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UNITRON INDUSTRIES, INC.
PORT HURON, MICHIGAN

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I. SUMMARY

On February 5, 1993, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation (HHE) from employee and management representatives of Unitron Industries, Inc. in Port Huron, Michigan stating that employees in a hearing aid mold manufacturing laboratory were concerned whether the chemicals used in the manufacture of the molds would have acute or long-term health effects. Upon further discussion with the requester, it was learned that workers were experiencing a variety of health symptoms, such as headache, sore throat, eye irritation, fatigue, skin rash, and difficulty concentrating, which they attributed to various chemical exposures in the workplace.

Industrial hygiene surveys were conducted over two days in April 1993, and over one day in August 1993, to measure the airborne concentration of several chemicals used in the laboratory, including methylene chloride, methyl methacrylate, cyanoacrylates, and various organic solvents. Exposures to methylene chloride, and possibly to ethyl-2-cyanoacrylate were excessive during the April evaluation. Subsequently, the company installed new ventilation systems during the period between the two surveys. During the August visit, results of the second industrial hygiene survey showed that the worker exposures had been reduced to not detectable levels in most instances. Additionally, during this visit, medical interviews were conducted with some of the previous, and all of the current, laboratory workers. A review of many of the workers' medical records was also performed. The medical evaluation concluded that laboratory employees were experiencing symptoms that were consistent with their workplace chemical exposures and that the severity and frequency of their symptoms had notably improved with implementation of new engineering controls.

KEYWORDS: SIC 3842 (Orthopedic, Prosthetic, and Surgical Appliances and Supplies); hearing aid mold laboratory; methyl methacrylate; cyanoacrylates; methylene chloride; organic solvents; contact dermatitis; headache; chest tightness; eye, nose, and throat irritation; ventilation systems.

II. INTRODUCTION

On February 5, 1993, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation (HHE) from employee and management representatives of Unitron Industries, Inc. in Port Huron, Michigan. The request stated that the employees in a hearing aid mold manufacturing laboratory were concerned about the ventilation parameters in the laboratory and whether the chemicals used in the manufacture of the molds would have acute or long-term health effects. A list of chemicals used to manufacture the ear molds, as well as a list of current employee medical symptoms, accompanied the request for the HHE. Laboratory workers reported suspected work-related symptoms, such as headaches, chest tightness, and eye, nose, and throat irritation.

An industrial hygiene survey of the ear mold laboratory (EML) was conducted on April 14-15, 1993, that included air sampling of the laboratory for possible contaminants and an evaluation of the ventilation systems in the EML. Discussions were also held with the employees of the EML about their concerns and individual symptoms. Based on the information gained during the first survey, a second survey of the EML was made on August 25, 1993. The second survey repeated the air sampling for contaminants in the laboratory and, in addition, included medical interviews of EML employees by a NIOSH medical officer. Between the two survey periods, Unitron Industries, Inc. contracted with a ventilation firm who made changes in the air handling systems and installed a local exhaust ventilation hood at a work station in the laboratory. The second survey was completed after the ventilation changes were made. Preliminary information about the surveys was conveyed to Unitron Industries, Inc. by letters dated April 26, 1993, July 15, 1993, and January 26, 1994.

III. BACKGROUND

Unitron Industries, Inc. produces hearing aids at its Port Huron, Michigan facility. The building has two floors, with the sales and management staff on the first floor and an electronics laboratory and EML in the basement. An employee breakroom is also located in the basement. The on-site manufacture of ear molds has been performed since 1989. Previously, the ear molds were purchased from suppliers before the opening of the EML. The EML is located in a converted supply storage area with 500 square feet (ft^2) of work space. Employee work benches and work stations are situated around the perimeter of room. Also, work stations for buffing finished ear molds and mixing the chemicals for the molds are located in the center of the room.

General dilution air is brought into the EML through intakes located near the ceiling on the west wall. The air handling unit for the laboratory is located outside, at the rear of the building. The supply air can be either 100% outside air that can be cooled with an air conditioning unit, or can be recirculated air from the building. A damper control for the amount of outside air is located on a wall in the EML which can be controlled by employees in the laboratory. Exhaust air vents located near the floor, under work stations on the north, south, and east walls are ducted to two 1/4 horsepower (hp) motor exhaust blowers located in the attic of the building. The exhausted air is released into the environment through the roof. A dust collection system that uses a bag filter and a 1400 cubic feet per minute (CFM), 3 hp blower has ports at each work station that are connected to the dust collector with approximately 3" diameter PVC piping which runs the full length of the EML. The piping has several T-valves, which workers open and close as needed to maintain maximum air movement. Workers also close the port opening at their work station whenever the sander or buffer is not in use. Heated air from a natural gas furnace is delivered to the EML through ceiling diffusers.

An impression of the patient's ear canal, made by an audiologist or hearing aid dispenser, is delivered to the laboratory. A negative image mold is immediately made from silicon or acrylic and stored for emergency use in case of damage to the original impression. The original is trimmed and shaped with a buffer or sander to smooth the sharp edges and rough spots at the Cutting Station. At the Putty Station, the impression has all of its holes and gaps filled with putty. Solvents are used for the final smoothing of the impression. At the Line Station, the worker dips the impression in wax and makes a negative image mold with dental plaster. Acrylic plastic is mixed (powder and liquid mixture) by the Line worker and poured into the dental plaster mold which is then baked for 10 minutes. The plaster mold is broken away from the ear mold and sent to one of the six Finishers. The plastic ear mold is prepared for the insertion of the aid's electronics by the Finishers. Repairs to hearing aids that have been returned to Unitron Industries, Inc. are also done by the Finishers. During the NIOSH evaluation, approximately 125 ear molds were manufactured each day.

