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PART II:

ENVIRONMENTAL PROTECTION AGENCY

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NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

Standard For Vinyl Chloride

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COPIED BY MCA FOR DISTRIBUTION TO THE VINYL CHLORIDE TECHNICAL PANEL, NOVEMBER 11, 1976, MR. MILTON FREIFELD

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 618-1]

PART 61—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

Standard for Vinyl Chloride

On December 24, 1975, under section 112 of the Clean Air Act, as amended (42 U.S.C. 1857), the Environmental Protection Agency (EPA) added vinyl chloride to the list of hazardous air pollutants (40 FR 59477) and proposed a national emission standard for it (40 FR 59532). The standard covers plants which manufacture ethylene dichloride, vinyl chloride, and/or polyvinyl chloride.

EPA decided to regulate vinyl chloride because it has been implicated as the causal agent of angiosarcoma and other serious disorders, both carcinogenic and noncarcinogenic, in people with occupational exposure and in animals with experimental exposure to vinyl chloride. Reasonable extrapolations from these findings cause concern that vinyl chloride may cause or contribute to the same or similar disorders at present ambient air levels. The purpose of the standard is to minimize vinyl chloride emissions from all known process and fugitive emission sources in ethylene dichloride-vinyl chloride and polyvinyl chloride plants to the level attainable with best available control technology. This will have the effect of furthering the protection of public health by minimizing the health risks to the people living in the vicinity of these plants and to any additional people who are exposed as a result of new construction.

Interested parties participated in the rulemaking by sending comments to EPA. The comments have been carefully considered, and where determined by the Administrator to be appropriate, changes have been made to the regulation as promulgated.

Summary of the Standard

In ethylene dichloride-vinyl chloride plants, the standard limits vinyl chloride emissions from the ethylene dichloride and vinyl chloride formation and purification processes to 10 ppm. For the oxychlorination process, vinyl chloride emissions are limited to 0.2 g/kg of ethylene dichloride product.

In polyvinyl chloride plants, the standard limits vinyl chloride emissions from equipment preceding and including the stripper in the plant process flow to 10 ppm. Emissions from equipment following the stripper are to be controlled by stripping dispersion resins to 2000 ppm and other resins to 400 ppm, or by using equivalent controls. Vinyl chloride emissions from reactor opening are to be reduced to 0.02 g/kg polyvinyl chloride product.

In both ethylene dichloride-vinyl chloride and polyvinyl chloride plants, relief valve discharges and manual venting of gases are prohibited except under emergency conditions. Fugitive emissions are required to be captured and controlled.

Health and Environmental Impacts

EPA prepared a document entitled the *Quantitative Risk Assessment for Community Exposure to Vinyl Chloride* which estimates the risk from vinyl chloride exposure to populations living in the vicinity of vinyl chloride-emitting plants before and after implementation of controls to meet the standard. There are no dose-response data for the concentrations of vinyl chloride found in the ambient air. Therefore, assessments of risk at ambient levels of exposure were extrapolated from dose-response data from higher levels of exposure using both a linear model and a log-probit model. Extrapolations made with each of these models entailed using different sets of assumptions. Because different assumptions can be made in extrapolating to low doses, the health risks are reported in ranges.

It was estimated that 4.6 million people live within 5 miles of ethylene dichoride-vinyl chloride and polyvinyl chloride plants and that the average exposure around these plants before installation of controls to meet the standard is 17 parts per billion. The exposure levels for uncontrolled plants were calculated based on estimated 1974 emission levels. Using the linear dose-response model, EPA found that the rate of initiation of liver angiosarcoma among people living around uncontrolled plants is expected to range from less than one to ten cases of liver angiosarcoma per year of exposure to vinyl chloride. The log-probit model gave predictions that are 0.1 to 0.01 times this rate. This wide range is an indication of the uncertainties in extrapolation to low doses. Due to the long latency time observed in cancer cases resulting from vinyl chloride exposure, increases initiated by exposure this year will not be diagnosed until the 1990's or later. Vinyl chloride is also estimated to produce an equal number of primary cancers at other sites, for a total of somewhere between less than one and twenty cases of cancer per year of exposure among residents around plants. The number of these effects is expected to be reduced at least in proportion to the reduction in the ambient annual average vinyl chloride concentration, which is expected to be 5 percent of the uncontrolled levels after the standard is implemented.

Changes in the standard since proposal do not affect the level of control required. Thus, the environmental impact of the promulgated standard is, with one exception, the same as that described in Chapter 6 of Volume I of the *Standard Support and Environmental Impact Statement*. According to data submitted by the Society of Plastics Industry, Inc. (SPI), the impact on water consumption in the draft environmental impact statement was overstated. In estimating the impact on water consumption, EPA based its estimates on worst case conditions. That is, EPA assumed that those control systems with the greatest water usage would be employed and that there would be no recycling of water. There is no regulation which would require water recycling. According to SPI, the control system utilizing the most water will not be used generally by the industry and economic factors will cause plants to recycle much of the water. Therefore, according to SPI the impact of the standard on water consumption will be negligible.

The environmental impacts of the promulgated standard may be summarized as follows: The primary environmental impacts of the standard are beneficial and will consist of vinyl chloride emission reductions of approximately 94 percent at ethylene dichloride-vinyl chloride plants and 95 percent at polyvinyl chloride plants. Percentage numbers for both source categories are based on an estimated 90 percent reduction in fugitive emissions and 1974 emission levels.

The potential secondary environmental impacts of the standard are either insignificant or will be minimized without additional action, except for one adverse impact. Hydrogen chloride is already emitted by process equipment at ethylene dichloride-vinyl chloride plants and by other petrochemical plants in the complexes where ethylene dichloride-vinyl chloride plants are typically located. An incinerator used to attain the standard at an ethylene dichloride-vinyl chloride plant could increase hydrogen chloride emissions by several fold. Typically, however, due to the corrosion problems which would otherwise occur both on plant property and in the community, plants use scrubbers to control already existing hydrogen chloride emissions. Hydrogen chloride emissions resulting from control of vinyl chloride emissions are expected to be controlled for the same reason. If even a moderately efficient scrubber (98 percent control) were used to control the hydrogen chloride emissions resulting from incineration of vinyl chloride emissions, the increase in hydrogen chloride emissions from a typical ethylene dichloride-vinyl chloride plant due to the standard would be reduced to 35 percent. However, EPA plans to further evaluate the need to control hydrogen chloride emissions, since diffusion model results indicate that under "worst-case" meteorological conditions, the hydrogen chloride emissions from the process equipment and the incinerator combined would cause maximum ambient concentrations of hydrogen chloride in the vicinity of ethylene dichloride-vinyl chloride plants to be in the same range or somewhat higher than existing foreign standards and National Academy of Sciences (NAS) guidelines for public exposure.

Economic Impact

In accordance with Executive Order 11821 and OMB circular A-107, EPA carefully evaluated the economic and inflationary impact of the proposed standard and alternative control levels and certified this in the preamble to the proposed standard. These impacts are

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discussed in Chapter 7 of Volume I of the *Standard Support and Environmental Impact Statement*. Comments on the proposed standard have resulted in only one major change in the economic impact analysis. EPA estimated that there would be four plant closures as a result of the promulgated standard. Of the four plants identified as possible closure candidates, one has given notice that it no longer produces polyvinyl chloride and the other three have indicated that they do not intend to close as a result of the standard.

The economic impacts of the promulgated standard may be summarized as follows: The total capital cost for existing plants to meet the standard is estimated to be $198 million, of which $15 million is for ethylene dichloride-vinyl chloride plants and $183 million is for polyvinyl chloride plants. EPA estimates that these plants will have to spend $70 million per year to maintain the required emission levels. In addition, the total capital cost for existing plants to meet the EPA's 1983 water effluent guideline limitations is expected to be $83 million and the total annualized operation cost is $17 million. The costs to the industry of meeting the OSHA standard cannot be quantified at this time, but they are expected to overlap to some degree with the costs to meet EPA's fugitive emission regulations. The costs of meeting the fugitive emission regulations are included in the total costs cited above for meeting the promulgated regulation. Broken out separately, the capital cost of meeting the fugitive emission regulations is $37 million and the annualized cost is $25 million.

The standard is not expected to deter construction of new ethylene dichloride-vinyl chloride plants or most types of new polyvinyl chloride plants. For one type of polyvinyl chloride plant (dispersion process) that represents 13 percent of the industry production, the standard would significantly deter the construction of smaller plants.

It is estimated that the price of polyvinyl chloride resins will rise by approximately 7.3 percent in order to maintain precontrol profitability and also to recover the total annualized control costs necessitated by the standard at ethylene dichloride-vinyl chloride plants and polyvinyl chloride plants. This increase is estimated to translate into a maximum consumer price increase in goods fabricated from polyvinyl chloride resins of approximately 3.5 percent. Recovery of effluent annualized costs plus maintenance of precontrol profitability is estimated to add approximately 2 percent to polyvinyl chloride resin prices and result in an additional maximum consumer price increase of 1 percent.

Public Participation

During the public comment period, 50 comment letters on the proposed standard were received. There were 24 from industry; 3 from environmental groups; 15 from Federal, State, and local agencies; and 8 from individual citizens. As required by section 112(b)(1)(B) of the Act, a public hearing was held on the proposed standard on February 3, 1976, in Washington, D.C. Presentations were made by the Environmental Defense Fund, the Society of the Plastics Industry, Inc., Dow Chemical Company, Diamond Shamrock Corporation, and Air Products and Chemicals, Inc. Copies of the comment letters received, the public hearing record, and a summary of the comments with EPA's responses are available for public inspection and copying at the EPA Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street, SW., Washington, D.C. In addition, copies of the comment summary and Agency responses may be obtained upon written request from the Public Information Center (PM-215), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 (specify *Standard Support and Environmental Impact Statement, Emission Standard for Vinyl Chloride, Volume II*).

Significant Comments and Changes to the Proposed Regulation

(1) *Decision to list vinyl chloride as a hazardous air pollutant.* In general, the commenters did not contest EPA's decision to list vinyl chloride as a hazardous air pollutant. However, three commenters (two companies and one Federal agency) argued that EPA placed undue emphasis on factors suggesting that vinyl chloride presented a health risk and ignored factors suggesting that no significant risk was involved. Under section 112, however, EPA could remove vinyl chloride from the list of hazardous air pollutants only if information were presented to EPA that shows that vinyl chloride is clearly not a hazardous air pollutant. As discussed more fully in the comment summary, the commenters did not provide conclusive evidence that vinyl chloride is not a hazardous air pollutant which causes or contributes to death or serious illness, nor did they conclusively prove that the health risk factors emphasized by EPA were insignificant.

Several other commenters agreed with EPA's decision to list vinyl chloride as a hazardous air pollutant, but argued that EPA had overstated the health problem, the emission levels, and the projected ambient air concentrations around uncontrolled plants. With regard to the alleged overstated health problem, the commenters stated, for example, that the U.S. worker EPA discussed as having been exposed to vinyl chloride levels lower than those usually encountered in polyvinyl chloride production has been dropped from the National Institute of Occupational Safety and Health's listing of workers with angiosarcoma. EPA agrees that there are questions concerning the level of exposure and in some cases the pathology of these cases not involved directly in polyvinyl chloride and vinyl chloride production. These uncertainties are stated in the appropriate footnotes of the *Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride* (STAR) where the angiosarcoma cases are listed. However, in spite of these uncertainties, in view of the possible exposure patterns, these cases cannot be ignored in the evaluation of the potential public health problems.

With regard to the alleged overstated emission levels, the uncontrolled emission levels reported by EPA were based on 1974 data. This qualification was stated wherever emission data were presented. EPA recognizes that emissions have been reduced since that time, and stated this in the preamble to the proposed standard. EPA decided not to gather more recent data on emission levels, because these emission levels are expected to change, and gathering the data would take considerable time both on the part of EPA and on the part of industry. Since the purpose of the standard is to minimize emissions, these more current data would not affect the standard itself. The 1974 emission levels were also used in diffusion modeling to project maximum ambient air concentrations around uncontrolled plants. These maximum air concentrations would probably be lower if 1976 emission levels were used. This would reduce the relative impact of the standard below that described in the *Standard Support and Environmental Impact Statement*, but would not affect the basis of the standard itself.

(2) *Approach for Regulating Vinyl Chloride Under Section 112.* Two approaches other than using best available control technology were suggested by the commenters for regulating vinyl chloride under section 112. The first was to ban polyvinyl chloride products for which substitutes are currently available and to gradually phase out other polyvinyl chloride products as substitutes are developed.

In the preamble to the proposed standard EPA specified its reasons for not setting a zero emission limit for vinyl chloride, as follows: (1) There are beneficial uses of vinyl chloride products for which desirable substitutes are not readily available; (2) there are potentially adverse health and environmental impacts from substitutes which have not been thoroughly studied; (3) there are a number of employees, particularly in the fabrication industries, who would become at least temporarily unemployed; and (4) control technology is available which is capable of substantially reducing emissions of vinyl chloride into the atmosphere.

EPA agrees that substitutes do exist or could be manufactured for most polyvinyl chloride uses. However, in general, these substitutes do not have some of the more desirable characteristics of polyvinyl chloride, such as nonflammability. If vinyl chloride and polyvinyl chloride were banned, other substitutes with these more desirable characteristics would likely be developed. There is a risk that these substitutes would also have adverse health or environmental effects. Since control measures are available which can reduce vinyl chloride emissions by 90 percent or more, it does not seem prudent to reduce emissions by the remaining percentage and take the risk of introducing new untested chemicals into the environment.

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Another approach suggested by the commenters was to base the standard for each individual emission point on cost versus benefit. Several of the fugitive emission sources were named specifically as ones for which the costs of control were substantially higher than the benefits. Although EPA did determine a cost-benefit ratio for the controls required for a number of emission points, EPA does not believe such a ratio is an appropriate basis on which to set a standard. Section 111 of the Clean Air Act provides for the development of standards based on best control technology (considering costs). Even under section 111, however, standards are not based on a fine balancing of costs versus benefits. Instead, costs are considered in terms of the affordability of the control technology required to achieve a given emission level and the economic impact of possible standards on the industry in question. Unlike section 111, section 112 does not explicitly provide for consideration of costs, so it would clearly be inappropriate to consider costs to a greater extent under section 112 than would be done under section 111. As discussed in the preamble to the proposed standard for vinyl chloride, EPA believes costs may be considered under section 112, but only to a very limited extent; i.e., to assure that the costs of control technology are not grossly disproportionate to the amount of emission reduction achieved. In comparison with other emission points, the costs of controlling the fugitive emission sources mentioned by the commenters are relatively small compared with the amount of emission reduction achieved.

Several commenters recommended adding to the regulation a provision for excess emissions during startup, shutdown, and malfunction. EPA considered this comment, and decided that this addition is not necessary for the vinyl chloride standard. Startup and shutdown of the process has essentially no effect on emissions to the atmosphere for polyvinyl chloride production, and technology exists to avoid excess emissions during startup and shutdown at ethylene dichloridevinyl chloride plants. We do not believe plants should be allowed to emit excess emissions during malfunctions, and therefore are requiring them to shut down immediately.

(3) *Selection of source categories.* In the preamble to the proposed standard EPA recognized that some small research and development facilities may exist where the emissions of vinyl chloride are insignificant and covering these facilities under the standard would be unnecessary and inappropriate. However, EPA did not have sufficient information available to clearly define which facilities should be excluded from the standard, and encouraged interested parties to submit such information during the comment period. Based on the information submitted, EPA decided to exempt polyvinyl chloride reactors and associated equipment from applicability of all parts of the standard if the reactors are used in research and development and have a capacity of no more than 0.19 m^3 (50 gal). Reactors in this size range can generally be found in a laboratory, whereas the larger reactors are typically pilot scale facilities. Emissions from laboratory scale equipment are relatively small, and application of the controls required by the standard would be expensive and impractical. EPA also decided to exempt research and development facilities containing reactors greater than 0.19 m^3 (50 gal) and no more than 4.07 m^3 (1100 gal) in capacity from all parts of the standard except the 10 ppm limit for reactors, strippers, monomer recovery systems, and mixing, weighing and holding containers. EPA decided not to require these facilities to meet other parts of the standard because of the technical problems involved in doing so. For example, the standard for reactor opening is based in part on reducing the frequency of opening the reactor. Research and development reactors have to be opened after every batch for thorough cleaning. Also, stripping technology is developed individually for each resin in research and development equipment. Therefore, attainment of the stripping limitations in the research and development equipment would not always be possible. The 4.07 m^3 (1100 gal) figure was selected as an upper cut-off point because there are no commercial reactors smaller than this.

(4) *Emission limits.* The only major change in the emission limits between proposal and promulgation is the addition of a provision for emergency manual venting of vinyl chloride from reactors to the atmosphere. The proposed standard prohibited all manual venting to the atmosphere. In the preamble to the proposed standard, EPA invited interested persons to comment on whether permitting manual venting to the atmosphere could result in overall lower emissions. There are several methods available for preventing relief discharges from reactors, one of which is manual venting of part of the reactor contents for purposes of cooling and reduction in pressure within the reactor. The higher the temperature and pressure within the reactor, the greater the amount of vinyl chloride which has to be removed to bring the reactor under control. Manual venting can be done at a lower pressure than the pressure required to open the relief valve. For this reason manual venting can result in lower emissions than would occur by allowing the reactor to discharge through the relief valve. Furthermore, a manual vent valve is under the control of an operator and can be closed. A relief valve may become clogged with resin and not close. The result would be loss of all the reactor contents.

The contents of a reactor can be manually vented to a gasholder or other holding vessel. However, in some cases, such as during severe weather conditions, several reactors may be out of control at one time. There would be insufficient holding capacity under these conditions to manually vent the contents of all the reactors to a gasholder. Therefore, when all other measures to prevent relief valve discharges have been exhausted, manual venting will be permitted as a last resort before the relief valve opens. The same notification procedures are required for manual venting to the atmosphere as are required for relief discharges.

There are several changes in the numerical emission limits in the promulgated standard. Except for the standard for reactor opening loss, these changes simply involve conversion to the International System of Units (SI). There was an error involved in the original calculation used to derive the standard for reactor opening. Correcting this error doubles the allowable emissions. It is emphasized that the change in this standard is a correction, and not a change in the intent for the degree of control required.

The proposed standard required the installation of a rupture disc beneath each relief valve to prevent leakage from the relief valve. A provision has been added to the promulgated standard so that a rupture disc is not required if the relief valve is tied into a process line or recovery system. In this case, any leakage from the relief valve would be contained.

The regulation for obtaining vinyl chloride samples has been changed to an operating procedure. The proposed standard stated that there were to be no emissions from taking the samples. Several commenters pointed out that the use of the word "no" would make this regulation impractical to enforce. Therefore, the promulgated standard specifies the operating procedure which EPA originally intended to be used to control this source. This revision is only a change in wording and does not represent a change in the level of the standard.

The regulation for taking samples has also been revised to apply only to samples containing at least 10 percent by weight vinyl chloride. This is consistent with the other parts of the standard which apply to equipment "in vinyl chloride service." "In vinyl chloride service" distinguishes between situations where vinyl chloride is clearly involved and situations where vinyl chloride is a minor component or contaminant, and as defined in promulgated § 61.61(1) means that a piece of equipment contains or contacts either a liquid that is at least 10 percent by weight vinyl chloride or a gas that is at least 10 percent by volume vinyl chloride.

The proposed standard required a vinyl chloride monitoring system for continuously measuring vinyl chloride levels both within the plant (for leak detection) and within stacks. The proposed standard did not outline required specifications for the monitoring system, except that it was to analyze the samples with gas chromatography, or if all hydrocarbons were assumed to be vinyl chloride, with infrared spectrophotometry, flame ion detection, or equivalent. It required that each plant submit a description of its monitoring system to EPA, so that EPA could determine whether it was acceptable or not. Comments were received indicating a need for EPA to specify some criteria for judging the acceptability of monitoring systems. The accuracy of the monitor-

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ing system would be related to the frequency of calibration. Therefore, EPA has included in the promulgated standard requirements for the frequency of calibration and procedures to be carried out in the calibration of the monitoring instruments.

The portable hydrocarbon detector required by the proposed standard was required to have a sensitivity of 5 ppm. Comments were received indicating that instruments in this sensitivity range are delicate and require continuing maintenance. The portable hydrocarbon detector is required for leak detection and for measuring vinyl chloride concentrations inside the equipment before opening it. A 5 ppm sensitivity is not needed in either case, and the required sensitivity has been changed to 10 ppm in the promulgated standard.

The proposed standard contained a single regulation for compressors. The promulgated standard has separate regulations for rotating and reciprocating compressors. This is consistent with having separate regulations for rotating and reciprocating pumps in both the proposed and promulgated standards.

Section 61.66 of the proposed standard provided for the use of equivalent methods of control which have been approved by EPA. The promulgated standard requires that the plant owner or operator submit a request for determination of equivalency within 30 days of the promulgation date if the alternative control method is intended as the initial means of control. The purpose of this is to provide time for EPA to evaluate the method before the plant has to be in compliance (for existing sources, 90 days after the promulgation date). EPA also suggests that this request for determination of equivalency be accompanied by a request for waiver of compliance pursuant to section 112(c)(1)(B)(ii) of the Act. The request for a waiver for compliance should provide for the case where EPA determines that a method is not equivalent and the plant needs to purchase other equipment. In no case will the waiver of compliance be extended beyond two years from the date of promulgation.

There are several wording clarifications which have been made in the promulgated standard. The definition for "in vinyl chloride service" (§ 60.61(1)) has been clarified by stating that it means equipment that contacts vinyl chloride as well as equipment that contains vinyl chloride. This would include such equipment as agitators.

Words have been added in §§ 61.62, 61.63, and 61.64 to clarify that the 10 ppm emission limits do not have to be met when equipment has already been opened in compliance with the regulation for opening of equipment. Equipment that has met the opening of equipment regulation can contain more than 10 ppm vinyl chloride and would be in violation of the standard if this statement were not included.

The requirements for stripping polyvinyl chloride resins to specified levels have been revised in §§ 61.64(e), 61.67 (g)(3)(ii), and 61.70(c)(2)(i) so that measurement of the vinyl chloride levels in the resins is to be made immediately after stripping is completed rather than as the resin is being transferred out of the stripper. This allows a plant to carry out operations in a stripper after stripping has been completed but before it is transferred out of the stripper. This is consistent with the original intent of the standard.

The regulation for loading and unloading lines in § 61.65(b)(1) has been revised to clarify that it applies only to lines that are disconnected after each loading or unloading operation. Permanently installed pipelines that are opened infrequently for inspection or maintenance, for example, are covered by the opening of equipment regulation rather than the loading and unloading line regulation.

The regulation for inprocess wastewater in the proposed standard could have been misinterpreted to require individual treatment of wastewater streams. Section 61.65(b)(9)(i) of the promulgated standard clarifies that wastewater streams that are required to be treated (i.e., those containing greater than 10 ppm vinyl chloride) can be combined to be treated. However, wastewater streams that contain greater than 10 ppm vinyl chloride cannot be combined with wastewater streams that contain less than 10 ppm vinyl chloride before treatment; i.e., dilution cannot be used to meet the standard.

The commenters recommended several changes in the emission limits which have not been incorporated into the promulgated standard. These are discussed in the following paragraphs.

It was recommended that the requirement for double mechanical seals on pumps, compressors, and agitators be removed because the single seals currently used on this equipment have small emissions and are more reliable than double mechanical seals. EPA is aware that each fugitive emission source, such as one pump, taken by itself causes relatively small emissions. Fugitive emissions considered as a whole are a significant source of emissions, however, and the intent of the standard is to reduce these. Double mechanical seal pumps are commonly used in the industry for emission reduction. Sealless pumps or equivalent systems are available as options to double mechanical seals.

The commenters recommended increasing the averaging time for the 10 ppm limits and the emission limits for reactor opening and stripping to 30 days. Some of the commenters apparently thought that the 10 ppm limits had to be met on an instantaneous basis. However, since the performance test for determining compliance consists of three runs for a minimum of an hour each, the averaging time for the 10 ppm limit is at least three hours. Increasing the averaging time to 30 days for any of the emission limits would permit higher peak emission levels. EPA has determined that this is neither desirable nor necessary.

