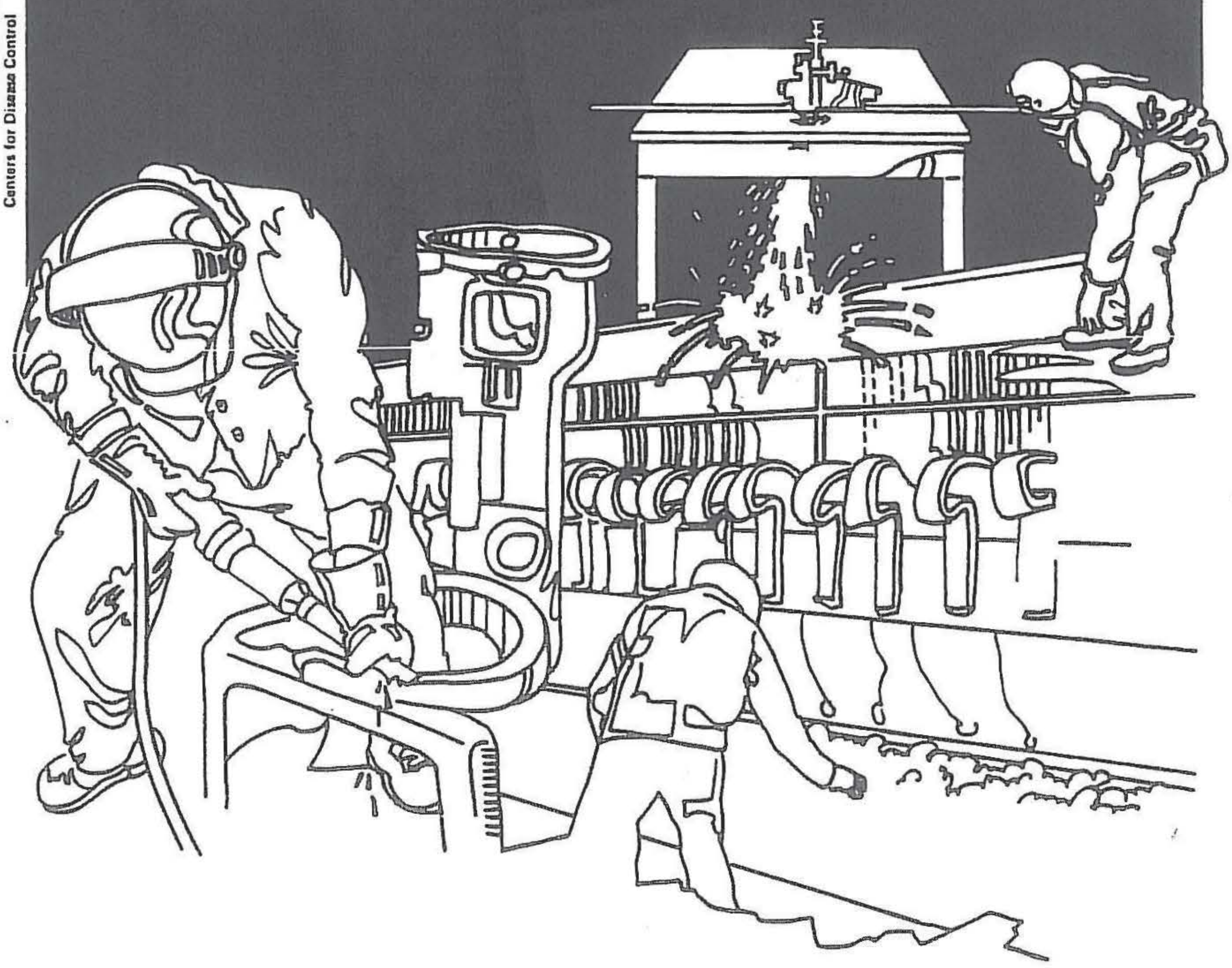
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health

NIOSH



Health Hazard Evaluation Report

HETA 85-126-1932
BRYN MAWR HOSPITAL
BRYN MAWR, PENNSYLVANIA

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

HETA 85-126-1932
SEPTEMBER 1988
BRYN MAWR HOSPITAL
BRYN MAWR, PENNSYLVANIA

NIOSH INVESTIGATORS:
Charles Bryant, M.S., C.I.H.
Richard Gorman, M.S., C.I.H.
John Stewart, B.S.
Wen-Zong Whong, Ph.D.

I. SUMMARY

On January 7, 1985, the National Institute for Occupational Safety and Health (NIOSH) received a request from a group of plastic surgeons at the Bryn Mawr Hospital in Bryn Mawr, Pennsylvania, to evaluate exposure to emissions generated by the use of electrocautery knives during reduction mammoplasty surgical procedures. Numerous health effects (headache, nausea, upper respiratory and eye irritation) reported by operating room personnel were cited in the request.

An initial on-site survey was conducted on February 14, 1985, with follow-up surveys performed on December 12, 1985 (Pennsylvania Hospital), April 28, 1987, and August 26, 1987. Industrial hygiene sampling was conducted to evaluate exposure to hydrocarbons, nitrosamines, total particulates, benzene soluble fraction, polynuclear aromatic compounds (PNAs), and airborne mutagens. In addition, since very little data had previously been collected for this exposure situation, sampling was performed to obtain qualitative exposure data utilizing a variety of solid sorbent tubes (high volume sampling), fourier transform infrared spectroscopy (FTIR), and aldehyde screening sorbent tubes (Orbo-23).

Personal (breathing zone) and area samples collected for hydrocarbons contained isopropanol at concentrations well below all relevant criteria.

None of the seven nitrosamines or sixteen PNAs that were evaluated were found in detectable quantities. Since several nitrosamines and PNAs are carcinogenic, any detectable levels would have been considered potentially significant.