Over 20 material safety data sheets (MSDS) were received with the HHE request which covered the chemicals used by the EML technicians. Chemicals used by the worker at the Cutting station included polydimethylsiloxane in the impression material; the work conducted at the Putty Station involved the use of polymethylmethacrylate, silicone, methylene chloride, isopropyl alcohol, and xylene; the Line worker used methyl methacrylate and diethyl phthalate to form the ear mold; and the Finisher used acetone, plastic cement, methyl ethyl ketone (MEK), cyanoacrylates, and mineral spirits to finish the molds and to repair old hearing aids.

The Michigan Department of Public Health conducted a consultative occupational health survey at Unitron Industries, Inc. in November 1989. Their report stated that employees were not exposed to excessive levels of isopropyl alcohol, methyl methacrylate, or hydroquinone, the chemicals sampled by the State investigator. There were suggestions made to correct ventilation deficiencies, lack of protective eyewear worn by EML employees, and hazards associated with the company's Right to Know Program. In the summer of 1992, EML employees were referred to NIOSH by the Michigan Occupational Safety and Health Administration (MIOSHA). Through contact with the agency, they received the NIOSH Current Intelligence Bulletin on Organic Solvent Neurotoxicity and, based on symptom similarity between what the employees were experiencing in the EML and the symptoms reported for organic solvent exposure in the NIOSH Bulletin, submitted an HHE request early in 1993.

IV. METHODS AND MATERIALS

A. Environmental

Air sampling was conducted on April 13-14, 1993, to identify airborne contaminants in the EML at Unitron Industries, Inc. and estimate their concentrations. Personal breathing zone (PBZ) air samples and general area (GA) air samples were collected over the full work shift on the two survey days. The large number of chemical constituents listed in the MSDSs provided to NIOSH prior to the site visit, dictated the decision to sample for as many of the chemicals as possible during the first survey without severely impacting the work being performed in the laboratory.

Six different sampling trains were used in conjunction with battery-powered pumps set at various flowrates to sample the air in the laboratory. Acetone and methyl ethyl ketone (MEK) were collected on Supelco ORBO™-90 sorbent tubes at a flowrate of 20 milliliters per minute (mL/min). The ORBO™-90 sorbent tubes were replaced every 90 minutes throughout the workday. The sampling media were sent to the analytical laboratory and analyzed according to the NIOSH Method 2500.[1]

Methyl methacrylate samples were collected on SKC® xad-2 sorbent tubes at a flowrate of 20 mL/min and analyzed according to NIOSH Method 2537.[1] The xad-2 sorbent tubes were replaced once during the workday.

Ethyl-2-cyanoacrylate was collected on SKC® XAD-7 sorbent tubes for consecutive 2-hour periods at a flowrate of 100 mL/min. The sampling media were analyzed according to the Occupational Safety and Health Administration (OSHA) Method 55.[2]

Dialkyl phthalate was identified on several MSDSs supplied to NIOSH investigators by Unitron Industries. General area samples, as well as personal air samples for phthalates were collected on the two survey days and submitted to the analytical laboratory for a qualitative analysis to identify specific phthalates. This analysis identified diethyl phthalate as the major component in the area samples. The personal air samples, sampled at a flowrate of 1 liter per minute (LPM) for 4 hours on 37 millimeter (mm) cellulose ester filters, were then analyzed. Because no NIOSH method exists for the analysis of diethyl phthalate, a modified version of NIOSH Method 5020 for dibutyl phthalate was used to semi-quantify the amounts of diethyl phthalate in the air samples.[1]

The two remaining sets of samples were collected on charcoal sorbent tubes with flowrates of 20 mL/min or 100 mL/min. General area samples were collected on the two survey days for the entire work shift for a qualitative analysis of organic compounds by gas chromatography - mass spectrometry (GC-MS). The components identified in this analysis were similar on both sets of sorbent tubes with the 100 mL/min samples having higher amounts of the component. The major components were methyl methacrylate, toluene, xylene/ethyl benzene, methylene chloride, isopropanol, ethanol, and acetone. The personal samples collected on charcoal sorbent tubes at 20 mL/min for two hours and 100 mL/min for four hours, were then analyzed by the laboratory based on the GC-MS qualitative results. The lower flowrate samples were analyzed for ethanol, isopropanol, and methylene chloride by NIOSH Method 1400 and Method 1005.[1] The higher flowrate samples were analyzed for methylene chloride, toluene, xylene, and ethyl acetate according to NIOSH Methods 1003, 1500, and 1501.[1]

On the second survey at Unitron Industries, Inc. in August 1993, a limited number of chemicals were sampled. The chosen chemicals were determined by the results measured in the April 1993 evaluation. The EML employees personal breathing zones were sampled for methyl methacrylate, methylene chloride, ethyl-2-cyanoacrylate, and methyl-2-cyanoacrylate. The sampling methods for the methyl methacrylate and cyanoacrylates were identical to the procedures used in the earlier survey (methyl-2-cyanoacrylate were measured and analyzed according to the OSHA Method 55).

