DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-225D]

Occupational Exposure to Formaldehyde

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Response to Court remand; final rule.

SUMMARY: By this action, the Occupational Safety and Health Administration (OSHA) hereby amends its existing regulation for occupational exposure to formaldehyde, 29 CFR 1910.1048, in response primarily to a remand by the U.S. Court of Appeals for the D.C. Circuit in *UAW* v. *Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989). The final amendments lower the permissible exposure level for formaldehyde from 1 ppm (part per million) as an 8-hour time-weighted average (TWA) to an 8-hour time-weighted average of 0.75 ppm. The amendments also add medical removal protection provisions to supplement the existing medical surveillance requirements for those employees suffering significant eye, nose or throat irritation and for those suffering from dermal irritation or sensitization from occupational exposure to formaldehyde. In addition, certain changes have been made to the standard's hazard communication and employee training requirements. These amendments establish specific hazard labeling requirements for all forms of formaldehyde, including mixtures and solutions composed of 0.1% or greater of formaldehyde in excess of 0.1 ppm. Additional hazard labeling, including a warning that formaldehyde presents a potential cancer hazard, is required where formaldehyde levels, under reasonably foreseeable conditions of use, may potentially exceed 0.5 ppm. The final amendments also provide for annual training of all employees exposed to formaldehyde at levels of 0.1 ppm or higher.

DATES: *Effective date:* This amendment shall take effect on June 26, 1992. Certain provisions of the amended standard have delayed start-up dates which are detailed in paragraph (p) of § 1910.1048.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, room N-3647, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 523-8151.

SUPPLEMENTARY INFORMATION:

Background and History of the Regulation

On December 4, 1987, after an extensive rulemaking proceeding, detailed in the preamble to the final rule (52 FR at 46169-46171), OSHA issued a comprehensive regulation covering occupational exposure to formaldehyde at 29 CFR 1910.1048. This rule reduced the permissible exposure limits (PELs) to 1 part formaldehyde per million parts of air (ppm) as an 8-hour time-weighted average (TWA), and established a 2 ppm 15-minute short term exposure limit (STEL). The comprehensive standard also included an "action level" of 0.5 ppm, measured as an 8-hour TWA, and provisions for employee exposure monitoring, medical surveillance, recordkeeping, regulated areas, emergency procedures, preferred methods to control exposure, maintenance and selection of personal protective equipment, and hazard communication. OSHA's rule was based on the consideration of a wide range of new evidence including animal bioassays and epidemiological evidence. It was based in part on OSHA's recognition of formaldehyde as a potential occupational carcinogen as well as its irritating and sensitizing effects.

The standard was challenged in the United States Court of Appeals for the District of Columbia Circuit, pursuant to section 6(f) of the Act, 29 U.S.C. 655(f), by both industry and labor. Four unions, the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), the Amalgamated Clothing and Textile Workers Union (ACTWU), the International Ladies' Garment Workers Union (ILGWU) and the International Molders and Allied Workers Union, and Public Citizen, a public interest group, challenged the standard as being insufficiently protective. They contended that the PEL was not set low enough to eliminate all significant risk of harm from both cancer and from formaldehyde's irritant effects. They also objected to OSHA's decision not to include a medical removal protection (MRP) provision in the standard, and to a number of other aspects of the standard, including the setting of the action level, the lack of a requirement for annual medical examinations, and the provisions regarding labeling and training.

The Formaldehyde Institute (FI), on the other hand, sought review of the hazard communication provisions in paragraph (m) of the standard. While challenging these provisions in court, the FI, along with others, petitioned OSHA for an administrative stay of the hazard communication provisions and reconsideration of these provisions. On December 13, 1988, after giving the public an opportunity to comment on this petition, OSHA stayed the hazard communication provisions, paragraphs (m)(1)(i) through (m)(4)(ii), and announced its intention to consider further regulatory action on these provisions (53 FR 50198). The effect of the stay was to continue the implementation of OSHA's generic Hazard Communication Standard (29 CFR 1910.1200) in effect with respect of formaldehyde. The administrative stay was subsequently continued to allow the Agency more time to resolve the issue (54 FR 35639, 8/29/89; 55 FR 24070, 6/13/90; 55 FR 32616, 8/10/90; 55 FR 51698, 12/17/90; 56 FR 10377, 3/12/91; 56 FR 26909, 6/12/91;56 FR 37651, 8/8/91); 56 FR 57593, 11/13/91; 57 FR 2681, 1/23/92).

The Court of Appeals affirmed the final standard in most respects but concluded that OSHA had failed adequately to explain its cancer risk estimates and why it had not included medical removal protection (MRP) provisions in the standard. *UAW* v. *Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989). The Court's decision required OSHA to better explain or reevaluate the risk assessment that led it to choose a PEL of 1 ppm. According to the Court, should OSHA conclude that a significant risk remains at 1 ppm, the Agency could then adjust the standard accordingly. The Court's decision also required OSHA to better explain or reevaluate its decision not to include an MRP provision in the standard.

The Court did not review the hazard communication provisions of the standard because they had been administratively stayed for reconsideration at the time. Because all of the provisions of the standard are interconnected, OSHA determined that the hazard communication provisions should be reconsidered together with the remand issues.

The Parties' Recommendation

Following the remand, parties to the litigation developed recommendations for revisions to the standard that they believed represented a reasonable resolution of all outstanding issues. Their recommendation, presented to OSHA on June 27, 1990, proposed to (1) lower the PEL to 0.75 ppm TWA; (2) include in the standard certain

provisions for MRP benefits; and (3) modify the standard's hazard communication provisions by revising labeling requirements for materials capable of releasing small amounts of formaldehyde and providing annual training in formaldehyde hazards for all employees exposed at or above 0.1 ppm (Ex. 278).

OSHA gave these recommendations careful consideration in developing the proposed amendments. On July 15, 1991, the Agency issued a proposed rule in response to the Court's remand (56 FR 32302). The proposal incorporated the substance of the recommendations of the parties to the litigation and requested public comment.

Properties, Manufacture, and Uses of Formaldehyde

The chemical "formaldehyde" is a colorless, pungent gas at room temperature with an approximate odor threshold of about 1 ppm [Ex. 73–120]. While the term "formaldehyde" is also used to describe various mixtures of formaldehyde, water, and alcohol, the term "formalin" more precisely describes aqueous solutions, particularly those containing 37 to 50 percent formaldehyde and 6 to 15 percent alcohol stabilizer. Most formaldehyde enters commerce as formalin. Alcoholic solutions of formaldehyde are available for processes that require low water content [Ex. 73–53]. Paraformaldehyde, a solid, also serves as a source of formaldehyde gas. Formaldehyde gas *per se* is not available commercially. The Chemical Abstracts Service (CAS) has assigned the number "50–00–0" to formaldehyde. This number applies to both formaldehyde gas and its aqueous or alcohol stabilized solutions.

Formaldehyde is a major industrial chemical, ranked 24th in production volume in the United States [Ex. 138–F]. In 1985, 5.7 billion pounds of 37 percent formaldehyde (by weight) was produced. Formaldehyde has four basic uses: As an intermediate in the production of resins; as an intermediate in the production of industrial chemicals; as a bactericide or fungicide; and as a component in the formulation of end-use consumer items. The manufacture of three types of resins: urea-formaldehyde, phenolformaldehyde, and melamine formaldehyde, accounts for about 59 percent of total consumption [Exs. 70–2; 73–52]. An additional seven percent is consumed in the production of thermoplastic acetal resins [Ex. 8]. About one-third is used in the synthesis of high volume chemical derivatives, including pentaerythritol, hexamethylenetetramine, and butanediol [Ex. 8]. Two percent is used in textile treating and small amounts of formaldehyde are present as preservatives or bactericides in consumer and industrial products, such as cosmetics, shampoos and glues.

Some products prepared from formaldehyde contain unreacted formaldehyde residues which may be released from the product over its useful life. One example is urea-formaldehyde resin. Urea-formaldehyde resin is a generic name that actually represents an entire class of related formulations. Over 60 percent of ureaformaldehyde resin production in 1977 was consumed by particleboard and plywood manufacturing, where the resin is used as a glue. Urea-formaldehyde resins are also used in decorative laminates, textiles, paper, and foundry sand molds [Ex. 73–53].