Concentrations of airborne particulates ranged from 0.4 to 9.4 milligrams per cubic meter of air (mg/m^3) with a mean of 2.75 mg/m^3. Although these levels all were below the OSHA PEL (15 mg/m^3) and ACGIH TLV (10 mg/m^3) for total nuisance particulates, it is not known at this time whether this particulate is biologically inert; comparison with the nuisance dust evaluation criteria may not be appropriate.

The benzene-soluble fraction of the particulate samples ranged from 0.5 to 7.4 mg/m^3, averaging 2.4 mg/m^3. Seven of the 11 samples exceeded the NIOSH recommended exposure limit of 0.1 mg/m^3 and OSHA PEL of 0.2 mg/m^3. The purpose of these exposure criteria are to minimize worker exposure to carcinogenic PNA compounds. However, this is based on industrial settings (coke ovens, asphalt, petroleum coke) and may not apply to a non-industrial hospital environment.

Sorbent tubes (charcoal, silica gel, Tenax-TA) that were utilized at high sampling volumes, qualitatively revealed a trace (between the limit of detection and quantitation) amount of hydrocarbons. All of the concentrations were far below evaluation criteria and would not be expected to cause any health effects. FTIR analysis identified a component of the smoke as a compound or compounds related to fatty acid esters. None of the aldehydes (C_1-C_8 aldehydes) evaluated were detected.

Solvent extracts of airborne particles were mutagenic (with microsomal (S9) activation, and slightly mutagenic without activation) to the Salmonella typhimurium TA 98 strain, clearly indicating operating room personnel exposures to potentially genotoxic agents. However, whether exposure of operating room personnel to agents that are mutagenic to bacteria or the level of these agents to which workers are exposed pose any genotoxic hazards is not known.

On the basis of the mutagenicity of the airborne compounds collected during this evaluation, and the acute health effects reported by operating room personnel, NIOSH investigators determined that there is a potential hazard from exposure to smoke generated by electrocautery knives during reduction mammoplasty surgical procedures. Recommendations aimed at reducing exposures among operating room personnel are presented in Section VIII of this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals), operating rooms, electrocautery knives, electrocautery smoke, reduction mammoplasty, mutagenicity assessment, polynuclear aromatics (PNAs), nitrosamines, benzene-soluble fraction.

II. INTRODUCTION

On January 7, 1985, NIOSH received a request for a health hazard evaluation at the Bryn Mawr Hospital, Bryn Mawr, Pennsylvania. The request was submitted by a group of surgeons who were concerned about exposure to emissions generated by electrocautery knives when performing reduction mammoplastics. NIOSH investigators conducted environmental surveys at the Bryn Mawr and Pennsylvania Hospitals on February 14 and December 12, 1985; April 28, 1987; and August 26, 1987.

III. BACKGROUND

The surgical procedure known as breast reduction is one of the most common procedures where considerable smoke is produced. The plastic surgeons at Bryn Mawr Hospital became concerned about the chemical composition and toxicity of this smoke, after noticing that several operating room personnel were experiencing acute health effects during this procedure. Reported health effects included upper respiratory and eye irritation, headache, and nausea (obnoxious odors).

The electrosurgical knife (ESK) is presently used for a wide variety of surgical procedures in many health care facilities throughout the United States. Currently there may be as many as 30-40 U.S. manufacturers of ESK devices. These devices cut or coagulate body tissues utilizing a electromagnetic (EM) field that is focused onto the body site. The presence of this EM field requires the use of a grounding pad to be placed on the opposite side of the body being cut in order to collect all fields produced by the ESK devices. The ESK units used in this evaluation were a Valley Laboratory (model SSE2L) and a Neo-Med (model 3000). The operating parameters used on these systems during surgical procedures were the same (i.e. mid-range cut and coagulate settings estimated to be 120 watts delivered to the cutting area).

On February 14, 1985, NIOSH personnel conducted an initial environmental survey at the Bryn Mawr Hospital. Personal (breathing zone) and area air samples were taken for hydrocarbons, nitrosamines, total particulates, benzene soluble fraction, and polynuclear aromatic compounds (PNAs). Findings from this visit were presented in a letter dated May 7, 1985.

A follow-up visit was made on December 12, 1985 at the Pennsylvania Hospital in Philadelphia, Pennsylvania. Environmental samples were taken (at the suggestion of NIOSH chemists) for PNAs, total particulates, benzene soluble fraction, qualitative organic sorbent tube sampling (charcoal, silica gel, Tenax-TA), and Fourier Transform Infrared Spectroscopy (FTIR) for qualitative organic analysis. Results were reported on February 14, 1986.

On April 28, 1987, NIOSH conducted an additional follow-up study at the Bryn Mawr Hospital. Environmental air samples for qualitative aldehyde scans were obtained. Monitoring for airborne mutagens was performed on April 28 and August 26, 1987. Results were reported in a letter dated December 1, 1987.

Although the purpose of this evaluation was to determine the nature of the emissions produced by ESK devices in the operating room, it should be realized that there are other potential occupational health issues in addition to the chemical and environmental concerns. One issue is the production of EM radiation. Previous NIOSH research work on such systems has indicated that radiofrequency radiation at 0.5 megahertz is produced by these systems.[1] This finding has also been confirmed in another report.[2]

IV. METHODS AND MATERIALS

A. Total Particulates, Benzene Solubles, and PNAs

Personal and area air samples were collected utilizing a sampling train consisting of a Zefluor 2-micron filter (Membrana Co.) and a cellulose acetate O-ring in a cassette, followed by a 7-mm O.D. glass tube containing two sections of pre-washed XAD-2 resin (100mg/50mg) connected to a battery-operated sampling pump calibrated at a flowrate of 2.0 liters per minute (lpm).

Total particulate weights were determined by weighing the samples plus the filters on an electrobalance and subtracting the previously determined tare weight of the filters. The instrumental precision is 0.01 mg.

The benzene soluble fraction of the filter samples was determined by placing the filters in screw-cap vials with 5 ml of benzene and sonifying for 15 minutes. The extract was filtered through a Millex-HV 0.45 um filter and collected in a screw cap vial. Each sample was transferred into a tared Teflon cup and evaporated to dryness in a vacuum oven at 40°C. The teflon cups were again weighed and the difference recorded. The analytical limit of detection is 0.05 mg/sample.