Some commenters requested that the stripping levels for dispersion resins be made the same as for other resins and others requested that they be made less stringent. EPA decided not to make the standard for stripping dispersion resins the same as for other resins because there is sufficient evidence to indicate that these resins are more difficult to strip than other resins. With regard to making the stripping levels for dispersion resins less stringent, only one of the eight manufacturers of dispersion resins specifically commented that the dispersion resin standard should be made less stringent. Only two of several grades of dispersion resins made by this company cannot meet the 2,000 ppm limit. The proposed standard takes into consideration that some resins are more difficult to strip than others by providing for averaging among different resins.

(5) *Testing, reporting, and recordkeeping.* There are several relatively minor changes in the testing, reporting, and recordkeeping requirements. A provision has been added to § 61.67 which requires that stack gas samples taken with Test Method 106 are to be analyzed within 24 hours. This is consistent with the requirements in the proposed Test Method 106. The promulgated standard also specifies that in averaging the results of the three runs required by Test Method 106, a time-weighted average is to be used.

One commenter requested that the oxygen content and moisture content be specified for the 10 ppm concentration standards. The proposed standard specified that the vinyl chloride concentration is to be corrected to 10 percent oxygen (wet basis) if combustion is used as the control measure. In the promulgated standard, this requirement has been expanded to all control measures.

A provision has been added to the promulgated standard which states that if a reactor is also used as a stripper, the reactor opening emissions may be determined immediately following the stripping operation. If a reactor is also used as a stripper, the resin is in the reactor when it is opened. This means that vinyl chloride in the resin which has already been stripped to acceptable levels can escape from the resin and become part of the reactor opening loss. It is EPA's intent that once a resin has been stripped to the required levels, that additional controls are not required. Under the new provision, vinyl chloride escaping from the resin after it has been stripped to acceptable levels is not counted as part of the reactor opening loss.

A section requiring continuous monitoring of stack emissions has been added to the promulgated standard. The continuous monitoring of stack emissions was required in the proposed standard. The addition of a specific paragraph for emission monitoring serves only to clarify the requirement.

The standard has been revised so that the initial report requires a "description" rather than a "detailed description" of the equipment used to control fugitive emissions. Several commenters pointed out that a detailed description would contain proprietary information. EPA agrees that a detailed description in the

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initial report is unnecessary. If additional information is needed, EPA can obtain it under section 114 of the Act and the plant can request confidential treatment in accordance with 40 CFR Part 2 for information it believes to be proprietary.

The proposed standard required that a semiannual report be submitted every 180 days. The promulgated standard specifies dates for the submittal of the reports. It also specifies that the first semiannual report does not have to be submitted until at least six months after the initial report is submitted.

The standard has been revised to eliminate the requirement to record the cause of any leak detected by the vinyl chloride detector, the action taken to repair the leak, and the amount of time required to repair the leak. EPA is concerned only that leaks are detected and repaired. That this has been done can be established by looking at the strip chart record of measurements made by the vinyl chloride detector. These records are still required for the portable hydrocarbon detector however.

Several commentators recommended that the companies be allowed an extra two weeks to submit to EPA data from the initial performance test. They also recommended that they submit the data by regular mail rather than registered mail. EPA has not adopted either of these recommendations. A source is supposed to be in compliance with the standard within 90 days of the promulgation of the standard. The standard requires that the emission tests be done within the 90 day period, and permits an extra 30 days for determination of results. The purpose of using registered mail is to document the fact that emission data have been sent and received. This way if the results are lost in the mail, there will be no question that they were sent.

(6) *Test method.* Test Method 106 has been changed to recognize that on a gas chromatograph equipped with a Chromosorb 102 column, acetaldehyde may interfere with the vinyl chloride peak. When a sample is expected to contain acetaldehyde, a secondary column as described in section 4.3.2 must be employed. Mass spectroscopy or another absolute analytical technique is required to confirm the vinyl chloride peak obtained with the gas chromatograph, only if peak resolution with the secondary column is not successful.

In section 4.1.4, aluminized Mylar bags can be substituted for Tedlar bags. EPA now has data to allow this substitution, provided that the samples are analyzed within 24 hours of collection.

In section 5.1.3 of Test Method 106 the requirement to use "oxygen gas" has been replaced with "oxygen gas or air, as required by the detector." Several commentors stated that most gas chromatographs are designed to use hydrogen and air for their flame detectors. When used in this way, they are capable of detecting 0.5 ppm vinyl chloride in air. This is sensitive enough for monitoring the 10 ppm emission limits stipulated in the standard.

In section 6.4 of Test Method 106 the requirement for an automatic integrator has been replaced with a requirement for a disc integrator or planimeter for measuring peak area. This change is in response to a comment which states that automatic integrators are unnecessarily elaborate and expensive.

A new section 6.5 has been added to Test Method 106 which requires determination of the water vapor content of the sampling bag by measuring the ambient temperature and pressure near the bag. The vinyl chloride concentration of the bag can then be reported on a dry basis. A provision for checking the rigid container for leaks has been added to section 7.4 of Test Method 106.

The only change in Test Method 107 is the provision in Section 5.3.2 for use of Carbopak C as well as Carbopak A.

AUTHORITY: Section 112 of the Clean Air Act as added by sec. 4(a) of Pub. L. 91-604, 84 Stat. 1685 (42 U.S.C. 1857c-7; Section 114 of the Clean Air Act, as added by sec. 4(a) of Pub. L. 91-604, 84 Stat. 1687, and amended by Pub. L. 93-319, sec. 6(a)(4), 88 Stat. 259 (42 U.S.C. 1857c-9); Section 301(a) of the Clean Air Act, as amended by sec. 15(c)(2) of Pub. L. 91-604, 84 Stat. 1713 (42 U.S.C. 1857g(a)).

Dated: October 12, 1976.

JOHN QUARLES,
Acting Administrator.

Part 61 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows: The table of sections for Part 61 is amended by adding a list of sections for new Subpart F and Part 61 is amended by adding a new Subpart F reading as follows:

Subpart F—National Emission Standard for Vinyl Chloride

Sec.
61.60 Applicability.
61.61 Definitions.
61.62 Emission standard for ethylene dichloride plants.
61.63 Emission standard for vinyl chloride plants.
61.64 Emission standard for polyvinyl chloride plants.
61.65 Emission standard for ethylene dichloride, vinyl chloride and polyvinyl chloride plants.
61.66 Equivalent equipment and procedures.
61.67 Emission tests.
61.68 Emission monitoring.
61.69 Initial report.
61.70 Semiannual report.
61.71 Recordkeeping.

AUTHORITY: Section 112 of the Clean Air Act as added by sec. 4(a) of Pub. L. 91-604, 84 Stat. 1685 (42 U.S.C. 1857c-7); section 114 of the Clean Air Act, as added by sec. 4(a) of Pub. L. 91-604, 84 Stat. 1687, and amended by Pub. L. 93-319, sec. 6(a)(4), 88 Stat. 259 (42 U.S.C. 1857c-9); section 301(a) of the Clean Air Act, as amended by sec. 15(c)(2) of Pub. L. 91-604, 84 Stat. 1713 (42 U.S.C. 1857g(a)).

Subpart F—National Emission Standard for Vinyl Chloride

§ 61.60 Applicability.

(a) This subpart applies to plants which produce:

(1) Ethylene dichloride by reaction of oxygen and hydrogen chloride with ethylene,

(2) Vinyl chloride by any process, and/or

(3) One or more polymers containing any fraction of polymerized vinyl chloride.

(b) This subpart does not apply to equipment used in research and development if the reactor used to polymerize the vinyl chloride processed in the equipment has a capacity of no more than 0.19 m^3 (50 gal).

(c) Sections of this subpart other than § 61.64(a)(1), (b), (c), and (d) do not apply to equipment used in research and development if the reactor used to polymerize the vinyl chloride processed in the equipment has a capacity of greater than 0.19 m^3 (50 gal) and no more than 4.07 m^3 (1100 gal).

§ 61.61 Definitions.

Terms used in this subpart are defined in the Act, in subpart A of this part, or in this section as follows:

(a) "Ethylene dichloride plant" includes any plant which produces ethylene dichloride by reaction of oxygen and hydrogen chloride with ethylene.

(b) "Vinyl chloride plant" includes any plant which produces vinyl chloride by any process.

(c) "Polyvinyl chloride plant" includes any plant where vinyl chloride alone or in combination with other materials is polymerized.

(d) "Slip gauge" means a gauge which has a probe that moves through the gas/liquid interface in a storage or transfer vessel and indicates the level of vinyl chloride in the vessel by the physical state of the material the gauge discharges.

(e) "Type of resin" means the broad classification of resin referring to the basic manufacturing process for producing that resin, including, but not limited to, the suspension, dispersion, latex, bulk, and solution processes.

(f) "Grade of resin" means the subdivision of resin classification which describes it as a unique resin, i.e., the most exact description of a resin with no further subdivision.

(g) "Dispersion resin" means a resin manufactured in such away as to form fluid dispersions when dispersed in a plasticizer or plasticizer/diluent mixtures.

(h) "Latex resin" means a resin which is produced by a polymerization process which initiates from free radical catalyst sites and is sold undried.

(i) "Bulk resin" means a resin which is produced by a polymerization process in which no water is used.

(j) "Inprocess wastewater" means any water which, during manufacturing or processing, comes into direct contact with vinyl chloride or polyvinyl chloride or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product containing vinyl chloride or polyvinyl chloride but which has not been discharged to a wastewater treatment process or discharged untreated as wastewater.

(k) "Wastewater treatment process" includes any process which modifies

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characteristics such as BOD, COD, TSS, and pH, usually for the purpose of meeting effluent guidelines and standards; it does not include any process the purpose of which is to remove vinyl chloride from water to meet requirements of this subpart.

(l) "In vinyl chloride service" means that a piece of equipment contains or contacts either a liquid that is at least 10 percent by weight vinyl chloride or a gas that is at least 10 percent by volume vinyl chloride.

(m) "Standard operating procedure" means a formal written procedure officially adopted by the plant owner or operator and available on a routine basis to those persons responsible for carrying out the procedure.

(n) "Run" means the net period of time during which an emission sample is collected.

(o) "Ethylene dichloride purification" includes any part of the process of ethylene dichloride production which follows ethylene dichloride formation and in which finished ethylene dichloride is produced.

(p) "Vinyl chloride purification" includes any part of the process of vinyl chloride production which follows vinyl chloride formation and in which finished vinyl chloride is produced.

(q) "Reactor" includes any vessel in which vinyl chloride is partially or totally polymerized into polyvinyl chloride.

(r) "Reactor opening loss" means the emissions of vinyl chloride occurring when a reactor is vented to the atmosphere for any purpose other than an emergency relief discharge as defined in § 61.65(a).

(s) "Stripper" includes any vessel in which residual vinyl chloride is removed from polyvinyl chloride resin, except bulk resin, in the slurry form by the use of heat and/or vacuum. In the case of bulk resin, stripper includes any vessel which is used to remove residual vinyl chloride from polyvinyl chloride resin immediately following the polymerization step in the plant process flow.

§ 61.62 Emission standard for ethylene dichloride plants.

An owner or operator of an ethylene dichloride plant shall comply with the requirements of this section and § 61.65.

(a) Ethylene dichloride purification: The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from any equipment used in ethylene dichloride purification is not to exceed 10 ppm, except as provided in § 61.65(a). This requirement does not apply to equipment that has been opened, is out of operation, and met the requirement in § 61.65(b) before being opened.

(b) Oxychlorination reactor: Except as provided in § 61.65(a), emissions of vinyl chloride to the atmosphere from each oxychlorination reactor are not to exceed 0.2 g/kg the 100 percent ethylene dichloride product from the oxychlorination process.

§ 61.63 Emission standard for vinyl chloride plants.

An owner or operator of a vinyl chloride plant shall comply with the requirements of this section and § 61.65.

(a) Vinyl chloride formation and purification: The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from any equipment used in vinyl chloride formation and/or purification is not to exceed 10 ppm, except as provided in § 61.65(a). This requirement does not apply to equipment that has been opened, is out of operation, and met the requirement in § 61.65(b)(6)(i) before being opened.

§ 61.64 Emission standard for polyvinyl chloride plants.

An owner or operator of a polyvinyl chloride plant shall comply with the requirements of this section and § 61.65.

(a) Reactor: The following requirements apply to reactors:

(1) The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from each reactor is not to exceed 10 ppm, except as provided in paragraph (a)(2) of this section and § 61.65(a).

(2) The reactor opening loss from each reactor is not to exceed 0.02 g vinyl chloride/Kg (0.00002 lb vinyl chloride/lb) of polyvinyl chloride product, with the product determined on a dry solids basis. This requirement applies to any vessel which is used as a reactor or as both a reactor and a stripper. In the bulk process, the product means the gross product of prepolymerization and postpolymerization.

(3) Manual vent valve discharge: Except for an emergency manual vent valve discharge, there is to be no discharge to the atmosphere from any manual vent valve on a polyvinyl chloride reactor in vinyl chloride service. An emergency manual vent valve discharge means a discharge to the atmosphere which could not have been avoided by taking measures to prevent the discharge. Within 10 days of any discharge to the atmosphere from any manual vent valve, the owner or operator of the source from which the discharge occurs shall submit to the Administrator a report in writing containing information on the source, nature and cause of the discharge, the date and time of the discharge, the approximate total vinyl chloride loss during the discharge, the method used for determining the vinyl chloride loss, the action that was taken to prevent the discharge, and measures adopted to prevent future discharges.

(b) Stripper: The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from each stripper is not to exceed 10 ppm, except as provided in § 61.65(a). This requirement does not apply to equipment that has been opened, is out of operation, and met the requirement in § 61.65(b)(6)(i) before being opened.

(c) Mixing, weighing, and holding containers: The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from each mixing, weighing, or holding container in vinyl chloride service which precedes the stripper (or the reactor if the plant has no stripper) in the plant process flow is not to exceed 10 ppm, except as provided in § 61.65(a). This requirement does not apply to equipment that has been opened, is out of operation, and met the requirement in § 61.65(b)(6)(i) before being opened.

(d) Monomer recovery system. The concentration of vinyl chloride in all exhaust gases discharged to the atmosphere from each monomer recovery system is not to exceed 10 ppm, except as provided in § 61.65(a). This requirement does not apply to equipment that has been opened, is out of operation, and met the requirement in § 61.65(b)(6)(i) before being opened.

(e) Sources following the stripper(s): The following requirements apply to emissions of vinyl chloride to the atmosphere from the combination of all sources following the stripper(s) [or the reactor(s) if the plant has no stripper(s)] in the plant process flow including but not limited to, centrifuges, concentrators, blend tanks, filters, dryers, conveyor air discharges, baggers, storage containers, and inprocess wastewater:

(1) In polyvinyl chloride plants using stripping technology to control vinyl chloride emissions, the weighted average residual vinyl chloride concentration in all grades of polyvinyl chloride resin processed through the stripping operation on each calendar day, measured immediately after the stripping operation is completed, may not exceed:

(i) 2000 ppm for polyvinyl chloride dispersion resins, excluding latex resins;

(ii) 400 ppm for all other polyvinyl chloride resins, including latex resins, averaged separately for each type of resin; or

(2) In polyvinyl chloride plants controlling vinyl chloride emissions with technology other than stripping or in addition to stripping, emissions of vinyl chloride to the atmosphere may not exceed:

(i) 2 g/kg (0.002 lb/lb) product from the stripper(s) [or reactor(s) if the plant has no stripper(s)] for dispersion polyvinyl chloride resins, excluding latex resins, with the product determined on a dry solids basis;

(ii) 0.4 g/kg (0.0004 lb/lb) product from the strippers [or reactor(s) if the plant has no stripper(s)] for all other polyvinyl chloride resins, including latex resins, with the product determined on a dry solids basis.

§ 61.65 Emission standard for ethylene dichloride, vinyl chloride and polyvinyl chloride plants.

An owner or operator of an ethylene dichloride, vinyl chloride, and/or polyvinyl chloride plant shall comply with the requirements of this section.

(a) Relief valve discharge: Except for an emergency relief discharge, there is to be no discharge to the atmosphere from any relief valve on any equipment in vinyl chloride service. An emergency relief discharge means a discharge which could not have been avoided by taking measures to prevent the discharge. Within 10 days of any relief valve discharge,

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the owner or operator of the source from which the relief valve discharge occurs shall submit to the Administrator a report in writing containing information on the source, nature and cause of the discharge, the date and time of the discharge, the approximate total vinyl chloride loss during the discharge, the method used for determining the vinyl chloride loss, the action that was taken to prevent the discharge, and measures adopted to prevent future discharges.

(b) Fugitive emission sources:

(1) Loading and unloading lines: Vinyl chloride emissions from loading and unloading lines which are opened to the atmosphere after each loading or unloading operation are to be minimized as follows:

(i) After each loading or unloading operation and before opening a loading or unloading line to the atmosphere, the quantity of vinyl chloride in all parts of each loading or unloading line that are to be opened to the atmosphere is to be reduced so that the parts combined contain no greater than 0.0038 m^3 (0.13 ft^3) of vinyl chloride, at standard temperature and pressure; and

(ii) Any vinyl chloride removed from a loading or unloading line in accordance with paragraph (b)(1)(i) of this section is to be ducted through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm, or equivalent as provided in § 61.66.

(2) Slip gauges: During loading or unloading operations, the vinyl chloride emissions from each slip gauge in vinyl chloride service are to be minimized by ducting any vinyl chloride discharged from the slip gauge through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm, or equivalent as provided in § 61.66.

(3) Leakage from pump, compressor, and agitator seals:

(i) Rotating pumps: Vinyl chloride emissions from seals on all rotating pumps in vinyl chloride service are to be minimized by installing sealless pumps, pumps with double mechanical seals, or equivalent as provided in § 61.66. If double mechanical seals are used, vinyl chloride emission from the seals are to be minimized by maintaining the pressure between the two seals so that any leak that occurs is into the pump; by ducting any vinyl chloride between the two seals through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(ii) Reciprocating pumps: Vinyl chloride emissions from seals on all reciprocating pumps in vinyl chloride service are to be minimized by installing double outboard seals, or equivalent as provided in § 61.66. If double outboard seals are used, vinyl chloride emissions from the seals are to be minimized by maintaining the pressure between the two seals so that any leak that occurs is into the pump; by ducting any vinyl chloride between the two seals through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(iii) Rotating compressor: Vinyl chloride emissions from seals on all rotating compressors in vinyl chloride service are to be minimized by installing compressors with double mechanical seals, or equivalent as provided in § 61.66. If double mechanical seals are used, vinyl chloride emissions from the seals are to be minimized by maintaining the pressure between the two seals so that any leak that occurs is into the compressor; by ducting any vinyl chloride between the two seals through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(iv) Reciprocating compressors: Vinyl chloride emissions from seals on all reciprocating compressors in vinyl chloride service are to be minimized by installing double outboard seals, or equivalent as provided in § 61.66. If double outboard seals are used, vinyl chloride emissions from the seals are to be minimized by maintaining the pressure between the two seals so that any leak that occurs is into the compressor; by ducting any vinyl chloride between the two seals through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(v) Agitator: Vinyl chloride emissions from seals on all agitators in vinyl chloride service are to be minimized by installing agitators with double mechanical seals, or equivalent as provided in § 61.66. If double mechanical seals are used, vinyl chloride emissions from the seals are to be minimized by maintaining the pressure between the two seals so that any leak that occurs is into the agitated vessel; by ducting any vinyl chloride between the two seals through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(4) Leakage from relief valves: Vinyl chloride emissions due to leakage from each relief valve on equipment in vinyl chloride service are to be minimized by installing a rupture disk between the equipment and the relief valve, by connecting the relief valve discharge to a process line or recovery system, or equivalent as provided in § 61.66.

(5) Manual venting of gases: Except as provided in § 61.64(a)(3), all gases which are manually vented from equipment in vinyl chloride service are to be ducted through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm; or equivalent as provided in § 61.66.

(6) Opening of equipment: Vinyl chloride emissions from opening of equipment (including loading or unloading lines that are not opened to the atmosphere after each loading or unloading operation) are to be minimized as follows:

(i) Before opening any equipment for any reason, the quantity of vinyl chloride is to be reduced so that the equipment contains no more than 2.0 percent by volume vinyl chloride or 0.050 m (25 gal) of vinyl chloride, whichever is larger, at standard temperature and pressure; and

(ii) Any vinyl chloride removed from the equipment in accordance with paragraph (b)(6)(i) of this section is to be ducted through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm, or equivalent as provided in § 61.66.

(7) Samples: Unused portions of samples containing at least 10 percent by weight vinyl chloride are to be returned to the process, and sampling techniques are to be such that sample containers in vinyl chloride service are purged into a closed process system.

(8) Leak detection and elimination: Vinyl chloride emissions due to leaks from equipment in vinyl chloride service are to be minimized by instituting and implementing a formal leak detection and elimination program. The owner or operator shall submit a description of the program to the Administrator for approval. The program is to be submitted within 45 days of the effective date of these regulations, unless a waiver of compliance is granted under § 61.11. If a waiver of compliance is granted, the program is to be submitted on a date scheduled by the Administrator. Approval of a program will be granted by the Administrator provided he finds:

(i) It includes a reliable and accurate vinyl chloride monitoring system for detection of major leaks and identification of the general area of the plant where a leak is located. A vinyl chloride monitoring system means a device which obtains air samples from one or more points on a continuous sequential basis and analyzes the samples with gas chromatography or, if the owner or operator assumes that all hydrocarbons measured are vinyl chloride, with infrared spectrophotometry flame ion detection, or an equivalent or alternative method.

(ii) It includes a reliable and accurate portable hydrocarbon detector to be used routinely to find small leaks and to pinpoint the major leaks indicated by the vinyl chloride monitoring system. A portable hydrocarbon detector means a device which measures hydrocarbons with a sensitivity of at least 10 ppm and is of such design and size that it can be used to measure emissions from localized points.

(iii) It provides for an acceptable calibration and maintenance schedule for the vinyl chloride monitoring system and portable hydrocarbon detector. For the vinyl chloride monitoring system, a daily span check is to be conducted with a concentration of vinyl chloride equal to the concentration defined as a leak according to paragraph (b)(8)(vi) of this section. The calibration is to be done with either:

(A) A calibration gas mixture prepared from the gases specified in sections 5.2.1 and 5.2.3 of Test Method 106, or

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(B) A calibration gas cylinder containing the appropriate concentration of vinyl chloride. If a calibration gas cylinder is used, the analysis must be traceable to the National Bureau of Standards or to a gravimetrically calibrated vinyl chloride permeation tube.

(iv) The location and number of points to be monitored and the frequency of monitoring provided for in the program are acceptable when they are compared with the number of pieces of equipment in vinyl chloride service and the size and physical layout of the plant.

(v) It contains an acceptable plan of action to be taken when a leak is detected.

(vi) It contains a definition of leak which is acceptable when compared with the background concentrations of vinyl chloride in the areas of the plant to be monitored by the vinyl chloride monitoring system. Measurements of background concentrations of vinyl chloride in the areas of the plant to be monitored by the vinyl chloride monitoring system are to be included with the description of the program. The definition of leak for a given plant may vary among the different areas within the plant and is also to change over time as background concentrations in the plant are reduced.

(9) Inprocess wastewater: Vinyl chloride emissions to the atmosphere from inprocess wastewater are to be reduced as follows:

(i) The concentration of vinyl chloride in each inprocess wastewater stream containing greater than 10 ppm vinyl chloride measured immediately as it leaves a piece of equipment and before being mixed with any other inprocess wastewater stream is to be reduced to no more than 10 ppm by weight before being mixed with any other inprocess wastewater stream which contains less than 10 ppm vinyl chloride; before being exposed to the atmosphere, before being discharged to a wastewater treatment process; or before being discharged untreated as a wastewater. The paragraph does apply to water which is used to displace vinyl chloride from equipment before it is opened to the atmosphere in accordance with § 61.64(a)(2) or paragraph (b)(6) of this section, but does not apply to water which is used to wash out equipment after the equipment has already been opened to the atmosphere in accordance with § 61.64(a)(2) or paragraph (b)(6) of this section.

(ii) Any vinyl chloride removed from the inprocess wastewater in accordance with paragraph (b)(9)(i) of this section is to be ducted through a control system from which the concentration of vinyl chloride in the exhaust gases does not exceed 10 ppm, or equivalent as provided in § 61.66.