A change in sampling technique was employed for the methylene chloride samples. The PBZ air samples for methylene chloride were collected on charcoal sorbent tubes connected to battery-operated sampling pumps worn by employees in the laboratory. The pumps were calibrated at a flowrate of 20 mL/min and were worn by the employee for a period of two hours per sorbent tube(s). Four successive sets of samples were collected for each employee so that an 8-hour time-weighted average could be calculated for the methylene chloride exposure. During the April 1993 survey, only one charcoal sorbent tube was used per sampling train because of the necessity to identify the organic chemicals to which the laboratory workers were exposed. During the August 1993 survey, two sorbent tubes were put in series on each sampling train according to the stipulations outlined in NIOSH Method 1005 for methylene chloride in order to account for the volatility of methylene chloride.

An assessment of the EML's ventilation system was conducted during the first visit to the facility. The air supply and room exhaust ventilation as well as the dust collection system were visually inspected and measurements of airflow were made. Airflow through the supply diffusers and exhaust grilles was measured with a Shortridge Instruments, Inc. FlowHood® Model CFM 88. This instrument allows for airflow to be measured directly in cubic feet per minute (cfm). Airflow velocity measurements, in feet per second (ft/sec), at the dust collector openings were collected with a TSI, Inc. Model 8360 VelociCalc® Plus Air Velocity Meter.

B. Medical Investigation

Medical interviews were conducted to obtain information on potential workplace health hazards and to generate leads concerning the etiology of adverse health effects. Twelve workers with work experience in the EML were identified by management and the employee representative. Of the twelve identified employees, eight were currently working in the lab, two employees were on medical leave secondary to EML work-related health symptoms, another employee was on maternity leave, and one had previously been transferred to another work area due to health symptoms related to working in the EML. Additionally, medical records for the interviewed workers were reviewed where available.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for the 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 ten hours a day, forty hours a week for a working lifetime without experiencing adverse health effects. However, it is important to note that not all workers will be protected from adverse health effects if their 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 to the limit set by the evaluation criterion. These combined effects are often not considered 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 the following: 1) NIOSH Criteria Documents and Recommended Exposure Limits (RELs), 2) the U.S. Department of Labor, OSHA Permissible Exposure Limits (PELs), and 3) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs).[3,4,5] The OSHA PELs may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; in contrast, the NIOSH-recommended exposure limits are primarily based upon the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing those levels found in this report, it should be noted that employers are legally required to meet those levels specified by an OSHA PEL. An additional complication is due to the fact that a Court of Appeals decision vacated the OSHA 1989 Air Contaminants Standard in *AFL-CIO v OSHA*, 965F.2d 962 (11th cir., 1992); and OSHA is now enforcing the previous 1971 standards (listed as Transitional Limits in 29 CFR 1910.1000, Table Z-1-A).[4] However, some states which have OSHA-approved State Plans will continue to enforce the more protective 1989 limits. NIOSH encourages employers to use the 1989 limits or the RELs, whichever are lower.

Evaluation criteria for chemical substances are usually based on the average personal breathing zone exposure to the airborne substance over an entire 8- to 10-hour workday, expressed as a time-weighted average (TWA). Personal exposures are usually expressed in parts of vapor or gas per million parts of contaminated air (ppm), milligrams per cubic meter (mg/m^3), or micrograms per cubic meter ($\mu g/m^3$). To supplement the 8-hr TWA where there are recognized adverse effects from short-term exposures, some substances have a short-term exposure limit (STEL) for 15-minute peak periods; or a ceiling limit, which is not to be exceeded at any time. Additionally, some chemicals have a "skin" notation to indicate that the substance may be absorbed through direct contact of the material with the skin and mucous membranes. A compilation of all evaluation criteria used in assessing the chemical exposures at Unitron Industries, Inc. is shown in Table 1.

Organic Solvents

Acetone, ethanol, methanol, methyl ethyl ketone (MEK), and toluene are organic solvents.[6] Many of the organic solvents, such as, acetone, ethanol, MEK, and toluene, are irritants of the eyes, mucous membranes, and upper respiratory tract. In addition, organic solvents can cause acute and chronic neurotoxic health effects.[7] Acute neurotoxic effects include headache, lightheadedness, dizziness, weakness, poor concentration incoordination, impaired balance, confusion, drowsiness and loss of consciousness, and respiratory depression. Peripheral neuropathies and chronic central nervous system disorders (organic affective syndrome and mild chronic toxic encephalopathy) have been reported among solvent-exposed workers. Organic affective syndrome is characterized by fatigue, memory impairment, irritability, difficulty in concentrating, and mild mood disturbance. Mild chronic toxic encephalopathy is manifested by sustained personality or mood changes such as emotional instability, diminished impulse control and motivation, and impairment in intellectual function manifested by diminished concentration, memory, and learning capacity. The extent to which chronic neurotoxicity is reversible remains to be established. Toluene was associated with severe but reversible liver and kidney injury in a person who had been a glue-sniffer for three years.[6]

Methylene Chloride and Carboxyhemoglobin

Methylene chloride affects the central nervous system, as well as the cardiovascular and respiratory systems. Historically, it was used as an anesthetic. Exposure may result in symptoms of dizziness, headache, tingling or numbness of the extremities, and impairment of mental alertness and physical coordination.[8] Inhalation of methylene chloride causes the endogenous formation of carbon monoxide (CO), which attaches to hemoglobin in blood, thus yielding carboxyhemoglobin (COHb). Elevated COHb levels may persist for several hours following removal from exposure, as fat and other tissues continue to release accumulated amounts of methylene chloride.[6] The CO has an affinity to hemoglobin 200 times that of oxygen; this limits the oxygen transporting capability of the body, causing oxygen deprivation. This can lead to heart, brain, and other tissue damage. This effect can also occur in a fetus, since methylene chloride has the ability to cross the placental barrier.