The filter and tube samples were analyzed for PNAs following NIOSH Technical Bulletin TB-001 issued December 1, 1982. The filters and tubes were desorbed in 5 ml of benzene and sonicated for 30 minutes. The resulting solution was filtered through a 0.45 um nylon filter. The samples and standards desorbed in benzene were solvent exchanged to acetonitrile by alternate and multiple additions of acetonitrile and evaporation. The samples and standards were not allowed to go to dryness at any time during the exchange. Analysis was then performed by high performance liquid chromatography (HPLC) with a fluorescence/UV detector. The retention times of the analytes in the standards were compared to the retention times in the sample chromatograms for analyte identification. The standard analytes and their associated analytical limits of detection (LOD) are listed below:

Analyte	LOD nanograms/sample
Acenaphthene	100
Acenaphthylene	500
Anthracene	250
Benz(a)anthracene	25
Benzo(a)pyrene	25
Benzo(b)fluorathene	25
Benzo(e)pyrene	50
Benzo(k)fluoranthene	25
Benzo(g,h,i)perylene	50
Chrysene	25
Dibenz(a,h)anthracene	25
Fluoranthene	50
Fluorene	100
Indeno(1,2,3,c,d)pyrene	50
Phenanthrene	100
Pyrene	50

B. Nitrosamines

Personal and area air samples for nitrosamines were collected on Thermosorb/N tubes attached to battery-operated sampling pumps operating at a flowrate of 2.0 lpm. The tubes were desorbed with 2.0 ml of a solution of 75% methylene chloride and 25% methyl alcohol. The samples were then analyzed by gas chromatography with a thermal energy analyzer in the nitrosamine mode. The analytical limits of detection for this method ranged from 10-100 nanograms per sample (depending upon the particular nitrosamine that was to be identified).

C. Hydrocarbons

The air samples for hydrocarbons were collected by drawing air through a glass tube containing 150 milligrams of activated charcoal at a flowrate of 1.0 lpm (qualitative samples) and 0.2 lpm (quantitative samples) using calibrated, battery-operated sampling pumps. The samples were desorbed with 1 ml of carbon disulfide and analyzed by gas chromatography (GC) with a flame ionization detector (FID). Some of the samples were concentrated and analyzed by GC using a mass spectrometer for major compound identification.

D. Sorbent Tubes - Qualitative Organic Analysis

Personal and area air samples for qualitative organics analyses were collected on charcoal, silica gel, and Tenax-TA tubes attached to battery-operated sampling pumps operating at a flowrate of 1.0 lpm (Tenax-TA, 0.5 lpm).

The high volume Tenax tubes were analyzed first by thermal desorption. A Tekmar model 4000 dynamic headspace concentrator equipped with a heated sampler module and capillary cryofocusing interface was used for this procedure. The concentrator unit was interfaced directly to a GC/MS system. Front 100 mg sections of the Tenax sample tubes were put into the sampler module heated to 200°C. The headspace was continually purged during this time and the effluent trapped on an internal Tenax trap. The trap was then thermally desorbed onto the front end of a 30-meter DB-1 capillary column, flash heated, and injected into the gas chromatograph and mass spectrometer for analysis.

Both the charcoal and silica gel sorbent tubes were screened by gas chromatography (FID) and GC/MS. Charcoal tubes were desorbed with 1 mL carbon disulfide and the silica gel tubes were desorbed with 1 mL ethanol. Both front sections and the front glass wool plugs were desorbed together. All analyses were performed using 30-meter DB-1 fused silica capillary columns (splitless mode).

E. Fourier Transform Infrared Spectroscopy (FTIR) - Qualitative Organic Analysis

Personal and area samples for FTIR analysis were collected by drawing air through a Zefluor filter at a flowrate of 1.0 lpm using calibrated, battery-operated sampling pumps.

Of the six samples submitted, one area and one personal sample were selected for analysis after visually inspecting the filters. The initial analysis involved the analysis of the filters using attenuated total reflectance spectroscopy (ATR). The area sample filter was removed from its cassette and placed in a Barnes Model 305 Horizontal ATR cell. The crystal in the cell was KRS-5 (thallous bromide). Spectra were collected with a Nicolet 60SX Fourier Transform Infrared Spectrometer using a combined Indium Actinimide/Mercury Cadmium Telluride detector at 0.5 cm^{-1} spectral resolution. After correcting the recorded sample spectra for the background effects of the filter, there appeared to be some compound present. When the filter was removed from the ATR cell, an oily residue was noted to remain on the ATR cell crystal. A spectra of this material was recorded and corrected for the background of the ATR cell. The corrected spectra was compared with the Aldrich FTIR spectral search library using Nicolet searching software. This filter was then desorbed with 1,1,2-trichlorotrifluoroethane. This solution was then evaporated onto the ATR crystal. The spectra was similar to that obtained from the residue of the filter. This desorption procedure was also used for the personal sample.

F. Qualitative Aldehyde Screen

Samples for airborne aldehydes were collected by drawing air through Orbo-23 tubes at a flowrate of 0.08 lpm. Samples were desorbed with 1 mL of toluene in an ultrasonic bath for 60 minutes. Aliquots of the sample extracts were then screened by gas chromatography (FID) twice; first with a 30-meter DB-1 GC column, and second with a 30-meter DB-was fused silica capillary column (spitless mode).

G. Airborne Mutagens

Airborne particles were collected on glass-fiber filters (type A/E, 4" diameter) using Hi-Vol pumps (General Metal Works) at flow rates between 17 and 24 cfm. Filters were changed if the flow rate dropped below 17 cfm.