(c) The requirements in paragraphs (b)(1), (b)(2), (b)(5), (b)(6), (b)(7) and (b)(8) of this section are to be incorporated into a standard operating procedure, and made available upon request for inspection by the Administrator. The standard operating procedure is to include provisions for measuring the vinyl chloride in equipment ≥4.75 m³ 01250 gal in volume for which an mission limit is prescribed in § 61.65(b)(6)(i) prior to opening the equipment and using Test Method 106, a portable hydrocarbon detector, or an equivalent or alternative method. The method of measurement is to meet the requirements in § 61.67(g)(5)(i)(A) or (g)((5)(i)(B).

§ 61.66 Equivalent equipment and procedures.

Upon written application from an owner or operator, the Administrator may approve use of equipment or procedures which have been demonstrated to his satisfaction to be equivalent in terms of reducing vinyl chloride emissions to the atmosphere to those prescribed for compliance with a specific paragraph of this subpart. For an existing source, any request for using an equivalent method as the initial measure of control is to be submitted to the Administrator within 90 days of the effective date. For a new source, any request for using an equivalent method is to be submitted to the Administrator with the application for approval of construction or modification required by § 61.07.

§ 61.67 Emission tests.

(a) Unless a waiver of emission testing is obtained under § 61.13, the owner or operator of a source to which this subpart applies shall test emissions from the source.

(1) Within 90 days of the effective date in the case of an existing source or a new source which has an initial startup date preceding the effective date, or

(2) Within 90 days of startup in the case of a new source, initial startup of which occurs after the effective date.

(b) The owner or operator shall provide the Administrator at least 30 days prior notice of an emission test to afford the Administrator the opportunity to have an observer present during the test.

(c) Any emission test is to be conducted while the equipment being tested is operating at the maximum production rate at which the equipment will be operated and under other relevant conditions as may be specified by the Administrator based on representative performance of the source.

(d) Each emission test is to consist of three runs. For the purpose of determining emissions, the average of results of all runs is to apply. The average is to be computed on a time weighted basis.

(e) All samples are to be analyzed within 24 hours, and vinyl chloride emissions are to be determined within 30 days after the emission test. The owner or operator shall report the determinations to the Administrator by a registered letter dispatched before the close of the next business day following the determination.

(f) The owner or operator shall retain at the plant and make available, upon request, for inspection by the Administrator, for a minimum of 2 years records of emission test results and other data needed to determine emissions.

(g) Unless otherwise specified, the owner or operator shall use test Test Methods in Appendix B to this part for each test as required by paragraphs (g)(1), (g)(2), (g)(3), (g)(4), and (g)(5) of this section, unless an equivalent method or an alternative method has been approved by the Administrator. If the Administrator finds reasonable grounds to dispute the results obtained by an equivalent or alternative method, he may require the use of a reference method. If the results of the reference and equivalent or alternative methods do not agree, the results obtained by the reference method prevail, and the Administrator may notify the owner or operator that approval of the method previously considered to be equivalent or alternative is withdrawn.

(1) Test Method 106 is to be used to determine the vinyl chloride emissions from any source for which an emission limit is prescribed in §§ 61.62(a) or (b) § 61.63(a), or §§ 61.64(a)(1), (b), (c), or (d), or from any control system to which reactor emissions are required to be ducted in § 61.64(a)(2) or to which fugitive emissions are required to be ducted in §§ 61.65(b)(1)(ii), (b)(2), (b)(5), (b)(6)(ii), or (b)(9)(ii).

(i) For each run, one sample is to be collected. The sampling site is to be at least two stack or duct diameters downstream and one half diameter upstream from any flow disturbance such as a bend, expansion, contraction, or visible flame. For a rectangular cross section an equivalent diameter is to be determined from the following equation:

$$\text{equivalent diameter} = 2\,\frac{(\text{length})\,(\text{width})}{\text{length}+\text{width}}$$

The sampling point in the duct is to be at the centroid of the cross section. The sample is to be extracted at a rate proportional to the gas velocity at the sampling point. The sample is to be taken over a minimum of one hour, and is to contain a minimum volume of 50 liters corrected to standard conditions.

(ii) For gas streams containing more than 10 percent oxygen, the concentration of vinyle chloride as determined by Test Method 106 is to be corrected to 10 percent oxygen for determination of emissions by using the following equation:

$$C_{b\,(\text{corrected})} = C_b\,\frac{10.9}{20.9-\text{percent } O_2}$$

where:

$C_{b(\text{corrected})}$ = The concentration of vinyl chloride in the exhaust gases, corrected to 10 percent oxygen.

C_b = The concentration of vinyl chloride as measured by Test Method 106.

20.9 = Percent oxygen in the ambient air at standard conditions.

10.9 = Percent oxygen in the ambient air at standard conditions, minus the 10 percent oxygen to which the correction is being made.

Percent O_2 = Percent oxygen in the exhaust gas as measured by Reference Method 3 in Appendix A of Part 60 of this chapter.

(iii) For those emission sources where the emission limit is prescribed in terms of mass rather than concentration, mass

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emissions in kg/100 kg product are to be determined by using the following equation:

$$C_{BX} = \frac{[C_b\ (2.60)\ Q\ 10^{-6}]\ [100]}{Z}$$

where:

C_{BX} = kg vinyl chloride/100 kg product.
C_b = The concentration of vinyl chloride as measured by Test Method 106.
2.60 = Density of vinyl chloride at one atmosphere and 20°C in kg/m³.
Q = Volumetric flow rate in m³/hr as determined by Reference Method 2 of Appendix A to Part 60 of this chapter.
10^{-6} = Conversion factor for ppm.
Z = Production rate (kg/hr).

(2) Test Method 107 is to be used to determine the concentration of vinyl chloride in each inprocess wastewater stream for which an emission limit is prescribed in § 61.65(b)(9)(i).

(3) Where a stripping operation is used to attain the emission limit in § 61.64(e), emissions are to be determined using Test Method 107 as follows:

(i) The number of strippers and samples and the types and grades of resin to be sampled are to be determined by the Administrator for each individual plant at the time of the test based on the plant's operation.

(ii) Each sample is to be taken immediately following the stripping operation.

(iii) The corresponding quantity of material processed by each stripper is to be determined on a dry solids basis and by a method submitted to and approved by the Administrator.

(iv) At the prior request of the Administrator, the owner or operator shall provide duplicates of the samples required in paragraph (g)(3)(i) of this section.

(4) Where control technology other than or in addition to a stripping operation is used to attain the emission limit in § 61.64(e), emissions are to be determined as follows:

(i) Test Method 106 is to be used to determine atmospheric emissions from all of the process equipment simultaneously. The requirements of paragraph (g)(1) of this section are to be met.

(ii) Test Method 107 is to be used to determine the concentration of vinyl chloride in each inprocess wastewater stream subject to the emission limit prescribed in § 61.64(e). The mass of vinyl chloride in kg/100 kg product in each in process wastewater stream is to be determined by using the following equation:

$$C_{BX} = \frac{[C_d\ R\ 10^{-6}]\ [100]}{Z}$$

where:

C_{BX} = kg vinyl chloride/100 kg product.
C_d = the concentration of vinyl chloride as measured by Test Method 107.
R = water flow rate in l/hr, determined in accordance with a method which has been submitted to and approved by the Administrator.
10^{-6} = Conversion factor for ppm.
Z = Production rate (kg/hr), determined in accordance with a method which has been submitted and approved by the Administrator.

(5) The reactor opening loss for which an emission limit is prescribed in § 61.64(a)(2) is to be determined. The number of reactors for which the determination is to be made is to be specified by the Administrator for each individual plant at the time of the determination based on the plant's operation. For a reactor that is also used as a stripper, the determination may be made immediately following the stripping operation.

(i) Except as provided in paragraph (g)(5)(ii) of this section, the reactor opening loss is to be determined using the following equation:

$$C = \frac{W\ (2.60)\ (10^{-6})\ (Cb)}{YZ}$$

where:

C = kg vinyl chloride emissions/kg product.
W = Capacity of the reactor in m³.
2.60 = Density of vinyl chloride at one atmosphere and 20° C in kg/m³.
10^{-6} = Conversion factor for ppm.
Cb = ppm by volume vinyl chloride as determined by Test Method 106 or a portable hydrocarbon detector which measures hydrocarbons with a sensitivity of at least 10 ppm.
Y = Number of batches since the reactor was last opened to the atmosphere.
Z = Average kg of polyvinyl chloride produced per batch in the number of batches since the reactor was last opened to the atmosphere.

(A) If Method 106 is used to determine the concentration of vinyl chloride (Cb), the sample is to be withdrawn at a constant rate with a probe of sufficient length to reach the vessel bottom from the manhole. Samples are to be taken for 5 minutes within 6 inches of the vessel bottom, 5 minutes near the vessel center, and 5 minutes near the vessel top.

(B) If a portable hydrocarbon detector is used to determine the concentration of vinyl chloride (Cb), a probe of sufficient length to reach the vessel bottom from the manhole is to be used to make the measurements. One measurement will be made within 6 inches of the vessel bottom, one near the vessel center and one near the vessel top. Measurements are to be made at each location until the reading is stabilized. All hydrocarbons measured are to be assumed to be vinyl chloride.

(C) The production rate of polyvinyl chloride (Z) is to be determined by a method submitted to and approved by the Administrator.

(ii) A calculation based on the number of evacuations, the vacuum involved, and the volume of gas in the reactor is hereby approved by the Administrator as an alternative method for determining reactor opening loss for postpolymerization reactors in the manufacture of bulk resins.

§ 61.68 Emisison monitoring.

(a) A vinyle chloride monitoring system is to be used to monitor on a continuous basis the emissions from the sources for which emission limits are prescribed in § 61.62(a) and (b), § 61.63(a), and § 61.64(a)(1), (b), (c), and (d), and for any control system to which reactor emission are required to be ducted in § 61.65(b)(1)(ii), and (b)(2), (b)(5), (b)(6)(ii), and (b)(9)(ii).

(b) The vinyl chloride monitoring system(s) used to meet the requirement in paragraph (a) of this section is to be a device which obtains air sampels from one or more points on a continuous sequential basis and analyzes the samples with gas chromotography or, if the owner or operator assumes that all hydrocarbons measured are vinyl chloride, with infrared spectrophotometry, flame ion detection, or an equivalent or alternative method. The vinyl chloride monitoring system used to meet the requirements in § 61.65(b)(8)(i) may be used to meet the requirements of this section.

(c) A daily span check is to be conducted for each vinyle chloride monitoring system used. For all of the emission sources listed in paragraph (a) of this section, except the one for which an emission limit is prescribed in § 61.62(b), the daily span check is to be conducted with a concentration of vinyl chloride equal to 10 ppm. For the emission source for which an emission limit is prescribed in § 61.62(b), the daily span check is to be conducted with a concentration of vinyl chloride which is determined to be determined to be equivalent to the emission limit for that source based on the emission test required by § 67.67. The calibration is to be done with either:

(1) A calibration gas mixture prepared from the gases specified in sections 5.2.1 and 5.2.3 of Test Method 106, or

(2) A calibration gas cylinder containing the appropriate concentration of vinyl chloride. If a calibration gas cylinder is used, the analysis must be traceable to the National Bureau of Standards or to a gravimetrically calibrated vinyl chloride permeation tube.

§ 61.69 Initial report.

(a) An owner or operator of any source to which this subpart applies shall submit a statement in writing notifying the Administrator that the equipment and procedural specifications in §§ 61.65(b)(1), (b)(2), (b)(3), (b)(4), (b)(5), (b)(6), (b)(7), and (b)(8) are being implemented.

(b)(1) In the case of an existing source or a new source which has an initial startup date preceding the effective date, the statement is to be submitted within 90 days of the effective date, unless a waiver of compliance is granted under § 61.11, along with the information required under § 61.10. If a waiver of compliance is granted, the statement is to be submitted on a date scheduled by the Administrator.

(2) In the case of a new source which did not have an initial startup date preceding the effective date, the statement is to be submitted within 90 days of the initial startup date.

(c) The statement is to contain the following information:

(1) A list of the equipment installed for compliance,

(2) A description of the physical and functional characteristics of each piece of equipment.

(3) A description of the methods which have been incorporated into the standard operating procedures for measuring or calculating the emissions for which emission limits are prescribed in §§ 61.65(b)(1)(i) and (b)(6)(i),

(4) A statement that each piece of equipment is installed and that each piece of equipment and each procedure is being used.

§ 61.70 Semiannual report.

(a)(2) is to be determined. The number source to which this subpart applies shall submit to the Administrator on Septem-

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ber 15 and March 15 of each year a report in writing containing the information required by this section. The first semiannual report is to be submitted following the first full 6 month reporting period after the initial report is submitted.

(b) (1) In the case of an existing source or a new source which has an initial startup date preceding the effective date, the first report is to be submitted within 180 days of the effective date, unless a waiver of compliance is granted under § 61.11. If a waiver of compliance is granted, the first report is to be submitted on a date scheduled by the Administrator.

(2) In the case of a new source which did not have an initial startup date preceding the effective date, the first report is to be submitted within 180 days of the initial startup date.

(c) Unless otherwise specified, the owner or operator shall use the Test Methods in Appendix B to this part to conduct emission tests as required by paragraphs (c)(2) and (c)(3) of this section, unless an equivalent or an alternative method has been approved by the Administrator. If the Administrator finds reasonable grounds to dispute the results obtained by an equivalent or alternative method, he may require the use of a reference method. If the results of the reference and equivalent or alternative methods do not agree, the results obtained by the reference method prevail, and the Administrator may notify the owner or operator that approval of the method previously considered to be equivalent or alternative is withdrawn.

(1) The owner or operator shall include in the report a record of any emissions which averaged over any hour period (commencing on the hour) are in excess of the emission limits prescribed in §§ 61.62(a) or (b), § 61.63(a), or §§ 61.64(a)(1), (b), (c), or (d), or for any control system to which reactor emissions are required to be ducted in § 61.64(a)(2) or to which fugitive emissions are required to be ducted in § 61.65 (b)(1)(ii), (b)(2), (b)(5), (b)(6)(ii), or (b)(9)(ii). The emissions are to be measured in accordance with § 61.68.

(2) In polyvinyl chloride plants for which a stripping operation is used to attain the emisison level prescribed in § 61.64(e), the owner or operator shall include in the report a record of the vinyl chloride content in the polyvinyl chloride resin. Test Method 107 is to be used to determine vinyl chloride content as follows:

(i) If batch stripping is used, one representative sample of polyvinyl chloride resin is to be taken from each batch of each grade of resin immediately following the completion of the stripping, and grade and the date and time the batch is completed. The corresponding quantity of material processed in each stripper batch is to be recorded and identified by resin type and grade and the date and time the batch is completed.

(ii) If continuous stripping is used, one representative sample of polyvinyl chloride resin is to be taken for each grade of resin processed or at intervals of 8 hours for each grade of resin which is being processed, whichever is more frequent. The sample is to be taken as the resin flows out of the stripper and identified by resin type and grade and the date and time the sample was taken. The corresponding quantity of material processed by each stripper over the time period represented by the sample during the eight hour period, is to be recorded and identified by resin type and grade and the date and time it represents.

(iii) The quantity of material processed by the stripper is to be determined on a dry solids basis and by a method submitted to and approved by the Administrator.

(iv) At the prior request of the Administrator, the owner or operator shall provide duplicates of the samples required in paragraphs (c)(2)(i) and (c)(2)(ii) of this section.

(v) The report to the Administrator by the owner or operator is to include the vinyl chloride content found in all the samples required in paragraphs (c)(2)(i) and (c)(2)(ii) of this section, averaged separately for each type of resin, over each calendar day and weighted according to the quantity of each grade of resin processed by the stripper(s) that calendar day, according to the following equation:

$$A_{T_i} = \frac{\sum_{i=1}^{n} P_{G_i} M_{G_i}}{Q_{T_i}}$$

$$= \frac{P_{G_1} M_{G_1} + P_{G_2} M_{G_2} + \ldots + P_{G_n} M_{G_n}}{Q_{T_i}}$$

A = 24-hour average concentration of type T_i resin in ppm.
Q = Total production of type T_i resin over the 24-hour period, in kg.
T_i = Type of resin; $i = 1, 2, \ldots m$ where m is total number of resin types produced during the 24-hour period.
M = Concentration of vinyl chloride in one sample of grade G_i resin, in ppm.
P = Production of grade G_i resin represented by the sample, in kg.
G_i = Grade of resin, e.g., G_1, G_2, and G_3.
n = Total number of grades of resin produced during the 24-hour period.

(vi) The owner or operator shall retain at the source and make available for inspection by the Administrator for a minimum of 2 years records of all data needed to furnish the information required by paragraph (c)(2)(v) of this section: The records are to contain the following information:

(A) The vinyl chloride content found in all the samples required in paragraphs (c)(2)(i) and (c)(2)(ii) of this section, identified by the resin type and grade and the time and date of the sample, and

(B) The corresponding quantity of polyvinyl chloride resin processed by the stripper(s), identified by the resin type and grade and the time and date it represents.

(3) The owner or operator shall include in the report a record of the emissions from each reactor opening for which an emission limit is prescribed in § 61.64(a)(2). Emissions are to be determined in accordance with § 61.67(g)(5), except that emissions for each reactor are to be determined. For a reactor that is also used as a stripper, the determination may be made immediately following the stripping operation.

§ 61.71 Recordkeeping.

(a) The owner or operator of any source to which this subpart applies shall retain the following information at the source and make it available for inspection by the Administrator for a minimum of two years:

(1) A record of the leaks detected by the vinyl chloride monitoring system, as required by § 61.65(b)(8), including the concentrations of vinyl chloride as measured, analyzed, and recorded by the vinyl chloride detector, the location of each measurement and the date and approximate time of each measurement.

(2) A record of the leaks detected during routine monitoring with the portable hydrocarbon detector and the action taken to repair the leaks, as required by § 61.65(b)(8), including a brief statement explaining the location and cause of each leak detected with the portable hydrocarbon detector, the date and time of the leak and any action taken to eliminate that leak measured in accordance with § 61.68.

(3) For the relief discharges from reactors subject to the provisions of § 61.65(a), a daily operating record for each reactor, including pressures and temperatures.

2. Appendix B is amended by adding Test Methods 106 and 107 as follows:

METHOD 106—DETERMINATION OF VINYL CHLORIDE FROM STATIONARY SOURCES

INTRODUCTION

Performance of this method should not be attempted by persons unfamiliar with the operation of a gas chromatograph, nor by those who are unfamiliar with source sampling, as there are many details that are beyond the scope of this presentation. Care must be exercised to prevent exposure of sampling personnel to vinyl chloride, a carcinogen.

1. Principle and Applicability.

1.1 An integrated bag sample of stack gas containing vinyl chloride (chloroethylene) is subjected to chromatographic analysis, using a flame ionization detector.

1.2 The method is applicable to the measurement of vinyl chloride in stack gases from ethylene dichloride, vinyl chloride and polyvinyl chloride manufacturing processes, except where the vinyl chloride is contained in particulate matter.

2. Range and Sensitivity.

The lower limit of detection will vary according to the chromatograph used. Values reported include 1×10^{-7} mg and 4×10^{-7} mg.

3. Interferences.

Acetaldehyde, which can occur in some vinyl chloride sources, will interfere with the vinyl chloride peak from the Chromosorb 102 column. See sections 4.3.2 and 6.4. If resolution of the vinyl chloride peak is still not satisfactory for a particular sample, then chromatograph parameters can be further altered with prior approval of the Administrator. If alteration of the chromatograph parameters fails to resolve the vinyl chloride peak, then supplemental confirmation of the vinyl chloride peak through an absolute analytical technique, such as mass spectroscopy, must be performed.

4. Apparatus.

4.1 Sampling (Figure 1).

4.1.1 Probe—Stainless steel, Pyrex glass, or Teflon tubing according to stack temper-

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ature, each equipped with a glass wool plug to remove particulate matter.

4.1.2 Sample line—Teflon, 6.4 mm outside diameter, of sufficient length to connect probe to bag. A new unused piece is employed for each series of bag samples that constitutes an emission test.

4.1.3 Male (2) and female (2) stainless steel quick-connects, with ball checks (one pair without) located as shown in Figure 1.

4.1.4 Tedlar bags, 100 liter capacity—To contain sample. Teflon bags are not acceptable. Aluminized Mylar bags may be used, provided that the samples are analyzed within 24 hours of collection.

4.1.5 Rigid leakproof containers for 4.1.4, with covering to protect contents from sunlight.

4.1.6 Needle valve—To adjust sample flow rate.

4.1.7 Pump—Leak-free. Minimum capacity 2 liters per minute.

4.1.8 Charcoal tube—To prevent admission of vinyl chloride to atmosphere in vicinity of samplers.

4.1.9 Flow meter—For observing sample flow rate; capable of measuring a flow range from 0.10 to 1.00 liter per minute.

4.1.10 Connecting tubing—Teflon, 6.4 mm outside diameter, to assemble sample train (Figure 1).

4.1.11 Pitot tube—Type S (or equivalent), attached to the probe so that the sampling flow rate can be regulated proportional to the stack gas velocity.

4.2 Sample recovery.

4.2.1 Tubing—Teflon, 6.4 mm outside diameter, to connect bag to gas chromatograph sample loop. A new unused piece is employed for each series of bag samples that constitutes an emission test, and is to be discarded upon conclusion of analysis of those bags.

4.3 Analysis.

4.3.1 Gas chromatograph—With flame ionization detector, potentiometric strip chart recorder and 1.0 to 5.0 ml heated sampling loop in automatic sample valve.

4.3.2 Chromatographic column—Stainless steel, 2.0 × 3.2 mm, containing 80/100 mesh Chromosorb 102. A secondary colum of GE SF-96, 20% on 60/80 mesh AW Chromosorb P, stainless steel, 2.0 m × 3.2 mm, will be required if acetaldehyde is present. If used, the SF-96 column is placed after the Chromosorb 102 column. The combined columns should then be operated at 110°C.

4.3.3 Flow meters (2)—Rotameter type, 0 to 100 ml/min capacity, with flow control valves.

4.3.4 Gas regulators—For required gas cylinders.

4.3.5 Thermometer—Accurate to one degree centigrade, to measure temperature of heated sample loop at time of sample injection.

4.3.6 Barometer—Accurate to 5 mm Hg, to measure atmospheric pressure around gas chromatograph during sample analysis.

4.3.7 Pump—Leak-free. Minimum capacity 100 ml/min.

4.4 Calibration.

4.4.1 Tubing—Teflon, 6.4 mm outside diameter, separate pieces marked for each calibration concentration.

4.4.2 Tedlar bags—Sixteen-inch square size, separate bag marked for each calibration concentration.

4.4.3 Syringe—0.5 ml, gas tight.

4.4.4 Syringe—50μl, gas tight.

4.4.5 Flow meter—Rotameter type, 0 to 1000 ml/min range accurate to ±1%, to meter nitrogen in preparation of standard gas mixtures.

4.4.6 Stop watch—Of known accuracy, to time gas flow in preparation of standard gas mixtures.

5. Reagents. It is necessary that all reagents be of chromatographic grade.

5.1 Analysis.

5.1.1 Helium gas or nitrogen gas—Zero grade, for chromatographic carrier gas.

5.1.2 Hydrogen gas—Zero grade.

5.1.3 Oxygen gas, or Air, as required by the detector—Zero grade.

5.2 Calibration.

5.2.1 Vinyl chloride, 99.9+%—For preparation of standard gas mixtures.

5.2.2 Calibration cylinders (3), optional—One each of 50, 10 and 5 ppm vinyl chloride in nitrogen with certified analysis. Analysis must be traceable to NBS (National Bureau of Standards) or to a gravimetrically calibrated vinyl chloride permeation tube.

5.2.3 Nitrogen gas—Zero grade, for preparation of standard gas mixtures.

6. Procedure.

6.1 Sampling. Assemble the sample train as in Figure 106-1. Perform a bag leak check according to Section 7.4. Observe that all connections between the bag and the probe are tight. Place the end of the probe at the centroid of the stack and start the pump with the needle valve adjusted to yield a flow of 0.5 lpm. After a period of time sufficient to purge the line several times has elapsed, connect the vacuum line to the bag and evacuate the bag until the rotameter indicates no flow. Then reposition the sample and vacuum lines and begin the actual sampling, keeping the rate proportional to the stack velocity. Direct the gas exiting the rotameter away from sampling personnel. At the end of the sample period, shut off the pump, disconnect the sample line from the bag, and disconnect the vacuum line from the bag container. Protect the bag container from sunlight.

