

NATURE OF THE HEALTH HAZARD FROM CHRONIC
EXPOSURE TO VINYL CHLORIDE INCLUDING
SPECIFICALLY THE CARCINOGENIC HAZARD

This part of your training is intended to cover the Nature of the Health Hazard from Chronic Exposure to Vinyl Chloride Including Specifically the Carcinogenic Hazard. Since those of us who are handling the training program are not medical men, this part will be read to you. To be sure it is adequately covered, part of what I will read was abstracted from the preamble to the OSHA standard.

Vinyl chloride has been used in making PVC Resin for approximately forty years. Until recently it was thought to have no long lasting effect on the health of those exposed. Its anesthetic properties were well known, and in the work place there were two main concerns. One was anesthetization or asphyziation. At concentrations in the range of 25,000 PPM dizziness occurs and with continued exposure above that concentration the exposed person may lose consciousness. There was always the danger to consider that a lone individual trying to control a serious leak might be overcome by the vapor and if not found, lose his life. The second concern was the danger of fire or explosion if an ignition source occurred coincident with a concentration of VCM vapor in the explosive range of approximately 4% to 27%. Plant design and safe operating procedures were planned around those two dangers.

More recently the danger of contracting angiosarcoma of the liver from long exposure to VCM has been discovered and this is the primary reason for OSHA VCM Standard 1910.93q about which you have heard so much lately. This is the reason for the use of respiratory equipment, the plant modifications taking place and planned, the medical surveillance program, and it is the subject of this current training program.

The training program as outlined by OSHA requires that the carcinogenic hazard of chronic exposure to VCM be explained to each employee. Actually this is inherent in our entire compliance program. You have heard why the respirators are required and will hear this again. However, to carefully comply with this requirement on the part of OSHA, I will read to you this abstract of part of the preamble of the standard titled Findings Regarding Carcinogenicity, Exposure Levels and Feasibility. Some additional explanatory comments have been inserted for clarity where a statement would not have meaning or might be misleading without reference to the rest of the document. (Bracketed sections are the additional comments.)

A. 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 studies of Maltoni and Bio-Test Laboratories. [Maltoni as you may already know is an Italian investigator who has been testing the effects of VCM on animals for several years.] Moreover, Maltoni's investigations have demonstrated a dose-dependent relationship for induction of tumors ([that is,] 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 in excess of control animals.

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 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 significant number in view of the rarity of this cancer in the U.S. adult male population (testimony of Dr. Marcus Key, Director of NIOSH, at the rulemaking hearing). [A number of additional cases were discovered since this report was made. My best information is that as of April 1, 1975, cases have been discovered in this country. This investigation covered physical examinations of current workers, examinations of autopsy records and slides of deceased individuals who at one time worked with vinyl chloride and health histories of current and past workers.]

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.

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 sub-

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2. Exposure limits (continued). stances cannot be scientifically determined.

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 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. W [OSHA], 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. [This statement by OSHA was made in September, 1974. The continued investigation has discovered the additional cases mentioned earlier. Whether more will be discovered and how many is, of course, not known at this time.] 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 long 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 necessary synchronous events. Because of 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. [The current level referred to in this case was the 50 PPM limit recommended by industry.]

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2. Exposure limits (continued).

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 (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 workplace 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.

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 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.

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I have just read parts of the explanation of the carcinogenic hazard from the OSHA standard. If you have any questions I will try to answer them if I can. However, as I said, I have no medical background so if I can't answer your questions, I will make a note of them and get answers for you if answers are available.

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