Samples from the first survey (April 28, 1987) were first extracted with 150 ml of methylene chloride (DCM) then with 150 ml of acetone plus methanol (A+M). Samples from the second survey (August 25, 1987) were divided, because of the quantity of particles. One half was extracted similar as that in the first survey, the other half was extracted with an XAD-2 resin column. Each extract was filtered and concentrated to a final volume of 0.45 ml and 0.3 ml in dimethyl sulfoxide for the first and second surveys, respectively.

The same sampling sites were used for both surveys. In the operating room (OR), air was sampled 3 ft directly above the operation. As a control (CR), samplers were placed 1/2 ft above the floor in the anteroom.

All extracts were tested for the mutagenic activity in both tester strains TA98 and TA100 of Salmonella typhimurium using the Salmonella/microsomal micro-suspension test.[3] The system is characterized by adding increased numbers of bacterial cells (approx. 10^9) which are exposed to airborne particle extracts with or without S9 in a concentrated treatment mixture. For metabolic activation, 0.065 ml of S9 mix (10% S9) was also added to each treatment tube. The S9 was prepared from the livers of male Fischer rats pretreated with Aroclor 1254 (500 mg/kg body wt). The micro-suspension test is a suitable assay system for limited quantities of test materials. After 90 minute pre-incubation at 37°C, the mixture is processed according to the standard Ames test protocol.[4] The mutagenic activity was scored in tester cells from histidine-dependence to histidine-independence.

In the <u>in situ</u> assay, samples were taken at intervals of 2,4, and 6 hours post-operation from the trapping media and were plated on the appropriate agar plates to determine survival and mutation frequencies.[5] Plates were scored after incubation at 37°C for 2 days.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week, for a working lifetime, without experiencing adverse health effects. It is, however, important to note that not all exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects, even if the occupational exposures are controlled at the level set by the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus, potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH criteria documents and recommendations, 2) the ACGIH TLVS, and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLVs are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLVs usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH recommended standards, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in the report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10- workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA, where there are recognized toxic effects from high short-term exposures.

Isopropanol

Isopropyl alcohol causes mild irritation of the eyes, nose, and throat. High vapor concentrations may cause drowsiness, dizziness, and headache. Repeated skin exposure may cause drying and cracking. NIOSH recommends an exposure limit of 980 mg/m^3.[6] The OSHA standard and ACGIH TLV are the same.[7,8]

Nitrosamines

Nitrosamines are a class of compounds which are readily formed by the interaction of secondary amines and nitrites or oxides of nitrogen. Because these precursors are ubiquitous, nitrosamines have been found in air, water, tobacco smoke, cured meats, cosmetics, and in many industrial processes, including leather tanneries, pesticide formulations, and tire and rubber manufacturing facilities.[9]

Nitrosamines are considered to be among the most potent of animal carcinogens. Of more than 150 nitrosamine compounds tested approximately 80% have been found to be carcinogenic in at least one species of animal. To date, there are no standards for employee exposure to airborne nitrosamines. OSHA has a regulation regarding work practices and handling of liquid and solid N-nitrosodimethylamine in concentrations greater than 1%.[8] In addition, the Food and Drug Administration has limited the amount of nitrosamines allowed in beer to 5 parts per billion (ppb) and the United States Department of Agriculture has limited nitrosamine concentration in cooked bacon to 10 ppb. The International Agency for Research on Cancer recommends that N-nitrosodimethylamine, N-nitrosodiethylamine, N-nitrosodibutylamine, and N-nitrosomorpholine be regarded for practical purposes as if they were carcinogenic to humans.[10] NIOSH policy on human exposure to known or suspected carcinogens is to reduce exposure to the lowest feasible level.[11]

PNAs and Benzene or Cyclohexane Solubles

PNAs are condensed ring aromatic hydrocarbons normally arising from the combustion of organic matter. They are commonly emitted into the air when coal tar, coal tar pitch, or their products are heated, but can result from burning the heavy petroleum fraction used in petroleum coke.[12] A number of PNAs, including benzo(a)pyrene and anthracene are carcinogenic (lung and skin). There are no federal standards pertaining to airborne concentrations of individual PNAs. In 1967, the ACGIH adopted a TLV of 0.2 mg/m^3 for coal tar pitch volatiles (CTPV), described as a "benzene-soluble" fraction, and listed certain carcinogenic components of CTPV. The TLV was established to minimize exposure to the listed substances believed to be carcinogens, viz, anthracene, BaP [benzo(a)pyrene], phenanthrene, acridine, chrysene, and pyrene. CTPV's are among the seven substances listed as "Human Carcinogens" in Appendix A of the current ACGIH TLVs. This group consists of "a substance, or substances, associated with industrial processes, recognized to have carcinogenic or cocarcinogenic potential with an assigned TLV". The TLV was promulgated as a federal standard under the Occupational Safety and Health Act of 1970 (29 CFR 1910.1000).[13] In 1972, the Federal Register (37:24749, November 21, 1972) contained an interpretative rule of the term "coal tar pitch volatiles": ". . . coal tar pitch volatiles include the fused polycyclic hydrocarbons which volatilize from the distillation residues of coal, petroleum, wood, and other organic matter". This has been reprinted as 29 CFR 1910.1002. The general philosophy behind this interpretation was that "all of these volatiles have the same basic composition and . . . present the same dangers to a person's health".[14]

In the development of the NIOSH recommended standard, it was concluded that CTPV's are carcinogenic and can increase the risk of lung and skin cancer in workers. Since no absolutely safe concentration can be established for a carcinogen, NIOSH recommended the exposure limit be the lowest concentration that can be reliably detected by the recommended method of environmental monitoring. At that time (September 1977) the lowest detectable concentration for CPTV's was 0.1 mg/m^3 for the recommended sampling method.

Although the benzene or cyclohexane extractable fraction offers an easier, less expensive method of analysis than PNA quantitation, there is no certainty that there is a correlation between the two. The analytical method for measuring the benzene-soluble fraction is not limited to PNAs but will include all other organic compoumds collected on the filter and soluble in benzene.[15]

Mutagenicity Assay

All the overlayed plates were scored for <u>his+</u> revertants after 2 days of incubation. An extract was considered mutagenic if the number of revertants in any of the four concentrations tested (undiluted, 1 to 2, 1 to 4, 1 to 8) was two fold or greater than the control, and showed a dose-related response.

