - One year prior.	Gaithersburg, MD
S21	Good condition, smooth boards. Shaded by trees.	9mon	Design from kit; lumber from hardware store.	NO	Arlington, VA
S22*	Good condition, smooth boards. Shaded by trees.	2 years	Yes	NO	Washington, D.C.
S23*	Good condition, smooth boards. Shaded by trees.	3 years	Yes	Yes - Power washed & water sealant applied approx. 10 months prior.	Washington, D.C.

* - Control , Non-CCA lumber play set.
NAS – no appearance of stain, based upon appearance and color (gray) of wood.

Phase III Study - Decks
Experimental Factors:

CPSC Directorate of Epidemiology staff developed the statistical design of this study. Eight adult volunteers were chosen to rub the structures which included 8 residential decks. Two volunteers were used on each of the deck structures, one volunteer was used on each of the playground structures. Four boards were tested at each deck structure. Two boards were tested at each playground structure. Methods used to rub the boards included the following:

1) 10 cycle hand rub over 700 cm^2 area
2) 20 cycle hand rub over 700 cm^2 area
3) 10 cycle dry polyester surrogate over 400 cm^2 area
4) 10 cycle wet polyester surrogate over 400 cm^2 area

The board areas for hand rubbing were larger than the board areas rubbed with surrogates. A larger board area was chosen for the hand rubs to ensure the ability to meet or exceed the analytical detection limit, since hands generally pick up less dislodgeable As than the surrogates.

On each board the 4 methods for rubbing the wood were randomly assigned to one of 5 segments labeled A through E. The labeling code for the samples is based on the structure, board, segment, and method used for rubbing. The first part of the code is in the form S_B_S_, where the _ after the first S is the structure number (1-10), the _after the B is the board number (1-4), and the _ after the second S is segment label (A-E).

The second part of the code records the method as follow:

10H	10 cycle hand rub
20H	20 cycle hand rub
WP	Wet polyester surrogate
DP	Dry polyester surrogate.

The hand method produced three samples, as described below, which are the pre-rub rinse, the first rinse/wipe/rinse, and the second rinse/wipe/rinse. This methodology was designed to ensure that most of the dislodgeable As that the hand picked up was removed and collected. This was designated on sample label with additional digit:

0	Pre-rub rinse
1	First rinse/wipe/rinse
2	Second rinse/wipe/rinse

Some additional samples were collected at some sites, their sample designations reflect the structure number, additional board number, and other segment/method information used.

Prior to each hand rub, the volunteer washed their hands with soap and water.

The hand used for the rubbing was then rinsed with 100 milliliters (ml) of deionized water and dried. The deionized water was collected as the pre-rub rinse sample. The volunteer then rubbed the designated board section. After the rubbing, the hand was rinsed with 100 ml of 5% acetic acid, wiped with a polyester wipe that had been wetted with 5% acetic acid, rinsed again with 100 ml of 5% acetic acid. The rinse, wipe, and second rinse were combined as one sample. The rinse wipe rinse procedure on the hand was repeated a second time, and all three were combined as a second sample. The 5% acetic acid rinse was used because As is more soluble in weak acid solutions than in deionized water. The 5% acetic acid solution is mild enough to cause no irritation to the volunteer's hands. Vinegar has approximately the same acetic acid concentration as the rinsing solution. Detailed hand sampling procedures are contained in attachment (B).

Procedures for performing surrogate rubbings involve wrapping the surrogate polyester cloth around 1.1 kg disk, and sliding the disk over the 400 cm^2 designated area for 10 strokes. A stroke in this instance is defined as one forward and back movement of the surrogate-covered disk over the designated area. The wet polyester surrogates were prepared by wetting the 4.5"x 4.5" polyester wipes with 0.9% saline until the weight of the wipe approximately doubles. The dry polyester surrogates were cut to 4.5"x4.5" from the polyester fabric. A clean piece of Parafilm® was placed between the disk and surrogate for each sample. Detailed surrogate sampling procedures are contained in attachment (B). After rubbing the boards, the surrogate materials were placed in labeled test tubes for extraction and analysis.

Sample Preparation and Analysis

The surrogate materials were extracted with 15 ml of 10% nitric acid at 60° Celsius (C) overnight (approximately 15 to 24 hours, generally done 16 hours) . The samples from the hand rubs were transferred to beakers, and evaporated to dryness at room temperature (>15C) in fume hood. The wipes were transferred to a test tube, the beakers rinsed with 5 ml of 10% nitric acid, and transferred to the same test tube as the sample wipe. The rinse procedure of the beaker was repeated 3 times, until final volume transferred to the test tube was 20 ml. The test tubes containing the wipes and 20 ml of 10% nitric acid were heated to 60°C overnight.

The samples were analyzed for As using inductively coupled plasma atomic emission spectroscopy. The analytical procedures and quality control methods are discussed in attachment (B).

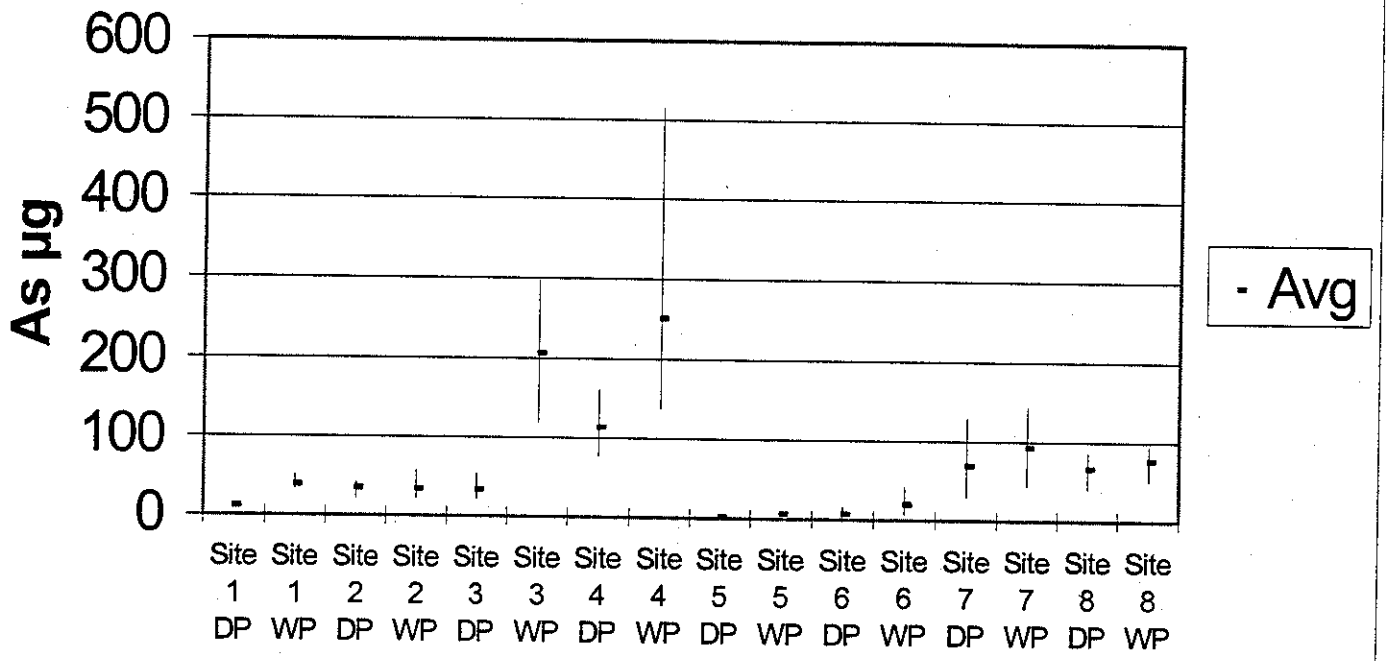
Results

The results are contained in Table 1 of attachment (C). The hand sample results in these tables are the combination of both rinse/wipe/rinse samples collected from each hand rub. The following observations were noted:

1. The wet polyester surrogate picked up the most dislodgeable As compared to dry polyester and the hand. Figures 24 and 25 compare the dislodgeable As for each structure using the surrogate and hand wipes.

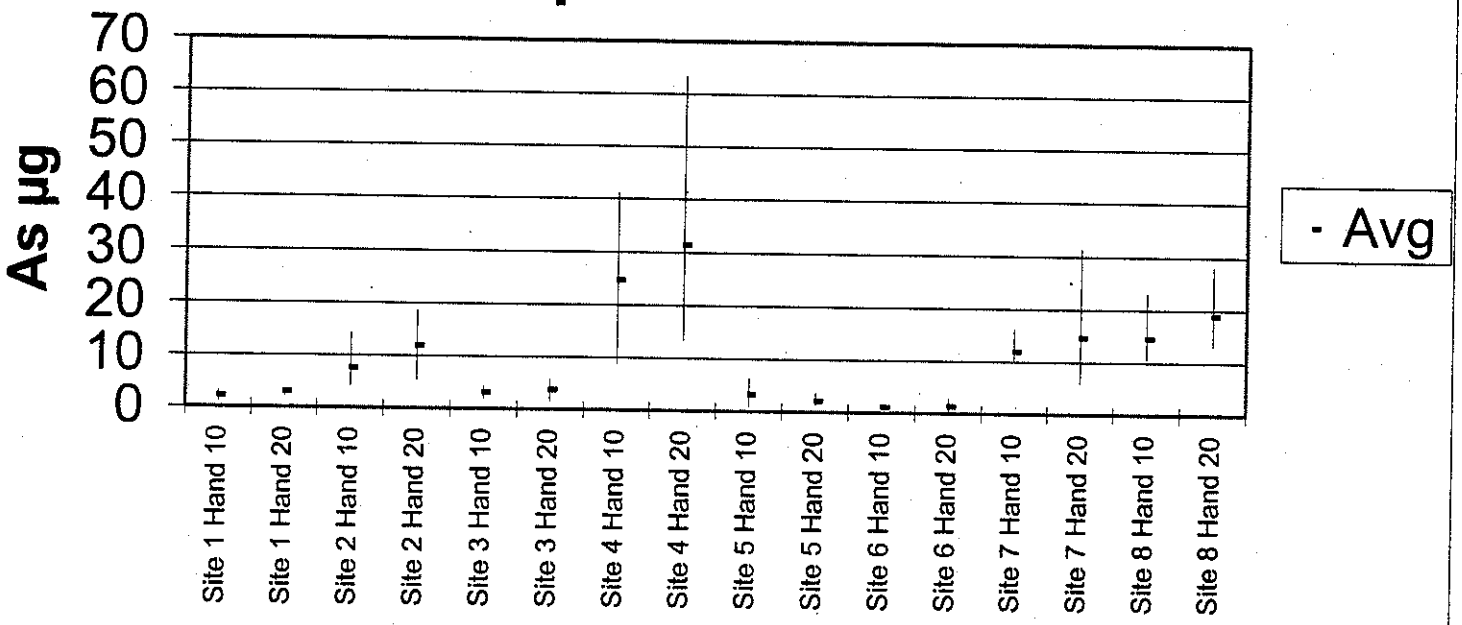
2. The 20-cycle hand wipe generally picked up only slightly more dislodgeable As than the 10-cycle hand wipe for the same board.

Figure 24. Comparison of Dislodgeable As Levels Using Wet Polyster (WP) and Dry Polyster(DP) Cloth on Decks



The range between the minimum and maximum values of dislodgeable arsenic is displayed

Figure 25. Comparison of Dislodgeable As Levels on Hand Wipes of Decks



The range between the minimum and maximum values of dislodgeable arsenic is displayed.

Phase IV Study - Playground

Total As in CCA-Treated Lumber:

Splinter samples from each playground were taken from the surface of one board under the playground floor using a small pocketknife. The splinter samples were digested in nitric acid and analyzed using inductively coupled plasma atomic emission spectroscopy (ICP) for As.

Dislodgeable As:

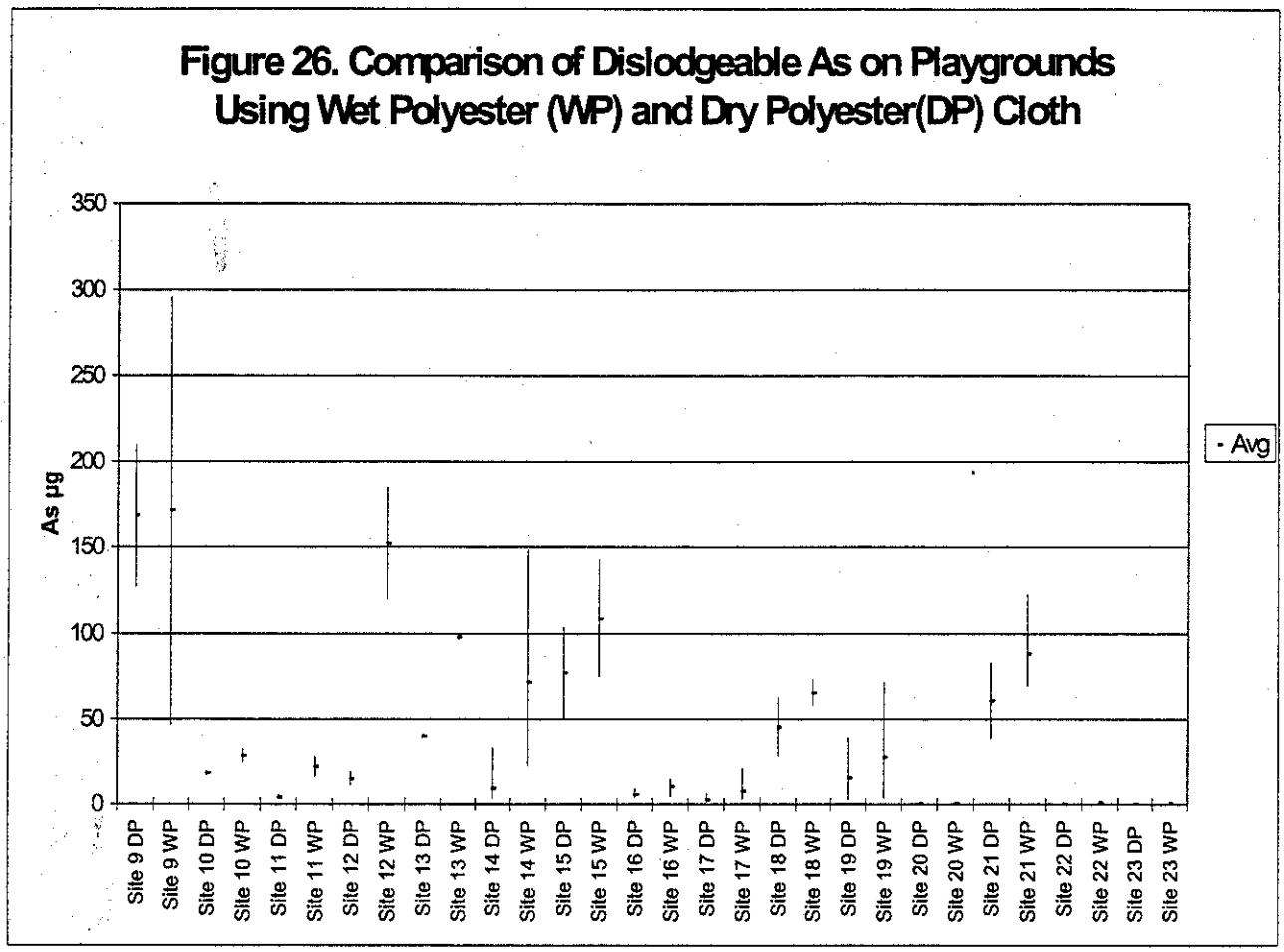
The primary wipe method conducted by the CPSC Chemistry Division Staff (LSC) involved using a 1.1-kilogram (kg) disk that is 8 centimeters (cm) in diameter, as described in attachment (B). The disk face was covered with a surrogate material and attached to an aluminum template. The template allows the user to slide the covered disk with even pressure, back and forth over a given area with the surrogate material. Both dry and wet polyester, 4.5 inch x 4.5 inch, wipes were used as surrogates in this study. The dry polyester surrogate was chosen because it had the best correlation with the hand in the Phase III field study[2]. The wet polyester surrogate was chosen because it picks up the most As during rubbing, and would be useful for evaluating boards with low amounts of dislodgeable As. On each playset, four boards were chosen for wiping based on what staff estimated to be those with varying sun exposure. For example, when possible two boards exposed to sun and two boards not exposed were tested. If the play set location or design did not allow for this board selection, boards were chosen that were convenient for the CPSC staff to access. Each board was wiped with one wet wipe and one dry wipe. The board areas to be wiped were adjacent to each other and labeled section "SA" and section "SB". The four-board sample scheme was adjusted to accommodate the short board play sets. For short boards only one sample wipe could be performed per board. The adjacent parallel board was sampled to complete the wet/dry wipe sample scheme. After rubbing the boards, the wipes were removed from the disk and placed in test tubes for extraction. The test tubes were filled with 20mL of 10% nitric acid and heated over night (approximately 15-24 hours, generally done 16 hours) in a water bath at 60°C.