The blood of smokers typically contains 2 to 10% COHb. Non-smokers with no known exposure to CO usually have a COHb level of 1% or less. Non-smokers in large cities have a COHb level of 1-2%, with the most probable source of CO being ambient air pollution from the combustion of fossil fuels.[6,9,10] As the level of COHb in the blood increases, the victim experiences health effects which become progressively more serious. Initially, the victim is pale; later, the skin and mucous membranes may be cherry red in color. Loss of consciousness occurs at about a 50% COHb level, and death can occur at levels of 70%.[6,9,11] It should be noted that the physiologic reaction to a given level of COHb in blood is extremely variable from person-to-person. The symptoms associated with various percent blood saturation levels of COHb are shown below:[9,10]

% COHb in Blood	Symptoms
0-10	No symptoms
10-20	Tightness across forehead, slight headache, dilation of cutaneous blood vessels.
20-40	Moderate to severe headache, weakness, dizziness, dimness of vision, nausea, vomiting, collapse.
40-50	Increased probability of collapse, loss of consciousness, rapid pulse and respiration.
50-60	Loss of consciousness, rapid pulse and respiration, coma, convulsions, and Cheyne-Stokes (periodic decreased) respiration.
60-70	Coma with intermittent convulsions, depressed heart rate and respiration, possible death.
Greater than 70	Weak pulse, slow respiration, respiratory failure, death.

Because COHb reduces the amount of oxygen transported by the blood, a number of cardiovascular effects are associated with CO exposure. Persons with chronic heart and/or lung disease are at increased risk. Even at low levels, CO exposure increases the risk for cardiac arrest in some people, particularly those with pre-existing cardiac ischemia (inadequate blood flow to the heart).[9,10,11]

Skin contact with methylene chloride is irritating with prolonged contact, causing severe burns. In one reported experiment, an intense burning sensation was noted within two minutes following immersion of a person's thumb into the liquid. A mild erythema (redness) and exfoliation (peeling) of the skin were observed after 30 minutes of immersion. The erythema subsided within an hour following exposure.[12]

NIOSH recommends that methylene chloride be regarded as a potential occupational carcinogen and that occupational exposures be controlled to the lowest feasible concentration. The recommendation is based on the observation of tumors of the lung, liver, salivary, and mammary glands in animals.[3]

The OSHA PEL for methylene chloride is an 8-hour TWA concentration of 500 ppm, with a ceiling concentration of 1000 ppm, and maximum peak concentrations of 2000 ppm for no more than 5 minutes within any 2-hour period.[4] On November 7, 1991, OSHA proposed to amend the regulation for employee exposure to methylene chloride to a permissible 8-hour TWA of 25 ppm. In addition, OSHA proposed to delete the existing ceiling limit concentration of 1000 ppm and to reduce the STEL from 2000 ppm (measured over 5 minutes in any 2 hours as a maximum peak concentration) to 125 ppm, measured as a 15-minute TWA.[13]

Methyl Methacrylate

Methyl methacrylate is used for the production of polymethyl methacrylate polymers or copolymers in the manufacture of acrylic sheet and molding, clear plastics (Lucite®, Perspex®, and Plexiglas®), extrusion powder, acrylic surface and paper coatings, latex paints, printing inks, floor polishes, dental restorations, adhesive cement, and surgical implants. It is characterized as a clear liquid with a distinctive, fruity, pungent odor with an odor threshold reported as low as 0.083 ppm.[14]

Exposure to methyl methacrylate causes irritation in the eyes, skin, and mucous membranes. Workers who were exposed to levels between 0.5 ppm and 50 ppm reported a high incidence of headache, pain in the extremities, irritability, loss of memory, excessive fatigue, and sleep disturbances. People who handle methyl methacrylate putty have significantly slower distal sensory conduction velocities in their fingers, implicating a mild axonal degeneration in the area of contact. Allergic contact dermatitis has been reported in workers handling methacrylate sealants. Finally, exposures to methyl methacrylate or cyanoacrylates have been shown to cause occupational asthma. The toxic effects from methyl methacrylate are due to the monomer form; the polymer appears inert. The severity of effects is felt to be inversely related to the degree of polymerization.[6]

Cyanoacrylates

Cyanoacrylates are used in the manufacture of adhesives and polymers. They are the principal ingredient in the high-bond-strength, fast-acting glues such as Krazy Glue® or Super Glue®. Both ethyl-2-cyanoacrylate and methyl-2-cyanoacrylate forms of the adhesive are available. Cyanoacrylates are irritating to the eyes, nose, and skin. Heating cyanoacrylate glues increases their volatility which will create increased irritation. However, heating will not release cyanide.