VI. RESULTS

A. Hydrocarbons

Table I presents the results of the air samples taken for hydrocarbons. Four of the five samples taken contained isopropanol in concentrations ranging from 1.4 to 4.9 mg/m^3. All of the samples were well below the evaluation criteria of 980 mg/m^3. The likely source was not the emissions from surgery, but the isopropanol used as a sanitizing agent in the operating room.

B. Nitrosamines

The results of the air samples taken for nitrosamines are presented in Table II. None of the seven nitrosamines evaluated were detected. The specific compounds evaluated included the nitrosamines of dimethyl, diethyl, dipropyl, and dibutylamine, plus those of pyrolidine, piperidine and morpholine. The limit of detection for these compounds ranged from 25-150 nanograms/sample. Since several nitrosamines are carcinogenic, any detectable levels would have been considered significant.

C. Particulates, Benzene Solubles, and PNAs

Tables III and VI contain the data from the analysis of the Zefluor filters and the Orbo-43 tubes. Each filter and tube sampling train provided the following three types of data:

1. Total Particulates - represents the total weight of the smoke per cubic meter of sampled air. Five personal breathing-zone air samples for total particulate ranged from 0.4 to 2.0 mg/m^3 with a mean of 1.0 mg/m^3. Six area samples ranged from 0.7 - 9.4 mg/m^3, with a mean of 4.2 mg/m^3.

2. Benzene Soluble Fraction - represents the total weight of the smoke that is benzene soluble per cubic meter of sampled air. No benzene soluble fraction was detected in any of the particulate samples taken on February 14, 1985. All of the samples taken on December 12, 1985, had a benzene soluble fraction, ranging from 0.7 - 6.7 mg/m^3, well above the NIOSH evaluation criteria of 0.1 mg/m^3.

3. PNAs - represents the analysis for 17 polynuclear aromatic hydrocarbons. None of the 17 PNAs which are monitored in the NIOSH standard method were detected in any of the samples.

D. Sorbent Tubes - Qualitative Organic Analysis (Table IV)

Table IV lists the substances that were identified by sorbent tube sampling during the survey on December 12, 1985. The air samples indicate that trace amounts (less than 10 micrograms) of hydrocarbons were present within the operating room. The substances identified would not be expected to cause ill health effects in most people at the levels detected.

E. Fourier Transform Infrared Spectroscopy (FTIR) - Qualitative Organic Analysis

The search area of the spectral library indicated that the compounds found on both the area and personal filters were related to fatty acid esters, based on spectral similarities. A search of the library using the absolute derivative search algorithm indicated that olive oil, cottonseed oil, methyl stearate and castor oil were all close matches to the sample spectra for the bulk sample. The goodness-of-fit values associated with each of these matches were all equivalent and higher than what would be expected for an exact match. A low goodness-of-fit value indicates a good match of library spectra. For the qualitative sample, matches included ethyl stearate, castor oil and other straight chain hydrocarbon compounds. Based on the source of the sample, the identification of the sample as fatty acid esters is logical.

Attempts made to analyze these samples by gas chromatography were unsuccessful. The samples were not volatile enough to allow chromatography.

As a final attempt at characterization of the samples, the two desorbed filter solutions were submitted for direct probe mass spectral analysis. The solutions were evaporated onto the direct probe of the mass spectrometer and heated under vacuum. Results from this analysis indicated that the samples gave mass spectral detail related to straight chain hydrocarbons, i.e. methylene group (CH_2) fragments. Since fatty acid esters contain long chain alkyl groups, this fragmentation pattern was not unexpected. The mass spectra were compared to methyl stearate and stearyl palmitate and were found to be similar to the sample spectra but were not an exact match, indicating that there was probably a mixture of fatty acid esters in the samples.

F. Qualitative Aldehyde Screen

Table VII presents the results of the area and personal samples taken for qualitative aldehyde scan analysis. No aldehydes were detected. It should be noted that the aldehyde scan has only been tried on the low molecular weight (C_1 - C_8) aliphatic aldehydes.

G. Airborne Mutagens

Airborne particles collected on glass-fiber filters from both surveys were found to be mutagenic (TA98). Samples from the first survey on April 28, 1987, (Table VIII) showed a positive response only with S9, but the second survey (August 26, 1987) samples also showed a slight response without activation. The mutagenic response of extracts from the organic solvent extraction of the second survey was higher than those from the XAD-2 column extraction (Table IX). No significant mutagenic response was found with the *in situ* assay system in either survey (Table X). The population of TA98W for the *in situ* testing was too low and gave sporadic results. This was not reported.

An extract was considered mutagenic if the number of revertants in any of the four concentrations tested (undiluted, 1 to 2, 1 to 4, 1 to 8) was two fold or greater than the control and showed a dose-related response.

VII. CONCLUSIONS

A. No specific organic vapors, other than isopropanol, were quantitatively identified during the surgical procedures.

B. There were no PNA's or nitrosamines detected during the procedures.

C. The exposures to particulates, which ranged from 0.4 to 2.0 mg/m^3, confirms that the visible emissions are more than just water vapor. However, there are no exposure criteria with which to compare this exposure. Exposure criteria of 10-15 mg/m^3 has been established for nuisance dust; however, to apply this criteria, the particulate would need to be biologically inert, which in this case, is not known. Airborne particulate can contribute to the eye irritation which has been reported during these procedures. We would have expected the samples from the surgeons and some of the area samples (hand-held approximating breathing-zone) to be similar. The "not-detected" on one surgeon suggests that we encountered a flow problem with that sample train even though the flow looked fine at the end of the sampling period.