Results

The results of the lumber splinter analyses are contained in Table 2 of attachment (C). The 20mL-wipe extracts were analyzed for As using ICP. Table 3 of attachment (C) contains the wipe results. Figure 26 compares the As levels found on the wipes for each playground. The results of this study showed the following:

1. The dislodgeable As playground results for the wet and dry polyester wipes are similar to the results of previous studies with old and new individual board samples tested in the laboratory and finished outdoor decks[1].

2. The wet polyester wipes picked up more dislodgeable As than the dry polyester wipes.



The range between the minimum and maximum values of dislodgeable arsenic is displayed.
Note: Playgrounds S20, S22, and S23 did not contain CCA-treated wood.

REFERENCES

1. Memorandum to Patricia Bittner (HS), from David Cobb (LSC) *Chromated Copper Arsenic (CCA) CCA-treated Wood Analysis* Jan 2003, U.S. Consumer Product Safety Commission
2. Memorandum to Patricia Bittner (HS), from Mark Levenson (EPI) *Statistical Analysis of CCA Wood Study Phase III: The Field Study* Jan 2003, U.S. Consumer Product Safety Commission

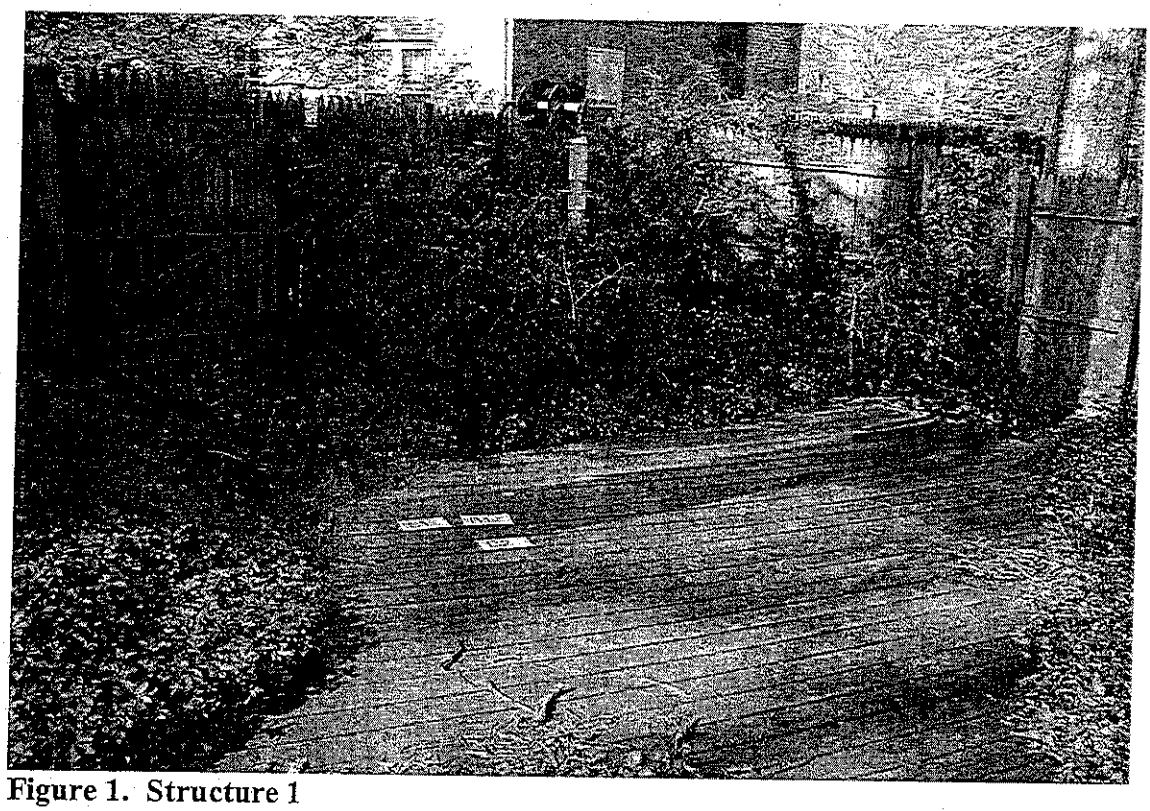


Figure 1. Structure 1

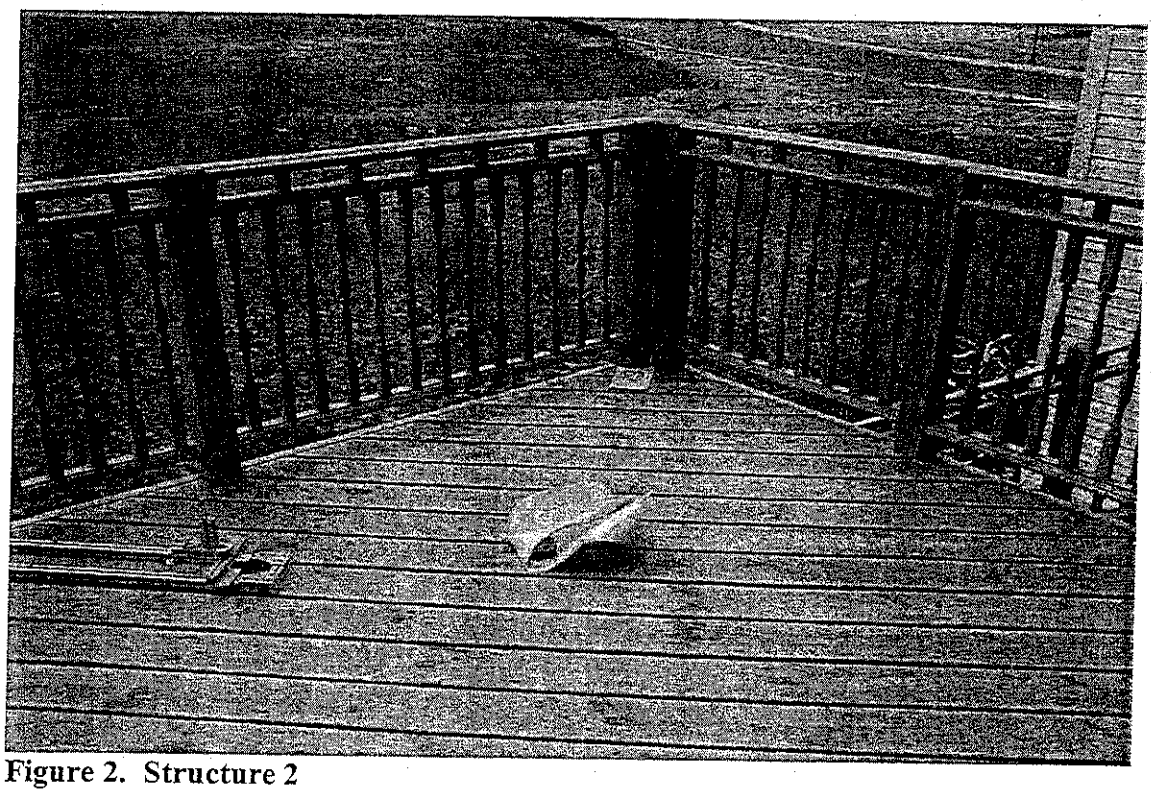


Figure 2. Structure 2

Figure 3. Structure 3

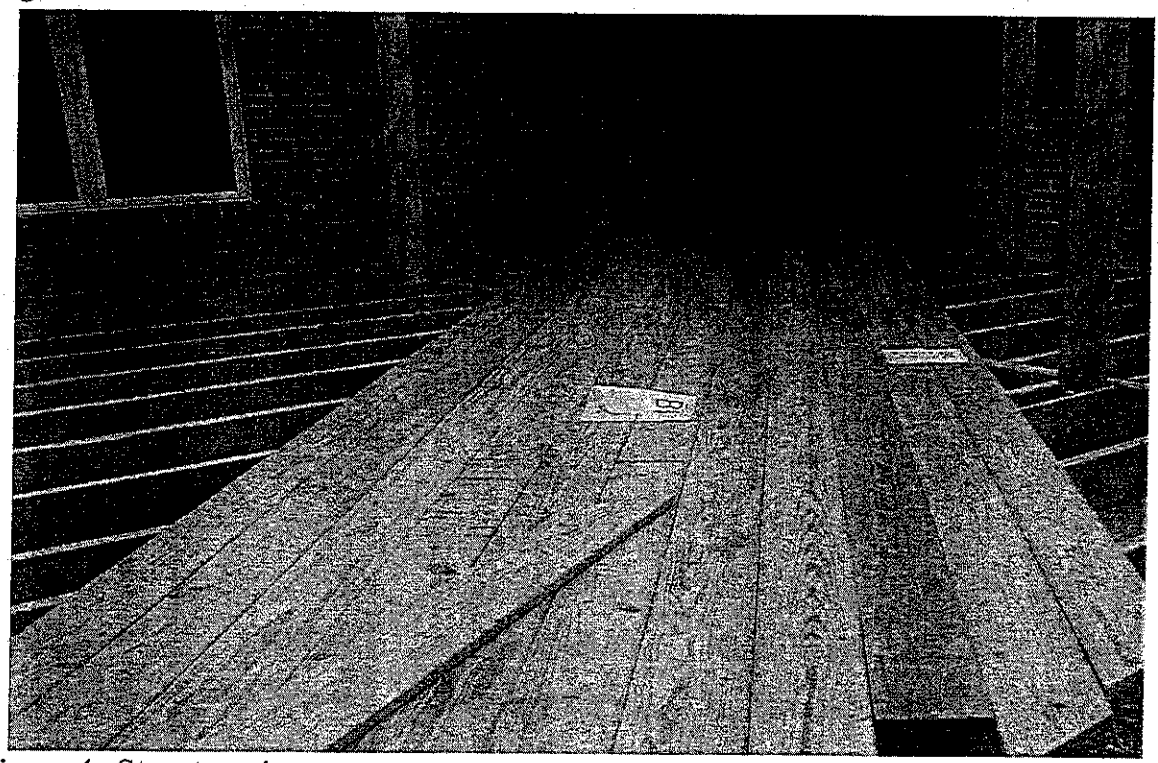


Figure 4. Structure 4

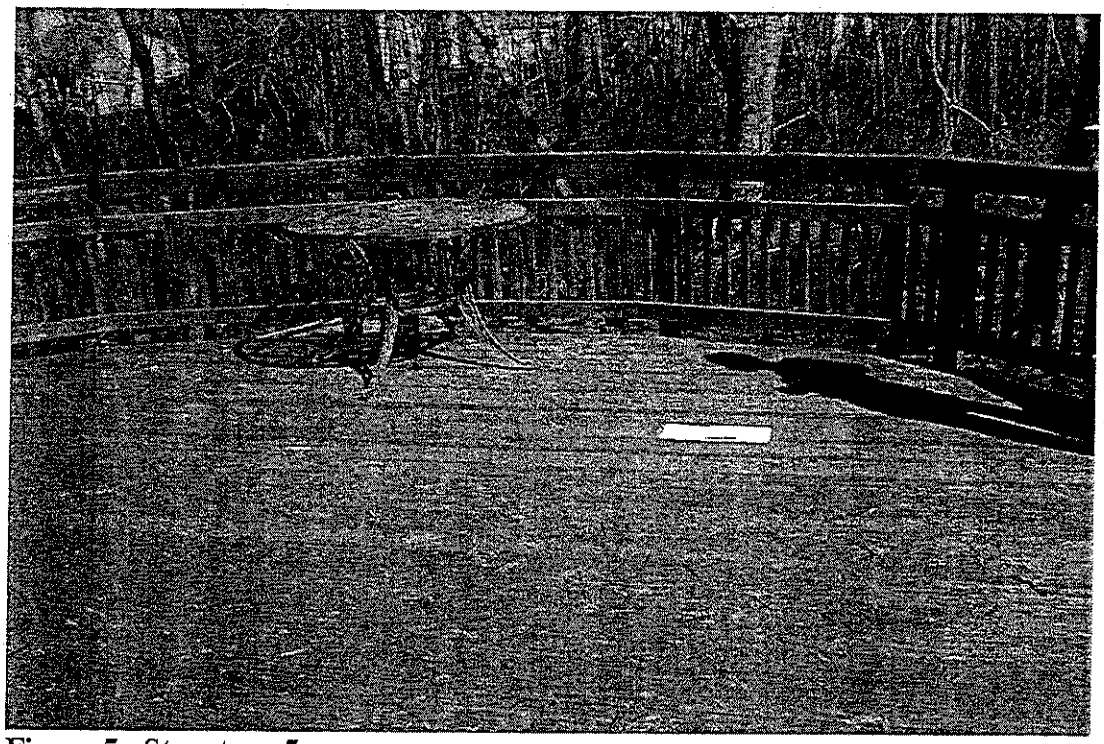


Figure 5. Structure 5

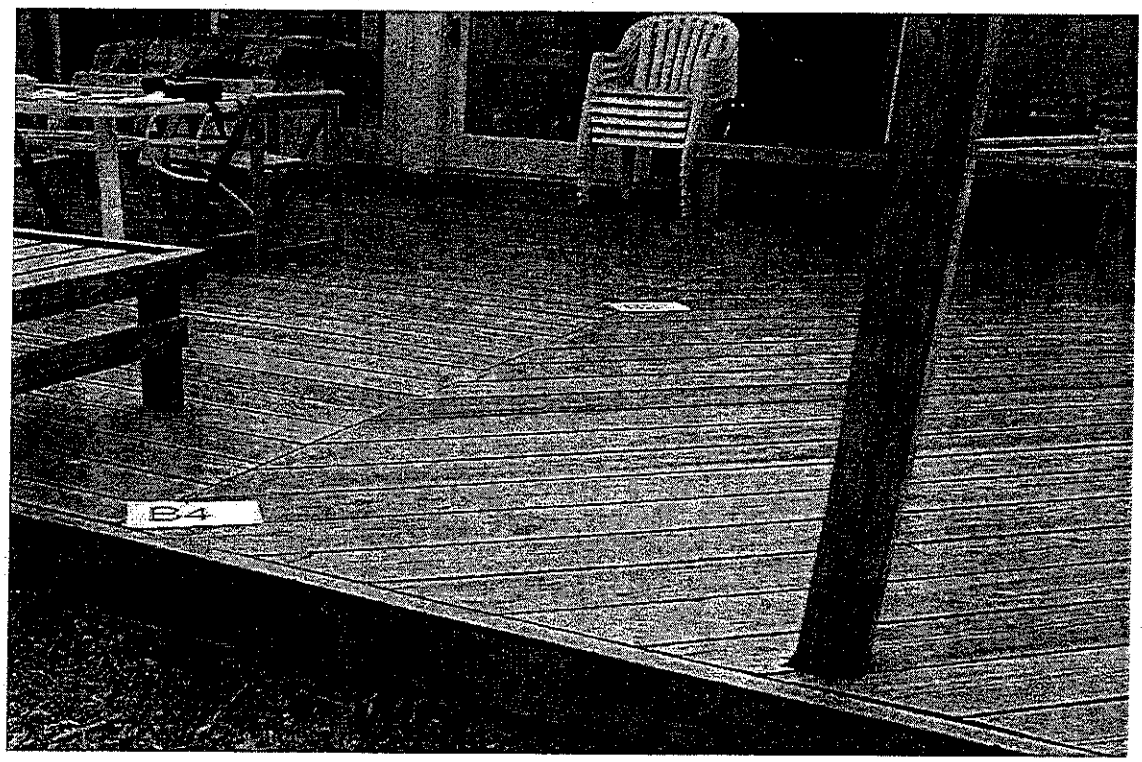


Figure 6. Structure 6

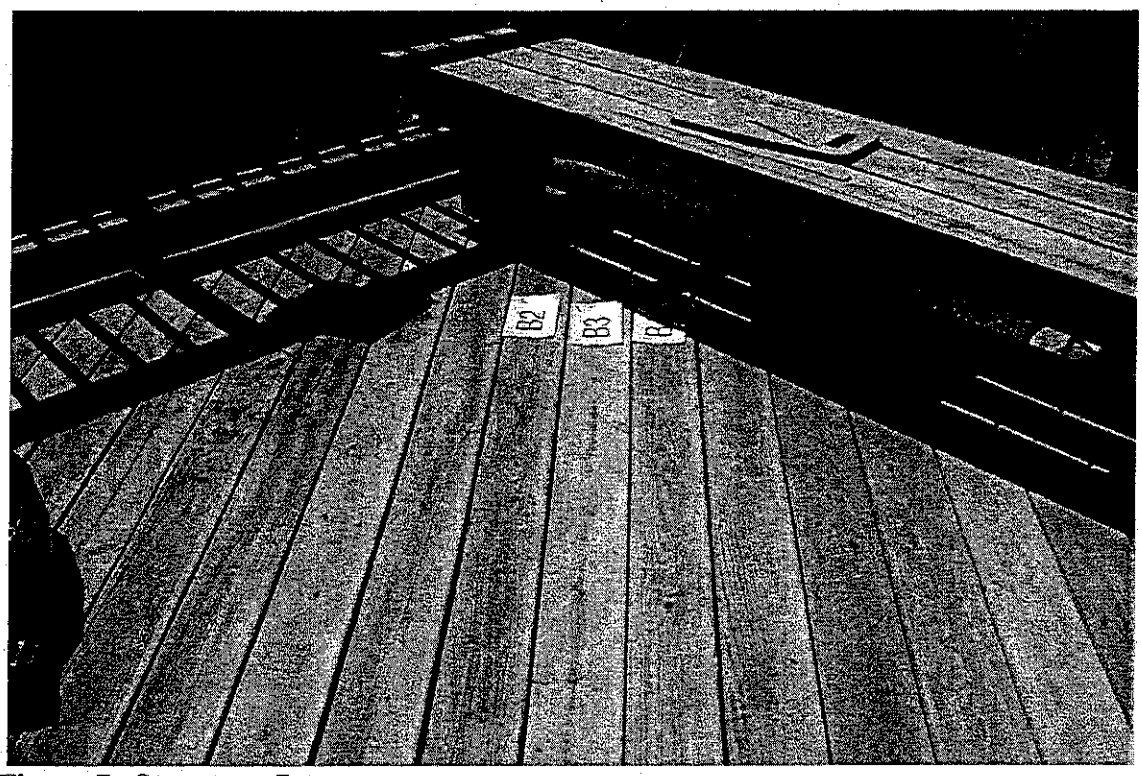


Figure 7. Structure 7

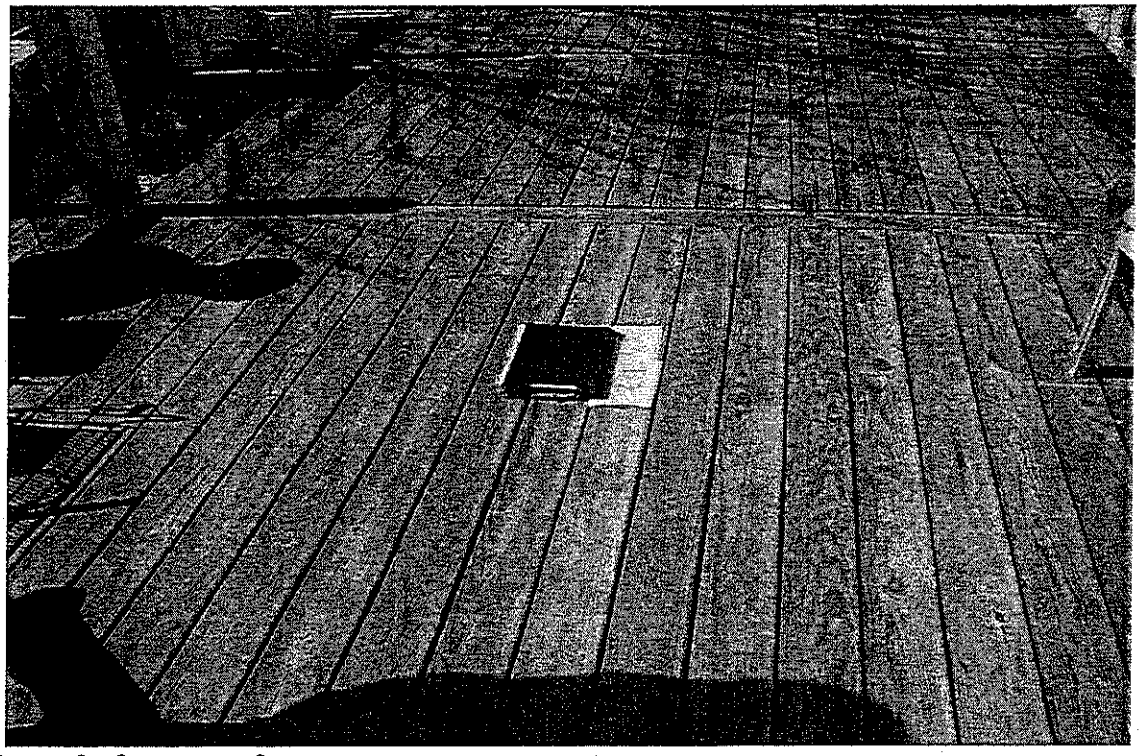


Figure 8. Structure 8

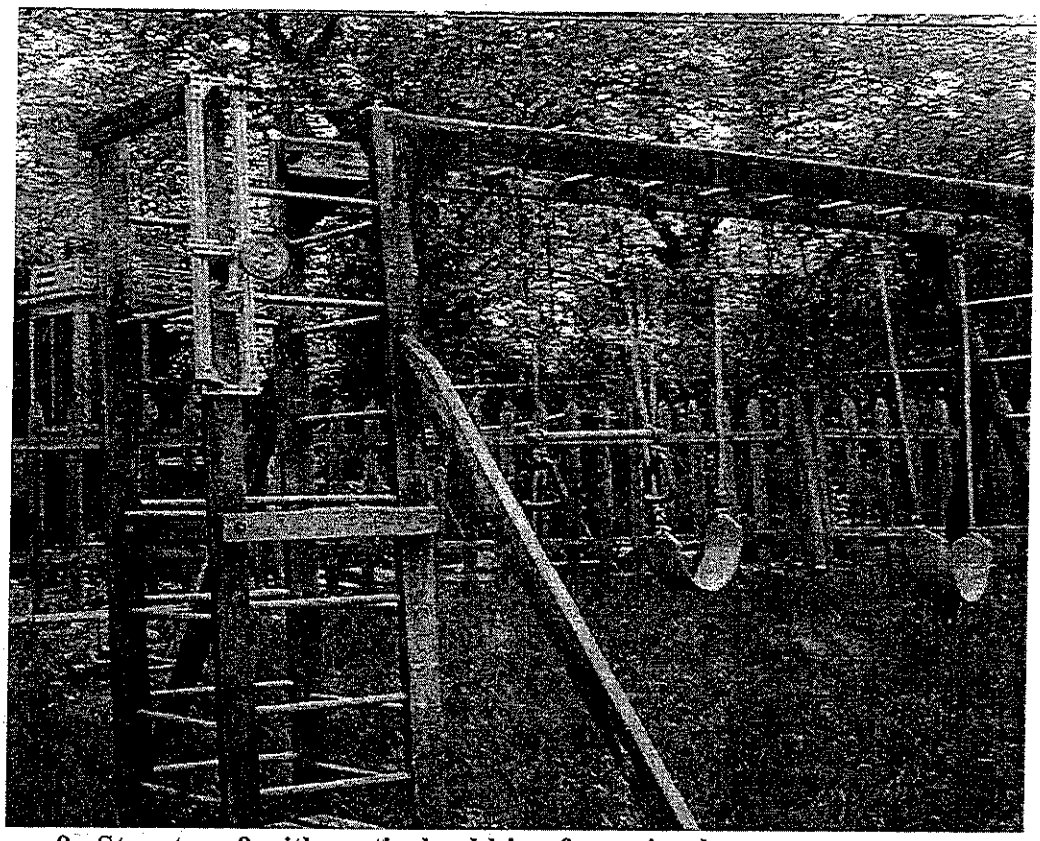


Figure 9. Structure 9 with vertical rubbing frame in place

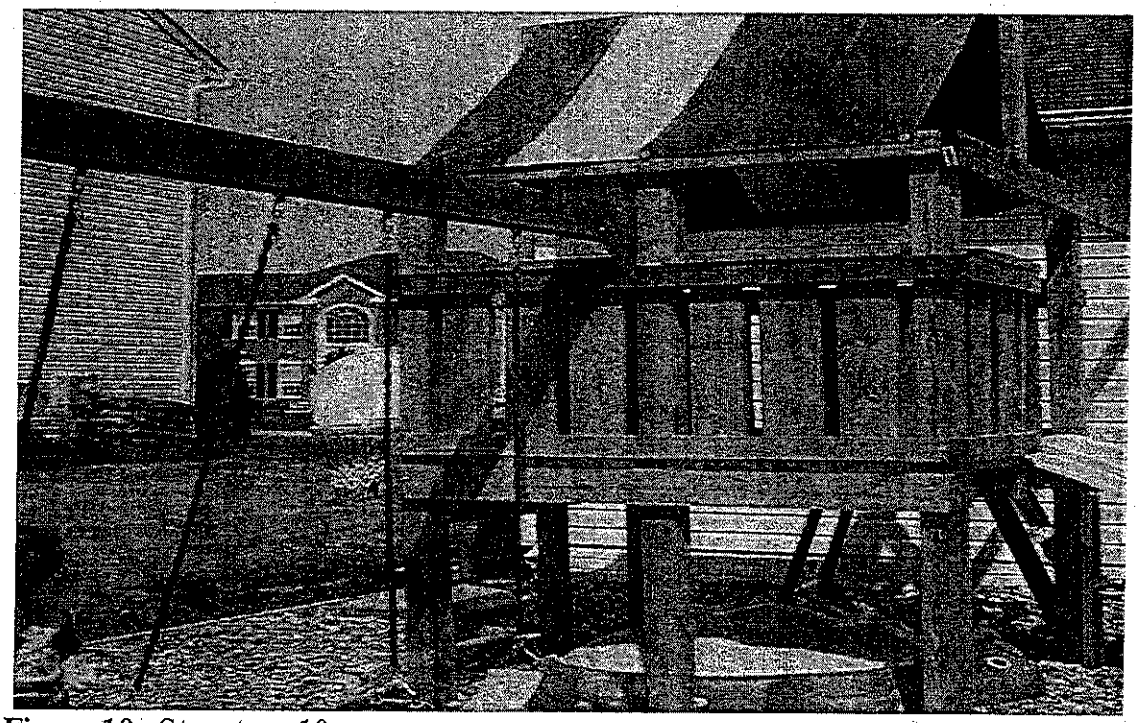


Figure 10. Structure 10

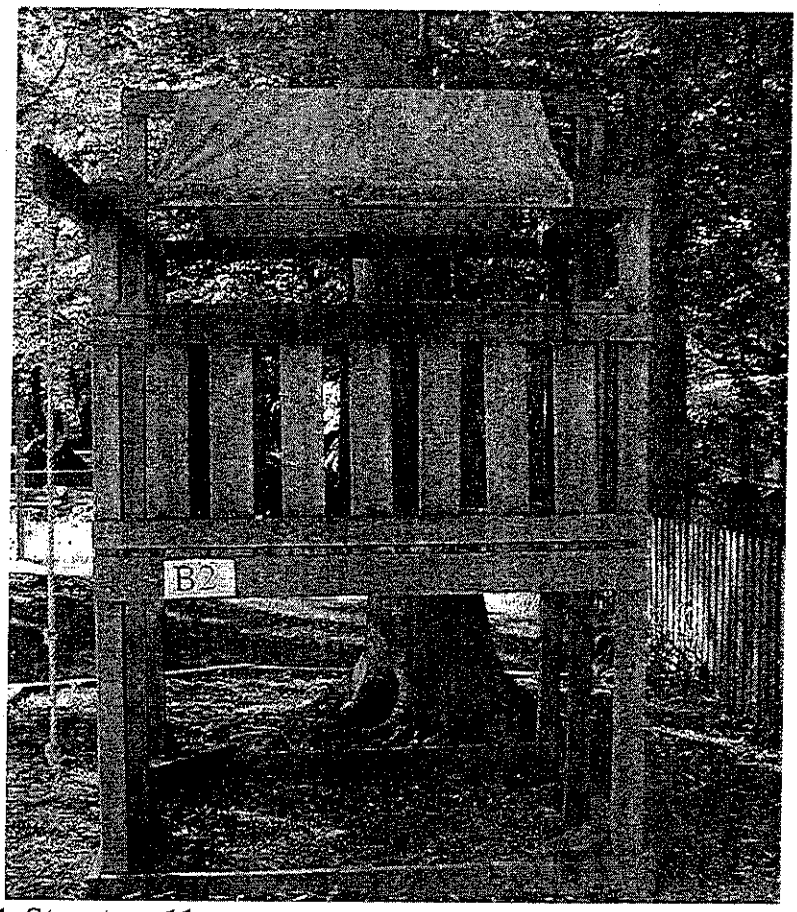


Figure 11. Structure 11

Figure 12. Structure 12

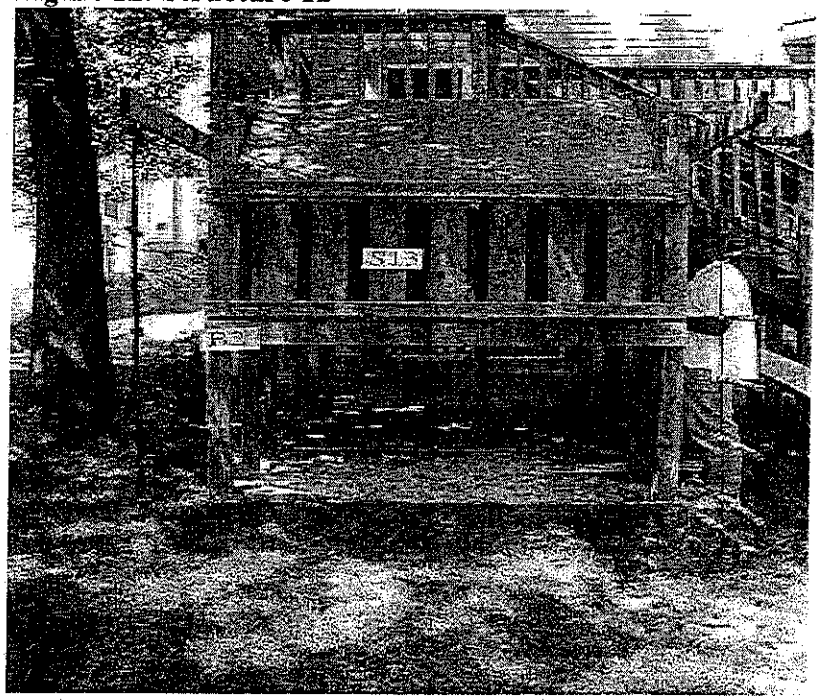


Figure 13 Structure 13

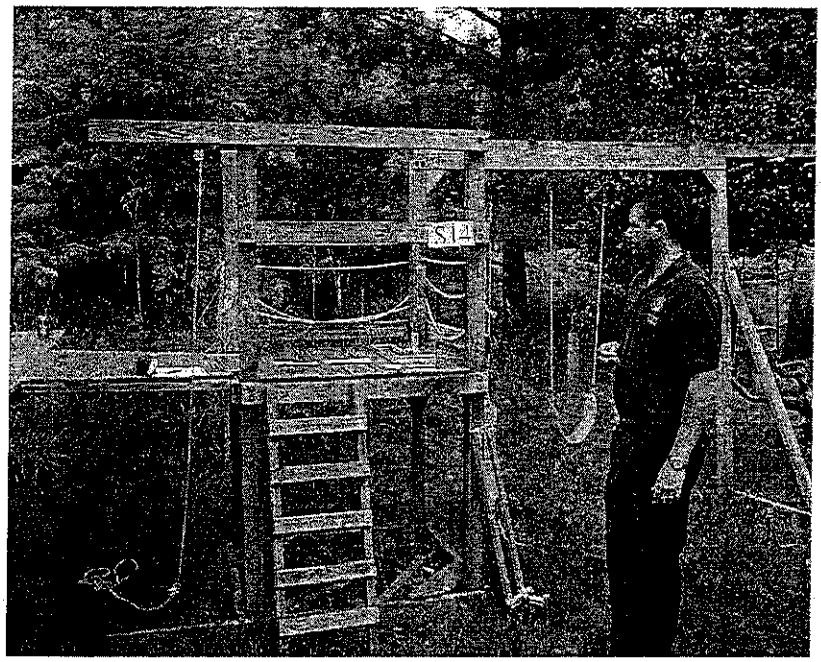


Figure 14. Structure 14

Figure 15. Structure 15

Figure 16. Structure 16

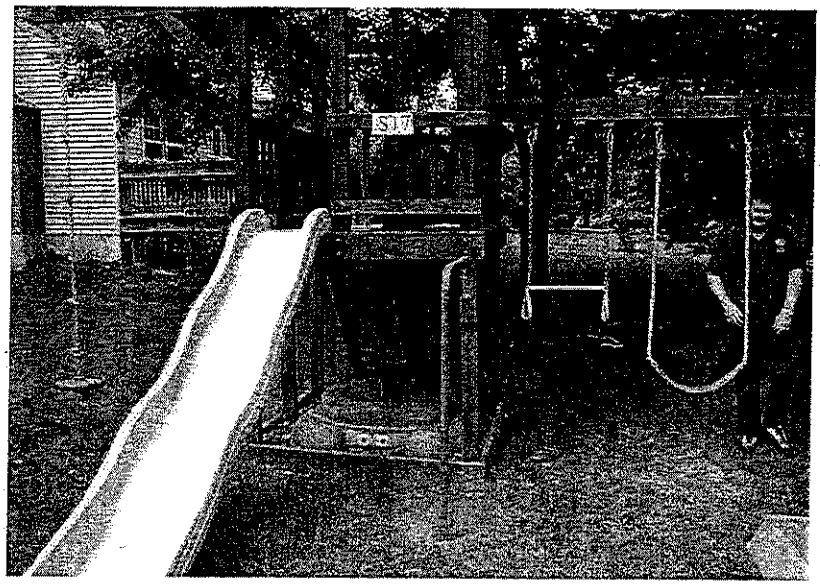


Figure 17. Structure 17

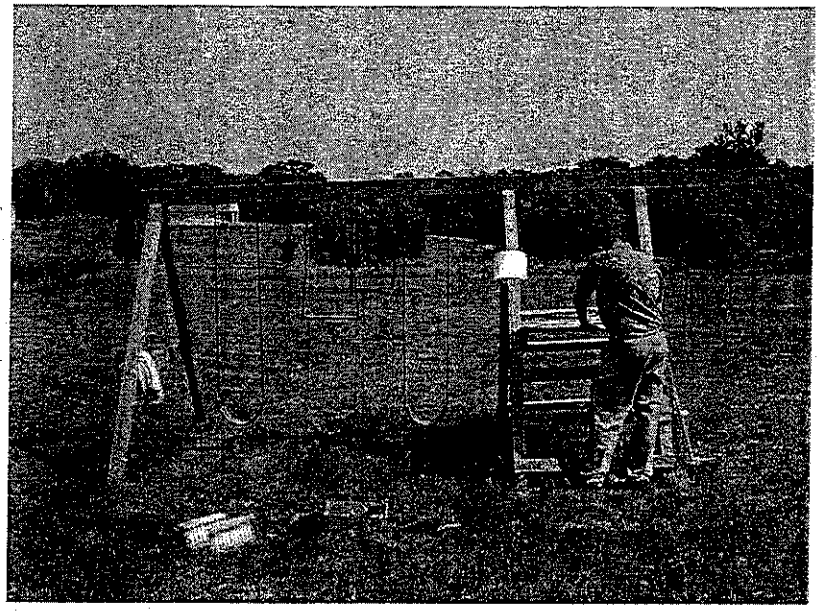


Figure 18. Structure 18

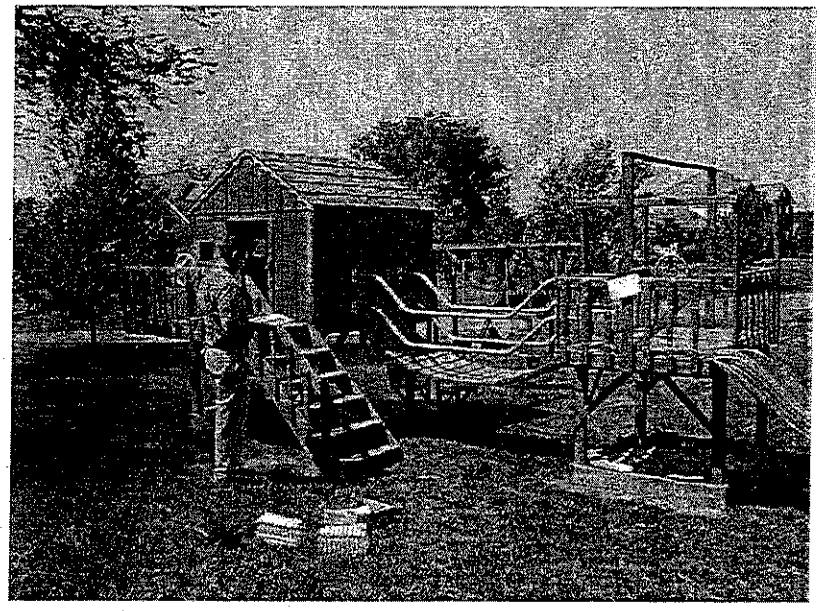


Figure 19. Structure 19

Figure 20. Structure 20

Figure 21. Structure 21

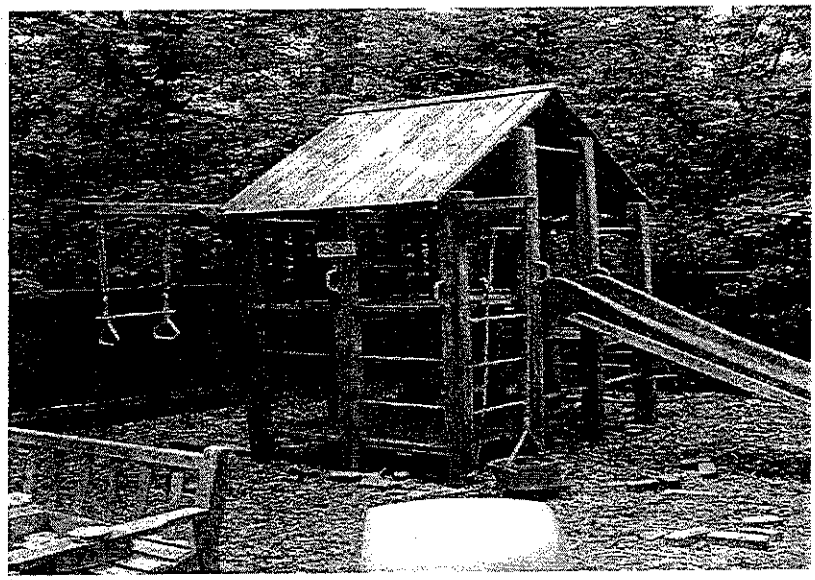


Figure 22. Structure 22

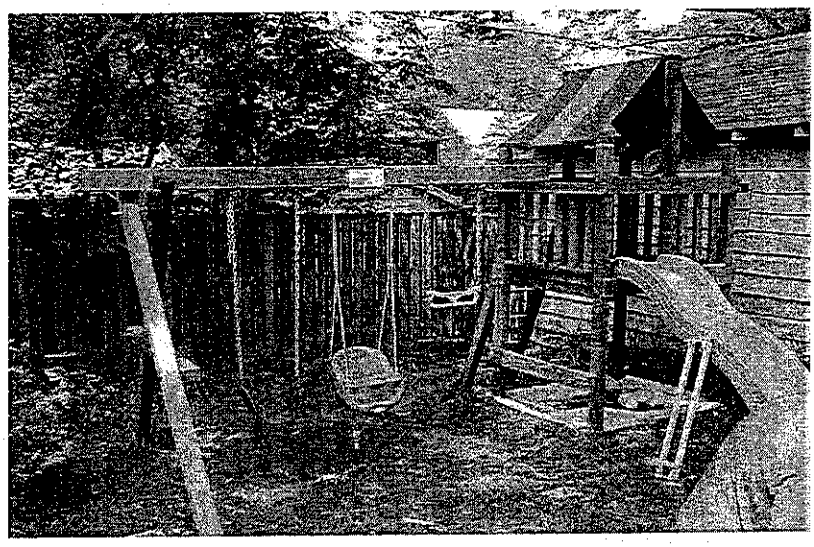


Figure 23. Structure 23

Experimental Methodology for the Collection and Analysis of Surrogate and Hand Wipes on CCA-Treated Wood

Definitions

1. Instrument Detection Limit (IDL) - 3 times standard deviation of 10 replicate measurements of reagent blank. The IDL determined is as follows:
   a. As = 0.01 ppm
2. Method Detection Limit (MDL) - Reagent blank fortified with 2-3 times the IDL. Seven replicate measurements are made. Calculate the MDL as follows:
   MDL = t X S, t =3.14 (99% confidence level for 7 replicates), S = standard deviation
   The MDL was determined (to the nearest hundredth ppm) to be:
   a. As = 0.02 ppm
3. Laboratory Reagent Blank (LRB) – Polyester wipe or other surrogate material treated with the same extraction procedure as samples. LRB data are used to assess contamination from the laboratory environment.
4. Calibration Blank – Deionized water acidified with nitric acid (10 ml concentrated nitric acid diluted to 100 ml with deionized water).