Inhalation of cyanoacrylates has been reported to cause respiratory symptoms in workers. Occupational asthma and allergic rhinitis may also occur after an inhalation exposure.[6,15,16] Contact dermatitis has been reported after chronic skin exposure to cyanoacrylates.[17,18,19] Cyanoacrylate contact dermatitis among electronic workers was aggravated when they worked in low humidity conditions; as the humidity was increased to at least 55%, the complaints decreased in number.[20]

Because of the similarity in the chemical structures of the two cyanoacrylate esters, there may be little difference physiologically between the ethyl-2-cyanoacrylate form and methyl-2-cyanoacrylate form.[21] There are no evaluation criteria specifically for ethyl-2-cyanoacrylate, only for the methyl-2-cyanoacrylate form. The methyl-2-cyanoacrylate criteria were set to minimize the potential for undue irritation from exposure to the chemical. In the absence of specific criteria for the ethyl-2-cyanoacrylate form of the adhesive, it is probably realistic to assume that the methyl-form criteria could be applied to both formulations of the glues.

VI. <u>RESULTS</u>

A. Environmental

Nine female employees worked in the EML on both days of the April survey. The job titles represented included the Laboratory Supervisor; Cutting Station, Putty Station, and Line employees; and five Finishers. Each of the employees wore sampling pumps to evaluate their personal breathing zone (PBZ) exposures to various chemicals in use in the laboratory. Additional general area air samples were also collected at the powder-mixing table, the Cutting Station, and the Putty Station to identify which chemicals were present in the EML and would be quantitatively analyzed in the PBZ samples.

The analytical results of the PBZ samples obtained during the April survey showed that ethyl acetate, MEK, and xylene were at levels that could not be detected. The MEK samples were obtained from two of the Finishers working in the laboratory. The ethyl acetate and xylene air samples were from a third Finisher and the Laboratory Supervisor. The analytical limit of detection (LOD) was 10 micrograms per sample (µg/sample) for ethyl acetate and MEK and 12 µg/sample for xylene. These LODs equate to a minimum detectable concentration (MDC) of 1.93 ppm for MEK at an average air volume per sample of 1.76 liters. The MDCs for xylene and ethyl acetate are 0.14 ppm when using an average air sample volume of 20 liters.

The two Finishers sampled for MEK were also sampled for acetone exposures. The results of the sampling showed trace levels of acetone over the two survey days with the exception of one TWA sample of 3.57 ppm on the second day. A trace amount is defined as a concentration between the analytical laboratory method's LOD and LOQ. The analytical LOQ for the acetone sample set was 33 µg/sample which equates to a minimum quantifiable concentration (MQC) of 3.44 ppm. The airborne concentration of acetone for the one TWA sample is well below all of the evaluation criteria for the compound.

Air samples for the two alcohol compounds, ethanol and isopropanol, were obtained from two employees working at the Putty and Cutting Stations. Results obtained during the two survey days at the Putty Station were 9.78 ppm TWA and 8.45 ppm TWA for ethanol and 8.04 ppm TWA and trace amounts for isopropanol. Ethanol was not detected at the Cutting Station and isopropanol was found at trace levels on the first day and not detected on the second day for the Cutting employee. The LOD and LOQ for both alcohol compounds are 10 µg/sample and 33 µg/sample, respectively. These limits equate to a MDC of 0.72 ppm and a MQC of 2.27 ppm for ethanol and a MDC of 0.52 ppm and a MQC of 1.74 ppm for isopropyl alcohol, based on an average sample air volume of 7.73 liters. The measured airborne concentrations for alcohols were well below the evaluation criteria for these two compounds.

The toluene airborne concentrations for the Laboratory Supervisor and one of the Finishers was measured at 0.31 ppm and 0.17 ppm, respectively for the first survey day. Trace amounts of the compound were found on the second survey day. The LOD and LOQ for toluene are 3 µg/sample and 9 µg/sample. For an average air volume sample of 40.4 liters, these values equate to 0.02 ppm for the MDQ and 0.06 ppm for the MQC. The measured air concentrations for toluene are well below the evaluation criteria.

Air samples for methyl methacrylate were obtained from employees working at the Putty Station and on the Line. The first day of the survey revealed concentrations of 2.25 ppm for the Putty Station employee and 6.59 ppm for the Line employee. The results for the second day were 2.85 ppm and 6.08 ppm for the Putty Station and Line employees, respectively. The analytical method for methyl methacrylate has a LOQ of 0.033 mg/sample. The equivalent MQC for an average air sample volume of 8.34 liters is 0.96 ppm. Neither of these employees were exposed to methyl methacrylate concentrations that exceeded the evaluation criteria.

A modified version of NIOSH Method 5020 used to analyze dibutyl phthalate was selected to semi-quantify the concentration of diethyl phthalate in the ear mold laboratory. Personal breathing zone air samples were collected from the employee on the Line and from a Finisher. Airborne concentrations of diethyl phthalate for the Line employee were measured at trace levels on the first day of the survey and at 0.04 mg/m^3 on the second day. The Finisher was found to be exposed to concentrations of 0.05 mg/m^3 and 0.08 mg/m^3 on the two survey days. The laboratory LOD and LOQ for diethyl phthalate are 3 µg/sample and 8.6 µg/sample, respectively. These values equate to a MDC of 0.007 mg/m^3 and a MQC of 0.021 mg/m^3 for an average air sample volume of 416 liters. Even though the modified analytical technique resulted in a "semi-quantitative" analysis, the results are very much below the evaluation criteria of 5.0 mg/m^3.