Formaldehyde resins are used to treat textiles to impart wrinkle-resistance to clothing. About 60-85 percent of all apparel fabric is finished with formaldehyde-containing resins. As apparel manufacture is the sixth largest industry sector in the United States [Exs. 70–2; 70–14], this use is the major source of widespread exposure to formaldehyde because of the large number of workers potentially exposed.

Formaldehyde destroys bacteria, fungi, molds, and yeast. Its commercial importance as a fungicide is probably its greatest use as a disinfectant [Ex. 70–2]. Because of its bactericidal properties, formaldehyde is used in numerous cosmetic preparations.

Formaldehyde's uses can lead to widespread exposure in downstream industries. For example, when formaldehyde is present in disinfectants, preservatives, and embalming fluid, worker exposure can occur. Although formaldehyde changes into other chemicals when urea-formaldehyde resins and concentrates are produced, decay may occur, causing workers in numerous industries including wood products and apparel manufacture to be exposed to airborne formaldehyde when it offgasses from products manufactured with these resins.

Summary and Explanation of the Final Amendments

The final amendments to the formaldehyde standard in response to the Court remand and related issues are generally unchanged from OSHA's proposal published July 15, 1991, with only a few exceptions. As explained below, the most significant change is in the hazard communication provisions, paragraph (m).

A total of 34 comments were received. Most comments supported the amendments as proposed.

This preamble describes the specific points raised by commenters and the resolution of the issues involved.

Paragraph (c)—Permissible Exposure Limit (PEL)

This amendment to the final rule reduces the permissible exposure limit to 0.75 parts formaldehyde per million parts of air as an 8-hour time weighted average (0.75 ppm TWA). The basis for this change is the reexamination of the formaldehyde risk assessment that was undertaken in response to the Court remand. In its risk assessment accompanying the promulgation of the standard in 1987, OSHA calculated both the maximum likelihood estimate (MLE) and the upper confidence limit (UCL) for several mathematical models that it concluded best represented the carcinogenic action of formaldehyde. The MLE calculations, which statistically represent the most likely estimate of the risk, indicated that no significant risk remained at the PEL of 1 ppm. However, the UCL figures, which have only a 5% probability of understating the risk, indicated that a significant risk remained at 1 ppm.

OSHA did not accept either the MLE or the UCL as the single best prediction of risk for formaldehyde, but concluded that they defined a range in which the degree of risk was highly uncertain and effectively indeterminable based on the present state of scientific evidence. Since it was uncertain whether a significant risk remained below 1 ppm, OSHA included ancillary provisions in the standard with the expectation that they would further reduce any residual risk that remained at a PEL of 1 ppm (see discussion at 52 FR 46223–46224).

As instructed by the Court, the Agency reconsidered the record evidence applicable to its original finding that a 1 ppm PEL and ancillary provisions would prevent a significant risk of cancer in workers who are exposed to formaldehyde. OSHA continues to believe that neither the UCL nor the MLE can be used to establish a precise estimate of the remaining risk, but rather believes that they define a continuum within which the risk falls. In choosing where in the continuum to establish the PEL, OSHA reevaluated its conclusion that the ancillary provisions promulgated on December 4, 1987 would reduce the residual risk that remained at a PEL of 1 ppm. The court criticized OSHA's reliance on the ancillary provisions to reduce risk because OSHA could not

quantify the extent of exposure reduction, and hence risk reduction, these provisions would produce. 878 F.2d at 396. Although OSHA is convinced that the ancillary provisions contribute to risk reduction (52 FR 46253, 46275, 46285, 46287), the Agency is still unable to quantify that reduction. OSHA therefore believes it cannot rely on the ancillary provisions to reduce risk and that it is appropriate to reduce the PEL further in order to increase the certainty that workers are adequately protected. The Agency has determined that the PEL should be reduced to 0.75 ppm TWA, a point within the continuum defined by the MLE and UCL risk estimates. This PEL represents OSHA's best judgment of the exposure limit, along with the ancillary provisions, necessary to eliminate a significant risk of harm to employees.

Of the commenters who responded to the proposed amendments, only six addressed this issue specifically. Of these comments, five (Ex. 304–3, 304–14, 304–15, 304–24, and 304–27) ranged from expressing positive or conditional support to providing recommendations that would, in the commenters' estimation, strengthen the evidence for adopting the 0.75 ppm level.

The comment submitted by the Society of the Plastics Industry (Ex. 304–3) expressed unconditional support for the lower PEL. However, the National Electrical Manufacturers Association (Ex. 304–14), while supporting the lower PEL, cautioned against further reduction. Similarly, Monsanto (Ex. 304–15) supported the proposed PEL.

While not disagreeing with a PEL of 0.75 ppm, Du Pont (Ex. 304–24) suggested that OSHA supplement the cancer incidence information by incorporating risk data compiled by Casanova and Heck, and published by the Chemical Industry Institute of Toxicology (CIIT), which utilized pharmacokinetic modeling. OSHA considered these types of studies in preparing the risk assessment for the 1987 final standard for formaldehyde. The Agency's reasons for not including these types of studies are discussed in the preamble to the 1987 final standard (52 FR 46225) and remain the same. Moreover, since Du Pont does not claim that these data would justify a different PEL than 0.75 ppm, OSHA does not believe it is necessary or appropriate to reopen the rulemaking record at this stage of the proceedings to include them.

In a related comment, Duke Power (Ex. 304–24) suggested that factors other than carcinogenicity, e.g. irritant properties, should be used to justify the reduction of the PEL. OSHA agrees that irritant effects are involved and that lowering the PEL will reduce incidences of these effects. Reducing the PEL below 1 ppm will reduce the residual irritant risk that remains at 1 ppm.

Only one comment, submitted by an individual worker, (Ex. 304–1) opposed the proposed action to lower the PEL, but offered no substantive information to support its opposition.

OSHA believes that the comments support the reduction in the PEL effected by this amendment. OSHA further concludes that this reduction in the PEL is economically and technologically feasible. See the discussion under Regulatory Impact and Regulatory Flexibility Assessment later in this preamble.

Paragraph (d)—Exposure Monitoring

Exposure monitoring informs the employer of the levels of formaldehyde to which employees are exposed. Such information is essential to determining whether the employer meets the obligation to keep employee exposures below the PEL and STEL and the obligations imposed by the standard when exposures exceed the action level. It permits the employer to evaluate the effectiveness of engineering and work practice controls, and identifies the need for additional controls. Exposure monitoring data are part of the information that must be supplied to the physician under the standard's medical surveillance provisions.

The monitoring provisions of the formaldehyde standard contain many of the same elements as the monitoring requirements in other OSHA health standards, including provisions for initial and periodic monitoring; the use of objective data in lieu of initial monitoring; use of representative sampling strategies; termination of monitoring; precision and accuracy of monitoring methods; and employee observation of monitoring and notification of the results. The final amendments do not affect these major components, which are described more fully in the preamble to the final standard (52 FR at 46254–46261). The general requirement that the employer monitor employees to determine their exposure to formaldehyde is unchanged, as is the exemption which allows the employer to utilize objective data to determine that measurements are not required for employees exposed below the action level or STEL.

A technical amendment was proposed for the monitoring provisions of the formaldehyde standard which is implemented in the final amendments. Specifically, paragraph (d)(1)(ii)(A), which contained an exception to the general exposure monitoring requirement, is deleted, since it related to the definition of formaldehyde health hazard which had been included in paragraph (m)(1)(i) but which is also being deleted in this final rule. The intent of this section, however, is not changed.

The other exception in paragraph (d)(1)(ii)(A) which made reference to the need to monitor if there are employee health complaints, i.e., reports of signs and symptoms of formaldehyde exposures, has been removed from paragraph (d)(1)(ii)(A) and added as a new paragraph (d)(2)(iii). This has the effect of stating the requirement positively rather than indirectly as was originally done in paragraph (d)(1)(ii)(A). It is felt that this change clarifies the employer's obligation.

The new paragraph requires employee monitoring if there are reports of signs or symptoms due to formaldehyde exposure, and additionally specifies that monitoring of employees reporting signs of symptoms be done promptly. While the time period represented by "promptly" is not specified in order to provide employers some flexibility, OSHA intends that no more than a few days elapse between the report and the exposure monitoring, unless there are extenuating circumstances.