5. Stock Standard Solution - 1000 ppm solution of analyte purchased from reputable commercial source, used to prepare calibration standards. Replaced before expiration date.
6. Calibration Standards - Solutions containing 0.25, 1, 5, and 10 ppm of As in 10% nitric acid matrix. Calibration standards shall be prepared weekly.
7. Laboratory Performance Check Solution (LPC) – A solution of the analytes of interest used to evaluate the performance and stability of the instrument system. The 5 or 10 ppm calibration standard is generally used.
8. Quality Control Sample (QCS) – A solution of the analytes of interest used to evaluate the performance of the instrument system. QCS is obtained from a commercial source external to the laboratory.
9. Laboratory Fortified Blank (LFB)- Polyester wipe or other material used in wiping experiments to which known quantities of method analytes are added in the laboratory. The LFB is extracted and analyzed exactly like a sample. Its purpose is to determine whether method performance is within acceptable control limits. The LFB will be spiked with 100 µg of As.

Materials: The materials used for sampling are as follows:

1. Polyester – TEXWIPE, TX 1009 Alpha Wipe, 9"x9"
2. 1.1 kg steel rubbing disk, 8 cm in diameter
3. Vertical Horizontal Wiper
4. Parafilm®

Reagents: Reagents used are as follows:

1. Nitric Acid, Trace Metal Grade
2. Acetic Acid, Trace Metal Grade

Surrogate Sample Collection: The sample collection procedures that CPSC staff follow to collect wipe samples of CCA-treated wood found in playgrounds, decks, or boards are as follows:

1. Cover the rubber-coated side of the 1.1 kg steel rubbing disk with a clean piece of Parafilm®. Place the wetted polyester wipe or other designated surrogate wipes over the Parafilm®. The wet polyester surrogate wipes are prepared by wetting a 4.5"x4.5" cut section of polyester with 0.9% saline solution until the weight of the wipe approximately doubles. The dry polyester surrogate wipes are prepared by cutting 4.5"x4.5" sections of the polyester fabric. Secure the wipe to the disk with a rubber band, and hose clamp. Ensure that the wipe is smoothly stretched over the disk. See Figure 1 and 2.
2. Attach wipe covered rubbing disk to the lower arm of vertical/horizontal wiper. Secure the wiper to the section of wood to be rubbed. Using c-clamps to attach the wiper to the board can do this. See Figure 3.
3. *Horizontal Sampling:* Place the wipe covered rubbing disk at one end of the wiper. Slide the rubbing disk along tracks of wiper forward and back for 5 strokes. A stroke in this instance is one forward and back movement of the wipe covered disk. Lift the rubbing disk from the board, rotate 90°, and slide disk forward and back 5 more strokes, for a total of 10 strokes. The area rubbed is 400 cm^2 (8 cm x 50 cm).
4. *Vertical Sampling:* Place the wipe covered rubbing disk at bottom of the wiper. Attach 1.25 kg weight to upper arm of wiper. See Figure 4. The 1.25 kg weight will exert approximately 1.1 kg force on the wipe covered disk in the vertical position. Slide the disk along tracks of wiper forward and back for 5 strokes. Pick the disk from the board, rotate 90°, and slide disk forward and back 5 more strokes, for a total of 10 strokes. The area rubbed is 400 cm^2 (8 cm x 50 cm).
5. Remove the wipe from the disk. Place wipe in a test tube, cover with screw cap, seal with sample label.

