Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Standard for Exposure to Vinyl Chloride

Pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657) Secretary of Labor's Order No. 12-71 (36 FR 8754) and 29 CFR Part 1911, § 1910.93 of Part 1910 of Title 29, Code of Federal Regulations is hereby amended in the manner set forth below, in order to provide an Occupational Safety and Health standard dealing with the exposure of employees to vinyl chloride.

I. *Background*—(1) *Vinyl chloride.* Vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014, is a synthetic organic chemical made from ethylene or acetylene and chlorine by any of several processes. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping film, electrical insulation, pipe, conduit, and a variety of other industrial and consumer products. Vinyl chloride has been made commercially in this country since 1939, and present production is in excess of seven billion pounds per year. The vinyl chloride industry divides into three segments: monomer production, polymer production, and fabrication. Production of the monomer is a large-scale continuous process, involving only a few firms. There are comparatively few employees in this segment of the industry, because the processes lend themselves to automation.

Vinyl chloride (VC) is used primarily in the production of polyvinyl chloride (PVC), a resin which is produced through batch processing. The conversion of the VC monomer into a polymer or copolymer is an incomplete process, i.e., not all of the monomer is reacted.

PVC is fabricated by a variety of techniques, including extrusion, injection molding and calendering, to form a finished product that needs no further chemical handling. The vast majority of employees involved in the VC industry are employed by fabrication firms. Such firms range in size from those with few employees and simple equipment to large plants involving many employees and considerable capital.

Vinyl chloride (VC), a gas at ambient temperature and pressure, is a chlorinated hydrocarbon, which heretofore has been regarded as having moderate liver toxicity. The initial standard, contained in Table G-1 of 1910.93, established a ceiling value of 500 parts of VC per million parts of air.

(2) *The emergency temporary standard.* On January 22, 1974, the Occupational Safety and Health Administration (OSHA) was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company had reported that deaths of several of its employees from a rare liver cancer (angiosarcoma) may have been occupationally related. As a result of this notification and after consultation with NIOSH, and a joint inspection of the B. F. Goodrich plant by OSHA, NIOSH and the Kentucky Department of Labor, a fact-finding hearing was announced on January 30, 1974 (30 FR 3874) and held on February 15, 1974.

Information obtained from this hearing, particularly the preliminary reports of experiments conducted by Professor Cesare Maltoni of the Instituto di Oncologia, Bologna, Italy, demonstrated that vinyl chloride induced angiosarcoma in rats at levels as low as 250 ppm, and in other species at higher levels. Experiments performed at lower levels of exposure were not completed at that time. Other testimony from medical witnesses and NIOSH, and the results of autopsies, led to the conclusion that the Goodrich workers had angiosarcoma of the liver and that VC probably was the causal agent in the angiosarcomas observed.

In post hearing comments, additional angiosarcoma deaths were reported among workers who had been exposed to VC in plants operated by Union Carbide Corporation, Firestone Plastics Corporation and Goodyear Tire & Rubber Company.

On the basis of all information available at that time, and the fact that employees were being exposed at levels around the experimentally observed effect level of 250 ppm, an emergency temporary standard (ETS) was promulgated on April 5, 1974 (39 FR 12341) pursuant to section 6(c) of the Act, as 29 CFR 1910.93q.

This standard reduced the permissible exposure level from a ceiling of 500 ppm to a 50 ppm ceiling, and established other requirements, including, for example, monitoring and respiratory protection. It was expressly recognized that this standard limiting exposures to a 50 ppm ceiling was a tentative, interim standard, and that the whole question of exposure to VC would be considered more fully in the light of additional information, especially the results of experiments which were known to be underway at that time.

On April 15, 1974, information and data were presented to representatives of OSHA, NIOSH, and the Environmental Protection Agency by the Industrial Bio-Test Laboratories, Northbrook, Illinois, concerning results of animal exposure studies with VC. These studies were sponsored by the Manufacturing Chemists Association. Although only preliminary in nature at that time, these results revealed that 2 out of 200 mice exposed to VC concentrations of 50 ppm for 7 hours a day, five days a week, for approximately 7 months, had developed angiosarcoma of the liver.

(3) *The proposed permanent standard.* Based on the demonstrated evidence of VC's carcinogenicity in three animal species (rats, mice and hamsters), and the substantial probability that VC had been the causal agent in the cases of liver angiosarcoma found in workers both here and abroad, OSHA proposed to revise 1910.93q and published a comprehensive proposal (39 FR 16896) on May 10, 1974, to protect employees from hazards of exposure to VC. The proposal called for limitation of employee exposure to VC to "no detectable level," as measured by a sampling and analytical method sensitive to 1 ppm, with an accuracy of 1 ppm ±50 percent. The proposal also called for the establishment of regulated areas and limited access to such areas to authorized persons. A requirement for monitoring of employee exposures was proposed, along with engineering and work practice controls to be implemented when exposures over the detectable limit were measured.

Respiratory protection would have been required while engineering and work practice controls were being implemented or where exposures exceeded the permissible limit even after feasible engineering controls were instituted.

In addition, the proposed standard included requirements for medical surveillance, protective clothing, emergency procedures, training, specific protection during maintenance and decontamination operations, transportation loading and unloading operations and recordkeeping.

(4) *Hearing on the proposal.* The proposal, as published on May 10, 1974, allowed 30 days for interested parties to submit written comments and to request an informal rulemaking hearing. Informal contacts with OSHA staff and early responses indicated that the subject was of great interest and importance to many persons. Because of the limited time available before expiration of the six month period provided in section 6(c)(3) of the Act for promulgation of a final standard, it was decided to hold a hearing as soon as possible. Accordingly, on May 24, 1974, a notice of a hearing was published (39 FR 18303), setting a hearing date of June 25, 1974. The hearing was conducted from June 25 through June 28, and again from July 8, through July 11, before Administrative Law Judge Gordon J. Myatt. All participants were given the opportunity to present testimony and to cross-examine other witnesses. Persons participating in the hearing were given until August 23, 1974, to file additional posthearing comments, including various items of information which were requested during the examination of witnesses.