Exposure to ethyl-2-cyanoacrylate (super glue) was measured on two Finishers who worked in the south end of the laboratory. Quantifiable levels of the compound were found in samples from both of the employees on both days of the survey. The levels measured on the first day were 3.32 ppm and 4.58 ppm, and 2.24 ppm and 3.38 ppm on the second day of the survey. The individual samples collected on the first day of the survey were found to contain up to 30% of the reported compound in the back section of the sampling media which is indicative of the chemical breaking through the sampling media and not being captured. Thus, the values reported can be considered as minimal concentrations for the first day of the survey. No breakthrough was discovered in the sample set collected on the second day. The MQC for this sample set, for an average air volume of 38.8 liters, is 0.03 ppm which is based on the analytical LOQ of 5.9 µg/sample. There are no evaluation criteria specifically for the ethyl ester of cyanoacrylate. However, the concentrations of ethyl-2-cyanoacrylate measured in the ear mold laboratory may have been excessive if the criteria for methyl-2-cyanoacrylate are used as an indication of hazardous exposures.

Methylene chloride exposures were sampled from four employees in the ear mold laboratory, including the Laboratory Supervisor, a Finisher, and the employees who worked at the Cutting Station and the Putty Station. The concentrations of methylene chloride measured on the first survey day ranged from 9.76 ppm for the Finisher to 74.60 ppm for the person at the Putty Station. The second day of sampling revealed trace amounts for the Cutting Station employee, to 33.94 ppm for the Putty Station worker. The LOD and LOQ are the same as those reported for the ethanol and isopropanol analyses. The corresponding MDC and MQC for methylene chloride are 0.37 ppm and 1.23 ppm, respectively. NIOSH considers methylene chloride to be a potential occupational carcinogen and thus recommends exposure to maintained at the lowest feasible concentration. All concentrations measured in the ear mold laboratory on the two survey days greatly exceeded this recommendation.

The ventilation system assessment of the EML made during the April survey found the laboratory space was supplied with 1,100 CFM of 100% outside air through a bank of diffusers near the ceiling on the west wall of the laboratory. An additional 350 CFM of recirculated, heated air was supplied through the ceiling diffusers. Air was exhausted from the laboratory through the floor exhaust vents which were ducted to blowers in the attic area of the building and through the dust collection system. The exhaust ventilation was poor. Several of the floor vents registered no air movement through them. The total volume of exhausted air through the attic equalled 225 CFM. The positive pressurization of the EML to the other work areas was confirmed with smoke-generating tubes. The dust collection system seemed to be undersized as evidenced by the need to shut as many of the unused collection ports as possible by the workers in order to maintain an efficient airflow where it was needed. No local exhaust ventilation, other than the dust collection ports, was present at individual work stations.

Between the April and August surveys, the company installed a local exhaust slot-hood ventilation system at the Putty Station where methylene chloride is used in the ear mold process. Additionally, the laboratory's exhaust ventilation system was upgraded to increase the amount of air exhausted from the room by installing new blowers and motors in the attic of the building.

During the August survey, five EML employees were sampled for PBZ exposures to methyl methacrylate and six employees were monitored for ethyl-2- and methyl-2-cyanoacrylate exposures. A total of eight female employees representing the same job titles seen in the earlier survey were in the EML during the second survey. Two of the Finishers had trace amounts of methyl methacrylate over the full-shift sampling period. All of the ethyl and methyl cyanoacrylate samples were found to contain not detected levels of the chemicals.

The Cutting Station and Putty Station employees, the Laboratory Supervisor, and two Finishers were sampled for methylene chloride exposures during the second survey. All of the two-hour samples were found to have not detected levels of methylene chloride with the exception of one sample at the Putty Station where a trace of methylene chloride was reported in the analytical results.

B. Medical

All 12 of the interviewed employees were white women, ranging in age from 20 to 47 years (average age = 32 years). Six, (50%) of the employees had spent four or more years in the EML, two (17%) had spent 2-4 years in the EML, and four (33%) had spent under two years in the EML. The medical interviews revealed that 83% of the employees experienced health symptoms that they related to their workplace. Among the most commonly reported symptoms associated with the workplace were: fatigue, 83%; eye and throat irritation, 75%; headaches, 67%; and nasal congestion and irritation, 50%. Central nervous system symptoms, such as impaired thought processes or difficulty with memory and concentration, were also reported by 75% of the employees interviewed. Skin irritation and rashes were reported by 25% of the employees interviewed. Four (33%) employees reported occasional night sweats. Four employees (33%) also reported symptoms of hand/wrist numbness and pain suggestive of possible carpal tunnel syndrome.

Additionally, chest tightness, was reported by 67% (8/12) of the workers, with audible wheezing being reported by 38% (3/8) of those with chest tightness. Review of medical records revealed that pulmonary function tests (PFTs) performed on two workers with chest tightness were negative. Of the three workers who reported wheezing; one worker underwent PFTs, including methacholine challenge testing; all test results were negative. Another worker reported complete resolution of symptoms after the installation of new engineering controls. Medical record review and medical interview of the remaining worker revealed that she had symptoms suggestive of occupation asthma. However, she reported that no confirmatory medical testing had yet been performed in which to substantiate a diagnosis of occupational asthma. Subsequent, to the installation of new engineering controls in the EML, all current workers who had previously experienced chest tightness or wheezing, reported a marked improvement of their symptoms.

Typically, employees were able to identify certain exposures/areas that were associated with their workplace symptoms. For example, employees who worked at the Putty Station with methylene chloride commonly associated patterns of mucosal irritation, headaches, and fatigue with tasks performed in this area. Also, one worker reported hand rashes associated with the hardener used at the Putty Station. Of note, workers employed at the Putty Station reported that most of their symptoms had significantly improved since the installation of the new ventilation hood and provisions for new protective gloves.