D. The sample (Table III) taken during a brief demonstration of the laser-cutting technique measured 9.4 mg/m^3 of total particulate of which 7.4 mg/m^3 was found to be benzene soluble. It is difficult to make conclusions based on one sample, but this data suggests that there is a tendency for the laser method to produce more particulate that is soluble in benzene. Whether this produces more PNA's is unknown.

E. All of the particulate samples taken on December 12, 1985, contained benzene soluble fractions above the evaluation criteria. However, it should be noted that the following three issues complicate the interpretation of the benzene soluble fraction data:

   1. Three of the four area samples contained benzene soluble fractions that were higher than the corresponding total particulate values. This is improbable; the benzene soluble fraction can be equal to, but never exceed the total particulate value. A review of the blank values revealed no discrepancies in the analytical procedures. No explanation for this anomaly can be offered at this time.

   2. None of the electrocautery samples taken during the February 14 survey contained a benzene soluble fraction, while all the samples taken on December 12 had a benzene soluble fraction above the NIOSH evaluation criteria. Sampling conditions were almost identical. Again, no explanation for the difference in concentrations can be given.

   3. PNAs are benzene soluble and would therefore be contained in the benzene soluble fraction of the total particulate samples. It follows that the higher the value for benzene solubles, the more potential for PNAs and, therefore, the greater the risk from the exposure. However, it should be noted that this concept is based on industrial exposures (coal tar pitch volatiles, petroleum coke, asphalt fumes, etc.). Although the benzene extractable fraction offers an easier, less expensive method of analysis than PNA quantitation, there is no certainty that there is a correlation between the two (especially in a non-industrial setting).

F. Trace amounts of hydrocarbons were identified, (utilizing high volume sorbent tube sampling) and would not be expected to cause ill health effects in most people at the levels detected.

G. Based on the FTIR (qualitative organic) analysis, the major component of the samples is a compound or compounds related to fatty acid esters.

H. Aldehydes (C_1 - C_8 aliphatic) were not present in quantifiable levels.

I. The results of the studies for airborne mutagens clearly indicate that the solvent extracts of airborne particles collected from the hospital operating room using cauterization were mutagenic. The mutagenic activity varies from patient to patient; age, fat content, and size. The patient in the first survey was older with more fat in the tissue than the patient in the second survey. By comparison, samples from the second survey showed at least double the mutagenic activity than those of the first. Whether exposure of operating room personnel to agents that are mutagenic to bacteria or the level and condition of these agents to which workers are exposed pose any genotoxic hazards is not known. Limited information suggests that there is a correlation between the bacterial mutagenicity level of airborne particles and lung cancer incidence.[16,17] Index of the mutagenicity of air particles has been considered to be a more powerful measure of the human health hazard of air pollution than the traditional indices of particulate concentration.[17] This information is yet to be validated by further epidemiological studies where the mutagenic activity of collected air samples is known. In the meantime, it may be prudent to monitor operating room personnel for any adverse health effects and to reduce mutagenically active contaminants whenever possible in the operating room.

J. Operating room staff experience acute health effects (upper respiratory and eye irritation, headache, nausea (obnoxious odors)) during this type of surgery where electrocautery techniques are used for a substantial part of the total operative procedure.

VIII. RECOMMENDATIONS

1. Engineering ventilation controls (smoke evacuation units) should be utilized to minimize the acute health effects and further reduce the potential for any chronic health effects. The smoke evacuation units will also eliminate the emissions that can impair the surgeon's vision.

2. Any further acute or chronic health effects experienced by the operating room staff should be evaluated and documented.

3. Exposure to electrocautery smoke should be reevaluated if other techniques for identifying and quantitating the smoke emissions can be found or developed.

IX. REFERENCES

1. Moss, C.E. 1988. Evaluation of Body Currents from Exposure to Radiofrequency Fields. Paper Presented at the American Industrial Hygiene Conference, San Francisco, CA, May 15-20, 1988.

2. Paz J, Ingram TW, Milliken R, Hartstein G. 1988. Real Time Dosimetric Survey During Electrocautery Surgery. Paper Presented at the American Industrial Hygiene Conference, San Francisco, CA, May 15-20, 1988.

3. Kådo, et. al. A simple modification of the Salmonella liquid-incubative assay. Mutation Res. 121:25-32, 1983.

4. Ames, et. al. Methods for detecting carcinogens and mutagens with Salmonella/mammalian microsome mutagenicity test. Mutation Res. 31:347-363, 1976.

5. Whong, W-Z., et. al. Development of an <u>in situ</u> microbial mutagenicity test system for airborne workplace mutagens: laboratory evaluation. Mutation Res. 130:45-51, 1984.

6. National Institute for Occupational Safety and Health. Current Intelligence Bulletin 48: Organic Solvent Neurotoxicity. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1987. (DHHS Publication No. (NIOSH) 87-104)

7. American Conference of Governmental Industrial Hygienists. Threshold Limit Values and Biological Exposure Indices for 1987-1988. Cincinnati, Ohio: ACGIH, 1987.

8. Occupational Safety and Health Administration. OSHA Safety and Health Standards. 29 CFR 1910.1000. Occupational Safety and Health Administration, revised 1987.

9. Frank CW and Berry CM. N-nitrosamines. In: Patty's Industrial Hygiene and Toxicology Vol IIB, Chapter 43, 3rd revised edition, New York, John Wiley and Sons, 1981.

10. Bogovski R, Preussman EA, Walker EA, and Davis W. Evaluation of Carcinogenic Risk of Chemicals to Man. IARC Monographs, Vol. 1, International Agency for Research on Cancer, World Health Organization, Lyon, France, 1972.

11. National Institute for Occupational Safety and Health. Working with Carcinogens. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1977. (DHEW publication no. (NIOSH) 77-206).

12. Scala, RA, "Toxicology of PPOM" <u>J. Occupational Medicine,</u> 17: 784-8, 1975.

13. National Institute for Occupational Safety and Health. Criteria for a recommended standard: occupational exposure to coal tar products. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1978. (DHEW publication no. (NIOSH) 78-107).