(5) *Economic and technical impact study.* During the hearing, OSHA determined that additional facts would be needed to determine the practicality of certain aspects of the proposed standard. Accordingly, OSHA contacted an independent consultant, Foster D. Snell Corporation, to conduct studies of the feasibility of compliance at various exposure levels, including those proposed by OSHA and others advanced by industry spokesmen. Snell was also commissioned to collect information regarding the economic costs of compliance. This action was announced at the close of the hearing, and Judge Myatt further announced that the record would be kept

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open for a period of time beyond August 23, to allow interested persons to comment in writing on the study. On August 26, 1974, OSHA announced that the preliminary study was available and that comments were to be submitted no later than September 6, 1974 (39 FR 30844). On September 13, 1974, OSHA invited comments on both the preliminary and the final study, which was to be received on or before September 25, 1974 (39 FR 33009).

(6) *Environmental impact statements.* A notice of intent to file an environmental impact statement assessing the impact of a proposed standard on occupational exposure to VC was published in the FEDERAL REGISTER on April 24, 1974 (39 FR 14522). The notice invited any person having information or data on the environmental impact to submit it to OSHA by May 17, 1974. On June 12, 1974, a draft environmental impact statement was prepared and circulated to all interested persons. Ten copies were forwarded to the Council of Environmental Quality (CEQ), which published a notice of its filing and availability in the FEDERAL REGISTER on June 25, 1974 (39 FR 22975). A 45 day period was allowed for the submission of comments on the draft statement. On September 5, 1974, the final environmental impact statement was prepared and a copy of it and all substantive comments were sent to appropriate governmental agencies, private organizations, and other interested persons. CEQ published a notice of availability for the final statement on September 6, 1974 (39 FR 32350). The submission of comment was invited until September 25, 1974. The final statement and all significant comments have been carefully considered in arriving at the final standard on occupational exposure to VC.

(7) *The record.* The record in this proceeding is one of the most exhaustive ever relied upon by OSHA. It consists of pre and post-hearing comments and testimony received at both factfinding and rulemaking hearings, the studies and inspections conducted by OSHA personnel, the environmental impact statements, the economic and technical impact studies, and all other relevant information. In all, over 600 written comments have been received, with more than 200 separate oral and written submissions made with regard to the two hearings. The record itself exceeds 4,000 pages. Employers, employees, labor unions, public health groups, independent experts, physicians, research scientists, and specialists in many fields have been invited to submit information and have made their views, knowledge and experience available to OSHA. The entire record encompassing these submissions was thoroughly reviewed and evaluated in reaching the determinations set forth below.

II. *Findings regarding carcinogenicity, exposure levels and feasibility*—(1) *Carcinogenicity of vinyl chloride.* The carcinogenicity of vinyl chloride for three animal species (rat, mouse, hamster) has been documented on the record by the studies of Maltoni and Bio-Test Laboratories. Moreover, Maltoni's investigations have demonstrated a dose-dependent relationship for induction of tumors (i.e., more tumors occur at higher exposure levels), including angiosarcoma of the liver, in rats. The investigations of Industrial Bio-Test Laboratories have demonstrated a similar relationship for both rats and mice. These investigators have induced angiosarcoma of the liver in rats and mice at exposure concentrations of 50 ppm, and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin of exposed animals, were also observed in frequencies much in excess of control animals. The incidence of tumors in mice in the Industrial Bio-Test Laboratories investigations is particularly pertinent. Of 200 mice (100 males, 100 females) exposed to 50 ppm of vinyl chloride by inhalation for eleven months, 100 died. Sixty-four animals died without gross postmortem pathologic examination being performed. Of the 36 remaining animals for which a gross postmortem pathologic examination was performed, 13 (36 percent) were found with liver tumors (including angiosarcomas), 21 (58 percent) with lung tumors, 9 (25 percent) with skin tumors, and one with a kidney tumor.

According to the 1970 report by the Surgeon General's Ad-Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, the finding of cancer in two or more animal species may be extrapolated to indicate a carcinogenic hazard to humans. Here, such a finding was made in three species that were exposed to VC by inhalation—a route comparable to employee exposure. In addition, there were at least 13 confirmed cases of angiosarcoma of the liver among employees exposed to VC, a particularly significant number in view of the extreme rarity of this cancer in the U.S. adult male population (testimony of Dr. Marcus Key, Director of NIOSH, at the rulemaking hearing).

The findings of angiosarcoma of the liver in both experimental animals and exposed employees is compelling evidence that exposure of humans to vinyl chloride induces this tumor. Industry spokesmen, at the hearing, conceded that VC is carcinogenic for humans (e.g. testimony of Dr. McBurney, Rulemaking hearing, 1041). Accordingly, it is concluded that VC must be regarded as a human carcinogen, and the probable causal agent of angiosarcoma of the liver, and that exposure of employees to VC must be controlled.

Additional evidence of tumor induction in a variety of other organs, including lung, kidney, brain and skin, as well as non-malignant alterations, such as fibrosis and connective tissue deterioration, indicates additional oncogenic and toxicologic properties of vinyl chloride, which must be considered in establishing control regulations. (See testimony and results of studies by Bio-Test Laboratories, Tabershaw-Cooper, Maltoni, NIOSH, and Selikoff.)