The Line area, where methyl methacrylate and phthalate compounds are mixed together to form plastic ear molds, was also associated by workers with nonspecific symptoms of fatigue, weakness, headaches, gastrointestinal upset and heartburn, and mucosal irritation. Additionally, medical record review and medical interview of one worker revealed a diagnosis of occupational contact dermatitis, which by history, was related to exposure to methyl methacrylate monomer. While employees working in and around the Line area continued to experience some of the above symptoms, they felt that the severity and frequency of their symptoms had notably improved with implementation of new engineering controls.

Another work area/exposure associated by employees with health symptoms was the Finishing area, where a buffing wheel and polishing compound was employed by the Finishers to polish the plastic ear molds. This area was primarily associated with eye, nose, and throat irritation. One worker reported facial skin rash/irritation when performing this task. Lastly, employees working in the Finishing areas were exposed to various glues and solvents, to which they attributed symptoms of mucosal irritation, fatigue, and occasional headaches.

Review of medical records revealed pre- and post-shift carboxyhemoglobin level evaluations performed on two of the workers employed at the Putty Station, prior to the implementation of ventilation controls. Both employees had notably increased post-shift carboxyhemoglobin levels. Pre- and post-shift carboxyhemoglobin results were: 0.1% pre-shift and 0.8% post-shift for one worker, who reported smoking approximately one half pack of cigarettes per day, and 0.4% pre-shift and 3.2% post-shift in the other worker who reportedly was a non-smoker. A post-shift only carboxyhemoglobin level in a non-smoking Putty Station worker, prior to EML renovations, was 6.6%. Another worker reported that their pre- and post-shift carboxyhemoglobin levels, after the installation of the new engineering controls at the Putty Station, were in the normal range with no post-shift elevation of carboxyhemoglobin.

Another issue of concern expressed by workers during interviews involved a purported excess of thyroid test abnormalities among EML workers. Of the twelve workers interviewed, nine (75%) had undergone recent thyroid function testing (TFTs). Of the nine workers with recent TFTs, five workers reported their results were normal, two reported being hypothyroid, one reported being hyperthyroid, and one reported a history of thyroid disease prior to employment at the EML. Review of medical records revealed that the one worker previously diagnosed as being hyperthyroid had returned to a euthyroid (normal) state. This workers' previous thyroid findings were attributed to a transient chemical thyroiditis felt to be secondary to occupational chemical exposures.

VII. DISCUSSION

During medical interviews symptoms of skin rashes and chest tightness/wheezing were reported by a large percentage of the EML workers. Exposure to chemicals can lead to symptoms, in most cases, by direct irritation of skin and mucosal membranes (i.e., nose, throat, airway passages), or in some cases, through allergic sensitization. In most cases, if symptoms are caused by direct irritation then they should dramatically improve with adequate exposure controls. To this end, it appears that the implementation of appropriate protective gloves and engineering controls within the EML has resulted in a marked improvement of workers symptoms at this time. However, if employees have been sensitized to one or more of the chemical compounds used in the EML, their symptoms may persist despite improved engineering controls. Employees sensitized to one or more chemical compounds may need to be advised against performing certain job tasks or working in certain areas, in order to safeguard their health. Alternative jobs should be made available to such employees.

Worker interviews and review of some employees' medical records revealed a mixed picture of thyroid test abnormalities (i.e., hypothyroid, hyperthyroid, thyroiditis). In some cases, workers reported abnormal earlier TFT test results that had returned to normal on subsequent testing. Discussion of these findings with other health professionals and review of medical literature for possible thyroid abnormalities associated with EML chemical exposures has not provided any insight or clues as to a possible workplace etiology at this time. Clusters of illness or abnormal test results that are close together in time or space may have a common cause (for example, a common exposure or laboratory error) or may be the coincidental occurrence of unrelated causes. The number of cases may seem high, particularly among the small group of people who have something in common with the cases, such as working in the same building or department. When a small number of cases occurs, it usually is difficult to determine whether they have a common cause. This is especially true when identified exposures have not been previously shown to be related to the observed health effects, as is the case in this situation.

VIII. CONCLUSIONS

The results from the two surveys for methylene chloride concentrations in the EML show that employees were exposed to levels of the chemical that exceeded the relevant evaluation criteria before the ventilation changes were made.[3] The ethyl-2-cyanoacrylate data are also indicative of potentially significant worker exposures to that chemical, even though no specific evaluation criteria exist for the compound. However, the alterations to the ventilation systems appear to have effectively reduced employees' exposures to these chemicals to concentrations below detectable levels. Nearly all of the symptomatic EML employees have now been accommodated, either by returning to their job in the laboratory or to other locations within the company.

IX. RECOMMENDATIONS

Based on the findings of the environmental surveys of the EML at Unitron Industries, Inc., and the medical evaluations of the employees, NIOSH investigators have determined that a health hazard existed at the facility. Employees in the EML were exposed to excessive levels of methylene chloride in the laboratory and were, in general, exhibiting health effects consistent with their various chemical exposures. The company, however, has installed engineering controls in the EML which have reduced chemical exposures to levels less than the relevant exposure criteria. Presently, under these controlled conditions there does not appear to be an ongoing health hazard in the EML. The following recommendations are offered by the NIOSH investigators to maintain current exposure levels, as well as to help alleviate other deficiencies identified during the evaluation.