Duke Power (Ex. 304–24) suggested that "a few days" may not allow sufficient time for some employers to conduct monitoring, particularly those who would need to hire outside consultants to conduct the monitoring. OSHA believes that in the event this situation arises it would constitute extenuating circumstances and would be permissible, provided the employer can prove his or her diligence in attempting to meet the requirement.

Under existing paragraph (d)(1)(ii)(B), which is not being changed, objective data may be used to determine that the employee's exposure cannot exceed the action level or STEL. However, the data used must accurately reflect the affected employee's exposure (see discussion of objective data below.).

A related comment submitted by Owens Corning Fiberglas (Ex. L304–31) pointed out that sampling methods were not specified relative to determining if concentrations exceed levels which would require labeling and training. Neither the proposal nor the final amendments require sampling in such cases but allow the use of objective data which would indicate the potential formaldehyde release under reasonably foreseeable conditions of use. Thus, the standard does not actually pose the difficulty which is perceived by this commenter.

Paragraph (g)—Respiratory Protection

Issues related to respiratory protection were not part of the proposed amendments. However, two comments were submitted that were a logical outgrowth of the proposal to reduce the PEL. Wilson Safety Products (Ex. 304–12) pointed out that Table 1 of the 1987 standard (52 FR 46293), "Minimum Requirements for Respiratory Protection Against Formaldehyde," should be corrected to reflect the change in the PEL from 1 ppm to 0.75 ppm. OSHA agrees and has accordingly reproduced the table with the necessary corrections in paragraph (g). Footnote "2" regarding the use of half-mask respirators is retained. In addition, a technical correction has been made to paragraph (g)(3)(iv) to reflect the change in the PEL. This paragraph addresses the required frequency of replacement for canisters in atmospheres up to 10 times the PEL and 100 times the PEL, respectively. The allowable concentrations are changed from 10 ppm to 7.5 ppm and from 100 ppm to 75 ppm to reflect the 0.75 permissible exposure limit.

ISEA (Ex. 304–21) observed that the proposed amendments did not discuss the relative merits of engineering controls and respirators to protect against airborne formaldehyde. ISEA suggested that before OSHA prescribes engineering controls in lieu of respirators as the primary means of complying with the new PEL for formaldehyde, it should complete its ongoing rulemaking on Methods of Compliance. (See 54 FR 23991, 6/5/89.)

The methods of compliance section of the formaldehyde standard was not challenged before the D.C. Circuit and OSHA did not propose to reconsider it when it proposed the amendments now under consideration. The formaldehyde record was reopened only to resolve the remand issues and the outstanding issues related to the hazard communication provisions. Moreover, the Methods of Compliance rulemaking proposed to amend only the Air Contaminants standard (29 CFR 1910.1000) and the Respiratory Protection standard (29 CFR 1910.134). Since that rulemaking does not propose to amend substance-specific standards such as the formaldehyde standard, it provides no basis to defer action on these proposed amendments.

Paragraph (l)—Medical Surveillance

(8)—Medical Removal

The final formaldehyde standard promulgated on December 4, 1987 did not include medical removal protection (MRP) provisions. In response to the Court remand on this issue, OSHA has reexamined its reasoning, and carefully reviewed the record. On reconsideration, the Agency has concluded that MRP provisions can contribute to the success of the medical surveillance programs prescribed in the formaldehyde standard. Unlike some other substance-specific standards, the formaldehyde standard does not provide for periodic medical examinations for employees exposed at or above the action level. Instead, medical surveillance is accomplished in the final rule through the completion of annual medical questionnaires, coupled with affected employees' reports of signs and symptoms and medical examinations where necessary. This alternative depends on a high degree of employee participation and cooperation to determine if employee health is being impaired by formaldehyde exposure. OSHA believes these new MRP provisions will encourage employee participation in the standard's medical surveillance program and avoid the problems associated with nonspecificity and quick resolution of signs and symptoms that originally concerned the agency (see 52 FR 46282).

The final amendments specify those conditions covered by MRP. Conditions which are potentially covered by MRP are limited to significant irritation of the mucosa of the eyes and of the upper airway, respiratory sensitization, dermal irritation, or dermal sensitization (Ex. 42–87, p.175). In the case of dermal irritation and dermal sensitization, and these conditions alone, the medical removal provisions do not apply when the percent of formaldehyde content in the product suspected of causing the dermal condition is below 0.05%. This is because, on the basis of evidence in the record, only those products with higher concentrations have clearly been associated with dermal irritation or dermal sensitization (Ex. 85–56, p.5).

The existing formaldehyde standard requires that employers institute medical surveillance programs for employees exposed to formaldehyde. The purpose of such programs is to indentify employees adversely affected by formaldehyde exposure, even if the exposure is below the PEL. In this way, the employee can be treated if necessary, potential causes can be identified, and remedial measures taken.

The medical surveillance program, and all procedures conducted under it, must be supervised by a licensed physician, and provided at no cost to employees. The program consists of screening formaldehyde-exposed employees, with follow-up medical examinations in those instances when the physician feels it necessary. As a minimum, the screening consist of the administration of a questionnaire, which must include a work history, a smoking history, and elicit information on a variety of medical conditions associated with formaldehyde exposure. These conditions include eye, nose, or throat irritation, chronic airway problems or hyperactive airway disease, allergic skin conditions or dermatitis, and upper and lower respiratory problems.

All employees exposed to formaldehyde at or above the action level or STEL must be screened annually, by means of a medical questionnaire. In addition, employees exposed to formaldehyde must be screened with the questionnaire if they develop signs or symptoms of possible formaldehyde-related illness. If the responsible physician, upon evaluating the questionnaire, determines that a medical examination is necessary, the employee must be examined, and given any tests which the physician feels are appropriate.

When the physician has determined that a medical examination is necessary, it must be conducted promptly (as soon as possible, but within a few days at most) and the employer shall promptly comply with any subsequent recommendations for removal or restriction. If an employee reports signs or symptoms, and the physician determines that a medical examination is not immediately necessary, a two-week observation period begins. The purpose of this two-week observation period begins. The purpose of this two-week period is to provide an opportunity for evaluation of the problem and for possible remediation of the condition or causative factors. This provision is supported by information in the record that many formaldehyde-induced signs and symptoms often resolve themselves within a few hours or days (52 FR 46282). It will permit the employer to see whether signs or symptoms subside spontaneously or with minimal treatment, or to improve working conditions to alleviate the exposure, and the resulting condition, without unnecessary expenditure. If the signs or symptoms have not subsided or been remedied by the end of the two week period, the employee must be examined by the physician. If the signs and symptoms worsen during the two week period, the employee must be examined by the physician as soon as this fact is determined.

Any examination conducted in response to an employee report of signs or symptoms must include a medical and work history and any other element, including tests, which the examining

physician deems necessary. The standard does not specify any particular tests. This is due to the variety of conditions associated with formaldehyde exposure which are covered by these provisions. Accordingly, the physician is given broad discretion in selecting any tests appropriate and useful under the circumstances.

If, in the examining physician's professional judgment, restrictions or removal are needed to alleviate the employee's symptoms of formaldehyde exposure, the physician's recommendations must be followed as soon as possible (a day or two at most). In the case of removal, transfer alternatives must be considered first. The employee must be moved to a job location with significantly less formaldehyde exposure (about twenty-five percent or greater reduction), which cannot exceed the action level. Transfer alternatives include possible job transfers that could be accomplished if the employee were to receive training for a short period of time. OSHA views a short period of time in this context as any period up to 6 months, the maximum period that MRP is available to employees under any circumstance. While the provisions require transfer, if possible, the type of training to be provided by the employer is not specified. OSHA does not intend that special job training programs be established. Job training opportunities such as the employer has afforded employees in the past should be sufficient to meet this requirement.

If there are no transfer alternatives, the employee must still be removed from the formaldehyde exposure for a period of up to six months or until a physician determines either that the employee is able to return to work or that the employee will not ever be able to return to work.