(2) *Exposure limits.* Upon finding that exposure of employees to vinyl chloride may create a carcinogenic hazard, the amount of exposure which is hazardous must be determined. The Surgeon General's Ad Hoc Committee referred to above concluded that safe exposure levels for carcinogenic substances cannot be scientifically determined. This position is supported by the testimony of NIOSH at the hearing, its recommendations for a standard of no detectable level, and by the testimony of expert witnesses from the National Cancer Institute.

Several witnesses and persons who submitted comments have taken a contrary view and have suggested that man is less sensitive to biologic aberrations induced by vinyl chloride exposure than experimental animals. Proponents of this position have argued that if humans were as sensitive as rodents, an "epidemic" of cancer resulting from VC exposures should have already been discovered among employees. They also argue that the employees in whom tumors have been observed are those who have considerable employment experience as polymerization reactor cleaners. Because it is generally agreed that reactor cleaning involved high exposures to vinyl chloride in years past, it is argued that the lower levels currently found in the workplace have not induced cancer and are therefore safe. We reject this argument.

The fact that approximately three-quarters of those employees with the longest exposure to VC (greater than 20 years since initial exposure) have not yet been located, makes it impossible to determine the actual number of affected employees. The cases of liver tumors observed to date have an average latency period, since initial exposure, of approximately 20 years. If it is assumed that induction of angiosarcoma is a dose-related phenomenon, and if employees engaged in cleaning reactors did, in fact, receive larger doses of vinyl chloride, it would be expected that such tumors would be observed earlier for this employee population. For this reason, the significance of presumed lower doses cannot be accurately assessed until a longer period of time has passed, as a longer induction period would be expected.

Initiation of exposure to chemical carcinogens and induction of cancer are not necesasrily synchronous events. Because of the physiologic complexities involved with carcinogenesis, induction of tumors does not occur in all employees with similar exposure histories. For example, Dr. Schneiderman of the National Cancer Institute emphasized during his testimony that only about a fifth of longer-term heavy smokers develop lung cancer. Accordingly, the industry contention that exposure levels have been dramatically reduced since the 1940's is not reliable evidence that current levels of exposure are safe.

Some industry spokesmen also suggested that the apparent nonrandom distribution of observed cancer in employees may indicate an exposure threshold for tumor induction, based on variations in the workplace design or practice and resultant employee exposures

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(testimony and questioning by Tenneco Chemicals, Inc.). It has also been emphasized that in only 3 of 8 polymerization plants where employees have been exposed to VC for more than 20 years have any employees developed angiosarcoma of the liver. This argument is very similar to that raised concerning variability of past employee exposure. Although geographic and workpractice differences may ultimately be demonstrated to be factors in distribution of angiosarcoma, sufficient information is unavailable to exclude from consideration of risk those employees in workplaces for which cases of angiosarcoma have not been observed.

It has also been suggested that the absence of cancer in a population of 335 Dow Chemical Company polymerization employees monitored over a period of 7 years, indicates that exposure to vinyl chloride at concentrations of less than 200 ppm is safe. (See study by Dr. Cook, submitted at the hearing by Dow Chemical Company.) However, the group surveyed did not include all workers who had been exposed, and the missing employees included many who had the longer term (over 20 years) exposures. Moreover, the statistically insignificant size of the sample population decreases the possibility that tumors would be observed.

Dow also presented preliminary data in testimony at the hearing on the possible metabolic pathways of VC. The hypothesis presented was that VC may exert its carcinogenic effect by a metabolite, and that the metabolite is produced only when VC is metabolized by a secondary metabolic pathway operating only when enzymes regulating the primary pathway are saturated, as would be the result at higher exposures. The preliminary data indicated the possibility of an additional pathway for metabolism of VC in rats exposed to concentrations of VC in excess of 220 ppm. However, the occurrence of angiosarcoma in both rats and mice at VC exposure concentrations of 50 ppm indicates that if a metabolite of VC is the ultimate carcinogen, then it must be generated at lower exposure concentrations in these species. Although this research may be helpful to the thorough understanding of the carcinogenicity of VC, it appears that it does not yet offer evidence which can assist in determination of safe exposure concentrations for employees, or even that such safe exposures exist.

A number of witnesses representing employers have stressed that there is no evidence of cancer, either in employees or experimental animals, at exposure concentrations of VC less than 50 ppm. (See e.g., testimony of Firestone, Tenneco Chemicals.) The conclusion of these witnesses was that no decision can be made concerning risk of exposure to VC at concentrations less than 50 ppm.

On the other hand, the testimony of most expert witnesses, including some industry biomedical experts, stated that quantification of a safe exposure concentration is not possible with the present state of scientific knowledge (See e.g., testimony of Selikoff, Firestone, NCI, and NIOSH.)

In our view, the demonstration of cancer induction in humans at a particular level is not a prerequisite to a determination that a substance represents a cancer hazard for humans at that level. It would be imprudent to assume man to be less sensitive to VC exposure than experimental animals in the absence of conclusive evidence. It would also be unfounded to assume that animals will not develop tumors when exposed at concentrations of VC of less than 50 ppm. Should a sufficiently large number of experimental animals be exposed to VC at concentrations of less than 50 ppm, Schneiderman said that it would be expected that some would develop VC induced tumors.

(3) *Feasibility.* There is virtually no dispute that most, if not all, fabricators are currently capable of reaching exposure levels of 1 ppm through engineering controls. These employers employ well over 95 percent of all employees exposed to VC. Indeed, several fabricators are already operating at this level (see SPI testimony). However, industry spokesmen have universally claimed that it is infeasible for the VC and the PVC industries to remain below 1 ppm consistently, using engineering controls. In addition, the Snell study on technical feasibility concluded that a 1 ppm ceiling is not feasible for the VC and PVC industries with present technology, but that the VC industry could currently attain lower exposure levels than the PVC industry. Labor union spokesmen and the Health Research Group, Inc., however, have suggested that such a level is attainable.