1. The reductions in worker exposure to methylene chloride, methyl methacrylate, and cyanoacrylate are contingent on the ventilation system operating at the efficiency levels seen during the second survey period, which includes the amount of outside air introduced into the laboratory space. The damper control was set at the 100% outside air setting when the second survey was completed. The company must implement routine procedures to verify that the efficiency of the laboratory's ventilation system has not been reduced. The procedures should stipulate what steps are necessary to maintain the systems at optimum operating efficiency and what corrections are necessary to increase the efficiency in case the ventilation system becomes compromised. Officials of Unitron Industries, Inc. should consider consultation with a mechanical contracting firm that is qualified in industrial ventilation systems, particularly firms that have designed and installed local exhaust ventilation systems. The contracting firm may recommend a specific level of outside air that is brought into the laboratory and leave the damper control set at that point since there are now local exhaust ventilation systems in place.

2. The MSDS for the buffing compound used in the Finishing area states that the compound contains silica. In response to this notification, the company has offered respiratory protection to employees whenever they use the buffers. Whenever this type of personal protection equipment is offered to the employees, the company must develop a complete employee respiratory protection program. The minimum standards for such a program are described in the OSHA General Industry Standard, 29 CFR 1910.134.[22] The airborne concentration levels of silica from the use of the buffing compound in the EML should be determined by industrial hygiene sampling.

3. Anti-skid protection on more floor surface of the EML is needed. The mats currently on the west side of the floor seemed effective in reducing employee's sliding on the floor and should be added to other areas.

4. The worker practice of cleaning their hands with the methyl ethyl ketone (MEK) Testor™ Plastic Cement remover should be discontinued. Proper glove protection will eliminate the need for this type of hand cleaning.

5. The use of gloves, which specifically offer protection from methylene chloride, should be continued by the Putty Station employee. The company should continue efforts to find a suitable substitution chemical for the methylene chloride used in the EML.

6. Dust collection ventilation ports should be opened each time an employee uses a sander or buffer. It was observed several times during the survey that the dust

collection system was not opened when buffers were being used. The possibility of improving the efficiency of the system should be investigated by the mechanical contracting firm.

7. Additional training in occupational health and industrial hygiene by Unitron Industries, Inc. personnel may be helpful to correct possible future problems. Local hospitals and universities should be able to offer this type of training. Also, routine meetings between management and employees about employee health concerns or concerns of working conditions could be beneficial to employees and management officials.

8. The EML workers should be periodically evaluated for new or persistent pulmonary and skin symptoms. If symptoms continue to be suggestive of possible ongoing pulmonary or dermatologic sensitization to EML chemical exposures, then additional medical studies, such as, pulmonary peak flow evaluations and skin testing, should be considered.

9. Unitron Industries should utilize joint labor/management safety and health teams to improve communications regarding work conditions and direct future investigations where a number of employee health complaints or illnesses are reported for an area or process.

10. As part of its health and safety program, Unitron Industries should maintain a log of all reported illnesses and injuries. This log should include pertinent information such as time, date, personnel affected, symptoms reported, severity and duration of symptoms, activity, and chemical usage. By keeping records over time, comparisons can be made as workplace changes are implemented. Although the general nature of health problems and suspected exposures should be available to the labor/management safety and health teams, the privacy of individuals and confidentiality of personal medical information should be protected.

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Copies of this report have been sent to:

1. Operations Manager, Unitron Industries, Inc.
2. Mold Laboratory Supervisor, Unitron Industries, Inc.
3. Region III Supervisor, Michigan Department of Public Health, Division of Occupational Health
4. OSHA, Region V

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 1

Evaluation Criteria for Airborne Chemical Concentrations

Unitron Industries
Port Huron, Michigan
HETA 93-0608

Chemical Compound	NIOSH Recommended Exposure Limit	OSHA Permissible Exposure Limit	ACGIH Threshold Limit Value
Acetone	250 ppm TWA	1000 ppm TWA	750 ppm TWA 1000 ppm STEL
Diethyl Phthalate	5 mg/m^3 TWA	None	5 mg/m^3 TWA
Ethanol	1000 ppm TWA	1000 ppm TWA	1000 ppm TWA
Ethyl Acetate	400 ppm TWA	400 ppm TWA	400 ppm TWA
Ethyl-2-cyanoacrylate	None	None	None
Isopropanol	400 ppm TWA 500 ppm STEL	400 ppm TWA	400 ppm TWA 500 ppm STEL
Methyl-2-cyanoacrylate	2 ppm TWA 4 ppm STEL	None	2 ppm TWA 4 ppm STEL
Methyl Ethyl Ketone	200 ppm TWA 300 ppm STEL	200 ppm TWA	200 ppm TWA 300 ppm STEL
Methyl Methacrylate	100 ppm TWA	100 ppm TWA	100 ppm TWA
Methylene Chloride	Lowest Feasible Concentration	500 ppm TWA 1000 ppm STEL 2000 ppm Max. Peak (5 min. in any 2 hrs.)	50 ppm TWA
Toluene	100 ppm TWA 150 ppm STEL	200 ppm TWA 300 ppm STEL 500 ppm Max. Peak (10 min.)	50 ppm TWA [Skin]
Xylene	100 ppm TWA 150 ppm STEL	100 ppm TWA	100 ppm TWA 150 ppm STEL