In addition to effecting actual physical removal, MRP assures that employees are provided with temporary economic protection. When an employee is removed from formaldehyde exposure, through transfer or other means, the employer must maintain the employee's earnings, seniority and benefits. This includes overtime, bonuses, increases and production rate payments the employee would normally receive. This must be continued until the employee is determined to be able to return to the original job, or is determined to be unable to return to any workplace formaldehyde exposure, or for six months, whichever occurs first. If the employee receives any compensation through workers' compensation or other programs, MRP payments can be reduced by that amount. If the employee's removal permits the employee to obtain other employment, the employer's obligation is similarly reduced.

The determination as to whether the employee can return to the original job or is permanently unable to return to formaldehyde exposure is a medical decision, which must be based on a follow-up exam conducted by the employer's chosen physician. When the employee is returned to the original job, any subsequent signs or symptoms that may be reported are subject to another initial evaluation and determination as to whether an exam is necessary. If there is a determination that no exam is immediately necessary, a two-week period for evaluation and remediation is again initiated, and the employer proceeds from that point as described above.

When medical removal protection is part of a standard, OSHA usually provides a multiple physician review mechanism to assure successful operation of such programs. Multiple physician review provides an employee with an opportunity for a second medical opinion in a situation where a worker questions the recommendations resulting from a medical exam or consultation performed by a physician chosen by the employer. By doing so, it assures employee confidence in the soundness of medical determinations which may impact them significantly. As employee confidence is necessary to assure that employees will cooperate with the standard's medical surveillance provisions, multiple physician review is an integral component of the standard. A full discussion of multiple physician review is contained in the preamble to the lead standard (43 FR 52972, 52998) which is applicable here since the multiple physician review mechanism provided by these final amendments is similar to that in the lead standard in all respects.

The initial choice of the examining physician is made by the employer. After any examination or consultation concerning medical removal or restriction is made by the employer's chosen physician, the employee must receive a copy of the physician's written opinion within 15 days from the time the employer receives it. The employer must also inform the employee of the right to seek a second medical opinion if the employee does not agree with the employer's physician's opinion. The employee must act within fifteen days from these notifications, or the employer may decline to participate in, or to pay for, any ensuing medical reviews. Otherwise, the multiple physician review mechanism must be provided by the employer without cost to the employee, including lost work time.

In seeking a second opinion, the employee may choose a physician to conduct appropriate examinations and tests and issue a written opinion concerning the employee's ability to work with formaldehyde. If the two physicians arrive at different conclusions, and quick (a few days at most) resolution is not possible, a third physician, jointly designated by the two physicians or by the employer and employee (or the employee's authorized representative) must be consulted. This third physician must be a specialist in the area of the body affected or the condition in question (e.g., dermatologist, allergist, pulmonary physician) or must be an occupational physician. The recommendation of the third physician shall be promptly (a few days at most) followed, unless the employer and employee agree to follow any one of the three physicians' recommendations.

The MRP provisions are in many respects similar to and consistent with the MRP mechanism of the lead standard, and a more detailed discussion of how the similar provisions work appears in the lead preamble (43 FR at 52972). For example, both MRP programs base removal decisions on the recommendation of a physician (although removal under the lead standard is also required if an employee's blood lead level exceeds a certain value), both programs include wage retention provisions, and both programs include a multiple physician review mechanism. To the extent the provisions of the formaldehyde MRP program are similar to those of the lead MRP program, OSHA adopts the legal justification supporting the lead standard, particularly the goal of encouraging employee participation in medical surveillance, in support of the MRP provisions of the formaldehyde standard. OSHA also intends that the provisions of the formaldehyde MRP program which are similar to those in the lead standard will operate and be enforced in a like manner.

Of course, OSHA recognizes that there are important differences between the lead MRP program and the MRP provisions of this standard. For example, formaldehyde MRP is limited to those employees exhibiting signs or symptoms of specified ailments; the formaldehyde MRP program includes a two-week remediation period for those employees not immediately referred to a

physician and formaldehyde MRP is not automatically triggered by a laboratory result, such as the blood lead measurements, relied upon in the lead standard. On the issues where the provisions of the formaldehyde MRP program are not consistent with those of the lead MRP program, OSHA expects that the lead standard will offer little enforcement guidance.

The Agency received a number of comments in connection with various aspects of the proposed MRP provision. Three commenters, Honeywell, Amoco Corporation, and Duke Power (Exs. 304–2, 304–18 and 304–24, respectively) raised the question as to whether the provision was intended to apply to office environments where employees may potentially be adversely affected by the off-gassing of formaldehyde from building materials and furnishings. OSHA believes that paragraph (a), scope and application, of the final standard indicates the Agency's intent to include all occupational exposures to formaldehyde under the standard, without regard to workplace environment. In particular, the standard's application to materials that release formaldehyde is relevant to offices and similar workplaces where formaldehyde exposures primarily result from off-gassing of building materials and furnishings. OSHA believes that to the extent that an employee in any occupational setting is exposed to formaldehyde at concentrations high enough to induce signs and symptoms of formaldehyde-related illness, that person should be protected by the MRP provisions of this standard. However, since formaldehyde exposures in offices are low, OSHA would expect MRP to affect employees in such environments only in exceptional cases.

MRP is directed toward employees suffering significant irritant effects attributable to formaldehyde exposures who, in the examining physician's judgment, will benefit from restriction or removal from work areas where formaldehyde is present. The MRP provisions are not designed to cover employees who have been determined to be permanently sensitized to formaldehyde. However, while that determination is being made, OSHA would expect that such employees receive MRP benefits. Sensitized employees often can resume work in areas with lower formaldehyde exposure without suffering adverse effects. The provision exempts from coverage dermal conditions (irritation or sensitization) caused by exposure to products containing less than 0.05 percent formaldehyde.

The commenters identified above also recommended that OSHA provide a cut-off level for airborne concentrations of formaldehyde below which the MRP provisions would not apply, e.g. 0.1 or 0.5 ppm. Because of the nature of the hazard presented by formaldehyde and the variation in individual susceptibility to its effects, OSHA does not believe that there is sufficient justification in the record to establish such a level. Moreover, OSHA does not feel that such a level is necessary, given the checks and balances built into the MRP provisions. For example, administration of the medical questionnaire precedes any action connected with MRP. On the basis of the employee's responses, the examining physician can make a determination regarding the need for medical examinations. If the physician decides that medical examinations are not immediately necessary, the employee begins a 2-week observation period. During this time the medical condition may be resolved either spontaneously or through remedial action such as removal of the formaldehyde source, a reduction in the exposure level or the intervention of minimal medical treatment. OSHA believes that this approach will allow employers an opportunity to resolve many employee medical problems associated with exposure to formaldehyde before medical removal would become necessary.

A comment submitted by ARCO Alaska, Inc. (Esx. 304–4) suggested that medical removal be triggered by "objective clinical evidence" rather than an employee's complaint of signs or symptoms of sensory irritation. ARCO Alaska requested that the standard permit the examining physician leeway to rely on evidence derived from a physical exam. OSHA believes that the proposed amendments already accommodate the concern expressed by the commenter. The MRP provisions do not preclude the examining physician from performing any type of medical exam that he or she feels is appropriate in reaching a decision as to whether the signs and symptoms presented by an employee are related to that employee's exposure to formaldehyde. The physician must first administer the medical questionnaire to employees exhibiting signs and symptoms of formaldehyde exposure. Following this, the physician is given broad discretion in selecting appropriate and useful medical tests.

In a related comment, the Amoco Corporation (Ex.304–18) recommended that OSHA require the examining physician to be one who specializes in occupational medicine. OSHA notes that the initial choice of an examining physician rests with the employer, and the standard does not preclude the employer from choosing a physician licensed in occupational medicine. However, as in previous rulemakings, the Agency does not feel that requiring physicians to be specialists in occupational medicine is practical or feasible, given the limited number of such physicians. (The number of occupational physicians is estimated to be around 5,000 according to the Institute of Occupational Medicine.) Also, OSHA believes that many licensed physicians who are not specialists in occupational medicine are fully qualified to make the medical determinations required under the MRP provisions. The final amendment does require that if a third physician is consulted with respect to the MRP provisions, this physician must be specialized in the area of the body affected or condition (e.g. dermatologist, allergist) or be an occupational physician. OSHA believes that this will not overly tax the number of occupational physicians available and will reserve the requirement to use one to those instances where there is a difference in professional opinion, the resolution of which might benefit from a physician trained in occupational medicine.

