default factors from EPA references (EPA 1997, EPA 1991) were employed along with best professional judgment to estimate upper-bound and central tendency values.

ET	9.5 hrs/day (upper-bound estimate)	7 hrs/day (central tendency)
EF	208 days/year (upper-bound estimate)	185 days/yr (central tendency)
ED	25 yrs (upper-bound estimate)	7 yrs (central tendency)

Cancer Risk

Target Risk 1 E -05

Inhalation Unit Risk = 5.7 E-04 per ug/m^3

CA = CR/IUR x AT/ (ET x EF x ED)

CA = 0.22 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 1.2 ug/m^3 (exposure guideline for central tendency exposure assumptions)

Non Cancer Hazard

Target Hazard Quotient = 1

RfC = 0.07 ug/m^3

RSC = 0.8

CA = HQ x RfC x RSC x AT/ (ET x EF X ED)

CA = 0.21 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 0.38 ug/m^3 (exposure guideline for central tendency exposure assumptions)

EF	185 days/year (upper-bound estimate)	185 days/yr (central tendency)
ED	25 yrs (upper-bound estimate)	7 yrs (central tendency)

Cancer Risk

Target Risk 1 E -05

Inhalation Unit Risk = 5.7 E-04 per ug/m^3

CA = CR/IUR x AT/ (ET x EF x ED)

CA = 0.23 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 1.2 ug/m^3 (exposure guideline for central tendency exposure assumptions)

Non Cancer Hazard

Target Hazard Quotient = 1

RfC = 0.07 ug/m^3

RSC = 0.8

CA = HQ x RfC x RSC x AT/ (ET x EF X ED)

CA = 0.26 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 0.38 ug/m^3 (exposure guideline for central tendency exposure assumptions)

Exposure Parameters (Custodial Staff)

Union contract stipulates a maximum of 208 work days per year for custodial workers. Other exposure parameters for custodial staff at P.S. 199 are not available, therefore

USEPA (2002). National Recommended Water Quality Criteria. Human Health Criteria Calculation Matrix. Office of Water, EPA-822-R-02-012, Nov., 2002.

U.S. EPA (2000). Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Office of Water, EPA-822-B-00-004, Oct., 2000.

USEPA (1997). Exposure Factors Handbook. Office of Research and Development

USEPA (1997). Integrated Risk Information System. Toxicity Assessment for Polychlorinated Biphenyl

USEPA (1996). Integrated Risk Information System. Toxicity Assessment for Aroclor1254

USEPA (1991). Risk Assessment Guidance for Superfund. Supplemental Guidance: Standard Default Exposure Factors. OSWER 9285. 6-03

USEPA (1990). National Contingency Plan. CFR Section 300.430(e)

USEPA (1989). Risk Assessment Guidance for Superfund. Volume 1. Human Health Evaluation Manual (Part A) (EPA A540/1-89-002)

USFDA (2008). Total Dietary Study. CFSAN - Office of Food Safety. U.S. Dept of Health and Human Services

Appendix

Exposure Parameters (Teacher/Administrative Staff)

The New York City Department of Health and Mental Hygiene reports that teachers at P.S. 199 work a calendar year of approximately 185 days. As previously noted, there are no summer programs. It was further reported that teachers may occasionally work up to 10 hours a day. The EPA Exposure Factors Handbook (EPA 1997) lists 405 minutes (approximately 7 hours) as the 50 percentile for time in school by full time employees.

ET	10 hrs/day (upper-bound estimate)	7 hrs/day (central tendency)

Recommendation

The health-based exposure guidelines derived in this report are intended to serve as a general reference for interpreting PCB indoor air sampling data at P.S. 199. Use of a conservative toxicity factor (RfD for Aroclor 1254) paired with upper-bound exposure assumptions yield exposure guidelines that are intended to protect against non-carcinogenic effects with an ample margin of safety. When the exposure guideline for students (upper-bound exposure) is set to protect against non-cancer heath effects, the corresponding excess lifetime cancer risk is less than one-in-one-hundred thousand, which is within EPA's acceptable risk range (one-in-ten-thousand to one-in-a- million) (EPA, 1990), and approaches the point-of-departure (one-in-a-million) for some exposure scenarios. It should be noted that the guidelines apply to long-term exposure scenarios. That is, the exposure guidelines presented herein are intended to represent a concentration that averaged over time and space (as it relates to the exposure setting) should not be exceeded. Isolated or occasional PCB indoor air measurements that exceed the recommended guideline would not signal the likelihood of an adverse effect. Maintaining PCB indoor air concentrations (obtained in a manner that reflects real-life exposure potential - i.e., normal building ventilation; day-time sampling, breathing-zone sample collection) below 0.20 ug/m^3 over the long term would be prudent and protective of all members of the school community given consideration to the range of exposure guidelines derived in this report.