14. National Institute for Occupational Safety and Health. Criteria for a recommended standard: occupational exposure to asphalt fumes. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1978. (DHEW publication no. (NIOSH) 78-106).

15. National Institute for Occupational Safety and Health. Petroleum Refinery Workers Exposure to PAHs at Fluid Catalytic Cracker, Coker, and Asphalt Processing Units. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1981. (NIOSH Contract No. 210-78-0082).

16. Kaiser C, Kerr A, McCalla DR, Lockington JN, Gibson ES (1981): Use of bacterial mutagenicity assays to probe steel foundry lung cancer hazard. Polynucl. Aromat. Hydrocarbons Int. Symp. Chem. Biol. Effects, 5th, Ohio 583-592.

17. Walker RD, Connor TH, MacDonald EJ, Trieff NM, Legator MS, MacKenzie KW, Dobbins JG (1982): Correlation of mutagenic assessment of Houston air particulate extracts in relation to lung cancer mortality rates. Environ. Res. 28:303-312.

X. AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared by:	Charles J. Bryant, C.I.H. Industrial Hygienist Industrial Hygiene Section
	Richard Gorman, C.I.H. Industrial Hygiene Engineer Industrial Hygiene Section
	John Stewart, B.S. Research Microbiologist NIOSH Morgantown, West Virginia
	Wen-Zong Whong, Ph.D. Geneticist NIOSH Morgantown, West Virginia
Field Assistance:	James Boiano, C.I.H. Industrial Hygienist Industrial Hygiene Section
Originating Office:	Hazard Evaluations and Technical Assistance Branch Division of Surveillance, Hazard Evaluations, and Field Studies
Report Typed By:	Kathy Conway Clerk-typist Industrial Hygiene Section

XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. John E. Gatti, M.D., J. Brien Murphy, M.D., and R. Barrett Noone, M.D.
2. NIOSH, Boston Region
3. OSHA, Region III

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

TABLE I

Isopropanol
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

February 14, 1985

Sample Location/Job	Sample Type	Sampling	Isopropanol (mg/m^3)*
Assistant Surgeon	Personal	13:30-15:20	1.4
Surgeon	Personal	13:30-15:20	2.1
Anesthesia Area or Operating Room Lights	Area	13:30-15:20	1.4
Surgical Nurse	Personal	13:30-15:20	4.9
Laser Used on Breast Tissues	Area	15:30-15:41	ND**
Evaluation Criteria: (8 hr. time weighted average)		NIOSH ACGIH OSHA	980 980 980

* = All air concentrations are reported as time-weighted averages for the time period sampled.

**ND = Non-Detectable. Limit of detection is 0.01 mg/sample, which would correspond to an atmospheric concentration of 0.48 mg/m^3 when the average sample air volume (21 liters) is considered.

TABLE II

Nitrosamines
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

February 14, 1985

Sample Location/Job	Sample Type	Sampling Period	Nitrosamines*
Assistant Surgeon	Personal	13:30-15:20	ND**
Surgeon	Personal	13:30-15:20	ND**
Anesthesia Area or Operating Room Lights	Area	13:30-15:20	ND**
Surgical Nurse	Personal	13:30-15:20	ND**
Laser Used on Breast Tissue	Area	15:30-15:41	ND**
Evaluation Criteria			LFL***

* = NIOSH currently uses a seven standard mixture to calibrate and identify specific nitrosamines. The mixture contains the nitrosamines of dimethyl, diethyl, dipropyl and dibutylamine plus those of pyrrolidine, piperidine and morpholine.

**ND = Non-Detectable. Limits of detection range from 25-150 ng/sample (air adjusted concentrations would range from 114-682 ug/m^3).

*** = No evaluation criteria has been established for nitrosamines. Exposure should be reduced to lowest feasible level (LFL).

TABLE III

Particulates, Benzene Solubles, and PNAs
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

February 14, 1985

Sample Location/Job	Sample Type	Sampling Period	Exposure Concentrations*		
			Total Particulates (mg/m^3)	Benzene Soluble (mg/m^3)	PNAs**
Assistant Surgeon	Personal	13:30-15:20	1.6	ND	ND
Surgeon	Personal	13:30-15:20	ND***	ND	ND
Anesthesia Area or Operating Room Lights	Area	13:30-15:20	1.2	ND	ND
Surgical Nurse	Personal	13:30-15:20	0.4	ND	ND
Laser Used on Breast Tissue	Area	15:30-15:41	9.4	7.4	ND
Evaluation Criteria (8 hr. time-weighted average)	NIOSH		-	0.1	****
	ACGIH		10	0.2	****
	OSHA		15	0.2	****

* = All air samples are reported as time-weighted averages for the time period sampled.

** = Represents the following EPA priority PNAs: acenapthene, acenaphthylene, anthracene, benz(a)anthracene, benzo(a)pyrene, benzo(a)fluorathene, benzo(e)pyrene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, dibenz(a,h)anthracene fluoranthene, fluorene, indeno(1,2,3,c,d)pyrene, phenanathrene, pyrene.

***ND = Non Detectable. Limits of detection are 0.01 mg/sample for total particulates, 0.05 mg/sample for benzene soluble fraction, and 25-500 ng/sample for the various PNAs analyzed for.

**** = No criteria curently exists for total PNA's, however a number of individual PNA's are carcinogenic (benzo(a)pyrene, anthracene, chrysene) and exposures should be controlled to the lowest feasible level.

TABLE IV

Sorbent Tube Sampling
Pennsylvania Hospital
Philadelphia, Pennsylvania
HETA 85-126

December 12, 1985

Sorbent Tube	Substance Identified
Tenax - TA*	Isoflurane (Anesthetic Gas) Halothane "
Charcoal**	Isoflurane Isopropanol 1,1,1 - Trichloroethane Trichloroethylene Toluene Perchloroethylene Xylene Several Aliphatic Hydrocarcarbons
Silica Gel	None Detected

* = Thermally desorbed tubes cannot be quantitated.