Since there is no actual evidence that any of the VC or PVC manufacturers have already attained a 1 ppm level or in fact instituted all available engineering and work practice controls, any estimate as to the lowest feasible level attainable must necessarily involve subjective judgment. Likewise, the projections of industry, labor, and others concerning feasibility are essentially conjectural. Indeed, as Firestone has suggested, it is not possible to accurately predict the degree of improvement to be obtained from engineering changes until such changes are actually implemented.

We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA level for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time. It is apparent that reaching such levels may require some new technology and work practices. It may also be necessary to utilize technology presently used in other industries. In any event, the VC and PVC industries have already made great strides in reducing exposure levels. (See testimony of Dow Chemical Co., TR 973). For example, B. F. Goodrich testified (TR 1120) that it has reduced average exposure levels in several PVC plants from 35–40 ppm early this year to 12–13 ppm at the time of the hearing. We are confident that industry will continue to do so.

(4) *Conclusions.* The conclusions below are based on a thorough review and evaluation of all the evidence submitted. Where decisions can be based on record evidence, this has been done. Where, however, factual certainties are lacking or where the facts alone do not provide an answer, policy judgments have been made.

There is little dispute that VC is carcinogenic to man and we so conclude. However, the precise level of exposure which poses a hazard and the question of whether a "safe" exposure level exists, cannot be definitively answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. Therefore, we have had to exercise our best judgment on the basis of the best available evidence. These judgments have required a balancing process, in which the overriding consideration has been the protection of employees, even those who may have regular exposures to VC throughout their working lives.

Based on the available evidence and in view of the above considerations, including feasibility, we believe that employee exposures to VC must be reduced to a 1 ppm time-weighted average (TWA). We also believe that PVC and VC establishments will, in time, be able to attain that level through engineering controls, and that fabricators can do so in the immediate future.

In addition to the TWA requirement, we have established a 5 ppm ceiling (averaged over a 15-minute period) in order to prevent exposure of employees to unacceptable high excursions. From an operation standpoint, this ceiling level is realistic because minor excursions up to the ceiling level are likely to occur on a regular basis.

III. *The final standard*—(1) *Scope and application.* Both the ETS and the proposal would apply the standard to the entire VC industry, including manufacturers of VC and PVC and fabricators, but excluding employers handling or using fabricated products made from VC.

There is no dispute that a standard is required for the monomer and polymer industries. However, the Society of Plastics Industry (SPI) and various fabricators (see testimony of Goodyear, General Cable, etc.) recommended that fabricators be excluded from the standard, or that a separate requirement be established for them because many of them were already at or below the proposed ceiling level.

The record evidence establishes that at least some employees in the fabricating industry are exposed in excess of the permissible control limits (See NIOSH testimony, TR 106; Robintech TR 642). In these circumstances, we believe that it is imprudent to grant a blanket exemption for all fabricators. Therefore, the final standard is applicable to the fabrication industry, as well as the monomer

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and polymer industries. Employers who, in fact, are substantially below the exposure limit will be subjected to only minimal burdens by virtue of the "action level" to be discussed below.

Where employers in the fabricating industry have exposures approaching the permissible limit, they will appropriately be subject to the standard. Employers handling or using fabricated products made of PVC were not included in the ETS or the proposal and are excluded from the final standard. This conclusion is based on the absence of adequate evidence of exposure to VC in these operations. The final standard clarifies the exemption by defining a fabricated product as a product made wholly or partly from PVC which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the PVC. SPI and others (cf. TR. 344) requested that PVC resins with less than 0.1 percent residual monomer be exempted from the regulation now, and that the exemption level be reduced to 0.01 percent in three years. SPI suggested that the exemption of materials with less than 0.1 percent of 14 carcinogens from 29 CFR 1910.93p (39 FR 3756) was an appropriate precedent. The cases are not comparable, because no attempt had been made to set air concentration limits for the 14 carcinogens. The record did not include information that reliable monitoring and measuring techniques were available. Moreover, the exemption did not exempt airborne traces of carcinogens. The administrative cutoff was provided to avoid regulation of materials about which there was no health hazard information, and which would have broadly extended the application of the regulation beyond the record. Herein, no information was presented to show safe concentration results from the use of resins with specific levels. Indeed, the proposal to change the level later, when improved technology would permit such reduction, would seem to indicate that SPI has doubts about the safety of 0.1 percent residue level. Diamond Shamrock (Exhibit 142) testified that there is no direct relation. They indicate that the airborne concentration is more related to the physical form of the resin and the ventilation provided. Also, monitoring data from industry (cf. Exhibits 131, 168, 170) and OSHA (Exhibit 151) indicate that levels in excess of 1 ppm may be found in fabrication operations. In view of these facts and of the opportunity for employers to discontinue many duties upon a showing of no exposures above the action level, it does not appear that any residue exemption is either justified or necessary at this time. This course also agrees with a number of industry proposals (cf. TR 660).

SPI (TR 345), among others, asked that compounded PVC pellets be exempted from the standard on the grounds that the pellets had too low a residue to cause harmful or measurable emissions. While it appears that PVC pellets would have a lower residue level than virgin PVC, the fact that the pellets must be heated to a molten mass at the same temperature as PVC, for further processing, indicates that a potential for release of the residue still exists. It appears that the exemption of fabricated products should be limited to just those items which will not undergo such mass heating. Further, the opportunity to demonstrate that exposures are below the action level, and thus, discontinue many duties of the standard, provides a more positive control and an adequate relief.