References

ATSDR (2000). Toxicological Profile for PCBs. U.S. Department of Health and Human Services

USEPA (2009). Superfund Technical Support Center. Provisional Peer Reviewed Toxicity Values

USEPA (2009a). Risk Assessment Guidance for Superfund. Volume 1. Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment) (EPA-540-R-070-002)

USEPA (2008). Child Specific Exposure Factors Handbook (EPA/600/R-06/096F)

it is relevant to note that dermal and ocular effects, including skin irritation, chloracne, hyperpigmentation and eyelid and conjunctival irritation, have been observed in humans occupationally exposed to Aroclor 1254 and other Aroclor formulations.

As previously noted, a route-to-route extrapolation was made to convert the Aroclor 1254 RfD to an RfC (for adults) by accounting for body weight (70 kg) and ventilation rate (20m3/day) as per the approach recommended in the Risk Assessment Guidance for Superfund (1989). A similar exercise was performed using age-appropriate body weight and ventilation rate (USEPA, 2008) for students. This simplified process does not account for pharmacokinetic differences between the exposure pathways or for portal of entry effects. However, the IRIS file on PCBs endorses route-to-route extrapolation of the oral Slope Factor to an Inhalation Unit Risk (IUR). The IRIS file details the similar high absorption by both the oral and inhalation route, the common metabolic pathway by both routes and the lack of portal of entry effects as factors supporting an inter-route extrapolation. Accordingly, this same rationale supports the route-to-route extrapolation of the Aroclor 1254 RfD to an RfC.

The student body is not the only group occupying P.S. 199 on a routine basis. Teachers, administrative staff and custodial workers are also subject to PCB exposure. The Appendix of this report contains exposure guidelines for this collective group of adults working at P.S. 199. Occupational regulations may supersede the exposure guidelines derived for worker populations. However, the recommended exposure guideline developed for students (see below) would be sufficiently protective of adult workers as well.

The exposure assumptions detailed in this report are intended to reflect both upper-bound and central tendency exposure scenarios. It should be noted that inhalation exposure is most proximally related to ventilation rate (the amount of air exchange per unit time). In this assessment, exposure time (hrs/day) is employed as a surrogate for ventilation rate. This approach is deemed acceptable as the ventilation rate for both students and teachers is not expected to differ significantly between the time spent in school and out of school over the course of a day To the extent that custodial workers may engage in more vigorous activity than teachers over the course of a workshift, it is acknowledged that the use of exposure time as a surrogate for ventilation rate may underestimate, to an unquantifiable but likely modest degree, the actual exposure to this worker population.

thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD for Aroclor 1254 is based on clinical and immunological studies in monkeys. The critical effects were oocular exudates, inflamed and prominent Meibomian glands, distorted growth of finger and toe nails; decreased antibody (IgG and IgM) response to sheep erythrocytes.

The RfD incorporates a 300 X uncertainty factor which is detailed below. A 10-fold factor is applied to account for sensitive individuals. A factor of 3 is applied to extrapolation from rhesus monkeys to humans. A full 10-fold factor for interspecies extrapolation is not considered necessary because of similarities in toxic responses and metabolism of PCBs between monkeys and humans and the general physiologic similarity between these species. A partial factor is applied for the use of a minimal LOAEL since the changes in the periocular tissues and nail bed see at the 0.05 mg/kg-day are not considered to be of marked severity. The duration of the critical study continued for approximately 25% of the lifespan of rhesus monkeys so that a reduced factor was used for extrapolation from subchronic exposure to a chronic RfD. The immunologic and clinical changes that were observed did not appear to be dependent upon duration which further justifies using a factor of 3 rather than 10 for extrapolation from subchronic to chronic, lifetime exposure. The total uncertainty factor (UF) is 300.

Human data available for risk assessment of Aroclor 1254 are useful only in a qualitative manner. Studies of the general population who were exposed to PCBs by consumption of contaminated food, particularly neurobehavioral evaluations of infants exposed in utero and/or through lactation, have been reported, but the original PCB mixtures, exposure levels and other details of exposure are not known Most of the information on health effects of PCB mixtures in humans is available from studies of occupational exposure. Some of these studies examined workers who had some occupational exposure to Aroclor 1254, but sequential or concurrent exposure to other Aroclor mixtures nearly always occurred, exposure involved dermal as well as inhalation routes (relative contribution by each route not known), and monitoring data are lacking or Insufficient data are available in these studies to determine possible contributions of Aroclor 1254 alone, extent of direct skin exposure and possible contaminants. However,

diets high in fish, from PCB-contaminated waters, can significantly increase an individual's dietary intake of PCBs (ATSDR, 2000). An 80% RSC may also account for nominal background PCB exposures unrelated to diet.