** = Substances were present in trace quantities, between the limit of detection (1-5 ug/sample) and limit of quantitation (5-10 ug/sample).

TABLE V

Zefluor Filter Sample/Fourier Transform Infrared Spectroscopy Analysis
Pennsylvania Hospital
Philadelphia, Pennsylvania
HETA 85-126

December 12, 1985

Sample Type	Substance Identified
Zefluor (Area)	Compound or compounds related to fatty acid esters
Zefluor (Personal)	Compound or compounds related to fatty acid esters

TAB

Particulates, Benzene Solubles, and PNAs
Pennsylvania Hospital
Philadelphia, Pennsylvania
HETA 85-126

December 12, 1985

Sample Location/Job	Sample Type	Sampling Period	Exposure Concentrations* Total Particulates (mg/m^3)	Benzene Soluble (mg/m^3)	PNAs**
Surgeon	Personal	11:30 - 12:40	2.0	1.4	ND
Assistant Surgeon	Personal	11:30 - 12:40	0.9	0.7	ND
Hand-Held/Operative Site	Area	11:35 - 12:35	0.7	1.3	ND
Hand-Held/Operative Site	Area	11:35 - 12:35	0.7	1.7	ND
Hand-Held/Breast Tissue/ Post-surgery	Area	13:00 - 13:15	8.7	6.7	ND
Hand-Held/Breast Tissue/	Area	13:00 - 13:15	4.7	6.7	ND
Evaluation Criteria: (8 hr. time weighted average)	NIOSH		-	0.1	***
	ACGIH		10	0.2	***
	OSHA		15	0.2	***

* = All air samples are reported as time-weighted averages for the time period sampled.

** = Represents the following EPA priority PNSs: acenaphthene, acenaphthylene, anthracene, benz(a)anthracene, benzo(a)pyrene, banzo(a)fluoranthene, benzo(a)pyrene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, dibenz(a,h)anthracene, fluoranthene, fluorene, indeno(1,2,3,c,d)pyrene, phenanthrene, pyrene.

***= No criteria curently exists for total PNA's, however a number of individual PNA's are carcinogenic (benzo(a)pyrene, anthracene, chrysene) and exposures should be controlled to the lowest feasible level.

ND = Non Detectable. Limits of detection are 0.01 mg/sample for total particulates, 0.05 mg/sample for benzene soluble fraction, and 25-500 ng/sample for the various PNAs analyzed for.

TABLE VII

Qualitative Aldehyde Scan
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

April 28, 1987

Sample Location	Type Sample	Aldehydes Identified*
Scrub Nurse	Personal	None
Surgeon	"	"
Assistant Surgeon	"	"
Anesthetist	Area	"
Operating Room	"	"

* = Aldehyde scan has only been tried on the low molecular weight (C_1-C_8) aliphatic aldehydes.

TABLE VIII

Mutagenicity of Airborne Particle Extracts
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

April 28, 1987

	Particles ug/plate	Air Vol. m^3/plate	His Rev/Plate			
			TA98		TA100	
			-S9	+S9	-S9	+S9
DCM Extraction						
Operating	78	0.25	4	6	54	55
Room	155	0.49	6	8	64	52
	310	0.98	10	19	62	50
	620	1.95	10	31	62	55
Control	9	0.25	4	8	51	43
Room	18	0.49	7	9	60	47
	37	0.98	8	8	48	45
	73	1.95	8	11	53	48
Filter Control			5	8	54	45
Negative Control			7	5	44	46
Positive Control*			1608			1926

* = 2-aminoanthracine; 2.5 ug/plate
His Rev = Histidine Revertants

TABLE IX

Mutagenicity of Airborne Particle Extracts
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

August 26, 1987

	Particles ug/plate	Air Vol m^3/plate	His Rev/Plate		
			TA98		TA100
			-S9	+S9*	+S9
DCM Extraction					
Operating Room	265	0.35	5	37	54
	530	0.70	6	69	67
	1060	1.41	12	92	79
Control Room	17	0.73	4	8	52
	33	1.46	2	7	73
Filter Control			3	6	64
XAD2 Column Extract					
Operating Room	265	0.35	4	24	57
	530	0.70	6	33	45
	1060	1.41	10	57	57
Control Room	17	0.73	2	8	55
	33	1.46	5	8	49
Filter Control			4	7	59
Negative Control			4	7	68
Positive Control**				1551	1610

* = Average of two experiments
** = 2-aminoanthracine; 2.5 ug/plate
His Rev = Histidine Revertants

TABLE X

In SITU Testing Of Airborne Particle Extracts*
Bryn Mawr Hospital
Bryn Mawr, Pennsylvania
HETA 85-126

	Control Room				Operating Room			
	C		T		C		T	
Hour	% Sur	Rev/ 10^7	% Sur	Rev/ 10^7	% Sur	Rev/ 10^7	% Sur	Rev/ 10^7
				April 28, 1987				
2	100	8	104	7	100	7	97	8
4	100	5	111	7	110	6	100	7
6	104	8	114	7	124	6	107	8
2S	100	7	79	10	100	11	123	10
4S	74	11	58	12	85	14	108	10
6S	40	17	33	21	52	20	92	13
				August 25, 1987				
2	100	14	164	12	100	12	131	13
4	118	13	182	10	108	8	123	11
6	109	12	200	13	108	10	131	12
2S	100	21	127	16	100	26	112	23
4S	97	21	116	21	102	24	138	19
6S	64	33	80	30	57	37	75	35

* = TA100 only
S = With S-9 activation
C = Recirculating closed system (control)
T = Ambient room air
%Sur = Percent survival
Rev/10^7 = Number of revertants/10^7 living cells

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ROBERT A. TAFT LABORATORIES
4676 COLUMBIA PARKWAY, CINCINNATI, OHIO 45226

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

Third Class Mail

U.S.MAIL

POSTAGE AND FEES PAID
U.S. DEPARTMENT OF HHS
HHS 396