Extraction/Digestion: The extraction procedure shall be started within 72 hours of receiving wipe samples. The procedure is as follows:

1. Add 15 ml of 10% nitric acid to test tubes containing rubbed wipes. Cover securely to minimize evaporation.
2. Place tubes in 60°C heated shaker bath overnight (approximately 15-24 hours, generally done 16 hours). Remove test tubes from water bath, and let cool to room temperature (>15C). An LRB and LFB shall be put through extraction analysis process with each batch of samples.
3. Vortex test tubes prior to analysis to ensure mixing. The wiping material remains in the test tube throughout the extraction and analysis process.

Hand Wipe Sample Collection: The sample collection procedures that CPSC staff follow to collect hand wipe samples of dislodgeable CCA treated wood found in playgrounds, decks, or boards tested in laboratory are as follows:

1. Prior to each hand rub, the volunteer washes his or her hands with soap and water.

2. Rinse the hand to be used for the rubbing with 100 ml of deionized water, and collect as the pre-rub rinse sample. Dry the hand.
3. The volunteer rubs the 700 cm^2 (14 cm x 50 cm) designated board section for 10 strokes. Place a 1.1 kg disk is on top of the hand during the rubbing in order to maintain a constant pressure. The hand is oriented diagonally across the width of the board so that the whole surface area of the palm of the hand covers the board.
4. After the rubbing rinse the hand with 100 ml of 5% acetic acid, wipe with a polyester wipe that has been wetted with 5% acetic acid, and rinse again with 100 ml of 5% acetic acid. Combine the rinse, wipe, and second rinse as one sample. Repeat the rinse wipe rinse procedure a second time, and combine to produce a second sample.
5. Transfer the samples from the hand rubs to beakers, and evaporate to dryness at room temperature in a fume hood.
6. Transfer the dry wipes to a test tube, rinse the beakers with 5 ml of 10% nitric acid and transfer to the same test tube as the sample wipe. Repeat the rinse procedure of the beaker 3 times until the final volume transferred to the test tube is 20 ml.
7. Cover the test tubes containing the wipes and 20 ml of 10% nitric acid and place in 60°C heated waterbath overnight.
8. Vortex test tubes prior to analysis to ensure mixing. The wiping material remains in the test tube throughout the analysis process.

ICP Operating Procedures and Quality Control Measures

Analysis

1. Perform wavelength calibration daily. This can be done prior to igniting plasma. An internal mercury source lamp is used for the wavelength calibration.
2. Ignite plasma. Set conditions as follows:
   a. R.F. power = 1150 watts
   b. Auxiliary flow = 15 liters/minute
   c. Nebulizer flow = 30.06 psi
   d. Pump rate = 100 rpm
   e. Purge time = 10 seconds
3. Allow the instrument to become thermally stable before beginning. This requires at least 30 minutes of operation prior to doing peak search for the analytes of interest.
4. The following elements and wavelengths (nm) are selected:
   a. As 189.042, and 193.759
5. Perform peak search using 10 ppm standard to ensure optimum setting.
6. Perform calibration using the calibration blank and standards. Calibration shall be performed a minimum of once a day when used for analysis, or each time the instrument is set up. Results for each standard shall be within 5% of the true value. If the values do not fall within this range, recalibration is necessary.