(2) *Permissible exposure limit.* The standard sets an exposure limit of 1 ppm averaged over any 8 hour period, and a ceiling of 5 ppm averaged over any period not exceeding 15 minutes.

As more fully discussed above, this limit is based on an evaluation of the best available evidence and on a judgment that the health and safety of employees must be protected to the fullest extent feasible. In view of the fact that release of VC in the VC and PVC manufacturing processes are variable, the 1 ppm ceiling level provided in the proposal would require maintenance of an average level significantly more difficult to attain through feasible engineering controls. Therefore, the exposure limit prescribed in the proposal has been rejected.

(3) *Action level.* The final standard, unlike the ETS and the proposal, provides for an "action level" of 0.5 ppm TWA, one-half of the permissible exposure limit. The purpose of the action level is to minimize the impact of the standard on the employers who have attained exposure levels well below the permissible limit. Thus, where the results of monitoring under paragraphs (d)(1) or (d)(2) demonstrate that no employee is exposed in excess of 0.5 ppm TWA, employers may, in effect, be exempted from some provisions of the standard. For example, fabricators who are below the action level are not required to provide medical surveillance or to monitor again, unless the employer has reason to suspect that any employee is exposed in excess of the action level. In our judgment, exposures below the action level do not present a sufficient hazard to warrant application of the entire standard to the many employers who are or will be below that level.

(4) *Monitoring.* The final standard, like the proposal, requires that individual employee exposure levels be determined. This may be accomplished by personal or area monitoring. Some witnesses and persons who submitted comments did not understand the meaning of the term "95 percent confidence level" in the proposal. Essentially it means that the employer is required to take a sufficient number of measurements so that the results obtained are statistically valid. We have modified the proposal to establish accuracy range requirements for various measurement levels. These ranges are narrow enough to ensure that a determination of compliance can be made, and broad enough to allow the application of a variety of technologies

All covered employers are required to conduct initial monitoring. Where monitoring and measuring results are at or below the action level, no further monitoring is required unless the employer has reason to suspect that any employee is exposed in excess of the action level, or unless changes have been made in production, process, control, type of resin, etc.

Where the exposure level, without regard to respirators, exceeds the permissible levels, monitoring must be conducted at least monthly. Where exposures are less than the permissible levels, but greater than the action level, monitoring must occur at least quarterly.

(5) *Methods of compliance.* The standard, like the proposal, requires that employers immediately institute feasible engineering and work practice controls to reduce exposures to at or below the permissible exposure limit.

Where feasible engineering and work practice controls will reduce exposures below the permissible levels, they must be instituted. Where such controls will not reduce exposures below the permissible level, they must nonetheless be implemented to reduce exposures to the lowest practicable level, and be supplemented by the use of respirators to provide the necessary protection. Thereupon, a continuing program of engineering and work practice controls must be instituted to reduce exposures to the lowest practicable level. When exposures are at or below the permissible exposure limits, the program may be discontinued.

In addition, a plan for achieving control by engineering and work practice methods must be drawn up and be made available, upon request, to representatives of OSHA and NIOSH.

We recognize that many employers covered by the standard can not currently achieve compliance with the permissible exposure limit solely by the use of feasible engineering and work practice controls. The record also reflects broad generic distinctions between the compliance capabilities of the VC and PVC industries. Some industry spokesmen, including SPI (TR. 358–362), recommended that a schedule of different permissile exposure limits and compliance dates be established for the VC and PVC segments of the industry.

This view assumes that the ability and the time required to feasibly reach increasingly lowef control levels is similar within each industry, but differs markedly between industries. While the record does suggest that such differences do exist between industries, as noted above, it is clear that intra-industry differences also exist. Thus, the ability and time required by each employer to attain lower control levels may depend upon such factors as the climate in which the plant is located, the age of equipment, the size of reactors, or the type of resin manufactured or used. (Snell study, Firestone testimony, etc.)

Monitoring data also tends to support such intra-industry variations. (See, e.g. Dow, Firestone, Tenneco.)

As noted above, the standard requires all employers to institute feasible engineering controls to the fullest extent and to continue to improve and apply engi-

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neering controls until full compliance is achieved.

We have not established any deadlines for full compliance through engineering controls because we are presently unable to determine when it will be feasible for most establishments to reduce exposure levels to the permissible level.

We also believe that the requirement that each employer reduce airborne concentrations to the permissible level, or to the lowest level feasible as soon as practicable will provide for inter-industry and intra-industry technological differences which do exist, and will avoid the setting of separate industry standards on the basis of the general situation and conditions in each industry.

(6) *Regulated areas.* The proposed standard would have required that regulated areas be established, that access be limited to authorized employees, and that daily rosters or summaries of those entering be kept for at least 20 years. In objection to these requirements, it was asserted that such control of access was not necessary from a health standpoint. Secondly, it was claimed that these controls would interfere with operations by preventing access of needed employees or non-employees, such as contractors, truck drivers, customers and consultants.

The purpose of establishing regulated areas in the proposal was to limit the risk of exposure to as few employees as possible. This concern is still paramount, and thus the limited access feature remains. The final standard amends the proposal slightly to allow "authorized persons" to enter regulated areas. This change, it is felt, will allow operations to continue without undue interference. The final standard has also increased the length of time daily rosters must be maintained from 20 to 30 years. This change was based largely on epidemiological considerations. (See NIOSH testimony, tr. 119.)