Additional comments were received regarding the economic protection clause of the MRP provisions. For example, the Amoco Corporation (Ex. 304–18) stated: "Worker protections such as these have traditionally been considered the province of labor relations and, in our opinion should remain so." OSHA notes that MRP is not a labor-relations provision but a mechanism to protect worker health. In promulgating the lead standard, (see 43 FR 52973, November 14, 1978), convincing evidence was presented that pointed out the painful dilemma confronting many lead-exposed workers. For examples, a worker could participate in the medical surveillance program and risk losing his or her job if abnormal medical findings were revealed that could be linked to occupational exposure to lead. On the other hand, a worker could resist participation in the medical surveillance program and thus lose the benefits that medical surveillance is designed to provide. To obviate the need for employees to have to make such decisions, OSHA required employers to protect employee benefits in the event a job transfer or removal became necessary. OSHA is not aware of

evidence in the formaldehyde record that suggests that the situation is different regarding formaldehyde workers. OSHA believes that formaldehyde workers need similar assurance that wages, seniority and other attendant benefits will be retained to secure their participation in medical surveillance.

The Photo Marketing Association International (L304–29) asserted: "[T]o the extent the allergic reaction prevents the employee from working or causes other injury, the employee has a remedy through the state worker's compensation laws." As noted earlier in this preamble discussion, where an employee has been determined to be unable to work in areas where formaldehyde is present due to permanent sensitization to the substance, the MRP provisions cease to apply. MRP is designed to bridge the short period while a symptomatic employee is waiting to recover or is being trained to do another job with lower formaldehyde exposure. Where an employee cannot work with formaldehyde and there is no other job available, the employee will need to rely on worker's compensation. In cases where employees are covered by MRP, if the employee receives any compensation through worker's compensation or other programs, the MRP payments can be reduced by that amount. However, in cases where the medical condition is reversible, OSHA believes that MRP is an appropriate measure for the reasons discussed above. The comment submitted by the Photo Marketing Association International goes on to urge OSHA to either delete the requirement of maintaining the affected employee's benefits or to exempt small businesses from these requirements. OSHA does not feel there is justification for an exemption for small businesses; the harm that may be inflicted on an employee will not differ with the size of the business and there is no evidence in the record to show that the MRP provisions would cause an unacceptable or infeasible burden on small businesses. The costs and benefits of MRP are addressed in the Regulatory Impact Analysis.

Organization Resources Counselors, Inc. (Ex. L304–19) raised objection to the requirement for a second medical opinion if the first medical opinion recommended that the employee be restricted rather than removed. ORC believed that a second opinion was not necessary in such a situation because the employee's compensation and benefits would not be at risk. This comment misconceives the purpose of multiple physician review. That purpose is to assure that a second medical opinion can be sought by an employee who is dissatisfied with the recommendations of the physician chosen by the employer. OSHA believes that this provision is essential to assure that employees have confidence in the soundness of medical determinations that affect them. If an employee is suffering sensory irritation from formaldehyde and the employer's physician recommends restriction rather than removal, the employee may believe that this recommendation will not adequately address his or her symptoms and seek a second medical opinion, which might recommend removal. Thus, even if the first physician recommends restriction, the outcome of the multiple physician review process may be removal.

The Department of Veterans Affairs (Ex. 304–23) asked that OSHA specify the frequency and duration of the symptoms reported by the employee before medical removal would apply. OSHA believes this approach to be unrealistic. As the provision is written, restriciton or removal of an employee is based on the physician's professional judgment. While frequency of symptoms may enter into the physician's decision with respect to determining the appropriate course of action, other factors such as the severity of symptoms as well as the employee's general state of health will also enter into this decision. Therefore OSHA does not feel that frequency should be mandated by this amendment.

Paragraph (m)—Hazard Communication

Generally, hazard communication requirements are governed by OSHA's generic Hazard Communication Standard (HCS), 29 CFR 1910.1200. The HCS requires the use of labels on containers of the hazardous substance, material safety data sheets (MSDSs) and employee information and training. The labels must include the identity of the hazardous chemicals, appropriate hazard warnings and the name and address of the chemical manufacturer, importer or other responsible party. The employer must retain MSDSs received from the manufacturer or distributor and make them available to employees working with the substance. The material safety data sheets include more extensive information than that on the label, such as the physical and chemical characteristics of the chemicals, the health hazards, the primary routes of entry, the PEL or other recommended exposure limit, whether the substance is listed in the NTP Annual Report on Carcinogens or has been found to be a potential carcinogen by IARC, precautions for safe use and handling, control measures, and emergency and first aid procedures. In addition, the employer must make sure that employees are informed of any operations in their workplace where hazardous chemicals are present, and the location and availability of a written hazard communication program with supporting materials, such as MSDSs. Employees must be trained in methods that may be used to detect the presence or the release of a hazardous chemical in their work area, the physical and health hazards of the chemicals in the work area and measures employees can take to protect themselves from these hazards.

The formaldehyde standard contained specific hazard communications provisions in paragraph (m) that supplemented the requirements of the generic HCS in an attempt to accommodate the unique properties of formaldehyde. Those provisions have been the subject of much of the controversy surrounding the formaldehyde standard. In brief, the hazard communication provisions of the formaldehyde standard applied to formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm. Employers were required, as a minimum, to address the following hazards: cancer, irritation, and sensitization of the skin and respiratory system, eye and throat irritation and acute toxicity. Manufacturers and importers of formaldehyde were required to provide downstream employers with an objective determination through labels and material safety data sheets if the items were considered to constitute a health hazard in accordance with the HCS under normal conditions of use. The labels were to comply with the requirements of the HCS, 29 CFR 1910.1200(f). As a minimum, the labels were required to identify the hazardous material; identify the responsible party; contain the language, "Potential Cancer Hazard;" and warn of all other hazards as defined in Appendices A and B of 29 CFR 1910.1200. Material safety data sheets were to be developed in accordance with paragraph (g) of the HCS.

The "de minimis exemption," which exempted materials capable of releasing formaldehyde in concentrations less than 0.1 ppm from hazard communication requirements, was an attempt to address the problem of

products which emit or "offgas" formaldehyde, and because of this fact do not fall under the "articles" exemption of the generic HCS. The de minimis exemption, contained in paragraph (m)(1)(i), proved confusing and controversial, because it implied, contrary to other provisions, of the standard, that any exposure above 0.1 ppm constituted a health hazard. The provision prompted a petition from the Formaldehyde Institute, which OSHA granted, to stay paragraphs (m)(1)(i) through (m)(4)(ii) (53 FR 50198). Having decided that its attempt to provide a workable de minimis exemption was not successful, the Agency desired to investigate means of clarifying the requirement and improving compliance. Upon reconsideration, OSHA proposed to amend paragraph (m). The proposed amendments were designed to provide hazard communication provisions that accommodate the unusual properties of formaldehyde and provide appropriate worker protection without undue burden on employers.

In order to clarify the intent of the standard, the text has been simplified. Wood products continue to be covered by the hazard communication requirements of this section. Although the language specifying wood products industry coverage no longer appears in the regulatory language, that industry continues to be covered by the hazard communication requirements of this section, because the exemption in paragraph (b)(6)(ii) of the generic hazard communication standard, 29 CFR 1910.1200, is not referenced and does not apply to this standard. (56 FR at 3207, 7/15/91.)

The following summarizes the changes in brief: Wood products continue to be covered under the hazard communication provisions of the formaldehyde standard; references to the generic Hazard Communication Standard in the stayed paragraphs of the formaldehyde standard (m)(1)(i) through (m)(4) were deleted; the definition of "health hazard" was deleted but trigger levels for action (0.1% or 0.1 ppm) were retained.