7. Analyze the QCS immediately after calibration. The analyzed value of each analyte should be within ±10% of the expected value. If analyte values are outside the ±10% limit, recalibration is required.
8. Analyze the LPC following QCS analysis, after every tenth sample, and at the end of the sample run. The analyzed value of each analyte should be within ±10% of its expected value. If an analyte value is outside the interval reanalyze the LPC. If the analyte is again outside the ± 10% limit, recalibrate the instrument, and all samples following the last acceptable LPC solution should be reanalyzed.
9. Potential spectral interferences for As are detected by observing the scans during analysis and by analyzing 2 emission lines for each element. If results for the two emission lines for a particular element differ by more than 10%, spectral interferences should be suspected. Observe the wavelength scans for each emission line. If peak overlap or high background is observed for one element emission line and not the other, spectral interference should be suspected for that emission line. Use results for the emission line that does not show peak overlap or high background.
10. At least one LRB must be analyzed with each sample set. If an analyte value in the LRB exceeds 2 times its determined MDL, then laboratory or reagent contamination should be suspected. The source of the contamination should be identified and resolved before continuing analyses.
11. At least one LFB will be analyzed with each batch of samples. Calculate accuracy as percent recovery. Analyte recoveries should be within ±20%. If recoveries are outside this limit, source of the problem should be identified and resolved before continuing analyses.
12. Dilute any samples that have analyte values exceeding 1.5 times the high calibration standard, or 15 ppm. Reanalyze.

Calculation

Average results for the two element emission lines for every sample in which results are within the 10% differential limit. If spectral interferences are observed, then calculate results in accordance with paragraph 9 of the above section "Analysis". Results will be reported as total µg and are calculated as follows:

c= concentration of analyte found in extract, ppm (µg/ml)
v= volume extract
d = dilution factor
Total analyte, as µg = 100cvd.

Hand Results

The results of the 2 rinse/wipe/rinse samples for each board section shall be combined and reported as total dislodgeable As.

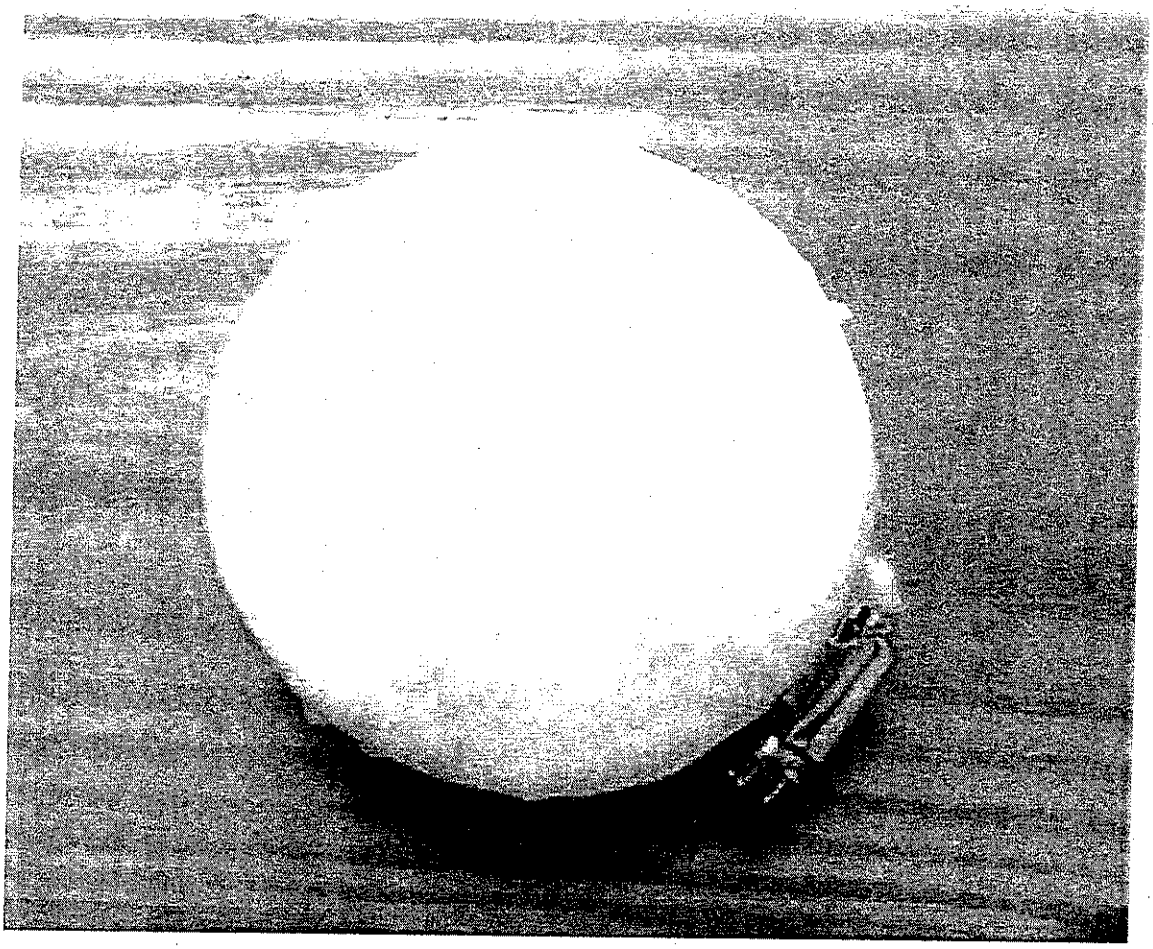


Figure 1 Polyester Covered Disk

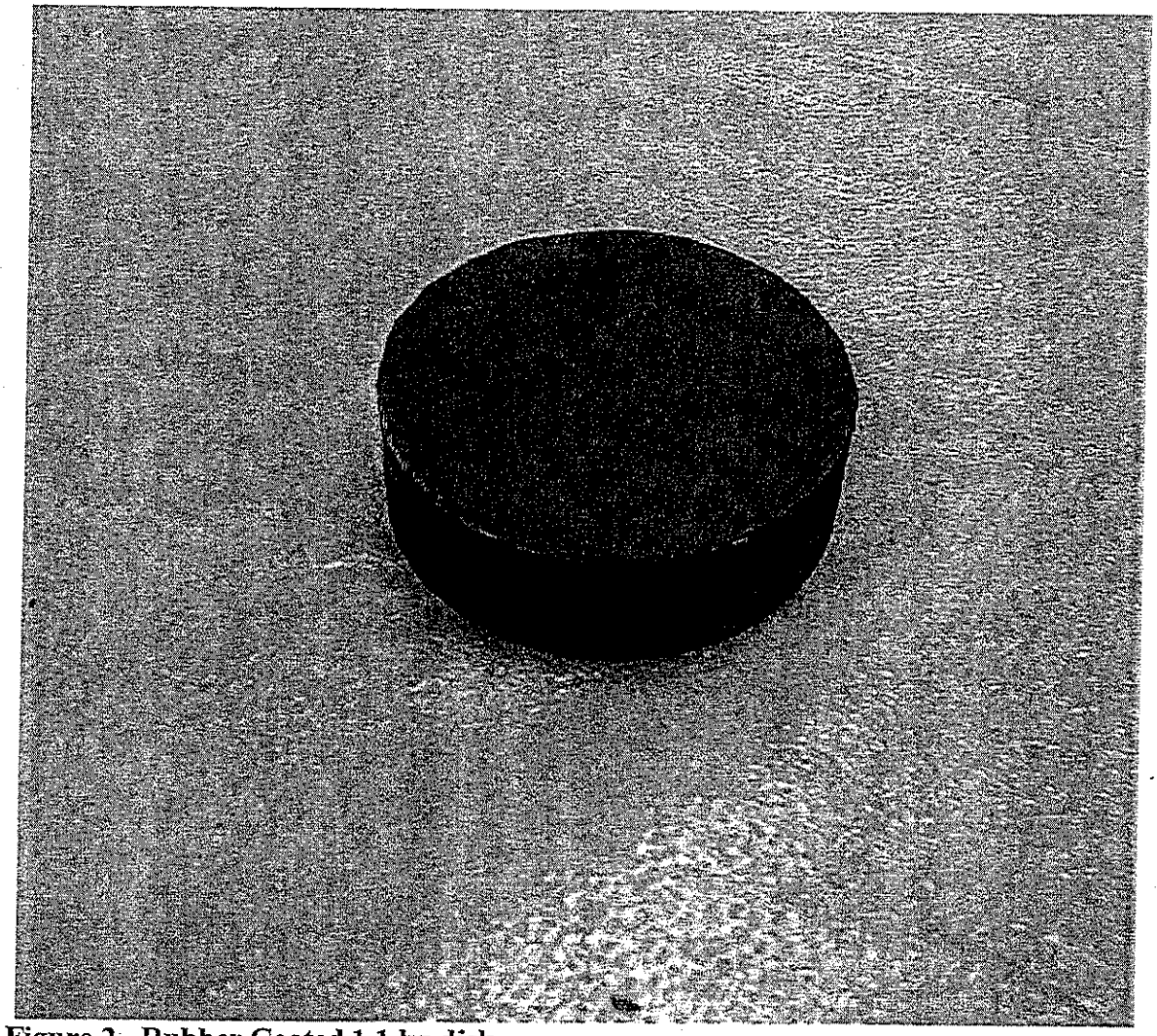


Figure 2. Rubber Coated 1.1 kg disk

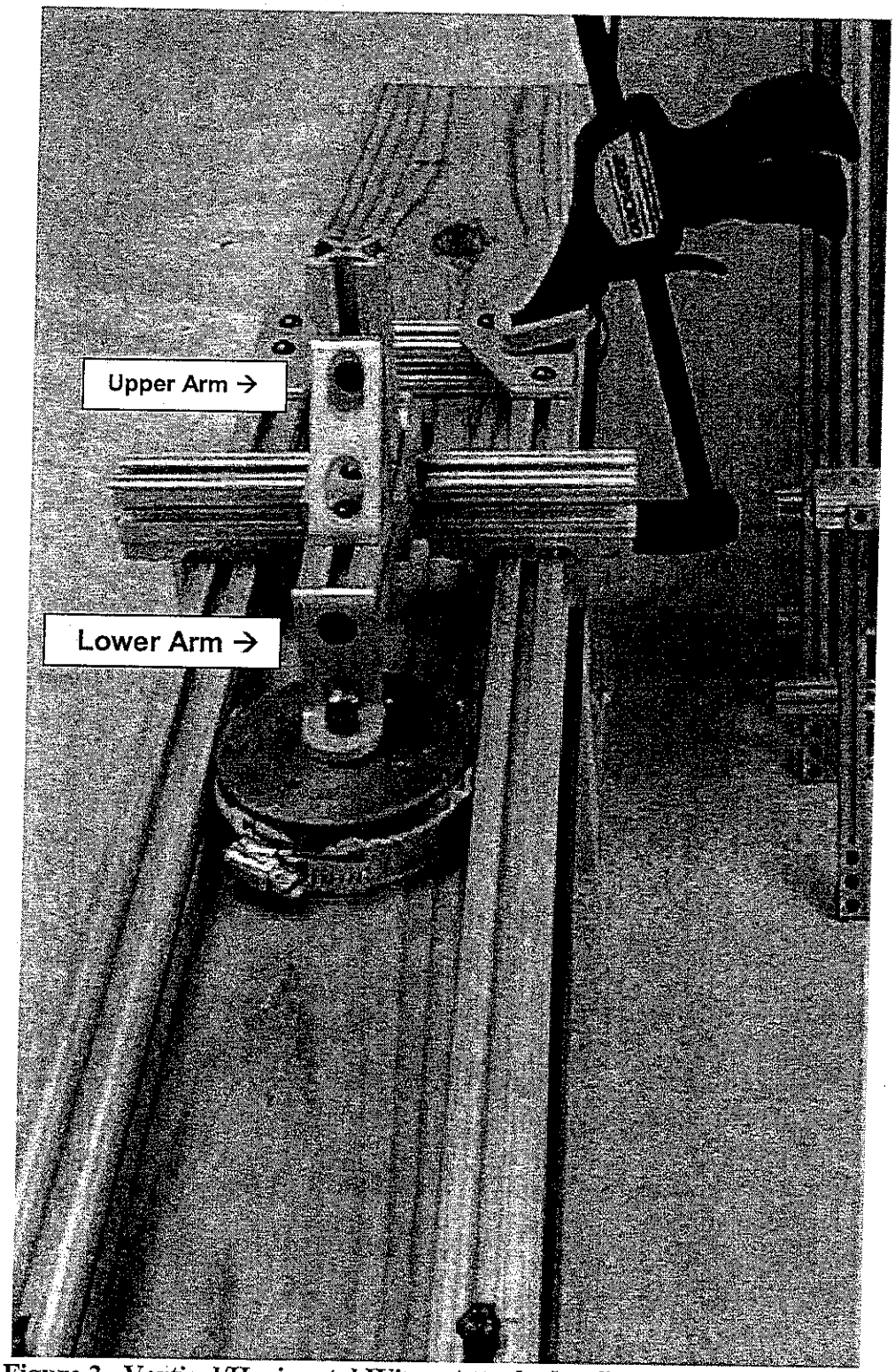


Figure 3. Vertical/Horizontal Wiper Attached to Board with C-Clamp

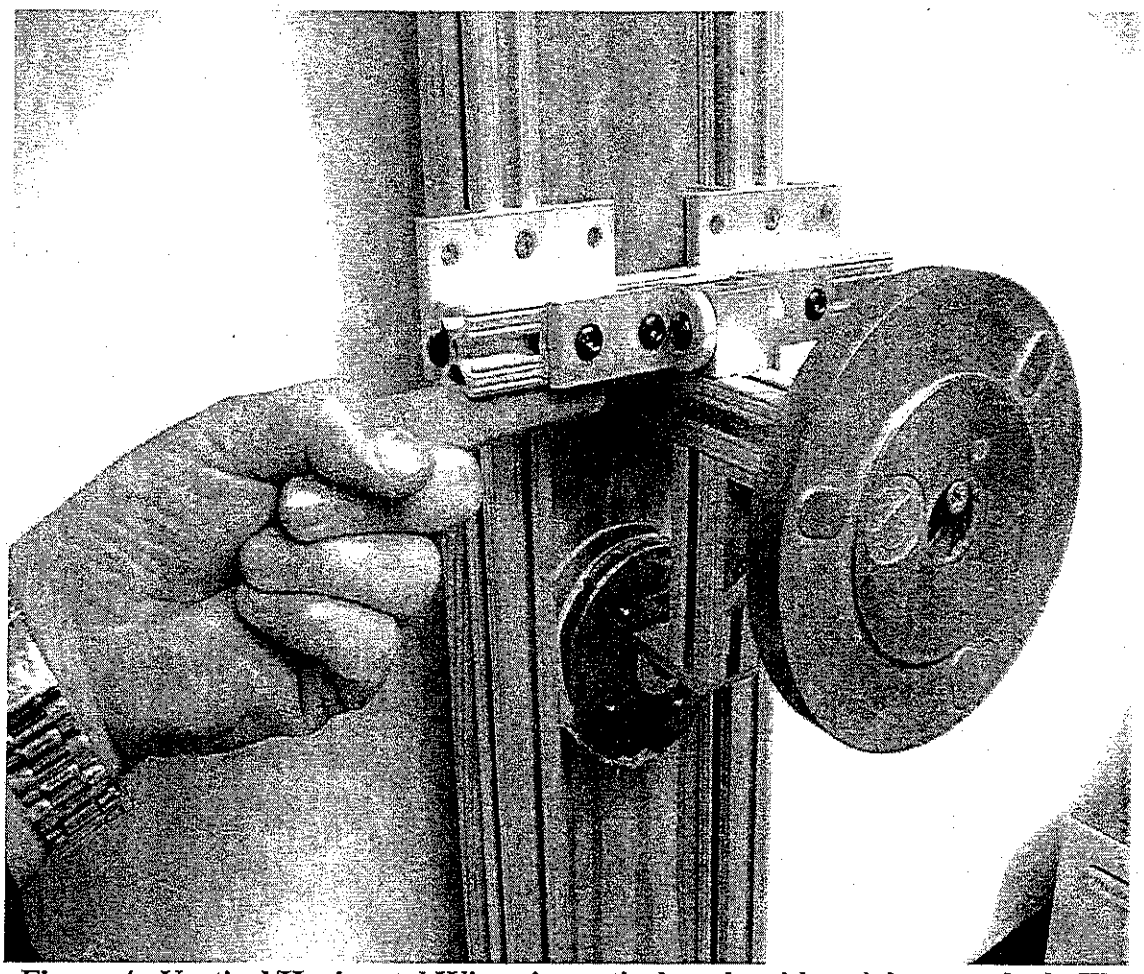


Figure 4. Vertical/Horizontal Wiper in vertical mode with weights attached. The disk is moved across board by pushing t-bar as demonstrated above.