6.2 Sample storage. Sample bags must be kept out of direct sunlight. When at all possible, analysis is to be performed within 24 hours of sample collection.

6.3 Sample recovery. With a piece of Teflon tubing identified for that bag, connect a bag inlet valve to the gas chromatograph sample valve. Switch the valve to withdraw gas from the bag through the sample loop. Plumb the equipment so the sample gas passes from the sample valve to the leak-free pump, and then to a charcoal tube, followed by a 0-100 ml/min rotameter with flow control valve.

6.4 Analysis. Set the column temperature to 100° C the detector temperature to 150° C, and the sample loop temperature to 70° C. When optimum hydrogen and oxygen flow rates have been determined verify and maintain these flow rates during all chromatograph operations. Using zero helium or nitrogen as the carrier gas, establish a flow rate in the range consistent with the manufacturer's requirements for satisfactory detector operation. A flow rate of approximately 40 ml/min should produce adequate separations. Observe the base line periodically and determine that the noise level has stabilized and that base line drift has ceased. Purge the sample loop for thirty seconds at the rate of 100 ml/min, then activate the sample valve. Record the injection time (the position of the pen on the chart at the time of sample injection), the sample number, the sample loop temperature, the column temperature, carrier gas flow rate, chart speed and the attenuator setting. Record the laboratory pressure. From the chart, select the peak having the retention time corresponding to vinyl chloride, as determined in Section 7.2. Measure the peak area, A_m, by use of H_m, and a disc integrator or a planimeter. Measure the peak height, H_m. Record A_m and the retention time. Repeat the injection at least two times or until two consecutive vinyl chloride peaks do not vary in area more than 5%. The average value for these two areas will be used to compute the bag concentration.

Compare the ratio of H_m to A_m for the vinyl chloride sample with the same ratio for the standard peak which is closest in height. As a guideline, if these ratios differ by more than 10%, the vinyl chloride peak may not be pure (possibly acetaldehyde is present) and the secondary column should be employed (see Section 4.3.2).

6.5 Measure the ambient temperature and barometric pressure near the bag. (Assume the relative humidity to be 100 percent.) From a water saturation vapor pressure table, determine the record and water vapor content of the bag.

7. Calibration and Standards.

7.1 Preparation of vinyl chloride standard gas mixtures. Evacuate a sixteen-inch square Tedlar bag that has passed a leak check (described in Section 7.4) and meter in 5.0 liters of nitrogen. While the bag is filling, use the 0.5 ml syringe to inject 250μl of 99.9+% vinyl chloride through the wall of the bag. Upon withdrawing the syringe needle, immediately cover the resulting hole with a piece of adhesive tape. This gives a concentration of 50 ppm of vinyl chloride. In a like manner use the other syringe to prepare dilutions having 10 and 5 ppm vinyl chloride concentrations. Place each bag on a smooth surface and alternately depress opposite sides of the bag 50 times to further mix the gases.

7.2 Determination of vinyl chloride retention time. This section can be performed simultaneously with Section 7.3. Establish chromatograph conditions identical with those in Section 6.3, above. Set attenuator to X 1 position. Flush the sampling loop with zero helium or nitrogen and activate the sample valve. Record the injection time, the sample loop temperature, the column temperature, the carrier gas flow rate, the chart speed and the attenuator setting. Record peaks and detector responses that occur in the absence of vinyl chloride. Maintain conditions. With the equipment plumbing arranged identically to Section 6.3, flush the sample loop for 30 seconds at the rate of 100 ml/min with one of the vinyl chloride calibration mixtures and activate the sample valve. Record the injection time. Select the peak that corresponds to vinyl chloride. Measure the distance on the chart from the injection time to the time at which the peak maximum occurs. This quantity, divided by the chart speed, is defined as the retention time. Record.

7.3 Preparation of chromatograph calibration curve. Make a gas chromatographic measurement of each standard gas mixture (described in Section 7.1) using conditions identical with those listed in Section 6.3 above. Flush the sampling loop for 30 seconds at the rate of 100 ml/min with each standard gas mixture and activate the sample valve. Record C_c, the concentrations of vinyl chloride injected, the attenuator setting, chart speed, peak area, sample loop temperature, column temperature, carrier gas flow rate, and retention time. Record the laboratory pressure. Calculate A_s, the peak area multi-

[1] Mention of trade names on specific products does not constitute endorsement by the Environmental Protection Agency.

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plied by the attenuator setting. Repeat until two injection areas are within 5%, then plot those points vs C_c. When the other concentrations have been plotted, draw a smooth curve through the points. Perform calibration daily, or before and after each set of bag samples, whichever is more frequent.

7.4 Bag leak checks. While performance of this section is required subsequent to bag use, it is also advised that it be performed prior to bag use. After each use, make sure a bag did not develop leaks as follows. To leak check, connect a water manometer and pressurize the bag to 5–10 cm H_2O (2–4 in H_2O). Allow to stand for 10 minutes. Any displacement in the water manometer indicates a leak. Also check the rigid container for leaks in this manner.

(NOTE: An alternative leak check method is to pressurize the bag to 5–10 cm H_2O or 2–4 in. H_2O and allow to stand overnight. A deflated bag indicates a leak.) For each sample bag in its rigid container, place a rotameter in-line between the bag and the pump inlet. Evacuate the bag. Failure of the rotameter to register zero flow when the bag appears to be empty indicates a leak.

8. Calculations.

8.1 Determine the sample peak area as follows:

$$A_c = A_m A_f$$

Equation 106–1

where:
A_c = The sample peak area.
A_m = The measured peak area.
A_f = The attenuation factor.

8.2 Vinyl chloride concentrations. From the calibration curve described in Section 7.3, above, select the value of C_c that corresponds to A_c, the sample peak area. Calculate C_b as follows:

$$C_b = \frac{C_c P_r T_i}{P_i T_r (1 - B_{ws})}$$

Equation 106–2

Where:

B_{ws} = The water vapor content of the bag sample, as analyzed.
C_b = The concentration of vinyl chloride in the bag sample in ppm.
C_c = The concentration of vinyl chloride indicated by the gas chromatograph, in ppm.
P_i = The reference pressure, the laboratory pressure recorded during calibration, mm Hg.
T_i = The sample loop temperature on the absolute scale at the time of analysis, °K.
P_r = The laboratory pressure at time of analysis, mm Hg.
T_r = The reference temperature, the sample loop temperature recorded during calibration, °K.

9. References.

1. Brown, D. W., Loy, E. W. and Stephenson, M. H. "Vinyl Chloride Monitoring Near the B. F. Goodrich Chemical Company in Louisville, Kentucky." Region IV, U.S. Environmental Protection Agency, Surveillance and Analysis Division, Athens, Georgia, June 24, 1974.

2. "Evaluation of A Collection and Analytical Procedure for Vinyl Chloride in Air," by G. D. Clayton and Associates, December 13, 1974. EPA Contract No. 68-02-1408, Task Order No. 2, EPA Report oN. 75-VCL-1.

3. "Standardization of Stationary Source Emission Method for Vinyl Chloride," by Midwest Research Institute, 1976. EPA Contract No. 68-02-1098, Task Order No. 7.

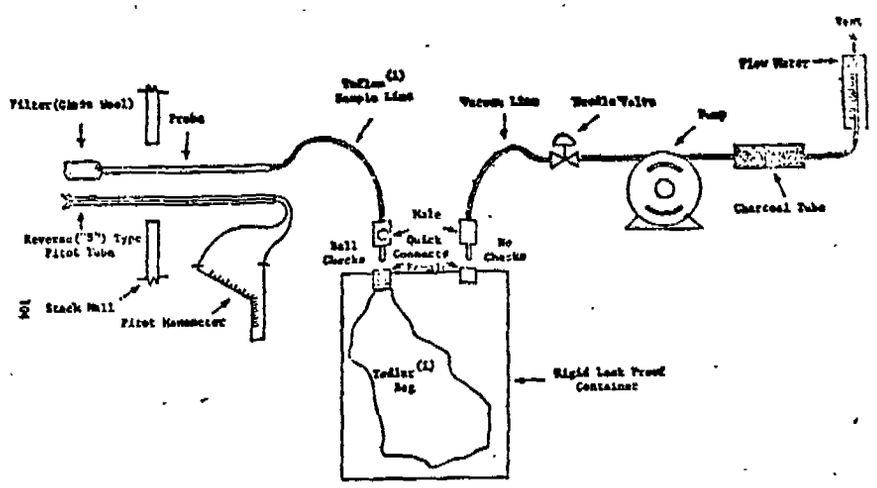


Figure 106-1. Integrated bag sampling train.

(1) Mention of trade names on specific products does not constitute endorsement by the Environmental Protection Agency.

METHOD 107—DETERMINATION OF VINYL CHLORIDE CONTENT OF INPROCESS WASTEWATER SAMPLES, AND VINYL CHLORIDE CONTENT OF POLYVINYL CHLORIDE RESIN, SLURRY, WET CAKE, AND LATEX SAMPLES

INTRODUCTION

Performance of this method should not be attempted by persons unfamiliar with the operation of a gas chromatograph, nor by those who are unfamiliar with sampling, as there are many details that are beyond the scope of this presentation. Care must be exercised to prevent exposure of sampling personnel to vinyl chloride, a carcinogen.

1. Principle and Applicability.

1.1 The basis for this method relates to the vapor equilibrium which is established between RVCM, PVC, resin, water, and air in a closed system. It has been demonstrated that the RVCM in a PVC resin will equilibrate in a closed vessel quite rapidly, provided that the temperature of the PVC resin is maintained above the glass transition temperature of that specific resin.

1.2 This procedure is suitable for determining the vinyl chloride monomer (VCM) content of inprocess wastewater samples, and the residual vinyl chloride monomer (RVCM) content of polyvinyl chloride (PVC) resins, wet cake, slurry, and latex samples. It cannot be used for polymer in fused form, such as sheet or cubes. If a resolution of the vinyl chloride peak is not satisfactory for a particular sample, then chromatograph parameters may be altered with prior approval of the Administrator. If there is reason to believe that some other hydrocarbon with an identical retention time is present in the sample, then supplemental confirmation of the vinyl chloride peak through an absolute analytical technique, such as mass spectroscopy, should be performed.

2. Range and Sensitivity.

The lower limit of detection of vinyl chloride will vary according to the chromatograph used. Values reported include 1×10^{-7} mg and 4×10^{-7} mg. With proper calibration, the upper limit may be extended as needed.

3. Precision and Reproducibility.

An interlaboratory comparison between seven laboratories of three resin samples, each split into three parts, yielded a standard deviation of 2.63% for a sample with a mean of 2.09 ppm, 4.16% for a sample with a mean of 1.66 ppm, and 5.29% for a sample with a mean of 62.66 ppm.

4. Safety.

Do not release vinyl chloride to the laboratory atmosphere during preparation of standards. Venting or purging with VCM/air mixtures must be held to a minimum. When they are required, the vapor must be routed to outside air. Vinyl chloride, even at low ppm levels, must never be vented inside the laboratory. After vials have been analyzed, the pressure within the vial must be vented prior to removal from the instrument turntable. Vials must be vented into an activated charcoal tube using a hypodermic needle to prevent release of vinyl chloride into the laboratory atmosphere. The charcoal must be replaced prior to vinyl chloride breakthrough.

5. Apparatus.

5.1 Sampling.

5.1.1 Bottles—60 ml (2 oz), with waxed lined screw on tops, for PVC samples.

5.1.2 Vials—50 ml Hypo-vials,[1] sealed with Teflon faced Tuf-Bond discs for water samples.

5.1.3 Electrical tape—or equivalent, to prevent loosening of bottle tops.

5.2 Sample recovery.

5.2.1 Vials—With seals and caps, Perkin-Elmer Corporation No. 105-0118, or equivalent.

5.2.2 Analytical balance—Capable of weighing to ±0.001 gram.

5.2.3. Syringe, 100 µl—Precision Series "A" No. 010025, or equivalent.

[1] Mention of trade names on specific products does not constitute endorsement by the Environmental Protection Agency.

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5.2.4 Vial Sealer, Perkin-Elmer No. 105-0106 or equivalent.

5.3 Analysis.

5.3.1 Gas chromatograph—Perkin-Elmer Corporation Model F-40 head-space analyzer, No. 104-0001, or equivalent.

5.3.2 Chromatographic column—Stainless steel, 2 m×3.2 mm, containing 0.4% Carbowax 1500 on Carbopak A, Perkin-Elmer Corporation No. 105-0133, or equivalent. Carbopak C can be used in place of Carbopak A.

5.3.3 Thermometer—0 to 100° C, accurate to ±0.1° C, Perkin-Elmer No. 105-0109 or equivalent.

5.3.4. Sample tray thermostat system—Perkin-Elmer No. 105-0103, or equivalent.

5.3.5 Septa—Sandwich type, for automatic dosing, 13 mm, Perkin-Elmer No. 105-1008, or equivalent.

5.3.6 Integrator - recorder — Hewlett - Packard Model 3380A, or equivalent.

5.3.7 Filter drier assembly (3)—Perkin-Elmer No. 2230117, or equivalent.

5.3.8 Soap film flowmeter—Hewlett Packard No. 0101-0113, or equivalent.

5.4 Calibration.

5.4.1 Regulators—for required gas cylinders.

6. Reagents.

6.1 Analysis.

6.1.1 Hydrogen gas—zero grade.

6.1.2 Nitrogen gas—zero grade.

6.1.3 Air—zero grade.

6.2 Calibration.

6.2.1 Standard cylinders (4)—one each of 50, 500, 2000, and 4000 ppm vinyl chloride in nitrogen, with certified analysis.

7. Procedure.

7.1 Sampling.

7.1.1 PVC sampling—Allow the resin or slurry to flow from a tap on the tank or silo until the tap line has been well purged. Extend a 60 ml sample bottle under the tap, fill, and immediately tightly cap the bottle. Wrap electrical tape around the cap and bottle to prevent the top from loosening. Place an identifying label on each bottle, and record the date, time, and sample location both on the bottles and in a log book.

7.1.2 Water sampling—Prior to use, the 50 ml vials (without the discs) must be capped with aluminum foil and muffled at 400°C for at least one hour to destroy or remove any organic matter that could interfere with analysis. At the sampling location fill the vials bubble-free, to overflowing so that a convex meniscus forms at the top. The excess water is displaced as the sealing disc is carefully placed, Teflon side down, on the opening of the vial. Place the aluminum seal over the disc and the neck of the vial and crimp into place. Affix an identifying label on the bottle, and record the date, time, and sample location both on the vials and in a log book. All samples must be kept refrigerated until analyzed.

7.2 Sample recovery. Samples must be run within 24 hours.

7.2.1 Resin samples—The weight of the resin used must be between 0.1 and 4.5 grams. An exact weight must be obtained (±0.001 gram) for each sample. In the case of suspension resins a volumetric cup can be prepared which will hold the required amount of sample. The sample bottle is opened, and the cup volume of resin is added to the tared sample vial (including septum and aluminum cap). The vial is immediately sealed and the exact sample weight is then obtained. Report this value on the data sheet as it is required for calculation of RVCM. In the case of relatively dry resin samples (water content <0.3 weight %), 100 μl of distilled water must be injected into the vial, after sealing and weighing, using a 100 μl syringe. In the case of dispersion resins, the cup cannot be used. The sample is instead weighed approximately in an aluminum dish, transferred to the tared vial and weighed accurately in the vial. The sample is then placed in the Perkin-Elmer head space analyzer (or equivalent) and conditioned for one hour at 90°C.

NOTE: Some aluminum vial caps have a center section which must be removed prior to placing into sample tray. If not removed, serious damage to the injection needle will occur.

7.2.2 Suspension resin slurry and wet cake samples—Slurry must be filtered using a small Buchner funnel with vacuum to yield wet cake. The filtering process must be continued only as long as a steady stream of water is exiting from the funnel. Excessive filtration time could result in some loss of VCM. The wet cake sample (0.10 to 4.5 grams) is added to a tared vial (including septum and aluminum cap) and immediately sealed. Sample weight is then determined to 3 decimal places. The sample is then placed in the Perkin-Elmer head space analyzer (or equivalent) and conditioned for one hour at 90°C. A sample of wet cake is used to determine TS (total solids). This is required for calculating the RVCM.

7.2.3 Dispersion resin slurry samples.—This material should not be filtered. Sample must be thoroughly mixed. Using a tared vial (including septum and aluminum cap) add approximately 8 drops (0.25 to 0.35 grams) of slurry or latex using a medicine dropper. This should be done immediately after mixing. Seal the vial as soon as possible. Determine sample weight accurate to 0.001 grams. Total sample weight must not exceed 0.50 grams. Condition the vial for one hour at 90°C in the analyzer. Determine the TS on the slurry sample (Section 7.3.5).

7.2.4 Inprocess wastewater samples—Using a tared vial (including septum and aluminum cap) quickly add approximately 1 cc of water using a medicine dropper. Seal the vial as soon as possible. Determine sample weight accurate to 0.001 gram. Condition the vial for two hours at 90°C in the analyzer.

7.3 Analysis.

7.3.1 Preparation of gas chromatograph—Install the chromatographic column and condition overnight at 150°C. Do not connect the exit end of the column to the detector while conditioning.

7.3.1.1 Flow rate adjustments—Adjust flow rates as follows:

a. Nitrogen carrier gas—Set regulator on cylinder to read 50 psig. Set regulator on chromatograph to 1.3 kg/cm². Normal flows at this pressure should be 25 to 40 cc/minute. Check with bubble flow meter.

b. Burner air supply—Set regulator on cylinder to read 50 psig. Set regulator on chromatograph to supply air to burner at a rate between 250 and 300 cc/minute. Check with bubble flowmeter.

3. Hydrogen supply—Set regulator on cylinder to read 30 psig. Set regulator on chromatograph to supply approximately 35±5 cc/minute. Optimize hydrogen flow to yield the most sensitive detector response without extinguishing the flame. Check flow with bubble meter and record this flow

7.3.1.2 Temperature adjustments—Set temperatures as follows:

a. Oven (chromatographic column), 50° C.

b. Dosing line, 140° C.

c. Injection block, 140° C.

d. Sample chamber, water temperature, 90° C±1.0° C.

7.3.1.3 Ignition of flame ionization detector—Ignite the detector according to the manufacturer's instructions.

7.3.1.4 Amplifier balance—Balance the amplifier according to the manufacturer's instructions.

7.3.2 Programming the chromatograph—Program the chromatograph as follows:

a. I—Dosing time—The normal setting is 2 seconds.

b. A—Analysis time—The normal setting is 8 minutes. Certain types of samples contain high boiling materials which can cause interference wtih the vinyl chloride peak on subsequent analyses. In these cases the analysis time must be adjusted to eliminate the interference. An automated backflush system can also be used to solve this problem.

c. B—Flushing—The normal setting is 0.2 minutes.

d. W—Stabilization time—The nomal setting is 0.2 minutes.

e. X—Number of analyses per sample—The normal setting is 1.

7.3.3 Preparation of sample turntable—Before placing any sample into turntable, be certain that the center section of the aluminum cap has been removed. The numbered sample bottles should be placed in the corresponding numbered positions in the turntable. Insert samples in the following order:

Positions 1 & 2—Old 2000 ppm standards for conditioning. These are necessary only after the analyzer has not been used for 24 hours or longer.

Position 3—50 ppm standard, freshly prepared.

Position 4—500 ppm standard, freshly prepared.

Position 5—2000 ppm standard, freshly prepared.

Position 6—4000 ppm standard, freshly prepared.

Position 7—Sample No. 7 (This is the first sample of the day, but is given as 7 to be consistent with the turntable and the integrator printout.)

After all samples have been positioned, insert the second set of 50, 500, 2000, and 4000 ppm standards. Samples, including standards must be conditioned in the bath of 90° C for 1 hour (not to exceed 5 hours).

7.3.4 Start chromatograph program—When all samples, including standards, have been conditioned at 90° C for 1 hour, start the analysis program according to the manufacturers' instructions. These instructions must be carefully followed when starting and stopping program to prevent damage to the dosing assembly.

7.3.5 Determination of total solids (TS).

For wet cake, slurry, resin solution, and PVC latex samples, determine TS for each sample by accurately weighing approximately 3 to 4 grams of sample in an aluminum pan before and after placing in a draft oven (105 to 110° C). Samples must be dried to constant weight. After first weighing return the pan to the oven for a short period of time and then reweigh to verify complete dryness. TS is then calculated as the final sample weight divided by initial sample weight.

8. Calibration.

Calibration is to be performed each eight-hour period when the instrument is used. Each day, prior to running samples, the column should be conditioned by running two of the previous days 2000 ppm standards.

8.1 Preparation of Standards.

Calibration standards are prepared by filling the vials with the vinyl chloride/nitrogen standards, rapidly seating the septum and sealing with the aluminum cap. Use a stainless steel line from the cylinder to the vial. Do not use rubber or tygon tubing. The sample line from the cylinder must be

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purged (into hood) for several minutes prior to filling vials. After purging, reduce the flow rate to approximately 500–1000 cc/min. Place end of tubing into vial (near bottom) and after one minute slowly remove tubing. Place septum in vial as soon as possible to minimize mixing air with sample. After the standard vials are sealed, inject 100 μl of distilled water.

8.2 Preparation of chromatograph calibration curve.

Prepare two 50 ppm, two 500 ppm, two 2000 ppm, and two 4000 ppm standard samples. Run the calibration samples in exactly the same manner as regular samples. Plot A_s, the integrator area counts for each standard sample vs C_s, the concentration of vinyl chloride in each standard sample. Draw a line of best fit through the points.

9. Calculations.

9.1 Response factor.

From the calibration curve described in Section 8.2, above, select the value of C_s that corresponds to A_s for each sample. Compute the response factor, R_f, for each sample, as follows:

$$R_f = \frac{A_s}{C_s} \quad \text{Equation 107-1}$$

9.2 Residual vinyl chloride monomer concentration, or vinyl chloride monomer concentration.

Calculate C_{rvc} as follows:

$$C_{rvc} = \frac{A_s P_a}{R_f T_1}\left(\frac{M_v V_g}{m_t R} + K T_3\right)$$

Equation 107-2

where:

C_{rvc} = Concentration of vinyl chloride in the sample, in ppm.
P_a = Laboratory atmosphere pressure, mm Hg.
T_1 = Room temperature, °K.
M_v = Molecular weight of VCM (62.5).
V_g = Volume of vapor phase (vial volume less sample volume).
m_t = Weight of sample, grams.
R = Gas constant (62,360).
K = Henry's Law constant for VCM in PVC at 90°C, $K = 6.52 \times 10^{-4} = K_p$ for VCM in 1 cc (approximate) wastewater sample at 90°C, $K = 5.0 \times 10^{-4} = K_w$.
T_3 = Equilibration temperature, °K.

If the following conditions are met, Equation 107-2 can be simplified as follows:

1. $T_1 = 22°$ C (295° K).
2. $T_3 = 90°$ C (363° K).
3. $P_a = 750$ mm. Hg.
4. $V_g = V_v - \frac{m_t}{1.4} = 28.5 - \frac{1m}{t}$

where

V_v = Vial volume, cc (28.5).

5. Sample contains less than 0.5% water.

$$C_{rvc} = \frac{A_s}{R_f}\left(4.197 \times 10^{-3} + \frac{5.088 \times 10^{-2}}{m_t}\right)$$

Equation 107-3

The following general equation can be used for any sample which contains VCM, PVC and/or water.

$$C_{rvc} = \frac{A_s P_a}{R_f T_1} \times \left[\frac{M_v V_g}{R m_t} + K_p (TS)\, T_3 + K_w (1 - TS)\, T_3\right]$$

Equation 107-4

where:

T_s = Total solids.

Note: K_w must be determined.

Results calculated using Equation 107-4 represent concentration based on the total sample. To obtain results based on dry PVC content, divide by TS.