In developing the proposed amendments the Agency gave a great deal of consideration to finding acceptable means to apply hazard communication provisions in the formaldehyde standard given the known unique properties of the chemical. In particular, formaldehyde's ability to "offgas," that is, to release formaldehyde gas from solid materials such as wood products and textiles distinguishes it from other chemicals for which the generic Hazard Communication Standard can readily apply. Solid materials capable of emitting formaldehyde do not neatly fall within the "article" exemption of the generic standard. An "article" as defined at 29 CFR 1910.1200 (c) means a manufactured item (i) which is formed to a specific shape or design during manufacture; (ii) which has an end function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result in exposure to, a hazardous chemical, under normal conditions of use. An article is not considered to release a hazardous chemical if only a few molecules or a trace amount are emitted. (See 52 FR at 31865, August 24, 1987.) With regard to formaldehyde, the amount of the chemical that is emitted is highly variable, depending on the amount of the chemical bound up in the material and the rate of decay or release which decreases over time. The rate of release is influenced by environmental factors such as temperature and humidity. Therefore to apply the generic hazard communication provisions without qualification would, in effect, require comprehensive labeling for all products capable or emitting more than a few molecules of formaldehyde without due consideration to other relevant factors.

To address this problem, OSHA proposed that, where the potential exposure is under 0.5 ppm, the label needs to indicate that formaldehyde may be present, give the name and address of a responsible party and indicate that physical and health hazard information is available from the employer and from MSDSs. Specific hazard information need not appear on the label, only the indication that such information exists, and directions and the location for obtaining such information. Where it cannot be documented that the concentration of formaldehyde will always remain at or below 0.5 ppm under reasonably foreseeable circumstances, the label information would be required to detail all appropriate hazards, including the information that formaldehyde is a potential cancer hazard.

The Agency felt that this "low potential exposure" labeling for solid materials which may offgas formaldehyde struck a balance, eliminating unnecessary hazard warnings where the potential may not be realized, and giving employees the appropriate warnings, via the label, MSDSs and training where there are low level emissions from products which may represent a health risk.

A considerable number of comments were received that questioned the Agency's proposed approach which, according to the commenters, established an artificial distinction between formaldehyde exposures from solid materials and other physical forms of formaldehyde. For example, in its comment the Association of Nonwoven Fabrics Industry stated:

> To the best of our knowledge, OSHA has provided no evidence documenting that the health hazard of exposure to 0.1—0.5 ppm of formaldehyde from a solid material can be distinguished by the exposed individual to an equal exposure of 0.1-0.5 ppm of formaldehyde from another source. (Ex. 304-9).

A similar comment was submitted by the Industrial Coatings Group, Inc. With respect to labeling, the comment stated:

> A distinction is drawn between solids and other materials for no apparent reason. Since the issue is the potential emission of a chemical, and since the property under discussion is the amount of formaldehyde capable of being released (not what form it is in) it seems peculiar to make a distinction based on the phase of the emission source.(Ex. 304-22).

Several other commenters supported the above view. (Exs. 304–8, 304–8, L304–19, L304–25, 304–27, and L304–34).

OSHA has therefore reevaluated the options with respect to hazard communication and agrees that the distinction between solids and other forms of formaldehyde is not appropriate. OSHA has concluded that labeling requirements should apply uniformly to all forms of formaldehyde. Specifically, where it is determined through monitoring or the use of objective data that employee exposures will not exceed levels above 0.5 ppm, the hazard warning label shall include the following information: The material or mixture contains formaldehyde; the name and address of the responsible party; and a statement that physical and health hazard information is readily available from the employer and from material safety data sheets. Where it cannot be documented that the concentration will always remain at or below 0.5 ppm under reasonable foreseeable conditions, the label information must detail all appropriate hazards, including information that formaldehyde is a potential cancer hazard. Formaldehyde-containing products incapable of causing exposures at or above 0.1 ppm or mixtures and solutions containing less than 0.1% formaldehyde will not be subject to any hazard communication requirements.

This provision should not be construed as precedential for other

rulemakings. Formaldehyde has unique properties and uses which make it necessary to distinguish its handling from that of the generic labeling requirements of the Hazard Communication Standard. The importance and effectiveness of the Hazard Communication Standard itself should in no way be diminished by the approach taken in these final amendments concerning formaldehyde.

OSHA notes that the foregoing should resolve other questions concerning the labeling requirements as proposed. For example, the BF Goodrich Company (Ex. 304–17) asked for a definition of "materials" and "solid materials" if OSHA continued to make such distinctions in the context of labeling requirements. OSHA believes that the final amendments clarify the fact that all physical forms of formaldehyde will be subject to identical labeling requirements as prescribed in paragraph (m)(1)(ii) and (m)(1)(iii) and therefore such definitions are unnecessary.

The Shipbuilders Council of America (Ex. 304–7) and Newport News Shipbuilding (Ex.304–33) recommended that OSHA allow employers the option of posting signs in work areas affected by formaldehyde off-gassing in lieu of labeling, where such conditions are transient and short-lived. The source of the off-gassing or conditions of use of formaldehyde were not apparent from the comment. However, paragraph (f) of the Hazard Communication Standard, referenced in this section, provides for the use of signs in situations where it is impractical to affix labels. Specifically, paragraph (f)(6) of the Hazard Communication Standard allows employers to use signs, placards, process sheets, etc. in lieu of affixing labels to individual process containers as long as the alternative method conveys the identity of the hazardous chemical and appropriate hazard warning. OSHA believes that it is reasonable to allow the use of signs in work areas where employees may be incidentally exposed to formaldehyde for brief periods of time as long as the appropriate hazard warning is noted and employees are trained regarding the significance of information on the sign.

Updike, Kelly & Spellacy (Ex. 304–5) suggested that the labeling provisions should apply only to products produced 6 months or more after the effective date to eliminate the need for employers to repackage and relabel any existing inventory to meet the requirements of the provision. OSHA notes that labeling has already been an ongoing obligation under the generic Hazard Communication standard. Consequently, the labels prepared in order to comply with the generic HCS will automatically be in compliance with this standard and therefore there is no need for repackaging or relabeling products by manufacturers, importers or employers.

The Amoco Corporation (Ex. 304–18) questioned whether manufacturers could anticipate a product's reasonably foreseeable conditions of use for labeling purposes. The comment asked for guidance on a number of points with respect to how the manufacturer or importer should calculate the rate of emission for labeling purposes.

The labeling requirement is intended to apply to the maximum potential emission under foreseeable conditions of use. It is the responsibility of the manufacturer and/or importer to establish what that value is and label accordingly. OSHA noted in the original rulemaking that it could be difficult for the manufacturer or importer to make this determination (52 FR at 46285), but OSHA nevertheless believes that this approach best provides for employees to have comprehensive hazard information without unnecessary burden to employers. If manufacturers or importers are uncertain over whether labeling is required under certain circumstances, they can assure compliance by labeling in accordance with conservative assumptions as to emission levels. OSHA therefore does not believe it is necessary or appropriate to give specific guidance on calculating emission rates beyond the "reasonably foreseeable conditions of use" language in the standard.

Finally, a considerable number of commenters (See Exs. 304–3, 304–7, 304–9, 304–11, 304–15, 304–17, L304–19, 304–24, L304–25, 304–27, L304–28 and 304–32) asked for clarification on whether the levels that trigger the labeling and training provisions are intended to be based on instantaneous exposures, short term exposures, or 8-hour time-weighted averages. OSHA intends for these levels to mean 8-hour time-weighted averages.

The proposed amendments to the formaldehyde standard specified that objective data could be used by the employer in determining anticipated levels of formaldehyde release. This provision remains unchanged in the final amendments and is consistent with paragraph (d)(1)(ii)(B), which is discussed above. Objective data consists of information which demonstrates that a particular product or material cannot release formaldehyde in concentrations exceeding the two labeling triggers of 0.1 ppm or above 0.5 ppm under reasonably foreseeable conditions. Examples of information which might be used as objective data include representative personal samples, area samples, historical monitoring data, industry-wide studies, lab test results, and manufacturer's data. A full discussion of objective data is contained in the preamble to the 1987 final standard (see 52 FR at 46255–46256).

Paragraph (n)—Employee Information and Training

The final amendments require that employee training be conducted on an annual basis for all employees exposed to formaldehyde concentrations of 0.1 ppm or greater. The 1987 final standard requires initial training for persons exposed at 0.1 ppm or above the action level or STEL. The content of the training is not affected by this final amendment.