Table 1. Dislodgeable As Levels on on CCA-Treated Wood - Decks

			Hand (µg)		Surrogate (µg)	
Structure	Board	Volunteer	10 Cycle	20 Cycle	Wet Polyester	Dry Polyester
1	1	2	2.8	3.6	35.7	14.1
1	2	5	1.2	2.2	50.7	13.1
1	3	2	1.6	3.0	36.3	9.8
1	4	5	3.2	3.0	34.4	10.2
2	1	4	4.2	5.4	32.7	21.5
2	2	6	7.4	13.0	22.7	42.2
2	3	4	4.6	11.0	23.0	38.3
2	4	6	14.2	18.6	57.9	38.6
3	1	3	2.0	3.6	297.0	53.6
3	2	8	3.2	5.8	285.8	22.4
3	3	3	2.8	1.6	119.6	21.3
3	4	8	4.4	3.8	123.5	37.2
4	1	1	16.0	28.4	145.4	116.1
4	2	7	8.8	13.4	137.6	77.3
4	3	1	41.0	63.4	515.3	160.5
4	4	7	32.8	20.2	205.5	102.6
5	1	2	4.8	3.6	5.3	3.0
5	2	5	1.4	1.6	9.5	2.0
5	3	2	6.3	1.4	7.2	2.9
5	4	5	0.8	1.6	3.9	1.2
6	1	4	1.0	1.2	41.7	16.5
6	2	6	1.2	1.0	7.2	0.8
6	3	4	1.2	0.4	12.6	2.9
6	4	6	0.8	3.0	19.2	8.3
7	1	1	10.2	6.0	107.6	75.6
7	2	7	10.6	12.4	43.8	43.4
7	3	1	16.2	31.4	143.3	128.7
7	4	7	11.0	8.8	77.4	29.9
8	1	3	10.6	13.2	94.2	86.3
8	2	8	12.6	28.1	93.6	82.5
8	3	3	12.0	17.8	50.9	40.7
8	4	8	23.0	16.4	70.7	56.1
Mean			8.6	10.9	91.0	42.5
Median			4.7	5.6	50.8	33.6
Minimum			0.8	0.4	3.9	0.8
Maximum			41.0	63.4	515.3	210.0

Table 2. Lumber Analysis for As %

Structure	% As
11	0.061
12	0.073
13	0.448
14	0.129
15	0.317
16	0.222
17	0.677
18	0.058
19	0.314
20	0.000
21	0.561
22	0.002
23	0.002

- As levels given in percent by weight
- Wood samples were not taken from playgrounds 9 and 10

Table 3. Dislodgeable As Levels on CCA-Treated Wood - Playgrounds

Structure	Board	Dry Polyester As µg	Wet Polyester As µg	Structure Avg Dry Polyester As µg	Structure Avg Wet Polyester As µg
9	1	210	296	**168.5**	**171.4**
9	2	127	46.8		
10	1	17.6	25.0	**18.6**	**28.8**
10	2	19.6	32.6		
11	3		28.0	**4.2**	**22.4**
11	4	5.6			
11	5		16.8		
11	6	2.8			
12	1		167	**15.4**	**146.7**
12	2		184.4		
12	3		119.8		
12	4	19.2			
12	5		115.4		
12	6	11.6			
13	3		98.0	**40.2**	**124.0**
13	4	40.2			
13	5		150.0		
14	1	4.0	68.4	**10.1**	**71.7**
14	2	5.2	148.6		
14	3	4.4	46.6		
14	4	3.6	23		
14	6	33.4			
15	1	50.6	74.8	**77.1**	**108.7**
15	2	103.6	142.6		
16	1	5.4	14.8	**5.9**	**11.2**
16	2	9.4	12.2		
16	3		13.2		
16	4	4.6			
16	5		4.4		
16	6	4			
17	1	1.6	4.8	**2.8**	**8.3**
17	2	1.6	3.0		
17	3	1.6	3.6		
17	4	6.4	21.6		
18	1	62.6		**45.6**	**65.5**
18	2		73.2		
18	3	28.6			
18	4		57.8		

Table 3. Continued					
Structure	**Board**	**Dry Poly As µg**	**Wet Poly As µg**	**Structure Avg Dry Poly As µg**	**Structure Avg Wet Poly As µg**
19	1		23.2	**16.1**	**28.1**
19	2	13.2			
19	3	9.2	13.4		
19	4	39.4	71.8		
19	5	2.6	3.8		
21	1	83	122.6	**60.8**	**88.4**
21	2	39	77.0		
21	3	43.8	84.6		
21	5	77.4	69.4		
20*	1		0.8	**0.4**	**0.7**
20*	2	0.4			
20*	3		0.6		
20*	4	0.4			
20*	5		0.8		
20*	6	0.6			
20*	7		0.6		
20*	8	0			
22*	1	0	1.0	**0.3**	**1.0**
22*	2	0.4	0.8		
22*	3	0.8	1.8		
22*	4	0	0.4		
23*	1		0.8	**0.3**	**0.8**
23*	2	0.6			
23*	3		0.8		
23*	4	0.4			
23*	5		0.8		
23*	6	0			
23*	7		0.6		
23*	8	0			
Mean As for CCA-Treated Playgrounds		**32.1**	**68.3**		
Median As for CCA-Treated Playgrounds		**12.4**	**52.3**		
Min As for CCA-Treated Playgrounds		**1.6**	**3.0**		
Max As for CCA-Treated Playgrounds		**210**	**296.0**		

* Playgrounds built with wood not treated with CCA. Results of these boards not included in mean, median, minimum, and maximum calculated at bottom of Table 3.

TAB I

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: 23 January 2003

TO : Patricia M. Bittner, M.S., Project Manager, CCA-Treated Wood in Playground Equipment, Directorate for Health Sciences

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences
Lori E. Saltzman, M.S., Division Director, Directorate for Health Sciences

FROM : Kristina M. Hatlelid, Ph.D., Toxicologist, Directorate for Health Sciences

SUBJECT : Cancer risk assessment for arsenic exposure from CCA-treated wood playground structures

Introduction

In May 2001, the U.S. Consumer Product Safety Commission (CPSC) was petitioned by the Environmental Working Group (EWG) and the Healthy Building Network (HBN) to enact a ban of CCA-treated wood for use in playground equipment and to review the safety of CCA-treated wood for general use. In June 2001, the CPSC docketed the part of the petition that requested a ban on the use of CCA-treated wood in playground equipment (66 FR 36756). The petition was docketed under provisions of the Federal Hazardous Substances Act (FHSA) 15 U.S.C. 1261-78. The second part of the petition, to review the safety of CCA wood for other uses, was not docketed as a petition for rulemaking because it would not require rulemaking to implement. Docketing is the initial step in Commission consideration of what action, if any, to take in response to the assertions in the petition.

In 1990, CPSC staff conducted a risk assessment for arsenic exposure from chromated copper arsenate (CCA) treated playground structures for its project on playground equipment (Lee, 1990a). The risk assessment considered ingestion of arsenic residue through contact with CCA-treated wood surfaces, and was based on skin cancer as the toxic endpoint. The study concluded that the majority of new playground equipment samples tested would not present a cancer risk to children. That study also found that wood that was not specifically processed for playground use could present a risk.

CCA is composed of chromic oxide, cupric oxide, and arsenic pentoxide (47.5 percent, 18.5 percent, and 34.0 percent, respectively). The chemical forms of the CCA constituents that exist in the wood after treatment are not known. Although copper and chromium compounds may be toxic to humans, the CPSC technical staff considers arsenic the most potent of the three compounds (Ferrante, 2003; Hatlelid, 2003; Osterhout, 2003). Little data are available on the chemical and physical characteristics of arsenic compounds that result from treatment of wood with CCA. Studies have shown, however, that arsenic compounds may leach out of treated wood, and may be removed from the surface of the wood by wiping or rubbing (CDHS, 1987; Jain, 1990; Lebow, 1996; Cobb, 2003). These data also suggest that the arsenic in treated wood or in the residue removed from the surface is somewhat soluble in water, and that solubility increases under acidic conditions.

Although arsenic causes both cancer and noncancer health effects, the CPSC technical staff considers arsenic carcinogenicity to be the most sensitive endpoint. Thus, this analysis will consider the cancer risk associated with exposure to arsenic. Any risks associated with the other compounds would be in addition to the risk from arsenic exposure.

This analysis will assess the lifetime cancer risk for the individual who plays primarily on CCA-treated wood playground structures during early childhood. It does not consider individuals who have access to all kinds of play structures, with only some of them (or none at all) being constructed of CCA-treated wood.

Routes of Exposure

The CPSC technical staff considers that the principal exposure to arsenic from CCA-treated wood occurs through transfer of wood surface arsenic residues to a child's hands and fingers and subsequent direct (*e.g.*, thumb-sucking) and indirect (*e.g.*, handling of toys or food) hand-to-mouth transfer of the residues. In addition to oral exposure, arsenic residues transferred from the wood to the skin (*e.g.*, hands, arms, legs) could be absorbed through the skin, contributing to

exposure. Limited data on dermal absorption of arsenic compounds suggests that some uptake by the dermal route can occur (Hatlelid, 2003).

Further, arsenic from CCA-treated wood may leach or wash off the wood onto the surface below the play structure (Stilwell and Gorny, 1997). Children playing near or beneath the play structure could contact the contaminated soil or ground cover. As with arsenic residues transferred directly from the wood surface, arsenic in the contaminated soil could be ingested through hand-to-mouth contact, or it could be absorbed through the skin. If contaminated soil or wood surface residues can become airborne, inhalation of the arsenic could also occur.

In addition, other avenues of exposure to CCA residues are possible, such as through contact with residential decks, porches, or picnic tables, through direct mouthing of handrails or other surfaces, or other activities. Responding to the petition's request concerning playgrounds necessitates focusing on playground exposures. Any potential risks from other sources of exposure could add to the final estimate of risk that might result from the exposure under investigation.

The risk assessment described in this document is focused on the most relevant arsenic exposure from CCA-treated wood playground equipment: the transfer of wood surface residues to a child's hands and subsequent hand-to-mouth transfer. It does not include the dermal route of exposure or hand-to-mouth transfer of arsenic from contaminated soil. The overall risk to children from playing on or near CCA-treated wood playground structures is likely to be higher than that estimated in this analysis because of potential arsenic exposures by routes other than hand contact and subsequent hand-to-mouth transfer of arsenic-containing residues from CCA-treated wood playground structures.

Risk Assessment Approach

There are two general approaches to risk assessment modeling: deterministic and probabilistic. These are both valid mathematical approaches for estimating risk. Probabilistic risk assessments have been used for several years in predicting accidents, systems failures, and weather forecasting. More recently, probabilistic approaches have been used in ecological risk assessments, and their use is just beginning in human health risk assessment (Kendall *et al.*, 2001). The key difference between these approaches is that deterministic modeling enters point estimates for the model parameters while probabilistic modeling uses distributions. One benefit of modeling using distributions is the ability to quantify uncertainty. However, uncertainty also can be expressed in deterministic modeling by conducting separate uncertainty analyses. Probabilistic approaches are generally more time and resource intensive than deterministic assessments. The quality of both types of risk assessment is dependent on the quality of the input data.

Probabilistic and deterministic approaches can be expected to produce similar results for the mean risk, but the probabilistic approach can provide information on the distribution of risks over the population. The probabilistic approach provides a benefit to the risk assessor only when there are sufficient data on the distributions of the critical input parameters. Because limited data are currently available on the distributions of some critical parameters for a probabilistic analysis, it is questionable in this case whether probabilistic modeling would provide more reliable and realistic estimates of the upper and lower bounds of risk than a deterministic assessment with a separate uncertainty analysis. Therefore, the CPSC technical staff concluded

that a deterministic risk assessment is appropriate in the present case and performed an analysis in which each of several critical input parameters was individually changed to its upper and lower bounds to approximate reasonable "best" and "worst" case estimates of risk.

The general approach in a deterministic cancer risk assessment is to estimate exposure in terms of daily dose per unit body weight over a lifetime, and then to relate that dose to a lifetime risk. Each input into the model represents a point estimate of the parameter. Central tendency values, such as the mean or median, upper confidence limit of the mean, or other values (*e.g.*, 90^{th} percentile) may be entered into the model. The current assessment relies predominantly on mean values for each variable, because the use of upper bound values in a multiplicative model could result in exposure and risk estimates that are unrealistically high for the majority of exposed individuals.

The primary disadvantage of a deterministic approach is the lack of information on the distribution of exposure and risk in a population. However, a detailed analysis of the uncertainty and variability in several of the model inputs, and the possible effects of uncertainty and variability on the estimate of risk, is included in Appendix A. The staff believes this type of analysis provides reasonable estimates of the upper and lower bounds of risk.

The deterministic model for estimated exposure is given by:

$$LADD\left(\frac{\mu g}{kg \cdot day}\right) = \frac{C\left(\frac{\mu g}{handload}\right) \times HT\left(\frac{Handload}{day}\right) \times EF\left(\frac{days}{year}\right) \times ED(years) \times B}{BW(kg) \times LT(days)}$$

where,

LADD is the lifetime average daily dose
C is the amount of chemical residue on the palm side (including fingers) of both hands collected during play on a CCA-treated wood playground structure,
HT is the handload transfers to the mouth,
EF is the exposure frequency,
ED is the exposure duration,
B is relative bioavailability
BW is body weight, and
LT is lifetime.

The lifetime average daily dose (LADD) is the time-averaged daily exposure to arsenic for children who play on CCA-treated wood playground structures. It is based on estimates for children's behaviors, such as the amount of time children would be expected to have contact with such structures, and the average lifespan of people in the U.S.

Cancer risk (R) can then be estimated based on the calculated exposure:

$$R(cancer\ risk) = LADD\left(\frac{\mu g}{kg \cdot day}\right) \times Q\left(\frac{\mu g}{kg \cdot day}\right)^{-1}$$

where,

Q is the unit cancer risk (also called cancer slope factor or cancer potency), which is the numerical representation of cancer risk per unit of daily exposure.

Concentration of arsenic on the hands (C)

Chromated copper arsenate (CCA) contains arsenic [As^{+5} or As(V)] pentoxide. Although the chemical form of arsenic that exists in the wood after treatment is not known with certainty, several inorganic forms that have been studied are essentially similar in toxicity (Hatlelid, 2003). Furthermore, the International Agency for Research on Cancer (IARC) classifies arsenic and arsenic compounds as Group 1, carcinogenic to humans (IARC, 1987), and the National Toxicology Program Report on Carcinogens (NTP, 2002) classifies arsenic and arsenic compounds as "known to be" human carcinogens. In addition, most health effect studies in humans, such as the drinking water studies discussed below, do not distinguish between the possible forms. Therefore, the total amount of arsenic available on the surface of the wood, rather than the amounts of specific forms, will be used in this assessment.

The amount of arsenic residue transferred from the wood surface to both hands including fingers ("handload") was estimated from a series of wipe studies of wood structures conducted by CPSC chemistry laboratory (LSC) staff (Cobb and Davis, 2003; Levenson, 2003a; Thomas, 2003). Initially, experiments were conducted with adult volunteers using eight residential decks in the Washington, DC metropolitan area. The decks ranged in age from new construction to approximately 18 years.

The staff recognizes that its study is a relatively small, regional study. However, the current study represents one of the most comprehensive studies completed to date. The staff does not maintain that this sampling represents all of the different climatic conditions in the U.S., but the region sampled includes temperature and precipitation conditions similar to other areas of the U.S. with large populations. It is not clear what effect different weathering conditions might have on the amount of dislodgeable arsenic, but it likely involves several factors and complex mechanisms.