(7) *Respiratory protection.* The final standard, like the proposal, requires the use of respirators where employee exposures exceed the permissible control level. Industry representatives made a number of objections to proposed requirements for respiratory protection. They stated that the "no detectable level" would effectively require continuous wearing of respirators in PVC and VC plants, and that this is not feasible because respirators are cumbersome, present a safety hazard, and employees would not use them.

We would agree that respirators have many drawbacks; the proposal did not contemplate them as a final solution. The record shows that the PVC industry particularly may need several years before plant environmental levels can be reduced so that respirators are necessary only occassionally. However, we cannot agree that respiratory protection should not be required simply because it is inconvenient, may require additional personnel, interferes with production, or may require extensive retraining of employees and restructuring of work practices. We have carefully considered all the objections, and have concluded that if the environmental level is not controlled to the permissible exposure limit, then employees must be afforded respiratory protection.

While exposures in excess of the permissible level do constitute a hazard, we believe that it is necessary to mitigate some of the problems associated with implementing a program of respiratory protection while employees are being fitted and trained in respirator use, and while other adjustments which may be required are implemented. Therefore, until January 1, 1976, where exposures are not in excess of a 25 ppm ceiling, each employer must provide each employee with an appropriate respirator. However, employees whose exposures do not exceed a 25 ppm ceiling, may decline to use the respirator, in which case the employer is not obligated to require its use. During this adjustment period, employees will be trained in the uses, purposes and limitations of respirators, and the hazards of exposure to vinyl chloride. Moreover, each employee will be notified in writing if he has been exposed in excess of the permissible exposure limit.

Where exposures exceed a 25 ppm ceiling, respiratory protection is mandatory in light of our judgment that much greater risks are associated with such exposures.

The provisions in the final standard regarding the selection and use of respiratory protective devices differ from those in the proposal. The descriptions of atmosphere-supplying respirators have been revised to indicate more clearly the types of devices intended, and the maximum permissible concentration level for each device. Moreover, the number of types of atmosphere-supplying devices has been increased.

At the hearing Mr. Edwin C. Hyatt, an OSHA consultant, made suggestions regarding the use of particular respiratory devices. We have concluded that his suggestions are meritorious. Therefore, the provisions for selection of atmosphere-supplying devices follow closely the recommendations contained in his testimony of SPI and B. F. Goodrich) (TR with Hyatt's suggestions. (See e.g. testimony of SPI and B. F. Goodrich) (TR 85 ff) We had originally omitted air-purifying respirators because none had been approved by NIOSH for use against VC, principally because they lacked indicators to signal the expiration of the service life of the sorbent. Hyatt and other witnesses discussed in detail the desirability of being able to use canisters or cartridge air-purifying respirators, provided a sorbent could be shown to effectively absorb vinyl chloride with an adequate service life. Recently, OSHA has received respiratory data from laboratories regarding the effectiveness of commercially available canisters and cartridges for vinyl chloride. These evaluations were conducted separately by NIOSH and by the B. F. Goodrich Company and submitted to OSHA in post-hearing comments. The results indicate that certain presently available canisters and cartridges effectively absorb vinyl chloride at relatively low concentrations. In discussions of these findings with NIOSH, it has indicated that it is willing to consider on an expedited basis the approval of air-purifying respirators for use against VC. Consequently, we have included three types of air-purifying respirators in the list of acceptable units, subject to the approval of such units by NIOSH. The maximum concentration for which each respirator may be used is based upon our evaluation of the data submitted by NIOSH and Goodrich. Because air-purifying respirators do not indicate sorbent exhaustion or breakthrough of VC, and because VC has no inherent warning properties at levels for which these devices are used, strict administrative controls will be required for their use. Such controls include a program to assure timely replacement of canisters or cartridges and an alarm system to alert employees when vinyl chloride concentrations exceed the concentrations allowed for the particular type of respirator in use.

(8) *Hazardous operations.* This is a new section within the final standard. It encompasses essentially the proposal's requirements for maintenance and decontamination but has restated them in terms of performance language to allow greater flexibility for employers to deal with such operations. The intent of the new section is to protect employees engaged in activities that present a risk of exposure to vinyl chloride in excess of the permissible levels. An example would be the cleaning of a filter where resin containing high residual monomer is trapped.

The proposal's requirement for full-body, impervious clothing has been replaced by the direction to use impervious garments suited to the particular situation and probable extent of exposure. Thus, full-body clothing is not always necessary, and is therefore not required where less protection is adequate. Since vessel entry falls within the definition of a hazardous operation, the vessel entry section of the proposal has been deleted from the final standard.

(9) *Emergency situations.* The definition of emergency has been recast in terms of an unexpected massive release. The main objection to the section on emergency situations in the proposal was that, as the term was defined, many ordinary leaks or operations resulting in a small release of vinyl chloride would be considered emergencies. This was not the intent of the proposal. The final standard has been clarified to correct this ambiguity. It should be noted that the written operational plan required by the standard need not be developed for minor excursions above the permissible exposure limit, and that such excursions need not be reported.

(10) *Signs and labels.* The thrust of the signs and labels section is to apprise employees of the cancer and fire hazards. No objections have been raised with respect to informing employees of the fire hazard. However, a number of objections were raised at the hearing and in written submissions to the requirement that the word "cancer" appear on all signs and labels. The principal argu-

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ment advanced against its use was that the term "cancer" or "cancer-suspect agent" scares employees and that instead, the message should contain instructions on how to deal with the substance (TR. 347). We believe that a diluted form of warning will not suffice. We appreciate the concern of employers with the reaction of their employees. But we consider it imperative that a worker be fully informed, and that he realize the possible risks involved in his occupation. Coupled with the training requirement in the standard, we believe that the signs and labels required will adequately inform employees of the hazard. In addition, such signs will warn unauthorized personnel to keep out of regulated areas.