OSHA has determined that training for employees exposed to lower concentrations of formaldehyde is necessary for a number of reasons. Training is one of the three main elements of hazard communication. The success of risk management programs requires that employees be aware of hazard, work practice and other information essential to understanding the risks associated with their exposure, and the means of reducing that risk. The continued awareness on the part of the employee depends on constant reminders, such as hazard warning labels. Periodic training becomes especially important for formaldehyde, given the importance of the ancillary provisions in reducing risk, and the exemptions to the labeling requirements, which are discussed above. Although employees will have access to material safety data sheets, MSDSs are a passive source of information. It is anticipated that training will play a more essential role in employees' awareness of the specific hazards in their workplace and control measures employed. This is particularly true for illiterate or non-English speaking workers.

Annual training is also important for successful medical surveillance and MRP. These provisions will only be effective if employees know what signs or symptoms are related to the health effects of formaldehyde, if they know how to properly report them to the employer, and if they are periodically encouraged to do so. The record indicates that signs or symptoms are not uncommon in employees exposed to levels of formaldehyde below the action level and the STEL (52 FR at 46280). It is felt that annual training for employees exposed to lower concentrations of formaldehyde will help assure the

continued effectiveness of the ancillary provisions in resducing the risks of formaldehyde exposure. It will also help identify and assist those employees actually suffering health effects, through improving employee corporation and participation in medical surveillance programs.

Several comments were submitted concerning the employee information and training provision. The Food and Allied Service Trades (304–6) suggested that OSHA strengthen the training program for workers exposed to formaldehyde and recommended several subject areas that should be included. This was not an issue for consideration in the proposed amendments, and OSHA has no evidence that the training provisions of the final formaldehyde standard issued in 1987 are not sufficient. The intent of paragraph (n) as contained in the proposed amendments was to clarify when training is to be conducted for employees exposed to formaldehyde and the frequency of such training. The final amendment requires annual training for all formaldehyde-exposed workers at levels at or above 0.1 ppm.

The Shipbuilders Council of America (Ex. 304–7) and Newport News Shipbuilding (Esx. 304–33) asked OSHA to extend to the start-up date for training by an additional four months beyond the proposed effective date to coincide with the 6 months allowed for the labeling provisions. The commenters' reasoning was that much of the requirement for training would be based on the presence of the manufacturer's label. OSHA agrees that warning labels must be covered under training. However, labeling is broadly required under the HCS and there is no need to delay training simply because the content of the labels may change. In other words, labels conforming to the Hazard Communication Standard will also comply with those required by this amended standard. As labels or other information change, the training, which must be conducted annually, can be modified as needed. Therefore, OSHA feels that the time allocated for the implementation of initial training is appropriate.

The other concerns regarding the training provisions dealt with requests that the 0.1 ppm trigger level that initiates training be specified as an 8-hour TWA. As discussed earlier in this preamble, OSHA interprets the 0.1 ppm trigger to be an 8-hour TWA.

Paragraph (p)—Dates

The final amendments become effective 30 days following publication in the **Federal Register**. This period enables employers to familiarize themselves with these new provisions. In addition, individual provisions, where appropriate, have delayed start-up dates.

Employers will be given one year to install any additional engineering controls necessary to achieve the new PEL of 0.75 ppm TWA. Many employers will be able to meet this new PEL presently and will not need any more time; with this in mind, this start-up date section requires that compliance be accomplished as quickly as possible, but no later than a year from the effective date of the amendment.

In those cases where respiratory protection is required, such protection must be provided to employees in compliance with paragraph (g) as quickly as possible but no later than 3 months after the effective date of the amendment. It is felt that this extra time may be needed because some employers may have situations where no respiratory protection was needed to meet the PEL of 1 ppm, while the new PEL of 0.75 ppm may require implementation of respiratory protection programs, at least temporarily until they can achieve compliance with the PEL through the use of engineering controls. Therefore a period of three months is considered necessary for these employers to properly select the appropriate respirator to protect their employees and complete fit testing and other necessary elements of an effective respiratory protection program.

The standard's medical surveillance provisions have been in effect for over two years. Employers have already implemented these provisions, including the administration of medical questionnaires to employees reporting signs or symptoms of formaldehyde exposure or employees exposed above the action level or STEL, medical examinations where appropriate and the receipt of physician's written opinions. Employers may need some additional time to implement the medical removal provisions and to ascertain how to adapt them to their particular workplace. The Agency believes that a six month period is appropriate under the circumstances.

Paragraph (m) of the formaldehyde standard as well as the hazard communication standard already impose general hazard communication requirements on employers handling formaldehyde-containing products in their workplaces. The final amendments would alter somewhat the labeling requirements for containers of certain products capable of releasing small amounts of formaldehyde. The Agency believes that employers handling formaldehyde products such as those described above may need some additional time to formulate the new labels. Six months is believed to be an appropriate amount of time to accomplish this task in view of the substantial amount of inventory that may be on hand. Moreover, this delayed start-up date would not adversely affect employee health since formaldehyde products would still need to be labeled in the interim in compliance with OSHA's generic hazard communication standard.

The amendments to the final standard increase the frequency with which employees exposed to formaldehyde between 0.1 ppm and 0.5 ppm must receive training. Following initial training, such employees must receive training annually. OSHA has concluded that a two month start-up period for this provision is appropriate to allow the employer to determine which employees must be trained more frequently.

Republication of Standard

In addition to the revisions and amendments discussed above, OSHA is republishing at the end of this document the revised formaldehyde standard in toto. The Agency determined that the republication would be a helpful tool for the public to ascertain information and compliance obligations based on the entire standard as revised. The preamble to the 1987 final rule is not reprinted herein; interested persons are encouraged to refer to the preamble to the original rule for explanations of provisions not changed in this promulgation (see 52 FR 46168, 12/4/87).

Regulatory Impact and Regulatory Flexibility Assessment

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory analysis be prepared for any proposed regulation that meets the criteria for a "major rule"; likely to result in an annual impact on the economy of $100 million or more; have a major increase on cost or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or, have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) requires an analysis of whether a regulation will have a significant economic impact on a substantial number of small entities. Finally, the

Occupational Safety and Health Act requires proof of economic and technological feasibility.

Consistent with these requirements, OSHA has prepared a Regulatory Impact and Regulatory Flexibility Assessment. This regulatory assessment is a supplement to the final Regulatory Impact Analysis (RIA) currently in the docket [Ex. 206].

Industry Profile

As described in the 1987 RIA [Ex. 206], OSHA estimates that approximately 2.2 million workers are exposed to formaldehyde at levels of 0.1 ppm or greater. As a result of the introduction of the 1.0 ppm PEL, no workers should currently be exposed at levels above 1.0 ppm. An estimated 83,818 workers are exposed at levels between 0.75 ppm and 1.0 ppm. The balance of about 2.1 million workers are estimated to be exposed at levels between 0.1 and 0.75 ppm. The largest number of exposures currently is in the apparel industry, with an estimated 941,300 exposed workers, 58,831 of which have exposures between 0.75 and 1.0 ppm.

For the purpose of this analysis, it is assumed that (1) establishments are in compliance with the existing OSHA standard and (2) exposure levels have responded as projected in the 1987 RIA.

OSHA's estimates of employee exposures to formaldehyde in 1991 are based upon the exposure estimates in the 1987 RIA with two modifying assumptions:

(1) As projected in the 1987 RIA, all employees previously exposed above 1.0 ppm are now exposed at 0.75 ppm;

(2) Exposure levels in textile finishing, laboratories and formaldehyde production are now below 0.75 ppm due to improved work practices for complying with the 1.0 ppm rule as well as other rules which have been implemented since the 1987 formaldehyde rule. Therefore, of the 2,156,801 employees currently exposed to formaldehyde, 1,950,429 employees are exposed between 0.1 ppm and 0.5 ppm.

the remaining employees, 60% (122,554) have exposure levels between 0.5 ppm and 0.75 ppm and 40% (83,818) are exposed between 0.75 ppm and 1.0 ppm.

Only establishments with exposures between the new PEL of 0.75 ppm and the existing PEL of 1.0 ppm would be affected by the new PEL. These establishments are expected to target average exposures at 75% of the new PEL, or 0.56 ppm [1]. The number of establishments and exposed employees in affected industries are displayed by exposure level in Table I.