The volunteers rubbed one hand on sections of boards. The hands were washed in a mild acetic acid solution and wiped with clean cloths moistened with the same acetic acid solution. This procedure was performed twice, and the rinsates and cloths were analyzed for arsenic (Cobb and Davis, 2003). Based on the series of initial experiments, the rubbing procedure allowed the volunteer to have sufficient contact with the wood to approach an equilibrium level (Cobb, 2003; Thomas, 2003). In other words, the amount of residue on the hand would approach a "maximum". This equilibrium level is reached relatively easily, *i.e.*, by rubbing a small area of wood a few times. In addition, the specified wood surface area for the sampling was considered similar to what would be reasonable for contact by children during play on wood playground structures (Midgett, 2003a). Based on the staff analysis of the results of the adult volunteer sampling (Levenson, 2003a), the mean arsenic handload for one adult hand was about 7.7 μg, and the median was 4.8 μg.

This deck study also involved developing a "surrogate" cloth wiping methodology so that laboratory staff could more efficiently sample larger numbers of wood structures themselves, rather than depending on the availability of adult volunteers. The experimental procedure involved "paired" sampling of deck boards with the adult volunteers' hands and surrogate cloth wipes, in order to establish a correlation between the results of the two methods. The decks were better suited to the surrogate studies than the playground structures due to their larger surface areas.

Thus, using the surrogate cloth wiping methodology developed in the deck studies rather than human volunteers, the LSC staff sampled twelve CCA-treated wood playground structures ranging in age from about six months to 18 years (Cobb and Davis, 2003). As with the decks, this part of the investigation involved a convenience sampling of private playground structures made with CCA-treated wood. This sampling and extrapolation from surrogate data results in the equivalent "handload" values for arsenic of 7.6 µg for the mean, and 3.5 µg for the median (Levenson, 2003b).

The first part of this investigation involved a convenience sampling of residential decks made with CCA-treated wood, chosen to represent a variety of use patterns, surface treatments, ages, and weathering. The LSC staff determined that using decks allowed for more controlled sampling of the wood and sampling method development. The staff believes that playground structures can be constructed from the same lumber used to build decks, and that outdoor decks and play structures in a given geographic area will be exposed to the same weather conditions. Based on these reasons and the sampling results discussed above, the staff believes that the inclusion of wood from decks in a study of wood playground structures is appropriate.

Based on tracings of the volunteers' hands from the deck studies, the mean surface area of the palm side (including fingers) of one adult volunteer hand was calculated to be about 141 cm^2 (Thomas, 2003). This is roughly equal to the mean surface area of the palm side (including fingers) of both hands for children aged 2-6 years (Table I). Therefore, extrapolating from the playground structure data, a child would collect an average of about 7.6 µg arsenic on both hands from contact with CCA-treated wood surfaces.

Table I. Calculation of Palm Side Surface Area by Age*

Age (years)	Mean Hand Length (cm)	Mean Hand Width (cm)	Mean Palm Side Surface Area (cm^2)
2-3.5	10.5	5.1	53.6
3.5-4.5	11.4	5.4	61.6
4.5-5.5	12.0	5.6	67.2
5.5-6.5	12.7	5.9	74.9
Mean palm side surface area, one hand, ages 2-6.5			64.3
Mean palm side surface area, both hands, ages 2-6.5			129

*Males and females, combined. Data from Snyder *et al.*, 1977.

Hand-to-Mouth Transfer (HT)

The original CPSC staff assessment (Lee, 1990a and 1990b) calculated exposure based on the approach that arsenic residue on the surface of the wood would be transferred to the child's hands during play and then a proportion of that "handload" would be transferred to the child's mouth during the day. This approach did not estimate the number of times children contact their mouths with their hands, the portion of the hands involved in each hand-to-mouth event, or the portion of residue on the contacted hand surface area that is ultimately transferred from the hands to the mouth during each event. Rather, this approach was chosen because it includes incidental and indirect hand-to-mouth contact, as well as direct mouthing of the hands.

Other methods for estimating hand-to-mouth transfers consider the amount of time spent on the activity (*e.g.*, playing on the playground equipment), generally measured in hours per day, but neglect the contribution of hand-to-mouth activity that occurs outside of the activity, while residue is still present on children's hands (*e.g.*, after the child leaves the playground).

No data exist concerning the ingestion of playground wood arsenic residue from children's hands. The approach used by Lee (1990b) assumed that during play, children's hands pick up residues from the wood, and that during subsequent activity, either on the playground, or later during the day, residues from the hands are transferred to the mouth. Since no data exist for wood residues, data from studies of soil ingestion were used to estimate the amount of residue transferred to the mouth. By assuming that soil ingestion occurs predominantly from transfers of soil from hands to the mouth, this method links data on soil ingestion by children with data on soil adherence to the skin to estimate the proportion of a given handload of soil that would be transferred to the mouth during the day.

The use of this method and the soil data that support it requires the assumption that transfers of wood residues from the hands to the mouth occurs in a manner similar to the transfer of soil from hands to the mouth. While the physical and chemical characteristics of arsenic-containing wood residues, such as whether the chemical is particle-bound (wood, soil, dust, organic matter, *etc.*), crystalline, or in solution, have not been well described, it is not unreasonable to assume that the material that can be removed from the wood surface by touching or rubbing is similar to the dust and soil that children pick up on their hands during play and normal childhood activities. The staff maintains that despite the uncertainties concerning the characteristics of arsenic-containing wood residues, studies of soil exposure and ingestion by children are applicable to this analysis. Therefore, the approach by Lee (1990b) is used in the current assessment, with modifications as follows.

The previous CPSC staff analysis (Lee, 1990b) used published studies on soil adherence to skin and soil ingestion by children. Soil adherence information was derived from a study that measured lead on the hands of 9- to 14-year-old children (median age, 11 years) engaged in normal daily activities (Roels *et al.,* 1980). The amounts of soil adhering to the hands were calculated for boys and girls, given the soil lead concentrations (assuming that the lead originated in the soil), and assuming that the soil adhered to the palm side (including fingers) of the hands.

The CPSC technical staff believes that this large (661 children), well-conducted study (Roels *et al.,* 1980) is still an appropriate study to assess soil adherence to children's hands, but the staff also believes that additional data are available from other studies, including several studies of younger children (1-6 years old), that would be more relevant to the age group of children of concern in this assessment (Charney *et al.*, 1980; Gallacher *et al.*, 1984; Duggan *et al.*, 1984). These four studies included different populations of children in different circumstances, although all four studies (including Roels *et al.,* 1980) focused on exposure to lead from soil and dust rather than direct measurement of soil adhering to the skin. More than 1,200 children were included in these studies. Three of the studies included children 1-6 years old; Roels *et al.* (1980), as discussed above, included 9- to 14-year-old children. Two of the studies followed normal outdoor behavior, one study covered children playing indoors, and one study included both indoor and outdoor activity. Each study used a different method for measuring the residues on the children's hands.

Finley *et al.* (1994) have reviewed these four soil adherence studies, and, using Monte Carlo analysis, developed probability density functions (*i.e.*, mathematically defined distributions) for the data of the individual studies as well as the combination of the studies. Each of the studies, as well as the Monte Carlo analysis, carries with it certain strengths (*e.g.*, large sample size) or weaknesses (*e.g.*, soil measurement efficiency) in addition to assumptions (*e.g.*, surface area of the children's hands). Despite the uncertainties, the staff believes that the four studies are well designed and conducted and that the methodology used by Finley *et al.* (1994) is an appropriate way to combine the data from these studies. In addition to these studies, a limited amount of data exists for direct measurement of soil on skin for both children and adults, in both laboratory experiments and normal daily activities (Holmes *et al.*, 1999; Kissel *et al.*, 1996). The results of these limited studies are consistent with the studies based on lead exposure discussed above.

The analysis of each of these four studies by Finley *et al.* (1994) resulted in mean soil adherence values of 0.2 to 2.2 mg soil/cm^2 skin. The combination of all studies resulted in an overall mean soil adherence of 0.65 mg/cm^2 with a median (50^{th} percentile) of 0.36 mg/cm^2, and a 95^{th} percentile of 2.4 mg/cm^2.

If soil primarily adheres to the palm side (including fingers) of the hands, and children aged 2-6 years have an average surface area of about 129 cm^2 for the palm side of both hands (Table I), then the average soil handload for both hands of 2- to 6-year-old children is 84 mg (0.65 mg/cm^2 x 129 cm^2).

The second piece of the hand-to-mouth transfer estimate is soil ingestion. The original CPSC staff analysis (Lee, 1990b) used an estimated median soil ingestion of 30 mg/day based on data from a study of 1- to 4-year-old children by Calabrese *et al.* (1989). Stanek and Calabrese (1995) subsequently published a reinterpretation of the original data that resulted in an estimated mean soil ingestion for the median child of 45 mg/day. This value was used in the current assessment, modified for the 2- to 6-year-old age range as follows.

The youngest children in the 2- to 6-year-old age group have the greatest amount of hand-to-mouth activity and likely ingest more soil and other residues from their hands than the older children. Little data are available on age-specific soil ingestion rates, but the U.S. Environmental Protection Agency (EPA) developed default age-specific inputs in the Integrated Exposure Uptake Biokinetic (IEUBK) model for assessing children's exposure to lead (EPA, 1994). These default rates will be used in this assessment as shown in Table II. Although the value for soil ingestion by 2- to 4-year-old children in the IEUBK model is not the same as the median value reported by Stanek and Calabrese (1995), the relative ingestion rates for the different children's age groups are applied to this analysis; *e.g.*, from the IEUBK inputs, a 6- to 7-year-old child ingests soil at a rate that is 63 percent of the rate of soil ingestion by 2- to 3-year-old children (85 mg/day *vs.* 135 mg/day). Thus, using the Stanek and Calabrese data, a 6- to 7-year-old would ingest 63 percent of 45 mg/day, or about 28 mg/day.

Given an average soil handload of 84 mg for children aged 2-6 years and an average soil ingestion rate of 36 mg/day, children in this age range ingest an average of about 43 percent (0.43) of a handload of soil per day (36 mg/day ÷ 84 mg). Thus, for the purposes of this risk assessment, the staff assumes that 43 percent of the arsenic residue on the hands is transferred into the mouth during the day. This estimate of hand-to-mouth transfer includes incidental and indirect hand-to-mouth contact as expected during normal childhood activities (*e.g.*, handling of toys and food), as well as direct mouthing of the hands (*e.g.*, thumb-sucking).

Table II. Calculation of Soil Ingestion Rate by Age			
Age (Years)	IEUBK Default Input (mg/day)	Percent of Maximum Ingestion	Adjusted Stanek and Calabrese (1995) Soil Ingestion (mg/day)
2-3	135	100	45
3-4	135	100	45
4-5	100	74	33
5-6	90	67	30
6-7	85	63	28
		Average, ages 2-6 years	36

Exposure Frequency (EF)

Exposure frequency, measured in days per year, represents the frequency of children's contact with CCA-treated playground equipment. The staff chose to focus on estimating the risk for a person who plays primarily on CCA-treated wood playground structures during early childhood. This variable is influenced by season and geographic region, based on suitability for outdoor play, and was assumed to be 156 days per year as an estimate for an intermediate playground visitation rate (Midgett, 2003b).

As discussed above, the method used in this analysis for estimating the amount of residue that a child may transfer to the mouth does not depend on the amount of time per day (hours/day) the child spends on the playground. It is assumed, however, that a child spends sufficient time in contact with the CCA-treated wood play structure during the day to "load" the hands with residue (Midgett, 2003a; Thomas, 2003).

Exposure Duration (ED)

Children aged 2-6 years, inclusive, are likely to have both extensive contact with playground equipment and significant hand-to-mouth contact. Therefore, the ED in this analysis is 5 years (Midgett, 2003a). However, the staff acknowledges that children use playground equipment beyond age six.

Relative Bioavailability

Bioavailability is the term used to indicate the extent to which a substance is absorbed by the body. The need to consider bioavailability in estimating risk arises when a difference is anticipated between the absorption characteristics of the substance under the exposure under study and those characteristics of the substance when it is tested in animal toxicity studies or the human epidemiological studies used to define the dose-response relationship (CPSC, 1992). In the present case, it is appropriate to consider relative bioavailability. That is, the bioavailability from the exposure of interest, in this case ingestion of surface residues of CCA-treated wood, must be evaluated relative to the dose-response study, in this case, the epidemiological studies of arsenic exposure from drinking water.

Generally, bioavailability data from human studies are preferred over data from animal studies, which are preferred over *in vitro* studies. The CPSC staff knows of no human or animal studies of bioavailability of arsenic from surface residue of CCA-treated wood. A few studies measured bioavailability in experimental animals dosed with CCA-treated wood sawdust or with soil contaminated with arsenic relative to the bioavailability of soluble forms, such as in water [reviewed in Hatlelid, 2003, and by the EPA's Scientific Advisory Panel (SAP) (SAP, 2001)]. These studies have shown that the relative bioavailability of arsenic from sawdust or soil is quite variable, ranging from about 0 to 98 percent. Most results were less than about 50 percent. The SAP expressed concern that the high-dose, bolus administration of arsenic-containing soils used in these studies does not reasonably simulate the anticipated low-dose, repeated exposures in children. The SAP was likewise concerned with the relatively high levels of arsenic in the test soils. Based on questions about the limited data on bioavailability of arsenic from soils, and the lack of data about arsenic-containing surface residues, the SAP recommended that 100 percent relative bioavailability be used in risk assessment until appropriate research is conducted.

For the same reasons, the CPSC technical staff believes that the available data are not adequate to address the bioavailability of arsenic from CCA-treated wood surface residues. Therefore, the staff used the default assumption of one (100 percent) for relative bioavailability of arsenic from ingestion of arsenic-containing surface residue. In this case, a relative bioavailability of 100 percent means that the bioavailability of arsenic from the wood surface residue is assumed to be the same as from the drinking water in the epidemiological studies.

Body weight (BW)

The mean body weight for U.S. children aged 2-6 years is 17.7 kg (EPA, 1997). This is the body weight used in the risk assessment.

Lifetime (LT)

The CPSC technical staff uses 75 years (27,400 days) to represent a lifetime, based on the average life expectancy from the EPA's "Exposure Factors Handbook" (EPA, 1997).

Unit Cancer Risk (Q)

The EPA (EPA, 1998), the International Agency for Research on Cancer (IARC, 1987), the National Toxicology Program (NTP, 2002) and the CPSC technical staff consider arsenic to be a known human carcinogen (Hatlelid, 2003). Key data supporting the dose-response relationship between arsenic ingestion and skin cancer are found in studies of arsenic exposure through drinking water in southwestern Taiwan published by Tseng *et al.* (1968) and Tseng (1977). The association between liver, lung, and bladder cancer and drinking water in southwest Taiwan is described in Chen *et al.* (1985), Chen *et al.* (1986), Chen *et al.* (1988), Wu *et al.* (1989), Chen and Wang (1990), and Chen *et al.* (1992). Studies in other populations (*e.g.*, Chile, Argentina, northeast Taiwan) support the association between arsenic ingestion and skin and internal cancers (Hopenhayn-Rich *et al.*, 1998; Ferreccio *et al.*, 2000; Chiou *et al.*, 2001).

There have been several assessments of the unit cancer risk for arsenic exposure. The studies of arsenic exposure in southwest Taiwan have been used in quantitative analyses in EPA's Integrated Risk Information System (IRIS) (EPA, 1998), and by EPA's Office of Water (2001) and the National Research Council Subcommittee on Arsenic in Drinking Water (NRC, 1999; NRC, 2001), as well as in the earlier CPSC study (Lee, 1990c). Tseng and coworkers (Tseng *et*

al., 1968; Tseng, 1977) studied a population in an area of southwest Taiwan that began using artesian wells containing up to 1,820 parts per billion (ppb) arsenic about 1910. In the 1960s, more than 40,000 residents were examined for hyperpigmentation, keratosis, and skin cancer. Chen and coworkers used death certificate data from villages in the same region to assess liver, lung, and bladder cancer mortality (Chen *et al.*, 1985; Chen *et al.*, 1986; Chen *et al.*, 1988; Wu *et al.*, 1989; Chen and Wang, 1990; and Chen *et al.*, 1992). These studies are ecological epidemiology studies in that exposures were not ascertained for individual subjects. Rather, exposure was assigned to individuals or to groups of individuals based on residence. Criticisms of these studies include the ecological nature of the studies, as well as inadequate accounting for exposure to arsenic from sources other than drinking water, poor nutritional status of the population, and the possibility of genetic susceptibility. Further, it is possible that well-water arsenic levels changed over time, or that residents moved or used different wells during their lives. Moreover, some villages had multiple wells with widely differing arsenic levels. These sources of uncertainty and variability could obscure the relationship between arsenic exposure and cancer, or affect the ability to extrapolate to the U.S. population. Nonetheless, these studies have certain strengths (e.g., large size, and extensive population records) and are generally considered adequate for estimating the dose-response relationship between arsenic ingestion and development of cancer (Lee, 1990c; EPA, 1998; EPA 2001; NRC, 1999; NRC, 2001).