The proper application of most protective measures requires an amount of training and indoctrination of employees that cannot easily be conveyed on a sign or label. Also, the variety of measures that could be prescribed would result in an unwieldly or excessively detailed legend. Consequently, the required message on signs and labels will not include information on precautions, relevant symptoms, etc. The addition of suitable information by the employer would be permitted, providing it does not detract in any way from the required statement.

The requirement in the proposal for labeling containers of vinyl chloride has been amended by deleting the reference to the possible hazard of violent polymerization. Very little information was developed on this hazard during the standard-setting procedure. It does appear that this hazard is essentially under control and that the fire and carcinogenic hazards at present are the most significant. Since labeling or placarding that is in compliance with the U.S. Department of Transportation regulations (*49 CFR* Part 173, Subpart H) already warns of the fire hazard, only a statement concerning the carcinogenic hazard need be added to the Department of Transportation labels.

(11) *Medical surveillance.* The principal questions that have been raised regarding medical surveillance are the necessity and efficacy of requiring certain specific serum enzyme determinations (SMA–12 series) and the application of medical examination requirements to the fabrication segments of the industry where employees are exposed to lower levels of VC. The objection has also been raised that the specification of tests and procedures interferes with the application of advances in medical knowledge.

A particular difficulty in considering medical surveillance is that the most commonly discussed lesion, angiosarcoma of the liver, currently cannot be diagnosed until the victim is terminal and, usually, within months of death. Precursor physiologic alterations, which might be reversible, have not yet been directly associated with the lesion. Consequently, there are no specific diagnostic tests which can be prescribed which will determine presence or absence of this tumor at an early stage of development. However, most medical witnesses indicated that the medical tests proposed are currently the only ones available which are useful for medical surveillance (TR 121, Exh. 95, TR 589–591). Consequently, the specific blood tests proposed have been retained as a minimum requirement to assist the examining physician in determining fitness of potential employees for assignment to workplaces involving VC exposure. In addition, alternative medical examinations may be used where the examining physician determines that they are at least as good as those specified by the standard.

The Tabershaw-Cooper study and the various animal experiments suggest that VC may produce a wide spectrum of malignant and non-malignant disorders. The general scope of the required medical examination has, therefore, been broadened to include kidneys, skin, connective tissue, spleen, and pulmonary system, as well as the liver. No additional specific procedures or tests are required, but recommendations have been included in the Appendix to assist the examining physician. Because of the nonspecific nature of the required medical tests, it is not appropriate to prescribe timing, or type of followup tests, or to mandate withdrawal from exposure based solely on results of the tests. Instead, the employer is required to obtain a statement from the examining physician of the employee's suitability for continued exposure, when the examining physician has completed such tests as he considers appropriate. The employer is required to withdraw an employee only when this statement indicates that the employee may be at added risk from continued VC exposure.

As with monitoring, there appears to be no basis for complete exemption of the fabrication industry from the requirement for medical examination. The record does show fabricating establishments with concentrations of VC monitored considerably above the action level. In these instances, medical surveillance of affected employees will provide baseline data for future evaluation of their health, even if both monitoring and medical surveillance are discontinued because improved controls reduce concentrations below the action level. Where exposures are below the action level, the medical surveillance requirements do not generally apply.

(12) *Training.* A separate provision for employee training has been added to the final standard rather than including it within the section on emergency situations as in the proposal. The new paragraph provides for training of employees concerning the carcinogenic hazard of VC, emergency procedures, the need for monitoring and an annual review of the standard. It also provides for training of employees concerning the purpose for, proper use of, and limitations connected with respiratory protection.

(13) *Records and reports.* The provisions for recordkeeping contained in the final standard require the preparation and maintenance of essentially the same information required by the proposal. The major change from the original proposal is the requirement for maintenance of monitoring records and daily roster sheets of authorized persons for 30 years, instead of 20 years. Additionally, the employer is required to maintain medical records for the duration of an employee's employment plus 20 years, or 30 years, whichever is longer. The original proposal called for only 20 years.

This change has been implemented because the latency period for induction of angiosarcoma ranges up to 30 years from initial exposure. Therefore, as a minimum, medical records must be maintained for at least that long. It should be noted that spokesmen for both labor and industry recommended that this change be made.

The reporting requirements are not significantly different from those in the original proposal. However, instead of the requirement for reporting incidents which result in the release of VC into areas where employees may be exposed, the final standard clarifies our original intent by stating that only emergencies must be reported. Also the requirement for filing a detailed, written report within 15 days has been deleted. It has been concluded that submission, within 24 hours, of an initial report that includes facts immediately available, would ordinarily be sufficient. However, if the OSHA Area Director requests further information relevant to the emergency, the employer will be required to furnish such information.

(14) *Deleted portions of the proposal.* The proposal contained provisions requiring that shower facilities and change rooms be provided, and that storage or consumption of food be prohibited in regulated areas. We have deleted these provisions because it is our conclusion they are no longer necessary. Showering facilities are not required because protective clothing, where required by the final standard, should protect employees from skin absorption by direct contact with VC and because there is no reliable evidence that VC vapor is absorbed through the skin. In addition, since we anticipate that most employees will not be wearing protective clothing and that employees who wear protective clothing will change such clothing infrequently, we are not requiring that change rooms be provided.

In addition, we feel that there is inadequate evidence showing that hazardous amounts of VC can be absorbed through ingestion. For this reason, the requirement prohibiting the storage or consumption of food in regulated areas has been deleted.

The proposal also contained provisions on maintentance and decontamination, transportation loading and unloading, and polymer handling operations. These requirements are not mentioned in the final standard because attention to these items is implicit in the requirement that each employer reach the permissable exposure limit or attain the lowest feasible level.