For a 1 cc (approximate) wastewater sample, Equation 107-4 can be simplified to the following:

$$C_{rvc} = \frac{A_s}{R_f}\left[\frac{5.988 \times 10^{-2}}{m_t} + (2.066 \times 10^{-3})\right]$$

Equation 107-5

10. References.

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[FR Doc.76-30849 Filed 10-20-76;8:45 am]

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ITEM 3

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Capillary Abnormalities in Polyvinyl Chloride Production Workers

Examination by In Vivo Microscopy

Hildegard R. Maricq, MD; Maurice N. Johnson, MD;
Charles L. Whetstone, MD; E. Carwile LeRoy, MD

• **Examination by wide-field capillary microscopy of the hands of 152 workers in vinyl chloride (VC) polymerization plants demonstrated scattered, scleroderma-like microvascular abnormalities in 21 workers and isolated capillary abnormalities in 27, as compared with only three isolated abnormalities in 50 manual workers not exposed to vinyl chloride. Thirteen of 17 VC workers with objective evidence of VC-associated abnormalities (angiosarcoma or fibrosis of liver, acroosteolysis, or scleroderma-like skin lesions) were observed to have microvascular abnormalities.**

If prospective studies confirm the implications of this study, capillary microscopy may become a useful mass-screening procedure in the early detection and prevention of VC-associated disease.

(*JAMA* 236:1368-1371, 1976)

INITIAL reports of human disease in which vinyl chloride (VC) has been implicated as pathogenetic were limited to descriptions of such peripheral changes as distal phalangeal resorption, ie, acroosteolysis (AOL).[1-3] Recently, a systemic effect of VC has been suggested by an unusual pattern of hepatic portal, intralobular, and capsular fibrosis; angiosarcoma of the liver; and pulmonary functional abnormalities suggesting early pulmonary fibrosis, all of which occur more frequently among workers employed in polyvinyl chloride production plants than among the general population.[4-10] Furthermore, animal experiments have demonstrated that VC can produce a variety of tumors in rodents.[11,12]

There are several similarities between VC disease and scleroderma (systemic sclerosis): Raynaud phenomenon is prominent among the symptoms associated with AOL[1,3,4,9,13]; localized scleroderma-like lesions have been reported in some patients with AOL[9,13]; and, in both VC-associated disease and scleroderma, small-blood-vessel lesions and interstitial fibrosis are thought to be important in pathogenesis.[10,13,14]

In scleroderma, changes in small blood vessels of the skin have been observed in vivo by capillary microscopy.[15,16] Using the technique of wide-field capillary microscopy, distinctive abnormal capillary patterns in the fingers of patients with Raynaud syndrome and scleroderma have been demonstrated.[16] Furthermore, a positive correlation is noted between the severity of capillary pattern abnormalities and multisystem involvement in these connective-tissue disorders.[17] The possibility that VC-associated disease might be characterized by microvascular abnormalities similar to those observed in scleroderma led to the present study of VC workers, using techniques of wide-field capillary microscopy. The specific questions of this study were the following: (1) Do symptomatic VC workers have finger-skin-capillary abnormalities? (2) Are the abnormalities similar to or different from those seen in patients with idiopathic scleroderma and Raynaud syndrome? (3) Are microvascular abnormalities related to the type of VC-associated abnormality (peripheral vs systemic), especially liver abnormalities? (4) Are microvascular abnormalities related to the nature and duration of VC-exposure? (5) Are microvascular abnormalities found in a control group of manual workers not exposed to VC?

SUBJECTS

VC Workers Selected by Symptoms (n = 44).—The 44 subjects in this group gave a history of symptoms and signs possibly related to VC exposure. They were 31- to 57-year-old men (mean age, 42 years) who had worked in the polyvinyl chloride industry for 5 to 28 years (mean, 15 years). A history of past reactor-cleaning experience (ranging from 0.2 to 8 years; mean, 2.5 years) was present in 35 of 44 workers. Table 1 shows the complaints and the pathologic findings in group 1.

VC Workers Selected by Question-

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naire (n = 108).—These subjects were selected on the basis of their answers to a questionnaire used in the polyvinyl chloride production plant to detect early AOL. All available subjects who had given one or more affirmative answers to the questionnaire (Q+) were examined, a total of 66 subjects. Seventy-one subjects were examined from a random selection of those who had given negative answers to all questions (Q−). Data on 29 of the 137 subjects examined were excluded because of unreliable observations caused by skin injuries or deep pigmentation, leaving 108 employees (50 Q+ and 58 Q−) in this group.

Control Manual Workers (n = 50).—The possibility that repeated minor injuries associated with manual labor might contribute to the abnormal findings seen in VC workers led to the examination of workers from companies making neither VC nor polyvinyl chloride and hospital employees working as carpenters, truck drivers, and maintenance men, a total of 50 workers. All were men and ranged in age from 19 to 62 years (mean age, 43 years).

METHODS

Wide-field Capillary Microscopy.—The technique of wide-field capillary microscopy as previously reported[4] consists of the observation of selected skin sites under immersion oil, using a stereo wide-field microscope at magnification ×12. Wide-field microscopy permits the detection of microvascular patterns, such as the presence and distribution of dilated or deformed microvessels and the absence of capillary loops, without attempting to measure absolute vessel dimensions. The technique is rapid and suitable for mass screening.

Twelve standard sites were examined in each subject: four nailfolds and two each of the following sites: dorsum of the distal phalanx other than the nailfold, dorsum of the middle phalanx, dorsum of the proximal interphalangeal joint, and the finger pad.

Photography of Microvessels.—The wide-field photographic technique as previously described[4] was used to photograph at least one finger of each subject. All photographs were coded for blind comparison of capillary findings in VC workers and control subjects.

Clinical and Occupational Data.—All subjects were interviewed as to length of employment, job assignment, general state of health, presence or absence of Raynaud phenomenon, and smoking and drinking habits. A limited physical examination was performed. All data were coded for later analysis and were unknown to the capillary observer and photographer.

Table 1.—Clinical Findings and Complaints of Group 1 Vinyl Chloride Workers*

	No. of Subjects Examined	No. of Subjects With Capillary Changes†
Severe AOL with Raynaud phenomenon	6	4
Scleroderma-like skin lesions with Raynaud phenomenon	5	4
Liver abnormalities‡	6	5
Subtotal	17	13
Healed AOL with Raynaud phenomenon	6	0
Healed AOL without Raynaud phenomenon	1	0
Raynaud phenomenon alone	9	3
Nonspecific skin rashes without Raynaud phenomenon	7	1
Miscellaneous complaints	4	0
Subtotal	27	4
Total	44	17

*AOL indicates acroosteolysis.

†Of 17 subjects with abnormal capillaries, ten had scattered changes (8/13 and 2/4 of the two groups above) and seven had isolated changes.

‡Two patients with angiosarcoma of the liver and one each with (1) portal fibrosis and enlarged spleen, (2) portal fibrosis with early cirrhosis and fatty metamorphosis, (3) thrombosis of the splenic vein, mild liver damage, and reticuloendothelial cell hyperplasia, (4) fatty metamorphosis with focal capsular and subcapsular fibrosis and splenomegaly with vascular congestion.

Table 2.—Comparison of Capillary Observations Between VC Workers and Controls*

	Employees of VC Industry	Manual Workers Not Exposed to VC
Scattered capillary abnormalities	11	0
Abnormal capillaries present, but few in number	27	3
No capillary abnormalities seen	70	47
Total	108	50

*VC indicates vinyl chloride. Difference in the prevalence of capillary abnormalities between VC workers and controls is statistically significant ($\chi^2 = 15.50$, $P<.001$).

RESULTS

Group 1 (VC Workers Selected by Symptoms).—Examination of group 1 subjects showed scattered capillary abnormalities similar to those found in scleroderma (Fig 1 and 2). Definitely dilated capillary loops were seen in the nailfold and in other finger sites, contrasting with the surrounding normal vasculature. Pale avascular areas were frequently observed. The capillary abnormalities were usually more discrete and less numerous than those seen in most patients with scleroderma. They were seen more frequently in subjects with severe AOL, liver abnormalities (as defined in Table 1) and scleroderma-like lesions (13/17) than in those with healed AOL, nonspecific skin rashes, or Raynaud phenomenon alone (4/27; $\chi^2 = 14.21$, $P < .001$). Moreover, 5 of 6 subjects with liver abnormalities verified by biopsy specimens had microvascular abnormalities (Table 1).

In a few subjects, lesions resembling mini versions of clinically visible papular skin lesions were observed microscopically (Fig 3, left). In two subjects with active AOL, capillary hemorrhages were observed under the proximal nail plate in addition to the common type of "splinter hemorrhages" under the distal nail plate (Fig 3, center).

Group 2 (VC Workers Selected by Questionnaire).—Dilated capillaries were observed in 38 of 108 group 2 workers; both the number and distribution of dilated capillaries differed from those observed in most scleroderma patients. Many group 2 workers had isolated, extremely dilated capillaries (Fig 3, right and Table 2). No correlation was found between the length of time employed as a reactor-cleaner (or the length of time with the company) and the capillary abnormalities. Office and supervisory personnel who had never been produc-

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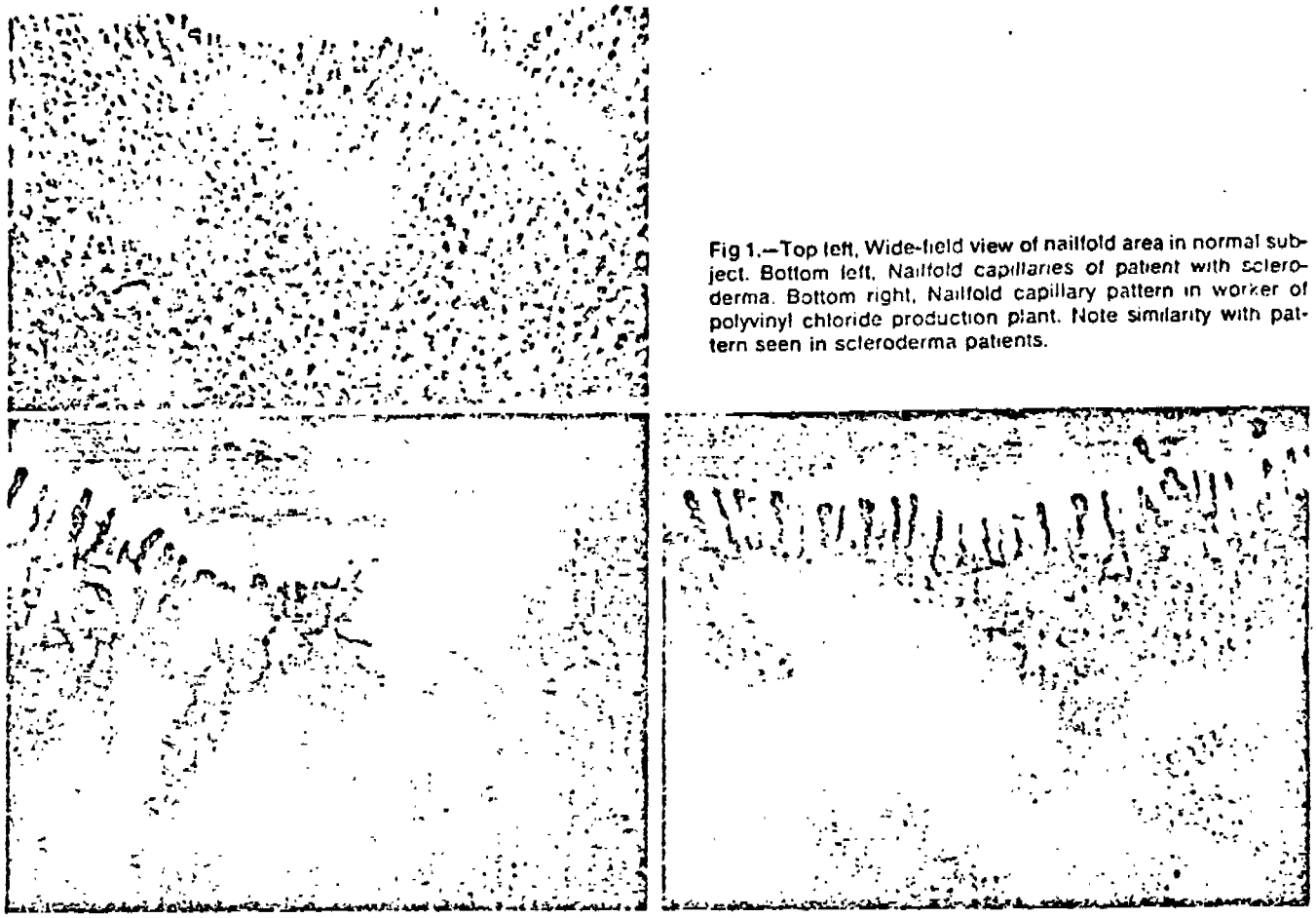
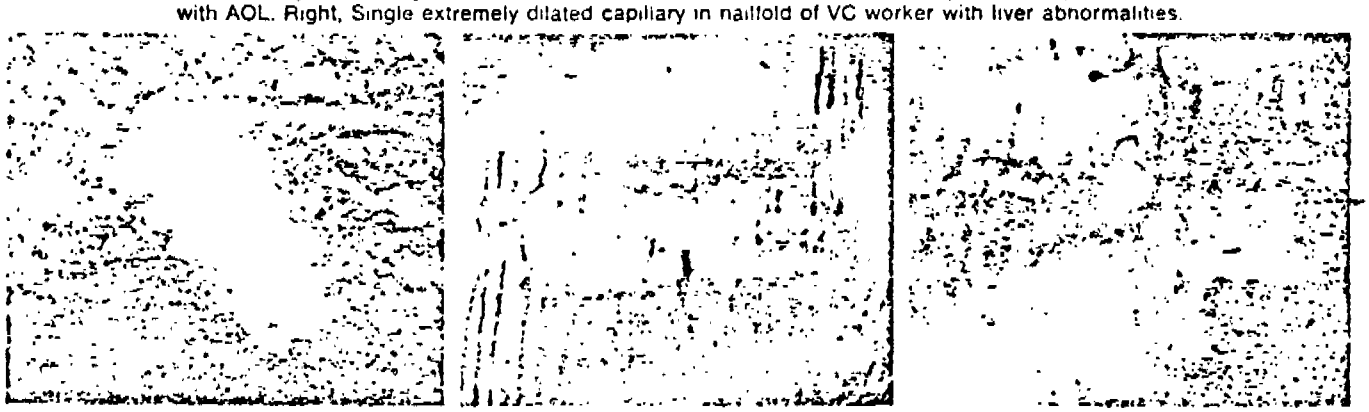


Fig 1.—Top left, Wide-field view of nailfold area in normal subject. Bottom left, Nailfold capillaries of patient with scleroderma. Bottom right, Nailfold capillary pattern in worker of polyvinyl chloride production plant. Note similarity with pattern seen in scleroderma patients.



Fig 2.—Left, Dorsum of middle phalanx in normal subject. Center, Cluster of dilated capillaries in same anatomical site in patient with scleroderma. Right, Vinyl chloride worker with pattern similar to that seen in scleroderma.

Fig 3.—Left, Miniplaque on dorsum of distal phalanx in VC worker with acroosteolysis (AOL). Center, Capillary hemorrhages under both distal and proximal nail plate in a vinyl chloride (VC) worker with AOL. Right, Single extremely dilated capillary in nailfold of VC worker with liver abnormalities.



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tion workers had fewer microvascular abnormalities (3/22) than production workers (35/86, $\chi^2 = 4.49$, $P < .05$); however, production workers showed no differences in capillary abnormalities according to job category. There was no significant difference ($\chi^2_{1} = 1.32$, $P > .5$) between employees who had been classified as Q+ or Q− on the basis of the questionnaire. It was noted, however, that there was little or no correlation between the responses regarding Raynaud phenomenon obtained from the questionnaire and those obtained from the interview at the time of examination. Physical examination disclosed two workers with AOL (one "active" and one "healing" by roentgenographic examination) and papular skin lesions, and ten workers with hepatomegaly (4 cm or more below the right costal margin). The subject with active AOL showed scattered capillary changes, the subject with healing AOL had a "normal" capillary examination. There was no correlation between hepatomegaly and capillary findings.

Comparison of VC Workers With Control Subjects.—Capillary abnormalities in group 2 VC workers were significantly more frequent than in the control manual workers examined ($\chi^2 = 15.50$, $P < .001$) (Table 2).

Analysis of Photographic Data.—Three hundred seventeen unidentified photographs of VC workers were mixed with 136 photographs of control subjects and 130 photographs of patients with scleroderma and related diseases; all photographs were rated for the presence of capillary abnormalities. The results demonstrated that significantly more VC workers (39/152) than control subjects (3/50) had capillary abnormalities ($\chi^2 = 7.69$, $P < .01$). Although objective, for technical reasons, photographs are slightly less sensitive than direct observations in detecting capillary abnormalities.

COMMENT

The results of this study demonstrate that capillary abnormalities seen in the finger skin by in vivo microscopy are present in VC workers more frequently than in control subjects. These capillary abnormalities are not exclusively related to peripheral pathological conditions such as AOL, scleroderma-like lesions of hands, and Raynaud phenomenon, but are also found in subjects with liver abnormalities (as defined in Table 1) and in subjects who have papular lesions elsewhere on the body. Microscopic papular or fibrotic lesions can also be observed in VC workers. In 33% of the subjects who show any capillary changes, the pattern appears similar to the microvascular changes seen in scleroderma; the remaining majority, changes consist of a few dilated capillaries only; very few control subjects show even these minimal capillary abnormalities. Since microvascular changes occur more frequently than overt VC-associated pathologic conditions in VC workers, they may represent an early manifestation of the VC effect.

More work is needed to determine the nature and evolution of such microvascular abnormalities, their relationship to VC-associated disease (as opposed to a transient reaction to VC exposure), and their relationship to the subject's susceptibility to VC disease. Further studies are also needed to compare the capillary changes reported here with those seen in small blood vessels and endothelia of animals exposed to VC.[11] Capillary microscopy might then be used as a reproducible, noninvasive technique to monitor VC workers and to identify VC-associated peripheral and visceral disease in susceptible individuals at an early and possibly preventable stage.

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HEPATIC ANGIOSARCOMA IN A VINYL CHLORIDE WORKER

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HEPATIC ANGIOSARCOMA IN A VINYL CHLORIDE WORKER

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MORE than 38 cases of angiosarcoma so far have been confirmed among workers exposed to vinyl chloride monomer gas (VCM) during the manufacture of polyvinyl chloride (PVC). The median interval from first exposure to diagnosis was 17 years; the average time of exposure was 16 years.[1] We are reporting on a patient whose exposure to VCM lasted only 3½ years.

A 36-year-old white male was admitted to the hospital for treatment of peptic ulcer pain that had recurred intermittently for 15 years. His health otherwise had been good; he did not smoke and he drank very little alcohol. For 3½ years he had worked as a "polycleaner," a cleaner of polymerization vessels in a factory where VCM is processed to PVC. After this he had worked for three years prior to admission as a storeman of raw materials, handling resins only.

On examination the patient looked well; the only abnormal physical sign was a liver palpable to 6 cm. Barium meal revealed the presence of

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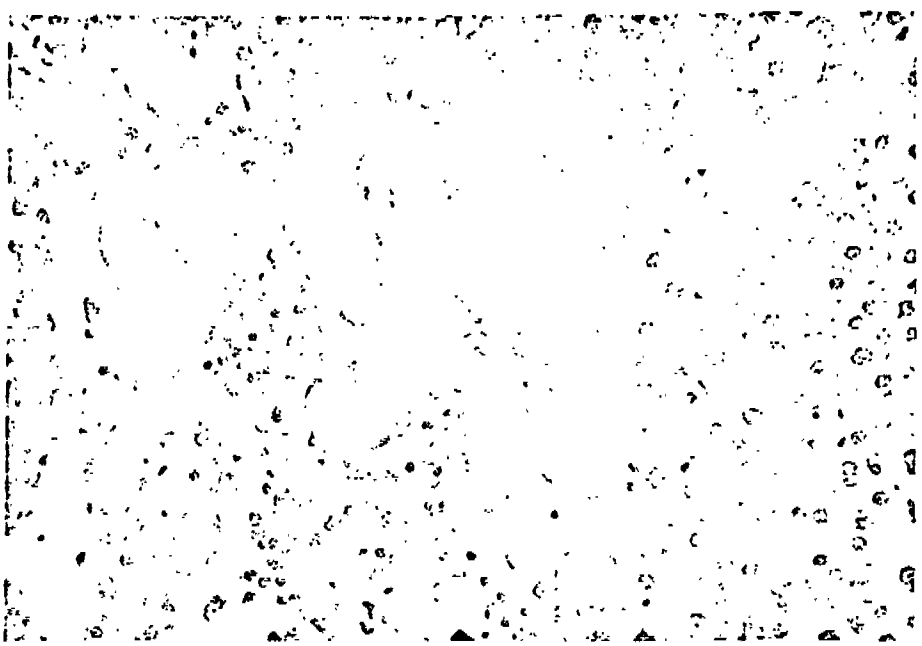


Fig. 1. Focal severe sinusoidal dilatation on liver biopsy (× 500)

a deformed duodenal cap. At operation a large duodenal ulcer was found, for which a Pólya partial gastrectomy was performed. The liver appeared cirrhotic, with grossly distended veins forming a collateral circulation in the anterior abdominal wall and the falciform ligament. Tests of liver function gave normal results, but an operative liver biopsy showed noncirrhotic fibrosis; there were several foci of severe dilatation of the sinusoids (Figure 1).

Recovery from operation was uneventful. The serum alkaline phosphatase level rose to 87 I.U./L (normal range: 15 to 40) after six weeks, but all other liver-function tests and the erythrocyte sedimentation rate were normal, apart from a bromsulphalein retention of 17% (45 min.). Tests for smooth-muscle and mitochondrial antibodies and for Australia antigen were negative.

One year after operation the patient was working full time as a dock laborer. There were no abnormal physical signs apart from the enlarged liver. Liver-function tests now showed a further rise in the serum alkaline phosphatase level to 115 I.U./L, with an elevated bilirubin value of 32 μmole/L (normal range: 5 to 17).

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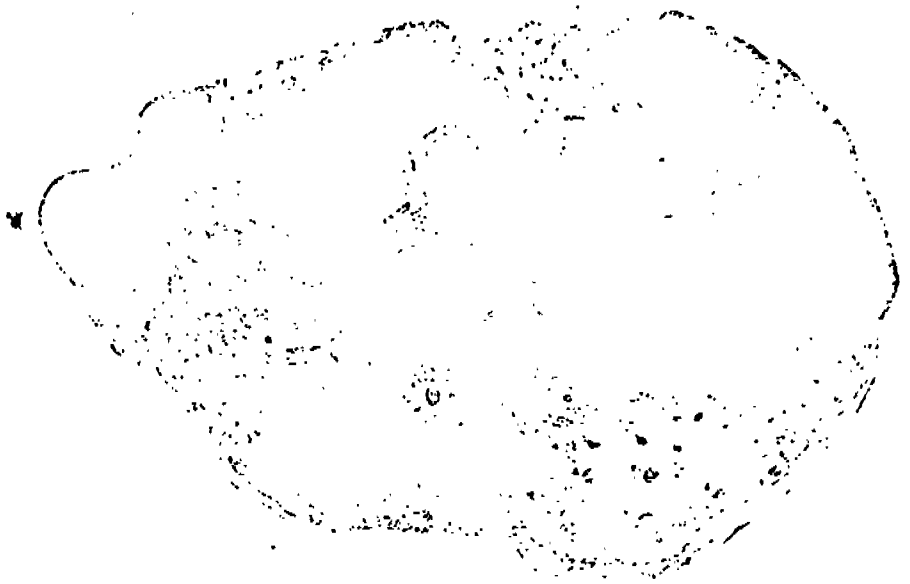


Fig. 2. Gross appearance of liver at postmortem

Four months later he was admitted to the hospital as an emergency patient. He now had dyspnea, ascites, ankle edema, and jaundice. He looked ill and wasted. Liver palms and numerous spider nevi were present. The liver extended 10 cm. below the costal margin. Diuretics caused an appreciable loss of edema, with great relief of the dyspnea. Results of the liver-function tests were grossly abnormal: serum bilirubin 103 μmole/L, alkaline phosphatase 120 I.U./L, serum glutamic oxalacetic transaminase 35 I.U./L, albumin 27 gm./L, globulin 40 gm./L. During the next month the bilirubin rose steadily to 390 μmole/L. A scan showed the liver to be massive, with numerous areas of decreased uptake. A hepatic arteriogram revealed a widespread pathological circulation, with multiple areas of tumor blush, suggestive of a highly vascular multicentric hepatic neoplasm. Tests for α-fetoprotein and carcinoembryonic antigen were negative. A barium-swallow test demonstrated varices.