The unit risk value developed in IRIS (EPA, 1998) was based on the summarized skin cancer and well water data published by Tseng and coworkers (Tseng *et al.*, 1968; Tseng, 1977). EPA modeled the dose-response based on the summary data, and extrapolated to the U.S. based on assumptions about U.S. and Taiwan body weights and rates of drinking water consumption. The unit risk for skin cancer was estimated to be 0.0015 $(\mu g/kg/day)^{-1}$. This means that, over a lifetime of exposure, each microgram of arsenic ingested per kilogram body weight per day would result in an increased chance of skin cancer of 15 per 10,000.

The unit risk for the original CPSC staff assessment (Lee, 1990c) was also derived from the skin cancer data from Tseng and coworkers (Tseng *et al.*, 1968; Tseng, 1977). At 0.00048 $(\mu g/kg/day)^{-1}$, the unit risk estimated by CPSC staff was approximately one-third of the EPA value, due to slight differences in the methodology used by the EPA and CPSC staff. As discussed in Lee (1990c), the differences in the unit risk estimates could be associated with the use of years of exposure rather than age, and the grouping and weighting of the published data.

The NRC, in its 1999 report on arsenic in drinking water, provided an extensive discussion of the relevant studies and important statistical modeling issues. The report cautions that risk assessment should consider the choice of model, the choice of comparison population (*e.g.*, internal population in the study area, the southwest Taiwan region, or all of Taiwan), and the shape of the low-dose extrapolation curve (*e.g.*, linear or threshold), as well as factors that could affect the arsenic-cancer relationship, such as diet and genetics. The NRC recommended using the data on internal cancers to conduct risk assessment, but advised that the choice of model is important.

The EPA Office of Water (2001) based its risk analysis of arsenic in drinking water on the bladder and lung cancer data of Chen and coworkers (Chen *et al.*, 1988; Wu *et al.*, 1989) with consideration of the recommendations from NRC (1999), an EPA Science Advisory Board Report (2000), and statistical analyses by Morales *et al.* (2000). EPA used a multiplicative Poisson model with an internal comparison group and linear extrapolation. EPA staff assumed two different levels of background arsenic exposure for the Taiwanese population, as well as

two levels of drinking water intake, which results in "low" and "high" risk estimates. EPA presented population risks for U.S. lung or bladder cancer in Tables III.D-2(a-c) in EPA (2001). However, the risks presented in EPA (2001) were not theoretical risks to individuals consuming water with specific arsenic concentrations. Rather, they were mean risks to the U.S. exposed population after water treatment to a specified maximum arsenic concentration, taking into account current occurrence levels in drinking water in the U.S. Thus, the population would be exposed to a range of arsenic levels up to the specified maximum level, but only a fraction of the population would be consuming drinking water with the maximum allowable concentration.

Personal communication from EPA's Office of Water staff (Reding, 2002) provided the additional information for the CPSC technical staff to calculate the unit cancer risks used in EPA's analysis. Thus, the EPA's Office of Water staff estimated a unit risk of about 0.00041 to 0.0037 $(\mu g/kg/day)^{-1}$ for bladder or lung cancer for males and females combined.

The NRC (2001) published an update of its 1999 report that included a critique of the EPA approach, and a discussion of recent studies. NRC used the data from Chen *et al.* (Chen *et al.*, 1985; Chen *et al.*, 1988, Wu *et al.*, 1989, and Chen *et al.*, 1992) and the analysis of Morales *et al.* (2000). NRC chose an additive Poisson model with an external comparison group (overall southwestern Taiwan region) and linear extrapolation. They used an approach developed in the analysis of lung cancer from radon exposure to extrapolate from the studied Taiwan population to the U.S. using the relative risk (NRC, 1988). Although the NRC did not publish the unit risk that resulted from their analysis, from the information given in the report (Table S-1), the CPSC staff calculated U.S. lung or bladder cancer risk for males and females combined to be about 0.023 $(\mu g/kg/day)^{-1}$. This was calculated from the theoretical maximum likelihood (*i.e.*, best estimate) risk for drinking water containing arsenic at 10 µg/L, assuming 70 kg body weight and ingestion of 1 L drinking water/day in the U.S.

The NRC (2001) concluded that although the estimates of EPA (2001) and NRC are not directly comparable because of EPA's additional adjustment for U.S. arsenic occurrence, the NRC risk estimates are greater than those of EPA due to differences in model choice, comparison population, and adjustment for arsenic in water and food. As discussed above, information provided by EPA staff allowed CPSC staff to determine that the unit risks used by the EPA staff [0.00041-0.0037 $(\mu g/kg/day)^{-1}$ for bladder or lung cancer for males and females combined] are about six to 56 times lower than that used by the NRC [0.023 $(\mu g/kg/day)^{-1}$].

The NRC report discussed several sources of variability and uncertainty in risk assessment and made recommendations for future research and consideration in future risk assessments. For example, the report highlights issues such as variability in drinking water concentrations, water consumption rates, age, sex, body weight, food arsenic content, and food consumption rates, other nutritional and dietary factors, and genetic differences among study populations and the U.S. population. The NRC subcommittee stressed that the mechanisms of arsenic carcinogenicity, in addition to the impact of the different chemical forms of arsenic and variations in metabolism, are not understood and, therefore, the shape of the dose-response curve at low doses is unknown.

There are differences among these unit risk estimates, even those based on the same population and data set. Each analysis discussed above includes discussion about key factors and model choices that could affect the final estimate by as much as an order of magnitude (*i.e.*, a factor of ten). The EPA IRIS calculation was based on skin cancer, while EPA's Office of Water (2001)

and both NRC reports considered the more recent data on internal cancers, especially lung and bladder cancer, to be the more appropriate outcomes to model. There are at least two reasons for choosing studies of internal cancers. First, the internal cancers, especially lung cancer, have a much higher case fatality rate than skin cancer in the U.S. Second, despite the weaknesses of the ecological data from both studies of southwestern Taiwan, the work published by Chen and coworkers provides case and exposure assessment that is more complete than in the skin cancer work by Tseng (1977).

Although EPA's Office of Water (2001) and NRC used the same data, they chose different dose-response models with different comparison populations. While the NRC agreed that several reasonable dose-response models exist for the data, they found that the additive Poisson model proved to be a better fit to the data based on two statistical measures (NRC, 2001). NRC also argued that an external comparison population (*e.g.*, the larger southwest Taiwan region, or all of Taiwan) is preferable to an internal comparison because using the external population results in a more accurate estimate of baseline cancer rates. In addition, the use of the unexposed external population minimizes the effect of exposure misclassification in the low-dose range. EPA argued that the internal comparison was better because an external population could differ from the study population in important characteristics other than the exposure of interest. They also believed that the use of an external comparison resulted in the apparent supra-linear dose-response curve (*i.e.*, exposures at the low end of the dose-response curve are associated with higher risks than would be expected if the relationship between dose and risk were directly proportional), which they considered unlikely. NRC countered that the arsenic-exposed population was not significantly different from the larger Taiwan population (based on Tsai *et al.*, 1999). They also discussed how a supra-linear dose-response could be appropriate, and argued that better exposure assessment, in conjunction with strengthened baseline data from the external population, could minimize the effect of measurement error at low doses.

Considerable controversy exists over the choice of the shape of the low-dose extrapolation. In general, both EPA (EPA, 2001) and CPSC staff choose linear extrapolation in the absence of data that the shape of the dose-response at low doses is not linear (*e.g.*, sublinear or threshold) (CPSC, 1992). The CPSC staff believes that data do not exist that elucidate the mechanism of arsenic-induced carcinogenicity or define a non-linear effect, and that linear extrapolation at low doses is appropriate in this case.

Once the risk has been modeled in the study population (in this case, Taiwan), extrapolating risk to the U.S. population requires several additional choices. Because drinking water is the source of arsenic in the southwest Taiwan study region, determining the exposure doses on a mg/kg body weight basis requires estimating the drinking water consumption rate and choosing a representative body weight for the exposed population. Another factor to consider is the background exposure to arsenic, such as from food. The approaches used by EPA and NRC differed somewhat, with EPA assuming a higher water consumption rate in the Taiwanese population than NRC. EPA also assumed the Taiwanese ingested more arsenic in food. The effect of assuming greater arsenic intake in this population is to decrease the risk associated with specific water arsenic concentrations. The NRC report criticized EPA for the lack of evidence to support their assumptions, but agreed that few data exist on water consumption in Taiwan. The NRC believed that the water consumption rates in the Taiwan were not as high as previously thought, but they recognized that higher or lower values could be chosen, and that changing the

assumption could have a large impact on the calculated risk. On the other hand, they determined that adjusting the background arsenic exposure from food has only a modest impact.

In addition, the method for extrapolating the estimated risk from the Taiwanese population to the U.S. population could rely on the background cancer rate in either Taiwan or the U.S. As described by the NRC (2001), the background rates of bladder and lung cancer are several times higher in the U.S. than in Taiwan, and using the U.S. rates results in a greater estimate of risk. The members of the NRC subcommittee did not agree that there was sufficient justification to use the U.S. background rates over the Taiwanese rates, but they did agree that if interactions exist between risk factors (*e.g.*, suggested synergism with smoking and arsenic-associated lung cancer; Ferreccio *et al.*, 2000), then using the U.S. background rates would be appropriate.

The CPSC staff believes that significant variability and uncertainty exist in the available data, statistical modeling, and extrapolation and that several reasonable approaches could be taken that would result in estimates of cancer risks that differ by an order of magnitude or more. The CPSC staff believes that the quantitative assessments by NRC (2001) and EPA (2001) are both reasonable and appropriate, despite the shortcomings of the available data. Therefore, the CPSC staff risk assessment is based on the range of estimates for these two analyses for lung or bladder cancer risk, for males and females combined, in the U.S. [0.00041 per µg/kg/day (EPA) to 0.023 per µg/kg/day (NRC)]. The estimated unit risk for skin cancer in IRIS (EPA, 1998), at 0.0015 per µg/kg/day, falls within this range. This unit risk range means that, over a lifetime, each microgram of arsenic ingested per kilogram body weight per day would result in an increased chance of bladder or lung cancer of 41 to 2,300 per 100,000.

Risk Assessment

The CPSC technical staff estimates an increased lifetime risk of bladder or lung cancer of approximately two per million to one per 10,000 (2 to 100 per million)[1], for a person who plays primarily on CCA-treated wood playground structures during early childhood (*i.e.*, 156 days per year for five years) due to exposure to arsenic. The CPSC technical staff believes that this risk assessment model results in a reasonable estimate of exposure for children who have regular, repeated contact with CCA-treated wood play structures, and who engage in behaviors typical of young children, such as frequent hand-to-mouth contact. Table III contains the values entered into the risk assessment model.

The CPSC technical staff believes that other estimates of cancer risk could be calculated by modifying the values of one or more model inputs. Appendix A contains a sensitivity analysis for selected inputs. For example, if we assume that children play on CCA-treated wood structures an average of four days per week (208 days per year), the lifetime cancer risk would increase to approximately three per million to two per 10,000 ($3\text{-}200\times10^{-6}$). However, the range of values that would be considered reasonable is quite narrow for most of the model inputs, varying only by factors of two or three (*e.g.*, relative bioavailability, exposure frequency, body weight). On the other hand, the amount of arsenic that may be transferred from wood surfaces to the hands or the amount of arsenic transferred from the hands to the mouth could vary to a greater extent.

[1] This risk may also be written numerically as $2\text{-}100\times10^{-6}$, or 2×10^{-6} to 1×10^{-4}.

Table III. Model Inputs for Arsenic Assessment			
Parameter	Definition	Value	Units
C	concentration of arsenic on the hands	7.6	µg/handload
HT	handload transfers to the mouth	0.43	handloads/day
EF	exposure frequency	156	days/year
ED	exposure duration	5	years
B	relative bioavailability	1	
BW	body weight	17.7	kg
LT	lifetime	27400	days
Q	Unit risk	0.00041-0.023	$(\mu g/kg/day)^{-1}$
Results			
LADD	lifetime average daily dose	0.0053	µg/kg/day
Cancer risk	lifetime cancer risk	2 to 100 per million ($2\text{-}100\times10^{-6}$)	

Thus, other reasonable estimates of cancer risk could be developed that could vary appreciably from the range of values calculated by CPSC staff, and, given the uncertainty in the risk assessment approach, the true risk could be higher or lower than the risk estimated by the CPSC staff in this document. Appendix A contains a more detailed analysis of the uncertainty and variability in several of the model inputs, and the possible effects on the risk estimate.

The previous CPSC staff assessment (Lee, 1990a) concluded that the cancer risk (based on skin cancer) from some samples of new CCA-treated wood obtained from playground manufacturers would be three-four per million ($3\text{-}4\times10^{-6}$), which is similar to the lower end of the risk range estimated in the current assessment. Appendix B contains a detailed discussion of the original CPSC staff assessment and of several other risk assessments conducted more recently.

Conclusions

CPSC addresses chemical hazards under the Federal Hazardous Substances Act (FHSA), which is risk-based. To be considered a "hazardous substance" under the FHSA, a substance or product must satisfy a two-part definition. 15 USC 1261(f)(1)(A). First, it must be "toxic" as defined under the FHSA, or present one of the other hazards enumerated in the statute. Second, it must have the potential to cause substantial illness or injury during or as a result of customary or reasonably foreseeable handling or use, including ingestion by children. Therefore, exposure and risk must be considered in addition to toxicity when assessing potential hazards under the FHSA (CPSC, 1992).

Based on the CPSC technical staff's toxicity assessment, arsenic can be considered to be toxic, based on acute and chronic effects, including carcinogenicity (Hatlelid, 2003). In particular, arsenic is a known human carcinogen.

If it is concluded that a substance is toxic under the FHSA due to chronic toxicity, then a quantitative assessment of exposure and risk is performed to determine whether the product from which the exposure occurs may be a "hazardous substance" under the FHSA. The quantitative risk assessment includes a consideration of dose response, bioavailability, and exposure. This document describes the risk assessment process for arsenic exposure from CCA-treated wood playground structures.

In the present risk assessment, a deterministic model was applied to provide an estimate of the average lifetime cancer risk due to exposure to arsenic to people who played on CCA-treated playground equipment during early childhood. The estimated increased risk, approximately two to 100 per million ($2\text{-}100\times10^{-6}$), exceeds one per million (1×10^{-6}), which is the risk level that is generally considered by federal agencies as relevant for regulatory considerations (CPSC, 1992). The use of one in a million has the most precedent in actions taken by the Commission and other agencies for evaluating the risk from carcinogens.

In this risk assessment, the CPSC technical staff chose single values for each parameter in the model, with the exception of the unit cancer risk, that the staff believes best represent the available scientific data. However, the staff recognizes the inherent uncertainty in the values, especially for parameters for which few data are available. Similarly, the staff acknowledges the immense variability among individuals, in both activities and behaviors, and in susceptibility to disease. Thus, it would be inaccurate to suggest that the range of risk estimates will precisely describe the actual risks for all individuals in a population, and the true risk could be higher or lower.

In order to explore the effect of uncertainty and variability on the staff's risk estimate, the staff performed a sensitivity analysis in which each of the input variables was individually changed to its upper or lower bound (Appendix A). This approach gives an approximation of reasonable "best" and "worst" cases of risk. The range of risk estimates from this analysis is about two per 10 million (2×10^{-7}) to approximately five per 1,000 (5×10^{-3}) (see p. A-4). This risk range may also be expressed as 0.2-5,000 per million.

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