(15) *Effective date.* In order to ensure that affected employers and employees will be informed of the existence of these

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provisions and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the new requirements, the effective date of the amendment to § 1910.93q will be January 1, 1975. To provide continued protection for employees until that date, the provisions currently contained in § 1910.93q are hereby promulgated, pursuant to section 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act, as an occupational safety and health standard effective October 4, 1974, the amendment to § 1910.93q set out below will supersede these provisions as of January 1, 1975.

Accordingly, upon consideration of the whole record of this proceding, Part 1910 of Title 29, Code of Federal Regulations is amended, effective January 1, 1975, by revision of § 1910.93q to read as follows:

§1910.1017 Vinyl Chloride

(a) *Scope and application.* (1) This section includes requirements for the control of employee exposure to vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75015.

(2) This section applies to the manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to the handling or use of fabricated products made of polyvinyl chloride.

(3) This section applies to the transportation of vinyl chloride or polyvinyl chloride except to the extent that the Department of Transportation may regulate the hazards covered by this section.

(b) *Definitions.* (1) "Action level" means a concentration of vinyl chloride of 0.5 ppm averaged over an 8-hour work day.

(2) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee.

(3) "Authorized person" means any person specifically authorized by the employer whose duties require him to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising an opportunity to observe monitoring and measuring procedures.

(4) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his designee.

(5) "Emergency" means any occurrence such as, but not limited to, equipment failure, or operation of a relief device which is likely to, or does, result in massive release of vinyl chloride.

(6) "Fabricated product" means a product made wholly or partly from polyvinyl chloride, and which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the polyvinyl chloride resulting in the release of vinyl chloride.

(7) "Hazardous operation" means any operation, procedure, or activity where a release of either vinyl chloride liquid or gas might be expected as a consequence of the operation or because of an accident in the operation, which would result in an employee exposure in excess of the permissible exposure limit.

(8) "OSHA Area Director" means the Director for the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic area in which the employer's establishment is located.

(9) "Polyvinyl chloride" means polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product.

(10) "Vinyl chloride" means vinyl chloride monomer.

(c) *Permissible exposure limit.* (1) No employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period, and

(2) No employee may be exposed to vinyl chloride at concentrations greater than 5 ppm averaged over any period not exceeding 15 minutes.

(3) No employee may be exposed to vinyl chloride by direct contact with liquid vinyl chloride.

(d) *Monitoring.* (1) A program of initial monitoring and measurement shall be undertaken in each establishment to determine if there is any employee exposed, without regard to the use of respirators, in excess of the action level.

(2) Where a determination conducted under paragraph (d)(1) of this section shows any employee exposures, without regard to the use of respirators, in excess of the action level, a program for determining exposures for each such employee shall be established. Such a program:

(i) Shall be repeated at least monthly where any employee is exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Shall be repeated not less than quarterly where any employee is exposed, without regard to the use of respirators, in excess of the action level.

(iii) May be discontinued for any employee only when at least two consecutive monitoring determinations, made not less than 5 working days apart, show exposures for that employee at or below the action level.

(3) Whenever there has been a production, process or control change which may result in an increase in the release of vinyl chloride, or the employer has any other reason to suspect that any employee may be exposed in excess of the action level, a determination of employee exposure under paragraph (d)(1) of this section shall be performed.

(4) The method of monitoring and measurement shall have an accuracy (with a confidence level of 95 percent) of not less than plus or minus 50 percent from 0.25 through 0.5 ppm, plus or minus 35 percent from over 0.5 ppm through 1.0 ppm, and plus or minus 25 percent over 1.0 ppm. (Methods meeting these accuracy requirements are available in the "NIOSH Manual of Analytical Methods").

(5) Employees or their designated representatives shall be afforded reasonable opportunity to observe the monitoring and measuring required by this paragraph.

(e) *Regulated area.* (1) A regulated area shall be established where:

(i) Vinyl chloride or polyvinyl chloride is manufactured, reacted, repackaged, stored, handled or used; and

(ii) Vinyl chloride concentrations are in excess of the permissible exposure limit.

(2) Access to regulated areas shall be limited to authorized persons. A daily roster shall be made of authorized persons who enter.

(f) *Methods of compliance.* Employee exposures to vinyl chloride shall be controlled to at or below the permissible exposure limit provided in paragraph (c) of this section by engineering, work practice, and personal protective controls as follows:

(1) Feasible engineering and work practice controls shall immediately be used to reduce exposures to at or below the permissible exposure limit.

(2) Wherever feasible engineering and work practice controls which can be instituted immediately are not sufficient to reduce exposures to at or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by respiratory protection in accordance with paragraph (g) of this section. A program shall be established and implemented to reduce exposures to at or below the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering and work practice controls, as soon as feasible.

(3) Written plans for such a program shall be developed and furnished upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director. Such plans shall be updated at least every six months.

(g) *Respiratory protection.* Where respiratory protection is required under this section:

(1) The employer shall provide a respirator which meets the requirements of this paragraph and shall assure that the employee uses such respirator, except that until December 31, 1975, wearing of respirators shall be at the discretion of each employee for exposures not in excess of 25 ppm, measured over any 15-minute period. Until December 31, 1975, each employee who chooses not to wear an appropriate respirator shall be informed at least quarterly of the hazards of vinyl chloride and the purpose, proper use, and limitations of respiratory devices.

(2) Respirators shall be selected from among those jointly approved by the Mining Enforcement and Safety Administration, Department of the Interior, and the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) A respiratory protection program meeting the requirements of § 1910.134 shall be established and maintained.

(4) Selection of respirators for vinyl chloride shall be as follows:

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