Chronic exposure to PCBs has been associated with both carcinogenic and non-carcinogenic effects. EPA's IRIS data base provides toxicity factors to evaluate the risk/hazard associated with chronic exposure to PCBs. EPA has cancer potency factors (oral Slope Factors and derived Inhalation Unit Risks) for three tiers of PCBs based on persistence. The Slope Factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The Inhalation Unit Risk is the quantitative estimate in terms of risk per ug/m^3 air breathed. PCBs are classified by IRIS as a probable human carcinogens based on cancer bioassays in animals but inadequate data in humans. A 1996 study found liver tumors in female rats exposed to Aroclors 1260, 1254, 1242, and 1016, and in male rats exposed to 1260. These mixtures contain overlapping groups of congeners that, together, span the range of congeners most often found in environmental mixtures. Earlier studies found high, statistically significant incidences of liver tumors in rats ingesting Aroclor 1260 The IRIS cancer assessment provides both upper-bound and central tendency Slope Factors and Inhalation Unit Risks. In this assessment, the most potent cancer value (upper-bound Inhalation Unit Risk for high persistence congeners) was employed. This is consistent with the recommendation in the IRIS file to use the high persistence tier for all early life exposure. The high persistence tier is also recommended for inhalation exposure to dust or aerosols. All exposure guidelines derived in this document based on the carcinogenic endpoint are less stringent than the most stringent guideline (0.2 ug/m^3 – upper bound exposed students) based on a non-carcinogenic endpoint. Therefore, protecting against non-cancer health effects would insure that all exposure populations would incur less than a one-in-one-hundred thousand excess lifetime cancer risk above background from indoor exposure to PCBs at P.S. 199. As noted earlier (see discussion on relative source contribution), background exposure to PCBs in the environment is relatively small and getting smaller, therefore cancer risk from background exposure to PCBs in the environment would be similarly minimal.

The EPA IRIS data base contains oral Reference Doses (RfDs) for Aroclors 1254 and 1016. The Aroclor 1254 RfD is more than a factor of three more stringent than the Aroclor 1016 RfD. The oral Reference Dose (RfD) is based on the assumption that

ET (hours/day) = exposure time;

EF (days/year) = exposure frequency;

ED (years) = exposure duration; and

AT (ED in years x 365 days/year x 24 hours/day) = averaging time

CA = HQ x RfC x RSC x AT/ (ET x EF X ED)

CA = 0.20 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 0.30 ug/m^3 (exposure guideline for central tendency exposure assumptions)

Table 1

Exposure Parameters	Cancer Risk	Non-Cancer Hazard
Upper-Bound	1.0 ug/m^3	0.20 ug/m^3
Central Tendency	1.4 ug/m^3	0.30 ug/m^3

Risk Characterization Discussion

This section is intended to provide context and interpretation for the indoor air PCB sampling data that has been collected at P.S. 199, and the associated indoor air exposure guidelines developed for the school. PCBs have been released to the environment solely by human activity. Typical atmospheric concentrations of PCBs have been found to be much lower in rural locations compared to urban locales. For example, the concentration of PCBs in urban Baltimore, Maryland ranged from 0.38 to 3.36 ng/m^3, while in rural Baltimore, the concentration ranged from 0.02 to 0.34 ng/m^3 (ATSDR, 2000). The general population may be exposed to PCBs by ingesting contaminated food, especially fish from contaminated waters, and by inhaling contaminated air. Food consumption has and continues to be the major contributor to body burden of PCBs in the general population. For this reason, a relative source contribution (RSC) was factored into the derivation of the health-based exposure guidelines to account for dietary exposure. The value used (0.8) is deemed to be conservative because FDA dietary data from 1997 account for less than 0.2 (1 minus 0.8) of the RfD for PCBs. In addition, a clear temporal downward trend in dietary PCB intake suggests that a contemporary balanced diet is likely to be lower in PCB content than a comparable 1997 diet. Still, this built-in conservatism is deemed prudent as several studies indicate that

Where:

IUR (μ g/m^3)$^{-1}$ = Inhalation Unit Risk; and

EC (μ g/m^3) = exposure concentration

EC = (CA x ET x EF x ED)/AT

Where:

EC (μ g/m^3) = exposure concentration;

CA (μ g/m^3) = contaminant concentration in air;

ET (hours/day) = exposure time;

EF (days/year) = exposure frequency;

ED (years) = exposure duration; and

AT (lifetime in years (70) x 365 days/year x 24 hours/day) = averaging time

CA = CR/IUR x AT/ (ET x EF x ED)

CA = 1.0 ug/m^3 (exposure guideline for upper-bound exposure assumptions)

CA = 1.4 ug/m^3 (exposure guideline for central tendency exposure assumptions)

<u>Non-Cancer Hazard Assessment:</u>

RfC = 0.05 ug/m^3

Hazard Quotient (HQ) = EC/RfC

Target Hazard Quotient = 1

Relative Source Contribution = 0.8

EC = (CA x ET x EF x ED)/AT

Where:

EC (μ g/m^3) = exposure concentration;

CA (μ g/m^3) = contaminant concentration in air;

EPA's guidance (USEPA 2000, 2002) on deriving drinking water and ambient water quality criteria recommends using a relative source contribution (RSC) factor to account for "background" exposure unrelated to the exposure medium of interest. That is, the RSC represents the allowable daily exposure from a specific source (e.g., indoor air) after subtracting the background exposure from other sources (e.g., diet) from the RfD. The recommended RSC range is 20% - 80% of the RfD. Food consumption has and continues to be the major contributor to body burden of PCBs in the general population (ATSDR, 2000). Accordingly, information on dietary consumption of PCBs was obtained to determine an appropriate RSC for deriving health-based exposure guidelines at P.S. 199. The United States Food and Drug Administration (USFDA) compile data on dietary intake of food-borne contaminants. PCB levels in food have been steadily decreasing (ATSDR 2000, and personal communication with Dr. Michael Bolger, USFDA). The USFDA has Market Basket Survey data on PCB concentrations in a variety of food sources through 2003; however, derived average daily intakes of PCBs for various age groups within the U.S. population are available only through1997 (ATSDR, 2000). Use of the 1997 data is deemed conservative given consideration to the clear downward trend in dietary PCBs since the 1970's. For children 6 - 10 years of age the dietary intake is 0.003 ug/kg-day. This value represents 15% of the RfD (0.02 ug/kg-day). For adults, the dietary intake is 0.002 ug/kg-day. This value represents 10% of the RfD. Since both values are below 20% of the RfD, the RSC for deriving health-based exposure guidelines fro PCBs in P.S. 199 is set at the limit (80% of the RfD) of the recommended range.

Risk Assessment

Separate assessments are performed for cancer risk and non-cancer hazard. Health-based exposure guidelines for students based on cancer risk and non-cancer hazard have been estimated below. The assessment assumes a Target Cancer Risk of 1 E -05 (one-in-one-hundred-thousand). This is the mid-point of the acceptable risk range typically used in EPA risk assessments (USEPA 1990).

Target Cancer Risk (CR) = 1 E -05
Inhalation Unit Risk = 5.7 E-04 per ug/m^3

<u>Cancer Risk Assessment</u>

CR (Cancer Risk) = IUR x EC

Exposure Scenarios

Toxicity factors are combined with exposure scenarios to calculate health-based exposure guidelines. The New York City Department of Health and Mental Hygiene provided information on the occupancy patterns for students and workers at P.S. 199. The school serves grades kindergarten through 5th grade (Ages: 5 years to 11 years). Additional exposure parameters are listed below.

- School year: 180 days

- School day: 6.5 hours (8:30 am to 2:50 pm) for majority of children

- Extended school day: Some students stay until 3:40 pm for tutoring 3 days a week; a few children arrive at 8 am for breakfast; some children stay for after school activities; the longest day for any given child is 10 hours from 8 am to 6 pm

- No weekend programs

- No summer programs that use the school except that some will use the cafeteria as a gathering spot before an activity (very brief)

Upper-bound and central tendency exposure parameters for students are listed below.