Dilated veins appeared on the anterior abdominal wall, but at no time was a hepatic bruit heard. Soon afterward the patient lapsed into hepatic coma and died.

At necropsy there was edema of both lungs. The right lower lobe

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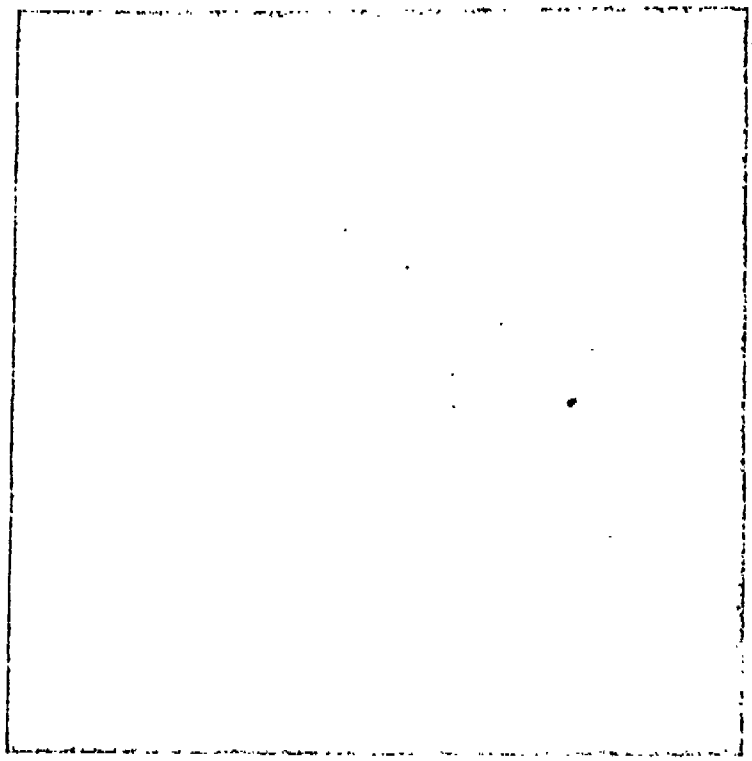


Fig. 3. Postmortem hepatic venogram

showed patchy collapse and consolidation and evidence of several hemorrhages. The pericardium contained clear yellow fluid but there was no significant ascites. Apart from the old partial gastrectomy, the alimentary tract was normal.

The liver weighed 3,240 gm. and was greatly enlarged by a vascular tumor which had almost completely replaced normal hepatic tissue (Figure 2). Large blood lakes and cavernous vascular spaces were shown well by injection of barium suspension into the hepatic vein after death (Figure 3). The spleen was congested and very firm, but weighed only 200 gm.

Microscopy showed replacement of much hepatic parenchyma by hemorrhagic and necrotic tumor tissue. The tumor consisted of vascular channels, varying greatly in size and shape, lined by plump endothelial cells and also by large multinucleate tumor cells (Figure 4), believed

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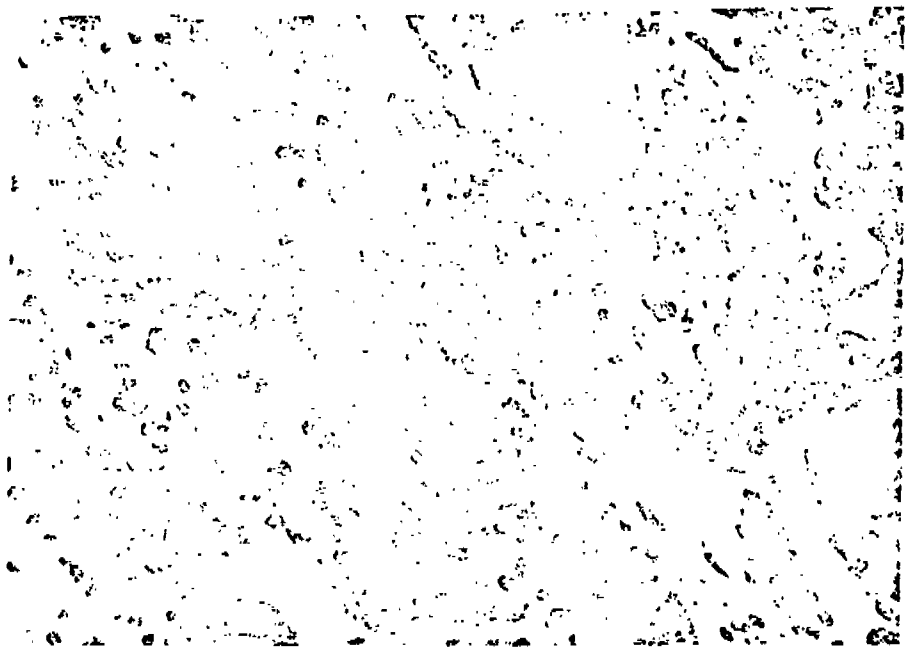


Fig. 4. Microscopy of tumor (× 500)

to be malignant Kupffer cells. In some parts of the tumor these cells were sparse and the dilated sinusoidal structure resembled that seen in the biopsy specimen, but in other parts these giant tumor cells were very numerous. A few had desquamated into the vascular channels and there was evidence of tumor-cell embolism in the pulmonary hemorrhages, although no cohesive metastatic tumor tissue was found in the lungs or other organs.

Discussion

This patient was remarkable in several respects. The duration of exposure to VCM of 3½ years, compared with the mean of 16 years for the previously reported 38 cases of angiosarcoma, was unusually short. Only one younger case has been described. The latent period from the first exposure to VCM to diagnosis was eight years, whereas for the other reported cases the mean interval was 17 years (ranges 11 to 30 years).[1] We have no evidence that the exposure to VCM was in any way unusual; in particular, the patient had not been a gas "sniffer" and

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his subsequent periods of employment had consisted of laboring and handling bananas. He had, however, been a polycleaner, and 84% of cases of VCM-treated angiosarcomas so far described have occurred in persons similarly employed.[1] He is only the second patient with angiosarcoma to be reported in Britain.

This patient also was unusual in that the liver biopsy performed 15 months prior to his death revealed striking focal dilatation of the sinusoids. This change has been described recently in the early stages of some other angiosarcomas linked to vinyl chloride.[2] We have performed liver biopsies on a number of other VCM workers with appreciable periods of exposure, but have seen only a noncirrhotic fibrosis[3] and are unable to confirm that the sinusoidal dilatation can be considered a precursor to the formation of tumor. It is to be hoped that stricter environmental controls will prevent further angiosarcomas arising *de novo*, but workers who have already developed portal hypertension and those who have been exposed to high concentrations of the chemical in the past must be monitored carefully in the future.

Summary

A man aged 36 years who had been a VCM process worker for only 3½ years was unexpectedly found at laparotomy for a peptic ulcer to have an enlarged liver and portal hypertension. Biopsy showed striking focal dilatation of the sinusoids. Fifteen months later the patient died of a hepatic angiosarcoma.

Acknowledgment

We thank Dr. G. de B. Hinde for the radiological studies and Mr. D. A. Aubrey for referring the patient.

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Press of Charles C. Marchand Co., Inc., N.Y.C.

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MRO-2167 ITEM 5

UNIROYAL, Inc.
Oxford Management & Research Center
Middlebury, Connecticut 06749

August 12, 1976

Dr. T. R. Torkelson
Building 2030
Dow Chemical Co.
Midland, MI 48640

Dear Ted:

On page 10 of the August 11 issue of Chemical Week is a notice that NIOSH is asking for information on toxicity of 10 chemicals including vinyl chloride. Recently I compiled the attached data taken from November 12, 1975 list of NIOSH known Angiosarcoma cases. I listed only actual deaths by year of death. It seems to me that the last column is the most meaningful. If we assume roughly a 20 year induction period 1975 relates to 1955 when the industry was expanding rapidly. However, plants were larger and as time went on for various reasons fewer people were exposed at high levels.

This indicates to me that the iceberg just isn't there. I would expect that at worst the average would rise a bit and then ease down until it blends with the background about 1990 or 2000. It is too much to hope that a government agency would ease off on its regulations but it might be wise to publicize these results so that they don't further tighten them. The information should be updated.

Sincerely,

W. D. Harris
Corporate Industrial Toxicologist

WDH/df
Attachment
cc: M. Freifeld
D. E. Dudrow

UNIROYAL, Inc.

OXFORD
(Location)

August 5, 1976

TO: R. J. Dowling

FROM: W. D. Harris

SUBJECT: U.S. Cases of Confirmed Deaths Due to Vinyl Chloride Exposure

The attached table from NIOSH lists the cases of angiosarcoma accepted by the pathologists as typical vinyl chloride induced angiosarcoma. The Bridgeport G.E. worker and the accountant in a fabricating plant have been eliminated. The two cases who are still alive were not included in my calculations which follow the table.

WDH/df
Attachments
cc: B. R. Leach
D. E. Dudrow
R. E. Lowell
J. D. Forbes, M.D.
L. F. Dieringer

REPORTED CASES OF ANGIOSARCOMA OF THE LIVER AMONG VINYL CHLORIDE POLYMERIZATION WORKERS

NIOSH Rev. 12

COUNTRY	CASE #	BIRTH DATE	1st VC or PVC EXPOSURE	DX ANGIO-SARCOMA	AGE AT DX	YRS 1st EXP TO DX	TOT YRS EXP	DATE OF DEATH
United States	01*	10-17-23	12-09-48	03-03-73	49	22	16	03-03-73
United States	02*	08-19-33	11-15-55	05-00-70	37	14	13	09-28-71
United States	03*	05-25-15	11-28-45	12-19-73	58	28	28	12-19-73
United States	04*	01-15-24	07-06-52	08-19-67	43	15	15	01-07-68
United States	05*	01-25-12	06-19-44	04-09-64	52	20	18	04-09-64
United States	06*	00-00-29	01-17-62	02-00-74	45	12	12	07-24-75
United States	07*	05-03-22	03-00-44	00-00-68	45	24	18	03-23-68
United States	08*	05-06-20	10-07-46	08-00-61	41	15	15	08-29-61
United States	09*	11-00-31	09-09-54	03-01-74	43	17	17	03-00-75
United States	10*	08-16-13	06-12-51	05-00-68	55	17	17	05-10-68
United States	11*	05-27-09	10-14-46	03-00-70	61	23	23	03-16-70
United States	12*	11-17-18	09-13-49	05-02-69	50	20	15	05-02-69
United States	13*	12-01-21	08-19-44	05-00-74	52	30	30	07-04-74
United States	16*	11-04-27	05-08-50	00-00-69	41	17	4	03-27-69
United States	17*	05-06-31	06-23-55	10-11-74	43	19	19	ALIVE
United States	18*	04-22-28	00-00-54	00-00-75	46	21	13	11-02-73
United States	19	00-00-15	00-00-43	06-19-75	60	32	32	ALIVE
Yugoslavia	01*	04-05-14	00-00-53	04-08-73	59	20	20	04-08-73
Yugoslavia	02*	11-15-31	00-00-50	07-12-73	42	23	18	07-12-73

Total Reported Cases = 45

Median Values:			
17 U.S. Cases	46.0	20.0	17.0
17 Non-U.S. Cases	43.0	17.0	15.0
34 Total Cases	45.0	18.0	16.0

* Indicates microscopically confirmed angiosarcoma of the liver.

"00" Indicates unknown data.

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Year of Death	Code No's. of workers who died during year	Rolling Ave. Starting 1961	Starting 1968
1961	08	1.0	
1962		0.50	
1963		0.33	
1964	05	0.50	
1965		0.40	
1966		0.33	
1967	04	0.43	
1968	07, 10	0.63	2.0
1969	12, 16	0.78	2.0
1970	02, 11	0.9	2.0
1971		0.82	1.5
1972		0.75	1.2
1973	01, 03	0.84	1.3
1974	06, 09, 13	1.0	1.7
1975	18	1.0	1.8

Recognizing that the big build-up of the industry came in the '50 and '60's and with a 20 year median period between first exposure and diagnosis, there has been no rapid build-up as was feared. It is likely that improvements in new plants offset volume. I would anticipate that there might be a slight increase in incidence over the next few years followed by a decline throughout the remainder of the century.

COPIED BY MCA FOR DISTRIBUTION TO THE VINYL CHLORIDE TECHNICAL PANEL, NOVEMBER 11, 1976, MR. MILTON FREIFELD

Journal of Occupational Medicine
October 1976 Vol 18 No 10

Effect of Occupational and Nonoccupational Factors on the Respiratory System of Vinyl Chloride and Other Workers

NOV 11 1976

John Gamble, Ph.D.; Shuguey Liu, M.S.; A. J. McMichael, M.D., Ph.D.; and Richard J. Waxweiler, M.S.I.E.

There are suggestions in the literature that vinyl chloride (VC) acts as a lung irritant. Respiratory questionnaires and lung function tests were administered to 174 chemical (VC) workers, 81 polyvinyl chloride (PVC) workers, 72 former VC workers, and 136 rubber workers, and 68 maintenance workers with exposure to VC, PVC, and rubber. Except for small airways obstruction associated with rubber, increased respiratory symptoms and decreased pulmonary function were not associated with working in chemicals, plastics, or rubber. Some increases in baseline pulmonary function were associated with VC exposure. Acute reductions in pulmonary function were observed in smokers working in chemicals, plastics, and rubber. Heavier cigarette smokers over 40 years of age had the most adversely affected respiratory system.

Work was not associated with chronic respiratory effects, but all exposure groups experienced some acute respiratory insult.

At high exposures, vinyl chloride (VC) is a nervous system depressant, and in fact was investigated as a possible anesthetic, but was not used because of circulatory and cardiac effects at concentrations of 10-20 vol. %.[1] In the late 1960's, acroosteolysis was associated with the polymerization of VC to form polyvinyl chloride (PVC).[2-4] Early in 1974, four fatal cases of angiosarcoma of the liver were reported in reactor operators working in a VC-polymerization plant.[5] Subsequently the disease has been discovered among VC workers all over the world. Experimental and epidemiologic studies suggest that exposure to VC may carry an increased risk of respiratory impairment.[6-14] As a result, the Occupational Health Studies Group (OHSG) at the University of North Carolina and the National Institute of Occupational Safety and Health (NIOSH) and CDC jointly carried out an epidemiologic study of VC-PVC workers. A part of this study was the investigation of respiratory function and symptoms in currently employed VC and PVC workers, former VC workers, and a sample of control rubber workers employed in the same plant.

From Occupational Health Studies Group, School of Public Health, University of North Carolina, Chapel Hill, NC 27514

Reprint requests to NCNB Plaza, Suite 32, Chapel Hill, NC 27514 (Dr. Gamble)

Methods and Materials

The plant under study has three major divisions. The chemical plant produces primarily polyvinyl chloride (PVC) resin, although some copolymers such as vinylidene chloride and styrene-butadiene are also produced. The polymers are either shipped or used in the Film and Sheeting division of this same plant in the production of plastic products. Film and Sheeting division (plastics) is in a building adjacent to the Chemical Plant, which also contains the Rubber Products division manufacturing primarily tires and tubes. All workers currently employed in the VC-PVC plants were invited for examination. A sample of 136 rubber workers from cleaner areas of the rubber division (i.e., tire building, final inspection, shipping and receiving) and without prior exposure to either VC or PVC, were selected and group-matched with the VC workers on age and sex. A total of 71 former VC workers and 68 maintenance workers were also examined. The response rate varied from a low of 62% in rubber workers to 77% in chemical workers. Clinical, smoking and occupational histories, complete physical examinations, chest roentgenograms, sputum cytology, symptoms, blood and urine chemistries were obtained on all 531 workers, and will be reported elsewhere.

The British Medical Research Council respiratory questionnaire was administered by trained medical interviewers. Each worker performed a minimum of five forced exhalations, seated and with a noseclip. The three best performances were selected on the basis of forced expiratory volume in 1 second (FEV) and forced vital capacity (FVC) within 10% of each other, and acceptable reproducibility of the flow-volume curve. In addition to FEV and

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FVC, expired flow at 25% (FEF_{25}), 50% (FEF_{50}), and 75% (FEF_{75}) of exhaled FVC were obtained. At least [illegible] single-breath nitrogen tests were also performed. Recommended procedures and selection criteria were followed for obtaining closing volume (expressed as ratio of closing volume to vital capacity, CV/VC).[5] In addition, a random sample of fifty-six VC, PVC and rubber workers were administered lung function tests before work and again after work. The difference in flow rates is calculated as after - before/mean with afterwork flow rates measured using the maximum pre-exposure FVC.

The following questions were of interest in this study:

1. What are the effects of work on respiratory symptoms and function? Symptoms and baseline lung function were analyzed according to three work exposure categories: (a) current job (hourly VC, salary VC, PVC, rubber, maintenance, former chemical); (b) all jobs, past and present (only in VC, only in PVC, only in rubber, or in a combination of the three). In this mixed exposure group an analysis of covariance was used to sort out the contributions of the VC, PVC, and rubber work experience to baseline pulmonary function; (c) man-months of exposure to VC: All VC jobs were given a high (10), medium (3) or low (1) exposure rating. Time (in months) spent in each job multiplied by the exposure index provided a cumulative exposure to VC. This cumulative exposure score (CES) was then compared to baseline pulmonary function.

The association of dose (years worked in the exposure categories or CES) and baseline lung function were assessed by calculating lung function regression equations for each smoking category of the total population. Then, within each exposure group, actual values of each smoking category were expressed as a percentage of expected values for all workers in that same smoking category. In this way, the effect of work exposure on lung function was adjusted for differences in age, height and smoking between exposure categories.

2. What are the potential hazards of work exposure as measured by changes in pulmonary function over a work shift (ΔPF)? A reduction in lung function suggests the likelihood of some harmful exposure in the working environment.

3. Are symptoms rates and lung function parameters comparable to other occupation groups? Because the PVC and rubber control groups were themselves exposed to varied levels of dust and fumes, comparisons with other studies are made.

Results

The age-smoking distribution of the population is shown in Table 1. Slightly over half of the population were smokers, 20% nonsmokers, and 16% exsmokers. The exsmokers were older than the other smoking categories, with proportionally fewer exsmokers in the ≤ 39 [illegible] age group. Smokers and nonsmokers had approximately the same distribution in all age groups, although a higher proportion of nonsmokers were older, and a higher proportion of smokers were in the middle age groups. None of the light smokers (< 1 pack/day) smoked more than 25 pack-years, and they were equally distributed in the < 25 pack-years category. Most (61%) of the heavy smokers (≥ 1 pack/day) were in the > 25 pack-year category; 25% smoked 10-25 pack-years, and 14% < 10 pack-years.

Table 2 shows the distribution of symptoms related to smoking and age. Prevalence of cough, phlegm, and persistent cough and phlegm did not increase with age. Breathlessness increased slightly but steadily with age, with the oldest age group reporting a rate of breathlessness 2.5 times greater than the youngest age group. Smoking had a strong effect that was dose-related for all respiratory symptoms. Light smokers (< 1 pack/day) had the same symptom rate for cough, phlegm, and persistent cough and phlegm as exsmokers and pipe or cigar smokers. Exsmokers, pipe, cigar, and < 1 pack/day smokers had similar rates of breathlessness.

Because of the potential confounding effects of age and smoking, comparison of symptoms in each exposure category were adjusted for smoking and age differences. Table 3 shows the prevalence of respiratory symptoms according to current job. The salaried chemical workers consistently had the lowest prevalence for all symptoms. Plastics, former chemical, and maintenance workers reported the highest rates for cough, phlegm, and persistent cough and phlegm; rubber and hourly chemical workers were intermediate for these symptoms. All workers except the salary chemical workers observed similar rates of breathlessness.

Table 4 reports the age and smoking adjusted prevalence of respiratory symptoms in workers working only in the rubber division, only in plastics, and only in the chemical plant. Maintenance workers move back and forth among chemical, plastics and rubber, with no epidemiologically appropriate records kept of time spent in any of these areas. The mixed group comprised those who had worked in two or more exposure categories. The plastics only and chemical plant only workers had marked reductions in reported symptoms when compared to all currently employed workers in these same categories. Symptom rates for the mixed group were slightly higher than observed in the total population, and similar to the former chemical group. Those working only in chemical, plastics, or rubber appear to be a select group of healthier workers. A high proportion of those with symptoms in current job categories had a mixed exposure of rubber, chemicals and/or plastics.

Table 1. — Age-Smoking Composition of Study Population.

Smoking Status	Age < 29 N (%)	30-39 N (%)	40-49 N (%)	50-59 N (%)	≥ 60 N (%)	Total N (% of Total)
Nonsmoker*	26 (24.3)	19 (21.3)	27 (16.7)	27 (17.9)	9 (40.9)	108 (20.3)
Exsmoker†	8 (7.5)	8 (9.0)	29 (17.9)	35 (23.2)	4 (18.2)	84 (15.8)
Smoker‡	67 (62.6)	52 (58.4)	92 (56.8)	75 (49.7)	6 (27.3)	292 (55.0)
Pipe and Cigar§	6 (5.6)	10 (11.2)	14 (8.6)	14 (9.3)	3 (13.6)	47 (8.9)
All	107 (20.2)	89 (16.8)	162 (30.5)	151 (28.4)	22 (4.1)	531

*Nonsmoker = has smoked less than 100 cigarettes in a lifetime

†Exsmoker = has stopped smoking for more than 1 year and does not now smoke a pipe or cigar

‡Smoker = has smoked more than 100 cigarettes in a lifetime and has smoked within the last year. Pipe or cigar smokers who also smoke cigarettes are included in this category

§Pipe and Cigar = all those who smoke a pipe or cigar now, but do not smoke cigarettes or have not smoked cigarettes for a year or more

Percentages in the marginals are % of totals, percentages in cells are column percentages

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Table 2. — Respiratory Symptoms* by Age and Smo

Smoking Category	N	Cough 1 & 2 %	Phlegm 1 & 2 %	Persistent Cough & Phlegm %	Breathlessness %
Nonsmoker	108 (20.3%)	5.6	8.3	2.8	11.1
Exsmoker	84 (15.8%)	7.1	13.1	6.0	19.3†
All smokers	292 (55.0%)	21.6	26.4	13.7	26.5†
< 1 pack/day	61 (11.5%)	9.8	13.1	1.6	23.3†
1 pack/day	143 (26.9%)	18.9	23.8	11.2	18.9
>1 pack/day	88 (16.6%)	34.1	39.8	26.1	40.9
Pipe and Cigar	47 (8.9%)	8.5	10.6	2.1	15.2†
All	531	14.9	19.2	9.2	21.2‡
Age Category					
< 29	107 (20.2%)	14.0	20.6	9.3	12.5‡
30-39	89 (16.8%)	15.7	15.7	9.0	19.1
40-49	162 (30.5%)	15.4	20.4	10.5	21.6
50-59	151 (28.4%)	14.6	18.5	7.9	26.5
>60	22 (4.1%)	13.6	22.7	9.1	31.8

* = Scored by criteria from British Medical Research Council Respiratory questionnaire
† = 1 missing
‡ = 3 missing

Figures 1-6 display the regressions of pulmonary function tests for the different smoking categories. Age and height significantly affected FEV and FVC values; age, but not height, was a statistically significant predictor of flow rates and closing volume (CV/VC). Heavy smokers (≥1 pack/day) had markedly reduced ventilatory capacity compared to other smoking groups (except for FVC where smoking did not significantly affect lung volume). Lung function values of exsmokers decreased at a rate intermediate between the heavy smoker and nonsmoker groups. Pipe or cigar smokers resembled nonsmokers for FEV, FEF_{50}, and FEF_{75}, but resembled exsmokers for FEF_{25-75} and closing volume (CV/VC). Except for CV/VC, the least reduction of ventilatory capacity was observed in the light smoker (< 1 pack/day) group. All smokers had similar functional reductions of CV/VC with increasing age. Current smoking behavior showed a better correlation with pulmonary function than did pack-years of smoking, and for this reason regressions based on current smoking categories were used in calculating predicted lung function values.