<u>Exposure Parameters (Student)</u>

ET	10 hrs/day (upper bound estimate)	6.5 hrs/day (central tendency)
EF	180 days/year (upper bound estimate)	180 days/yr (central tendency)
ED	6 yrs (upper bound estimate)	6 yrs (central tendency)

Where:
ET (hours/day) = exposure time;
EF (days/year) = exposure frequency;
ED (years) = exposure duration; and

<u>Relative Source Contribution (RSC)</u>

Reference Dose [RfD] for Aroclor 1254, and the oral Slope Factor for High Risk/Persistence PCBs) were employed. The basis for this approach is described below. EPA has recently (USEPA, 2009a) released supplemental guidance on inhalation risk assessment. The guidance provides updated approaches previously detailed in the Risk Assessment Guidance for Superfund (USEPA, 1989) for assessing risk to inhalation toxins. In the absence of an inhalation toxicity factor (RfC/IUR) or an analogous PPRTV, the supplemental guidance generally recommends against route-to-route extrapolations in favor of a qualitative assessment. The IRIS file on PCBs, however, endorses route-to-route extrapolation of the oral Slope Factor to an Inhalation Unit Risk (IUR). The IRIS file details the similar high absorption by both the oral and inhalation route, the common metabolic pathway by both routes and the lack of portal-of-entry effects as factors supporting a route-to-route extrapolation. The same rationale can be applied to converting the RfD of Aroclor 1254 to an RfC given the systemic nature of critical effects (ocular exudate, inflamed Meibomian glands, distorted growth of finger and toe nails, and decreased antibody response to sheep erythrocytes) observed in developing the Aroclor 1254 RfD.

The IRIS verified oral Slope Factor for High Risk/Persistence PCBs is 2.0 per (mg/kg)/day. As per IRIS this Slope Factor converts to an Inhalation Unit Risk = 5.7 E-04 per ug/m^3 through adjustment of body weight (70 Kg) and ventilation rate (20 m^3/day). (IUR = SF x 1/70 kg x 20 m^3/day x .001 ug/mg)

The IRIS verified Reference Dose (RfD) for Aroclor 1254 is 0.00002 mg/kg-day. For adults, this value converts to a Reference Concentration (RfC) of 0.07 ug/m^3 through adjustment of body weight (70 Kg) and ventilation rate (20 m^3/day). (RFC = RfD x 70 kg/20 m^3/day x 1,000 ug/mg) Because children have greater ventilation rates per unit body weight than adults the RfD to RfC conversion was also performed employing age-appropriate parameters for the student population. The Child-Specific Exposure Factors Handbook (USEPA, 2008) recommendations for children (6 to < 11 years old) are 31.8 kg for body weight and12.4 m^3/day for long-term mean inhalation rate. Use of these parameters result in a conversion from the RfD of 0.00002 mg/kg-day to an RfC = 0.05 ug/m^3 (RFC = RfD x 31.8 kg/12.4 m^3/day x 1,000 ug/mg).

Draft (4/28/09)

Do not Cite or Quote

Indoor Air Exposure Guidelines for Polychlorinated Biphenyls (PCBs) in P.S. 199

This document details the derivation of health-based exposure guidelines for PCBs in indoor air for students attending P.S 199 in Manhattan and has been developed by the United States Environmental Protection Agency (EPA) Region 2 in consultation with the New York State Department of Health (NYSDOH) and the New York City Department of Health and Mental Hygiene (NYCDOHMH). The exposure guidelines derived in this document are a function of the toxicity of the polychlorinated biphenyl (PCB) congeners and the exposure scenarios that are specific to P.S. 199. A health-based exposure guideline of 0.20 ug/m^3 was selected to protect students at P.S. 199 from long-term exposures to PCBs in the indoor air. An appendix to this document demonstrates that it is protective for teachers, administrative staff and custodial workers as well.

Toxicity

Sampling at P.S. 199 has indicated the presence of Aroclors 1248 and 1254. PCBs exhibit both carcinogenic and non-carcinogenic health effects. EPA's Integrated Risk Information System (IRIS) contains toxicity factors for both the cancer and the non-cancer health effects of various PCBs. Toxicity factors for non-carcinogenic effects are specific to particular Aroclors and for route of exposure. For carcinogenic effects, toxicity factors are categorized according to risk and persistence (i.e., high risk/persistence, low risk/persistence and lowest risk/persistence). For non-carcinogenic effects, the IRIS data base has quantitative toxicity assessments for two Aroclors (1016 and 1254) by the oral route of exposure. Inhalation toxicity factors for PCBs (Reference Concentrations [RfC]) are not available on IRIS. The IRIS data base has quantitative oral cancer potency values (Slope Factors) for the three aforementioned PCB risk/persistence categories. Inhalation specific cancer potency factors (Inhalation Unit Risk [IUR]) are not directly available on IRIS (see discussion below). An inquiry to EPA's Superfund Technical Support Center was made to check the status of Provisional Peer Reviewed Toxicity Values (PPRTVs). Inhalation PPRTVs for PCBs are not available for either non-cancer or cancer endpoints (USEPA 2009). In the absence of a route specific (i.e., inhalation) toxicity factors for PCBs, the toxicity factors (oral