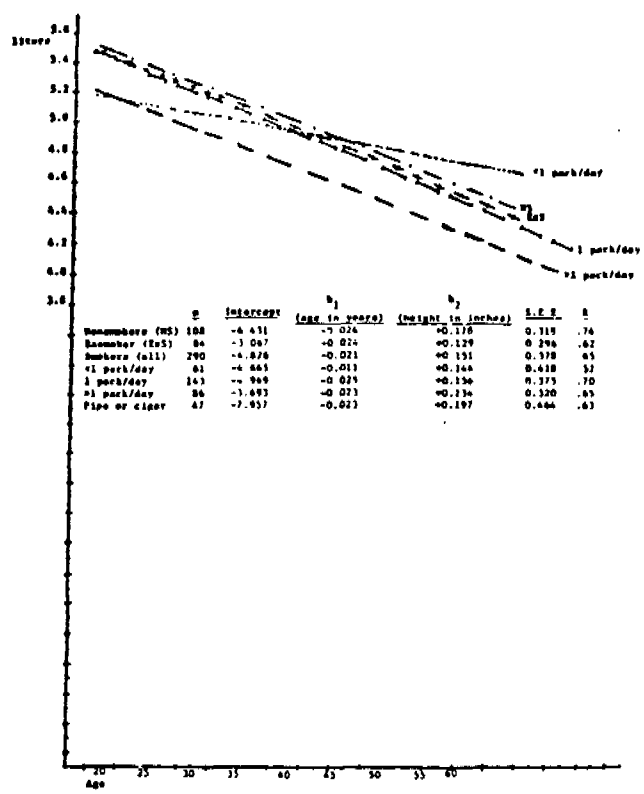
Table 5 summarizes the prevalence of impaired lung function as related to age and smoking. Except for FVC and CV/VC pulmonary function impairment (see Table 5 for definitions) consistently increased with age; and for all parameters consistently increased with increased smoking. Impairment rates for FEF_{25-75}, FEF_{50}/FVC and CV/VC were significantly higher for smokers than nonsmoking categories; the smaller number of pipe or cigar smokers precluded them from achieving statistically significant differences. Age and smoking were then analyzed simultaneously. Regressions of pulmonary function with age (Figs 1-6) suggested that after about age 40, smokers of ≥1 pack/day clearly had lower lung function values than the other categories of smokers. As there was little difference in prevalence of impairment among exsmokers, nonsmokers and pipe or cigar smoker categories, they were combined into a nonsmoker category, divided into age groups above and below 40 years of age, and compared with cigarette smokers. Smokers and nonsmokers in the younger age group had similar rates of lung function impairment. Smokers over

Table 3. — Age and Smoking Adjusted Prevalence Rates of Respiratory Symptoms by Current Job.

Symptom	Rubber	Plastics	Chemical		Former Chemical	Maintenance	All
			Hourly	Salary			
	%	%	%	%	%	%	%
Cough 1 and 2	10.3	20.9	14.8	8.7	15.5	16.5	15.6
Phlegm 1 and 2	15.1	26.1	15.5	8.4	25.9	22.3	19.2
Persistent Cough and Phlegm	5.9	13.8	8.3	3.5	11.4	13.7	9.2
Breathlessness† (Grade 2, 3, 4)	20.6*	22.1	21.6	15.*	26.9*	19.4	21.2‡
N	136	81	124	50	72	68	531
Age (years)	40.4 (12.8)	44.1 (13.8)	41.9 (12.8)	36.5 (8.9)	43.1 (10.7)	46.7 (10.2)	42.1 (12.3)
Height (in.)	69.5 (2.1)*	69.2 (2.5)	69.5 (2.2)	69.6 (2.96)	69.7 (2.8)	69.4 (2.8)	*69.5 (2.5)
Weight (lbs.)	174.9 (23.3)*	180.8 (27.3)	184.5 (30.7)	177.4 (25.7)*	183.9 (27.5)	186.1 (24.6)	181.0 (26.9)

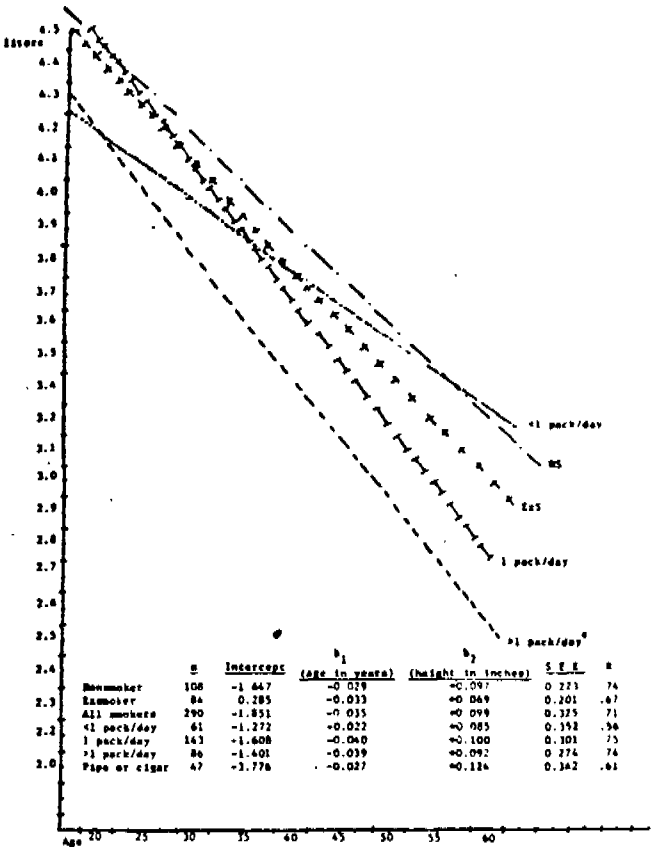
* = 1 missing
† = 3 missing

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	n	Intercept	b_1 (age in years)	b_2 (height in inches)	S.E.E.	R
Nonsmokers (NS)	108	-6.431	-0.026	+0.138	0.319	.76
Exsmoker (ExS)	84	-3.067	+0.024	+0.129	0.296	.62
Smokers (all)	290	-4.826	-0.021	+0.151	0.378	.65
<1 pack/day	61	-6.665	-0.033	+0.164	0.438	.52
1 pack/day	143	-4.969	-0.029	+0.156	0.375	.70
>1 pack/day	86	-3.693	-0.023	+0.134	0.320	.65
Pipe or cigar	47	-7.957	-0.023	+0.197	0.464	.63

Fig 1. — Prediction Equations for FVC in Total Population by Smoking.



	n	Intercept	b_1 (age in years)	b_2 (height in inches)	S.E.E.	R
Nonsmoker	108	+1.647	-0.019	+0.097	0.223	.74
Exsmoker	84	0.285	-0.033	+0.069	0.201	.67
All smokers	290	+1.851	-0.035	+0.099	0.325	.71
<1 pack/day	61	+1.272	-0.022	+0.085	0.152	.96
1 pack/day	143	+1.608	-0.040	+0.100	0.101	.75
>1 pack/day	86	+1.401	-0.039	+0.092	0.274	.74
Pipe or cigar	47	+3.776	-0.027	+0.126	0.342	.61

Fig 2. — Prediction Equations for FEV_1 in Total Population by Smoking.

40 years of age had significantly increased impairment compared to their nonsmoking counterparts. A synergistic effect of age and smoking was not observed for FVC (impairment was not affected by age or smoking) and CV/VC (both young and old smokers had rates of impairment higher than nonsmokers at any age).

To preclude confounding effects of age, height, and smoking in assessing the importance of occupational exposure, mean percent pulmonary function for each job group was calculated by dividing individual pulmonary function values by predicted values derived from the appropriate smoking category, and calculating the mean. Smoking-adjusted impairment rates were directly adjusted using the smoking distribution of the standard (total) population.

Baseline lung function as measured by mean percent predicted was the same in all current job groups. Table 6 summarizes the prevalence of impaired pulmonary function by current job. Former chemical workers tended to have the highest impairment, salary chemical workers the lowest. The other job categories generally had impairment rates between these extremes.

The effect of duration of exposure on lung function was then analyzed. Age, height, and smoking variables were adjusted in the manner previously described. Predictive equations were

Table 4. — Age and Smoking Adjusted Prevalence Rates of Respiratory Symptoms by Exposure Categories.

Symptom	Exposure Category: Mixed	Rubber Only	Plastics Only	Chemical Only: Hourly	Chemical Only: Salary	All
	%	%	%	%	%	%
Cough 1 and 2	20.2	10.3	8.4	2.8	8.2	15.6
Phlegm 1 and 2	21.0	15.4	12.9	9.5	7.9	19.2
Persistent Cough and Phlegm	11.2	6.4	2.5	2.0	2.0	9.2
Breathlessness† (Grade 2, 3, 4)	27.4*	21.3*	12.1	6.6	1.9*	21.2
N	217	132	28	44	42	531
Age (years)	44.7 (11.0)	40.1 (12.8)	41.6 (15.2)	34.7 (14.3)	36.1 (9.0)	42.1 (12.3)
Height (in.)	69.3 (2.6)	*69.5 (2.1)	70.0 (2.4)	69.8 (1.9)	69.7 (2.7)	69.5* (2.5)
Weight (lbs.)	184.9 (29.4)	175.2 (23.0)*	180.4 (25.9)	175.3 (26.6)	176.2 (25.8)*	181.0 (26.9)

*= 1 missing
†= 3 missing

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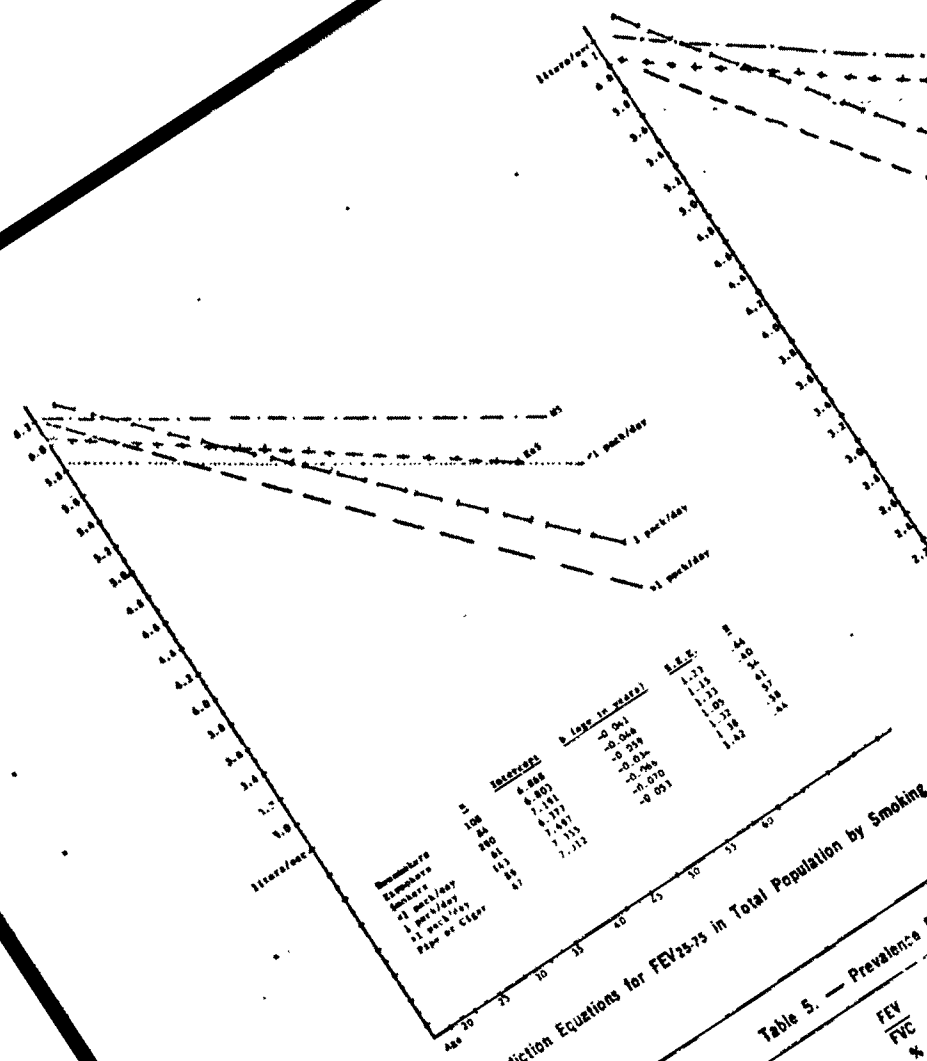


Fig. 3. — Prediction Equations for FEV_{25-75} in Total Population by Smoking.

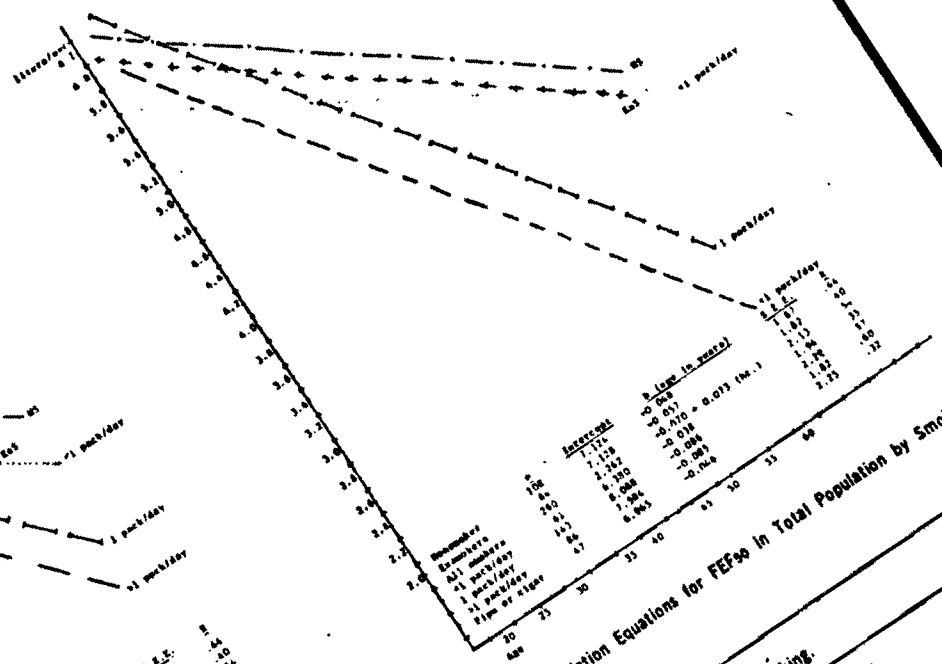


Fig. 4. — Prediction Equations for FEF_{50} in Total Population by Smoking.

Table 5. — Prevalence Rate of Impaired Pulmonary Function† by Age and Smoking.

Smoking Category	Age Category	n	FEV/FVC %	FVC %	FEF25-75 %	FEF50/FVC %	FEF75/FVC %	CV/VC %
Nonsmoker		108	25.9	4.6	8.3	2.8	31.5	0.9‡
Exsmoker		84	38.8	7.1	10.7	2.1	57.1	7.3‡
Smoker		292	43.8	8.6	19.5	8.3	52.4	16.1‡
Pipe or Cigar		47	29.8	14.9	8.5	10.2	36.2	4.3
All		531	38.2	8.1	14.9	7.5	47.5	10.5
	<29	107	16.8	7.5	10.3	1.9	6.5	1.5‡
	30-39	89	28.1	10.1	9.0	1.1	33.7	10.2‡
	40-49	162	36.4	8.0	13.0	9.9	51.9	11.3‡
	50-59	151	60.3	6.0	22.5	19.2	75.5	13.7‡
	≥60	22	45.5	9.1	22.7	18.2	72.7	0
*Nonsmokers ≤ 39		77	23.8	10.4	11.7	1.3	18.2	1.3
Smokers ≤ 39		119	22.7	7.6	8.4	1.7	19.3	13.6‡
All ≤ 39		155	21.9	8.7	9.7	1.5	18.9	8.8‡
*Nonsmokers ≥ 40		162	36.4	6.2	8.0	6.2	52.5	5.6‡
Smokers ≥ 40		173	58.4	9.3	27.2	23.7	75.2	17.9‡
All ≥ 40		335	47.8	7.8	17.9	15.2	64.2	11.6‡
All, *Nonsmokers		235	31.4	7.5	9.2	4.6	41.4	3.8‡
All, Smokers		292	43.8	8.6	19.5	14.7	52.4	16.1‡

*Nonsmokers = nonsmokers, exsmokers and pipe or cigar smokers
†Impaired Pulmonary Function=
FEV/FVC < 0.75
FVC/0.148 (height) − 0.025 (age) − 4.241 < 0.80 (from Reference 31)
FEF25-75/0.040 (height) − 0.050 (age) + 4.139 < 0.75 (from this population)
FEF50/FVC < 0.56
FEF75/FVC < 0.30
CV/VC/0.562 + 0.357 (age) > 8.30 above predicted (from Reference 34)
‡=1 missing, 2=2 missing, 3=3 missing, 4=4 missing, 5=5 missing, 6=6 missing

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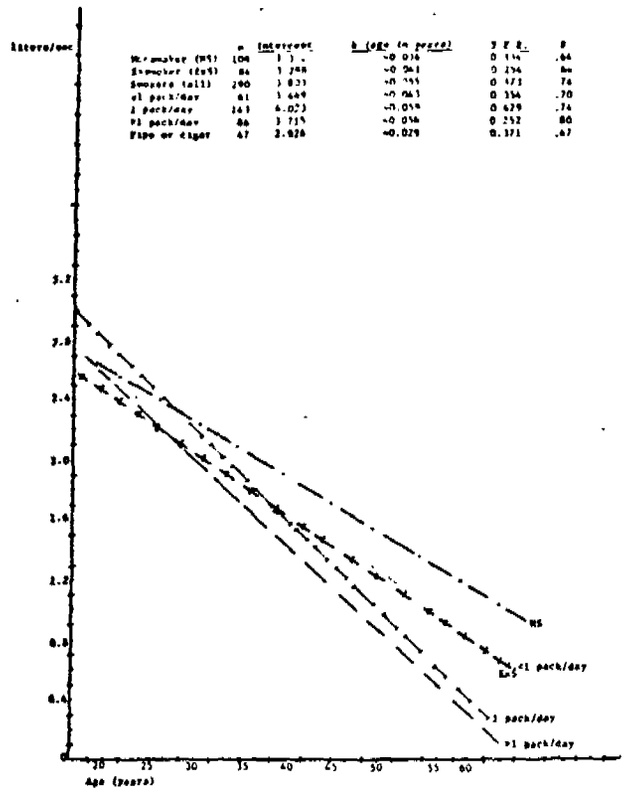


Fig 5. — Prediction Equations for FEF_{75} in Total Population by Smoking.

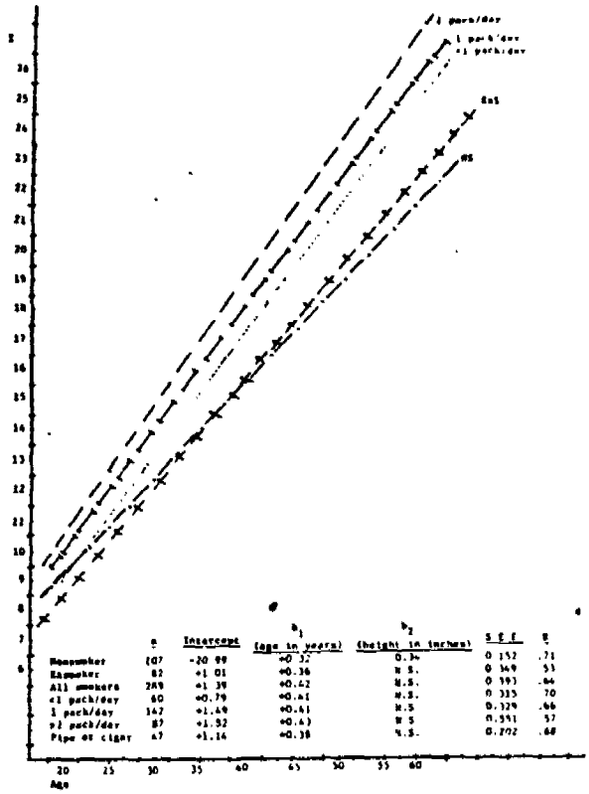


Fig 6. — Prediction Equations for Closing Volume/Vital Capacity (CV/VC) in Total Population by Smoking.

calculated using length of work in years as the independent variable, i.e., predicted pulmonary function = % predicted + % change in pulmonary function/year spent in exposure category. Table 7 summarizes regression for which a significant change occurred. For exposure category 1 (rubber only, chemical only, plastics only), rubber workers observed a significant decrease of -0.8%/year in FEF_{75}, plastics workers a decrease of -1%/year. All other significant changes were increases in lung function.

Health-related selective migration of workers is a potential source of bias in a cross-sectional study. In an attempt to take account of this, the effects of working in rubber and chemical, rubber and plastics, chemical and plastics, rubber, chemical, and plastics, or any one alone, were examined by analysis of covariance (Table 7). By backwards elimination method, exposure variables not statistically significant ($p > 0.05$) were sequentially removed until only the most significant exposure variables remained in the model. The analysis was done first on the total population (No. 2), then on the mixed exposure group (No. 3) and finally on the combination of categories within the mixed exposure group (Nos. 4-6). For the total population, working in chemicals was associated with increased FEV, FEF_{25-75}, FEF_{25}, and FEF_{50}. The only reductions in ventilatory capacity were observed in FEF_{75}, a highly significant reduction associated with rubber, and increased CV/VC, a functional decrease associated with plastics. The analysis of the mixed exposure groups (exposure categories 3-6) tended to support the results observed in the total population

Table 6. — Age and Smoking Adjusted Prevalence of Impaired Pulmonary Function* by Current Job.

Pulmonary Function	Rubber	Plastics	Current Job: Chemical, Hourly	Current Job: Chemical, Salary	Former Chemical	Maintenance	All
N	136	81	124	50	72	68	531
FEV/FVC	41.3%	32.5%	31.4%	29.7%	42.0%	31.4%	38.2%
FVC	7.4	13.2	6.4	0	8.5	10.1	8.1
FEF_{25-75}	15.9	13.7	13.3	14.1	25.2	12.9	14.9
FEF_{50}/FVC	12.6	11.7	6.2	0	14.4	7.9	10.2
FEF_{75}/FVC	46.4	42.4	46.7	33.6	54.4	45.6	47.5
CV/VC†	6.2	12.1	13.8	3.6	12.6	7.0	10.5

*Definition of Impaired PF in Table 5

1 = 1 missing

2 = 2 missing

6 = 6 missing

9 = 9 missing

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Table 7. — Selected Prediction Regressions for Pulmonary Function Related to Exposure, Age, Height and Smoking Adjusted

Exposure Category*	Predicted Pulmonary Function	= % Predicted	+ % Change	For Each Year Spent In Exposure Category	p Value for % Change
1	FEV	98.4%	+0.47%	Salary Chemical Only	0.02
2		99.2	+0.15	Chemical	0.05
3		100.8	-0.25	Rubber	0.10
1	FVC	93.3	+0.38	PVC Only	0.04
6		98.3	+0.52	PVC	0.08
1	FEF25-75	93.6	+0.86	Hourly Chemical Only	0.002
2		98.0	+0.33	Chemical	0.009
4		107.3	-0.94	Rubber	0.04
6		94.4	+0.86	Chemical	0.03
1	FEF25	91.0	+0.89	Hourly Chemical Only	0.003
2		98.0	+0.36	Chemical	0.005
3		96.8	+0.35	Chemical	0.10
4		106.0	-0.85	Rubber	0.07
6		94.8	+0.90	Chemical	0.02
1	FEF50	94.0	+0.99	Hourly Chemical Only	0.03
2		98.2	+0.30	Chemical	0.08
1	FEF75	109.2	-0.77	Rubber Only	0.01
1		111.8	-1.0	PVC Only	0.07
2		100.5	-0.67	Rubber	0.0001
3		94.8	-0.97	Rubber	0.008
4		109.9	-2.30	Rubber	0.004
5		95.5	-1.0	Rubber	0.04
2	CV/VC	98.3	+0.43	PVC	0.04
3		97.6	+0.46	PVC	0.09
5		107.9	-0.75	Chemical	0.08
6		92.7	+1.16	PVC	0.05

*Exposure Category
1 = Rubber Only, PVC Only, Chemical (H & S) Only
2 = Total Population (Rubber, Chemical, PVC)
3 = Mixed Exposure (Rubber & Chemical, Plastics & Chemical, Rubber & Plastics, Rubber, Chemical & Plastics)
4 = Rubber & Plastics (N = 52)
5 = Rubber & Chemical (N = 86)
6 = Rubber, Chemical & Plastics (N = 61)

Work in the chemical plant was associated primarily with increased flow measured over mid vital capacity. Work in plastics was associated with functional reductions of from 0.4 to 1.2%/year in CV/VC. The most consistent and greatest changes were reductions of from -0.7 to 2.3%/year in expired flow rates at low lung volumes (FEF_{75}), associated with work in rubber.

Table 8 summarizes the relation of pulmonary function and cumulative exposure to vinyl chloride (see Table 8 for definition of CES-cumulative exposure score). Increasing exposure to VC in all workers ever exposed to VC was not associated with any significant reduction in pulmonary function. The general tendency was for pulmonary function to *improve* with increasing exposure. Only reductions in FVC approached statistical significance. Dividing the group into those with current VC exposure, and those that worked in chemical or plastics in the past (former chemical) and repeating the analysis produced the same results.

The relation between respiratory symptoms and baseline pulmonary function is summarized in Fig 7. All respiratory symptoms were significantly associated with reduction in expiratory flow (FEF_{25-75}, FEF_{25}). Cough, phlegm, and persistent cough and phlegm were significantly associated with reductions in FEF_{50}. Those with cough 2, phlegm 2 and persistent cough and phlegm had reduced percent predicted CV/VC. Reduced FEF_{75} was associated with symptoms of cough and persistent cough and phlegm.

In addition to baseline pulmonary function, 56 workers were tested before work and again after work. Since the workers were also taking physical exams, actual working time averaged about 4-hours. As there were about twice as many smokers (82%) among chemical workers as plastics (36%) and rubber (41%) workers, acute effects were compared in cigarette smokers and all others combined (nonsmokers). Current smokers observed significant

Table 8. — Age, Height and Smoking Adjusted Regressions of Percent Predicted Pulmonary Function in Chemical and Former Chemical Workers (N = 196) by Cumulative Weighted Exposure* to Vinyl Chloride.

Pulmonary Function	Intercept (% predicted)	Slope (% change/CES*)	p value of Slope
FEV	98.9%	+0.10%	0.47
FVC	100.8	-0.16	0.13
FEF_{25-75}	96.4	+0.44	0.04
FEF_{25}	96.0	+0.53	0.02
FEF_{50}	95.9	+0.35	0.19
FEF_{75}	97.5	-0.43	0.17
CV/VC	102.4	-0.34	0.24

*CES = cumulative exposure score. All jobs in the chemical plant were rated for VC exposure as high (TWA = approximately 250 ppm), medium (TWA approximately 75 ppm) and low (TWA approximately 25 ppm). CES was calculated by multiplying months worked times a relative exposure rating (high = 10, medium = 3, low = 1) for that job, and summing over all jobs. Range = 0 - 2877 exposure-months.

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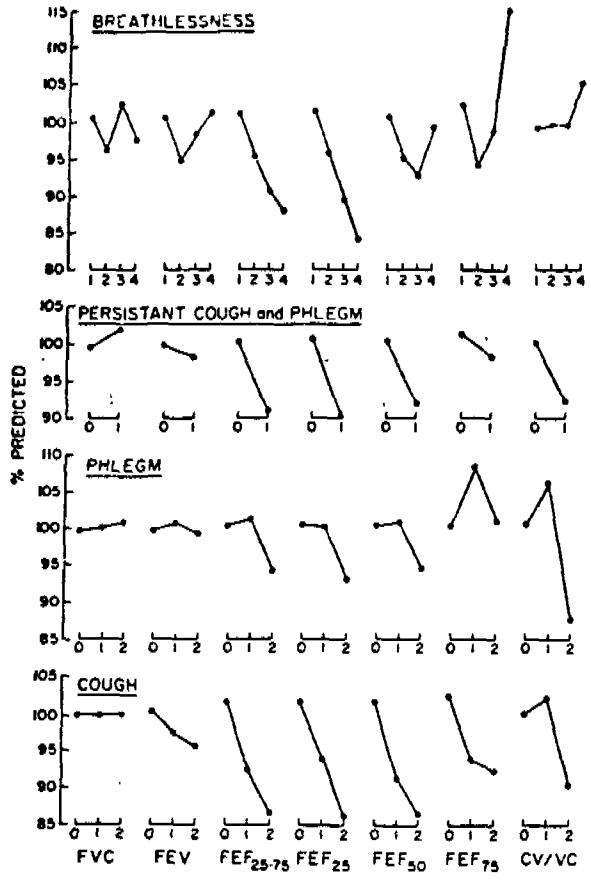


Fig 7. — Percent Predicted Pulmonary Function in Workers With and Without Respiratory Symptoms Adjusted by Age, Height and Smoking.

reductions in both flows and volumes. Nonsmokers showed decreases in FVC and peak flow, but other lung function parameters decreased significantly only for FEF50 (Table 9). Smokers in all job groups had reductions in ventilatory capacity, the greatest decrement occurring in flows at low lung volumes. The reductions were of the same order of magnitude for all three exposure groups, but were significant only for vinyl chloride and rubber workers. Except for reductions over the shift of FEF50 and FEF75 in nonsmoking rubber workers, ventilatory capacity of nonsmokers did not change significantly from zero.

Discussion

This study was stimulated by the finding of an increased incidence of liver angiosarcoma in vinyl chloride (VC) workers. Experimental studies, case histories, and epidemiologic studies all suggest VC acts as a lung irritant. This literature is briefly summarized.

Patty, Yant and Waite[6] exposed guinea pigs for 30 minutes to 10-40% VC. The principle gross pathological effect was congestion and edema of the lungs, and hyperemia of the kidneys and lungs. Exposure to 10% VC resulted in slight signs of lung hyperemia while hemorrhages, edema, and severe damage to the tracheal epithelium were observed at the higher concentrations in animals dying from the initial exposure. Pulmonary congestion was present after two weeks in surviving animals. Lower exposures for longer time periods (50-500 ppm for six months) resulted in no change in lung weight in rats, guinea pigs, rabbits and dogs. Exposures at concentrations greater than 100 ppm produced reversible liver injury in the more sensitive species.[7] Lester, et al[8] exposed rats to 20,000 ppm (2% VC) for three months, and 50,000 ppm (5% VC) for 19 days. They observed increases in liver weight and decreases in white blood cells, but concluded that the observed

Table 9. — Acute Effects (Mean % Change*) in Chemical, Plastics and Rubber Workers by Smoking Categories.
The hypothesis was that PF should not differ significantly from zero (H: Δ PF = 0).
The one-sided t test was used to test significance. Standard deviation is in parenthesis.

Current Job		n	Δ FEV %	Δ FVC %	Δ PEF %	Δ FEF25-75 %	Δ FEF25 %	Δ FEF50 %	Δ FEF75 %	Δ CV/VC‡ %
	NS†	3	1.53	-0.20	-0.97	+0.40	+1.63	-0.93	-2.77	+14.20
			(2.55)	(2.19)	(8.40)	(8.87)	(6.83)	(12.43)	(15.42)	(32.95)
Chemical	S§	14	-1.61**	-0.336	-4.21*	-10.06****	-9.43****	-8.28****	-14.75***	+8.51
Workers			(2.54)	(2.45)	(8.70)	(5.11)	(4.87)	(6.35)	(13.46)	(45.19)
	NS	8	+0.41	+1.09	-2.39	-1.93	-1.85	-0.53	-4.24	-12.35
			(3.15)	(2.61)	(9.59)	(9.65)	(8.60)	(6.78)	(25.85)	(25.26)
Plastics	S	4	-3.52	-2.03*	-4.05	-4.53	-1.00	-11.23	-22.76	+15.10*
			(5.62)	(1.54)	(8.73)	(9.48)	(14.99)	(13.01)	(26.83)	(12.82)
	NS	17	+0.54	+0.72	+3.82*	+0.25	+0.62	-.53	-5.76	0.55
			(4.82)	(2.64)	(8.73)	(10.08)	(7.56)	(13.99)	(23.93)	(29.51)
Rubber	S	10	-3.33**	-2.75**	-5.70	9.72**	8.30**	-8.75	-19.26**	+1.89
			(4.31)	(3.02)	(11.73)	(11.68)	(11.12)	(15.16)	(22.14)	(33.40)
	NS	28	+0.28	+0.73	+1.53	+0.36	+0.03	-1.44	-5.04	2.34
			(4.15)	(2.53)	(9.10)	(9.55)	(7.62)	(11.83)	(23.05)	(28.71)
All	S	28	-2.50***	-1.44***	-4.72**	-9.15****	-7.82****	-8.87****	-17.51****	+7.09
			(3.69)	(2.74)	(9.56)	(8.47)	(9.27)	(10.76)	(18.43)	(37.33)

*p = < 0.05
**p = < 0.025
***p = < 0.005
****p = < 0.005
†NS = nonsmoker, exsmoker, pipe or cigar smoker
§S = smoker
‡ = A positive sign indicates a decrease in performance as the after work CV/VC ratio is larger than the before work CV/VC ratio
*Mean % change = $\frac{\text{after work PF} - \text{before work PF}}{\text{mean PF}}$, mean PF = $\frac{\text{after} + \text{before}}{2}$

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lung edema and congestion could not be attributed to the irritating effects of VC, and the pneumonia observed was probably due to secondary infection. Keubler[10] exposed rats, mice, and guinea pigs to 5,000, 15,000 and 25,000 ppm VC for 2-hours a day for 100 days without observing any histological damage. In a report of a case of VC gassing in a plant in Great Britain, a worker washing out a polymerization vessel with water collapsed and was given artificial respiratory. Subsequent symptoms included chest tightness.[16]

Boytsov[9] reports (without giving the number of species or animals, length or amount of exposure) that inhalation and intratracheal administration of PVC resin produced a "development of peribronchitis in the lungs" and local thickening of interalveolar septa. Two studies of PVC workers in Russia and Germany conclude that the respiratory system was affected.[11, 12] A "considerable number" of 96 PVC workers in Russia had a "changed bronchovascular pattern and increased pulmonary ventilation at rest".[11] Eight of thirteen German PVC workers employed for 1.75 to 18 years showed partial pulmonary insufficiency with signs of predominantly restrictive changes of the lungs.[12] This latter finding is in agreement with the case described by Szende, et al.[13] A 31 year old male had shoveled PVC dust in a drafty place for 1-year prior to being examined for severe dyspnea. The possibility of pneumoconiosis elicited by inhalation of PVC resin was suggested.

There are a number of problems with the experimental studies of animals. Only at very high VC concentrations are effects observed, and these are anatomical changes from gross pathology or histology. More sensitive functional measurements at lower, more realistic, VC exposure concentrations have not been reported. The foreign studies are only suggestive, and do not provide enough information to evaluate.

There is only one reported epidemiologic study of VC and PVC workers in the U.S.[14] Cough and sputum production for most of 1-year or more, clinical signs of emphysema were reported in 31% of the 348 currently and previously employed VC and PVC workers. Smokers and nonsmokers over 40 years of age had similar rates of flow impairment. In the age group under 40 however, smokers had about twice the prevalence of flow impairment as nonsmokers. The higher prevalence of flow impairment in smokers compared to nonsmokers converged slightly with increasing duration of exposure. nonsmokers and smokers with more than 20 years exposure had the same prevalence of flow impairment. The authors conclude that the etiologic agents producing the reduced air flow in workers over 40 years of age or with > 20 years exposure is unclear but is not due to smoking. Exposure was to VC monomer, PVC resin dust, and pollution in a heavily industrialized city.

The effect of smoking on respiratory symptoms has become common knowledge following the report of the Surgeon General on the Health Consequences of Smoking (1964) and its subsequent supplements.[17] The results of this study confirm these reports, with the possible exception that light smokers (<1pack/day) in this study resembled exsmokers more than heavier smokers (≥1 pack/day). Pipe or cigar smokers have been less studied, although it has been suggested that pipe smokers are to be distinguished from cigar smokers.[18] Because of small numbers this has not always been done, and in this study these smokers were combined. They generally resembled light smokers and exsmokers in both symptoms and lung function.

The effects of smoking on symptoms have generally shown cough and phlegm to be higher in smokers, with prevalence relat-

Table 10. — Comparison of Respiratory Symptom Prevalence.

Population	N	Cough %	Phlegm %	Persistent Cough & Phlegm %	Breathlessness %
This Study (All)	531	14.9	19.2	9.2	21.2*
Nonsmokers	108	5.6	8.3	2.8	11.1*
Smokers	292	21.6	26.4	13.7	26.5*
Mining Community West Virginia[19]					
Nonsmokers	162	15.4	31.1	14.0	5.0†
Smokers	513	47.2	46.2	38.3	10.7*
Random Sample, Males Berlin, N. H.[4]					
Nonsmokers	75	10.7	16.5	7.3	3.8‡
Smokers	172	40.1	16.2	17.0	18.0†
Stratified Sample, Industrial town in England[5]					
Nonsmokers	96	—	—	9.0	5.1
Smokers	553	—	—	43.4	8.9
White, male nonsmokers 35-64[7]					
Maryland	469	5.5	4.1	1.5	22.6‡
NYC Postmen[8]					
Nonsmokers	903	7.0	13.1	4.0	21.6‡
Smokers	2687	27.0	28.9	19.0	34.0
NYC Transit Workers[8]					
Nonsmokers	1012	6.4	9.5	2.6	12.4‡
Smokers	3745	23.5	23.7	15.2	23.3

*Grade 2, 3, 4 breathlessness
†Grade 3 and 4 breathlessness
‡Grade 2 and 3 breathlessness

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ed to the amount of smoking, a re' ship supported by this study. Breathlessness, while generally higher in smokers, is often not related to the amount of smoking. This is hypothesized as due to selective reduction of smoking in those developing symptoms of breathlessness, a more severe and disabling condition than "smokers cough".[19] Although movement of less fit heavy smokers into lighter smoking or nonsmoking categories seems a plausible explanation, selection does not appear to be a strong factor in this population as there was a high prevalence of breathlessness on the heavy smoker category.

A trend for breathlessness to increase with increasing age is commonly observed,[19] and was apparent in this study. The association of cough and phlegm with increasing age has not been as consistent. Some studies report an increase with age;[19, 20] others (including this study) find little tendency for cough and phlegm to increase with age.[19, 21]

Two studies in West Virginia have observed an association between educational level and prevalence of respiratory symptoms and ventilatory lung function capacity, with the lower prevalence of symptoms partly attributed to fewer smokers in the higher educational categories.[22, 23] Stebbings[24] in 469 white male nonsmokers found no effect of social class (based on occupation, education, and income) on most respiratory symptoms; only dyspnea was significantly less common in the upper social class. Lower pulmonary function was also associated with lower socioeconomic status in these nonsmoking males.[24] Salaried chemical workers in this study resemble the upper social class in that they smoke less than hourly workers, and are probably more educated. Exposure to VC and PVC resin is generally less than that of the hourly workers. It is not known from this study whether social class, exposure, smoking, or some combination of these factors can explain the lower symptom rates of salaried chemical workers when compared to hourly workers. The same argument applies to the slightly better pulmonary function of salaried chemical workers compared to hourly workers. Among hourly workers, no consistent or convincing differences in respiratory symptoms or function were observed.

When workers were divided into exposure categories of working only in plastics or chemicals, the respiratory symptom rate was reduced considerably. Workers with more job mobility were less healthy in the sense that they reported more symptoms. This could be due to a greater susceptibility, to having a more unfavorable job experience in terms of exposure, to self-propelled movement to less symptom producing jobs, or some combination of these factors. Although the reasons are unknown, the fact remains that the less mobile "pure" exposure groups had lower symptom rates than control rubber workers, maintenance, and the mixed exposure workers.

Are the symptom rates observed in this population comparable to those in other populations? Table 10 compares the prevalence of respiratory symptoms in this study with other studies. There is considerable variation between reported symptoms in the various populations. The workers in this study compare favorably except for perhaps breathlessness.

The effects of age and smoking on pulmonary function observed in this population are comparable to other reported studies. There were no significant statistical differences in the intercepts of the smoking regression equations. Heavier smokers in this cross-sectional analysis had significantly greater reductions of FEV, FEF_{25-75}, FEF_{50}, and FEF_{75} with increasing age. Two points are of interest with regard to the effect of smoking. Before the age of 40, smoking had no apparent effect on pulmonary function. Secondly, light smok vere obviously less affected than moderate and heavy smokers. In the analysis of smoking, one should examine this dose response relation, and not arbitrarily lump together all smokers.

Careful consideration of possible smoking-exposure interactions is also required. For example, in a group of workers exposed to asbestos dust, smokers reported worse lung function than nonsmokers when a single regression was used for height and age adjustment.[25] The inference was that smoking increased the effect of dust exposure. Using only a single regression equation for standardization is misleading however, as smokers pulmonary function decreases more rapidly than exsmokers and nonsmokers. Rossiter and Weill[19] point out that an apparent synergism between dust and age may instead be a smoking-age interaction. When separate regression equations were used for standardization, i.e., one each for nonsmokers, exsmokers, and smokers, they observed no difference in pulmonary function related to dust exposure. In fact, the asbestos dust exposure had a more detrimental effect on nonsmokers than smokers. We know there was a smoking-age interaction in this study. Since we are primarily interested in the effect of VC exposure on pulmonary function, age and smoking adjustments were made using the regression equations of the various smoking categories (Figs 1-6). As there was no difference in pulmonary function between current job categories, and no nonexposed group of workers was available, the regression equations used for standardization were derived from the smoking categories of the total population.

After standardization, increasing duration of exposure in chemicals, plastics, and rubber was not associated with large changes in pulmonary function. Reductions in FEF_{75}, the most sensitive measure of small airways obstruction, was consistently and significantly associated with working in rubber; less significant reductions in FEF_{75} were associated with hourly chemical and plastics workers, and FVC in hourly chemical workers. Other pulmonary function parameters generally remained the same or improved with increasing duration in chemicals or plastics, and with increasing cumulative VC exposure. The reported case of pneumoconiosis on exposure to PVC resin[13] is suggestive that high exposure to PVC resin may result in a restrictive type of respiratory disease. Baggers in the chemical plant are exposed to from 1-5 $mg \cdot m^3$ of particulate (measured by area Hi-volume samplers); respiratory particulate is 1/10 to 1/20 these levels. Exposure to the PVC resin in plastics appears higher for Banbury operators but lower for workers in milling, and negligible for other plastics workers. The low prevalence of FVC impairment in both chemical and plastics workers does not support the hypothesis of PVC resin exposure producing volume restriction.

What difference is there between the workers in this study and those reported on by Miller, et al? Pulmonary function impairment for FEV/FVC, FVC, and FEF_{75}/FVC in this study employed the same definition as Miller, et al.[14] in their study of VC-PVC workers. The prevalence of impairment for FEF_{25-75}, using the same criteria, was essentially zero, and thus far below the 53% they observed. The cutoffs for impaired flow as measured by FEF_{50}/FVC and FEF_{75}/FVC have been shown to be reasonably effective in distinguishing normal subjects from those with obstructive lung disease.[1] The highest prevalence (almost 50%) of impairment was for FEF_{75}/FVC and supports the observed association of reduced FEF_{75} with increasing duration of work. All VC-PVC nonsmokers less than 40 years of age, and all workers in this study less than 40 years of age, had about a 20% prevalence of impairment for FEV/FVC and FEF_{75}/FVC. The prevalence of impairment increased for non-

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smokers over 40 in both populations but more so in the Miller study. The rates of flow impairment in both studies are the same for smokers over 40. In both studies the prevalence of impaired FVC (< 10%) is considerably lower for flow impairment (18-75%) and much lower than expected from exposure to asbestos.[11]

The association of increased pulmonary function performance with increasing exposure and work duration, particularly in chemicals, suggests that selection is occurring in this population. The reason for the lack of association between VC exposure and respiratory effects may be due to differential migration of more susceptible workers out of chemicals. Note that the mixed exposure group reported a higher symptom rate than chemical and rubber workers who had never moved. The current plastics worker had symptom rates comparable to or higher than this mixed exposure group, suggesting that net migration of "susceptibles" may have been into plastics. The association of small airways obstruction with exposure may be more informative than symptoms because (1) small airways may be more sensitive to the effects of environmental agents; and (2) small airways obstruction is probably not noticed by the individual to the same extent as symptoms and FEV reductions, and would therefore not be affected as much by selective migration.

Several conclusions emerge concerning factors that affect baseline pulmonary function in this population: (1) age and smoking were the two most important factors reducing pulmonary function; smoking was associated with obstruction only (no significant effect on FVC). (2) small airways function as measured by FEF_{75} was affected by both smoking and work exposure, primarily rubber worker exposure. (3) work, whether measured by duration or estimated cumulative exposure to VC and after adjustment for smoking effects, was not associated with reduced baseline pulmonary function (except for FEF_{75}). (4) although prevalence rates of impairment are not often reported, the air flow impairment (FEV/FVC, FEF_{75}), rates appeared elevated only in the older smoker.

Respiratory symptoms and measurement of pulmonary function are two somewhat independent and yet overlapping methods for investigating the risk of environmental exposures to the respiratory system. Symptomatology suffers from the disadvantage of being subjective, can show interobserver variation, and requires adequate recall on the part of the person being interviewed; symptomatology is useful in diagnosis, particularly chronic bronchitis. Independent validation of symptoms in practice turns out to be pulmonary function measures, despite the fact that different, albeit overlapping, parameters are being measured. The observed association of reduced pulmonary function with increasing severity of symptoms increased the validity of respiratory symptom information. The conclusion that VC exposure did not constitute a significant respiratory hazard in this population was strengthened by similar results for both symptoms and pulmonary function.

While one methodologic strength of this present study is the ability to make internal comparisons between work groups, it must be stressed that none of the groups can be regarded as having worked in hazard-free conditions. Both rubber and plastics workers are exposed to varied levels of dust and fume, and it could be that reduction in lung function among chemicals workers (whether due to vinyl chloride exposure, or to some other agent) are being obscured because of similar reductions in the other job groups. The results of FEF_{75}/FVC impairment (pertaining to that part of the respiratory tract thought to be first affected by harmful exposure — the small bronchioles) suggest increased abnormality rates in *all* workers. Indeed, for several of the pulmonary function tests the chemical workers had better results than rubber and plastics workers. To assess the potential respiratory hazard of each exposure category, before-and-after shift tests were carried out on some workers. Any reduction in respiratory function over the shift suggests the likelihood of some harmful exposure in the working environment.[14]

Smokers overall had statistically significant reductions for all ventilatory tests, nonsmokers showed little reduction. The most obvious reductions were flow rates at low lung volumes, i.e., measures of small airways performance. Chemical workers who were smokers had significant reductions for five of the seven tests, predominantly reflecting small airways obstructive change; both plastics and rubber workers who smoked showed reductions of similar magnitude. No clear picture emerges suggesting one job group faced greater daily respiratory insult than the others. Reduction in small airways performance among nonsmokers in each job group suggests that all workers were exposed to agents with adverse respiratory effects. In a clean environment the average result for these nonsmokers would have been a slight increase in test performance. Whether these acute reversible changes have any permanent effect is not known. The significance of these findings is unclear. The small airways obstruction associated with work in the rubber division, i.e., the control group, could be related to a number of environmental agents. The complexity of the industry and the heterogeneity of the control group does not allow for determining the etiologic agents. The rubber worker group was selected on the basis of lower particulate exposure and never having worked in chemical or plastics. But they could have, and probably did, work in other jobs with higher exposures within the rubber division. A complete work history for each rubber worker would be required to investigate further the association of reduced small airways function with work in rubber.

Fundamental and more difficult questions remain. What is the biological significance of acute reversible reductions in small airways function over a shift? What is the biological significance of statistically significant reductions in baseline pulmonary function over a longer time period? For FEF_{75}, the reduction is on the order of -1%/year. Over a 40 year period, this would amount to a 40% decrease. However, some individuals have a reversible change of 40% in the course of a day. The association of working in rubber with a downward slope of the percent predicted FEF_{75} is a finding that requires further investigation of workers in other areas of the rubber plant, an investigation currently underway.

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Correction

In "UV Keratoconjunctivitis Vs. Established Dose Effect Relationships," *JOM*, Aug. 1976, p. 573, the term "Amp" was erroneously used with reference to emission characteristics of lamp. Wherever "Amp" appears, it was intended to read "Angstrom Units."

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