[1] This targeting strategy is consistent with the assumption made in the RIA of the 1987 Standard, in which it was assumed employers would reduce exposures to 75% of the required PEL. [Ex. 206, p. V–3].

TABLE I.—NUMBER OF AFFECTED ESTABLISHMENTS AND EMPLOYEES BY FORMALDEHYDE EXPOSURE LEVEL

SIC	Industry	Establishments				Exposed employees			
		0.75–1.0 ppm	0.5–0.75 ppm	0.1–0.5 ppm	Total	0.75–1.0 ppm	0.5–0.75 ppm	0.1–0.5 ppm	Total
2435	Hardwood Plywood	33	73	94	200	787	1,242	8,699	10,728
2492	Particleboard	8	22	16	46	720	1,021	2,836	4,577
2499	Fiberboard	3	12	0	14	294	524	335	1,153
25	Furniture	1,323	1,507	2,645	5,475	11,612	12,643	235,095	259,349
2821	Resins	0	51	46	97	490	875	8,335	9,700
332, 336	Foundries	718	1,765	520	3,002	6,085	10,594	43,322	60,000
806, 807	Laboratories	0	3,998	8,167	12,165	0	12,220	24,441	36,661
7261	Funeral Services	0	0	15,000	15,000	0	0	30,000	30,000
226	Textile Finishing	0	685	0	685	0	19,125	10,298	29,423
23	Apparel	2,869	2,869	17,211	22,948	58,831	58,831	823,637	941,300
2869	Formaldehyde Production	0	16	33	49	0	480	3,401	3,881
3079	Plastic Molding	500	500	4,000	5,000	5,000	5,000	90,000	100,000
2436	Softwood Plywood	0	0	250	250	0	0	31,100	31,100
2611	Pulp Mills	0	0	43	43	0	0	12,800	12,800
2621	Paper Mills	0	0	299	299	0	0	100,100	100,100
2631	Paperboard Mills	0	0	222	222	0	0	43,000	43,000
2642	Envelopes	0	0	296	296	0	0	19,000	19,000
2653	Corrugated & Solid Fiber Boxes	0	0	1,491	1,491	0	0	67,400	67,400
2851	Paints, Pigments	0	0	1,441	1,441	0	0	27,600	27,600
2865	Cyclic Crudes, Cyclic Intermediates, Dyes & Organic Pigments.	0	0	189	189	0	0	16,000	16,000
2879	Agricultural Chemicals, NEC	0	0	330	330	0	0	9,700	9,700
2891	Adhesives & Sealants	0	0	683	683	0	0	10,900	10,900
2899	Chemicals & Chemical Preparations, NEC	0	0	1,439	1,439	0	0	23,100	23,100
3291	Abrasive Products	0	0	374	374	0	0	17,000	17,000
3293	Gaskets, Packaging & Sealing Devices	0	0	474	474	0	0	21,800	21,800
3296	Mineral Wool Insulation	0	0	179	179	0	0	15,500	15,500
3634	Electric Housewares & Fans	0	0	263	263	0	0	29,300	29,300
3643	Current-carrying Wiring Devices	0	0	415	415	0	0	31,900	31,900
3644	Noncurrent-carrying Wiring Devices	0	0	226	226	0	0	18,100	18,100
3694	Electrical Equip. For I.C. Engines	0	0	433	433	0	0	32,300	32,300
3792	Mobile Homes Manufacturing	0	0	1,655	1,655	0	0	11,200	11,200
7395	Photofinishing Labs	0	0	3,589	3,589	0	0	71,742	71,742
806	Hemodialysis	0	0	10,500	10,500	0	0	31,500	31,500
822	Biology Instructors	0	0	22,575	22,575	0	0	28,950	28,950
822	Veterinary Anatomy	0	0	19	19	0	0	38	38
	Total	5,453	11,496	95,117	112,066	83,818	122,554	1,950,429	2,156,801

**Totals may not add due to rounding.
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Nonregulatory Alternatives

As elaborated in the 1987 RIA [Ex. 206, p. VII–1–14], market mechanisms and actions by other governmental bodies have been inadequate in eliminating significant risk to workers from formaldehyde exposure. For this reason, both a lower PEL and annual training for all workers exposed at 0.1 ppm and above are being instituted. In the case of workers leaving employment for medical reasons, workers compensation or unemployment insurance systems can provide income to workers. These systems, however, vary from state to state and do not provide for complete substitution of wages and benefits. Without medical removal and wage protection safeguards, workers may continue to suffer acute formaldehyde-related symptoms out of fear of job loss.

Technological Feasibility

The feasibility of a 0.75 ppm PEL was not explicitly addressed in the previous record. However, based upon previous contractors' reports and consistent with OSHA's analysis of compliance with the 1.0 ppm PEL, OSHA believes a 0.75 ppm PEL is technologically feasible.

In the 1987 RIA, OSHA judged that it was technologically feasible to achieve compliance with a 1.0 ppm PEL [Ex. 206, p. III–2]. To assure compliance with a 1.0 ppm PEL, OSHA estimated that those establishments with exposures above 1.0 ppm would lower average personal exposures to 75% of the required PEL, or 0.75 ppm [2]. Those establishments with exposures below 1.0 ppm were judged to be unaffected by the new PEL [Ex. 206. IV–1]. This analysis is consistent with the methodology in the 1986 Heiden report [Ex. 133], which assigned no costs of engineering controls to establishments with exposures below 1.0 ppm.

In this analysis, those establishments with pre-1987 exposures between 1.0 ppm and 0.75 ppm are assumed to lower their exposures to 75% of the new PEL, or 0.56 ppm. These establishments generally had fewer structural or process-inherent exposure problems than those establishments which had exposures above 1.0 ppm in 1987 [Ex. 206, p. IV–19, 20, 30, 32, 46, 51, 52, 58, 59, 61]. Feasibility is not expected to be a problem for these establishments.

Four of the industries—textile finishing, apparel manufacturing, formaldehyde production and plastic molding—are estimated to have potential exposures in excess of 0.5 ppm, but below 1.0 ppm. Both the 1985 Heiden report [Ex. 77–19] and the 1981 Ashford report [Ex. 70–1], identified feasible strategies for reaching exposure levels below 1.0 ppm for these industry sectors.

In the preliminary Regulatory Impact Analysis of July 1991, OSHA estimated 152 nitrogen fertilizer plants have exposures between 0.5 and 1.0 ppm. Since then, OSHA had obtained new data from both the Fertilizer Institute [Ex. L304–35] as well as from OSHA's IMIS database. These data indicate that current work practices have reduced employee exposure to below 0.1 ppm. Thus, the final standard should have no affect upon the nitrogenous fertilizer industry (SIC 2873).

Costs of Compliance

Engineering Controls

Sources available in the record for analyzing the incremental cost of moving from the current 1.0 ppm PEL to a PEL of 0.75 ppm are limited. While a shift to a new technology would be the only means of achieving compliance with a 0.5 ppm PEL in some industries, this is not necessarily the case with respect to a 0.75 ppm PEL. For the purposes of this analysis, OSHA concludes that the technology necessary to comply with a 0.75 ppm PEL would be generally the same as that used to bring those plants with exposures above 1.0 ppm prior to 1987 into compliance with a 1.0 ppm PEL.

Unit price assumptions and revenue data within this analysis are based upon the 1987 Producer Price index, as they were for the 1987 Regulatory Impact Analysis.

Foundries

In the 1987 RIA [Ex. 206, p. IV–54], it was estimated that 1,047 foundries had exposures above 1.0 ppm and an additional 1,435 had exposures between 0.5 ppm and 1.0 ppm. It was projected that as a result of the 1.0 ppm PEL, average exposures in the first group would be lowered to 0.75 ppm, and that the second group would remain unchanged. OSHA estimates that half of the second group, or 718 foundries, would need to respond to the new PEL of 0.75 ppm.

As discussed in the 1987 RIA [Ex. 206, p. IV–53], OSHA found that this group is comprised largely of foundries using the shell core process. To comply with the standard, firms would incur capital costs for local exhaust ventilation of $10,000, with an annual operating cost of $900 per machine, and would have an average of 3 affected machines per plant [Ex. 206, p. IV–52], for a total capital cost of $21,540,000 (718×3×$10,000) and annual operating costs of $1,938,600 (718×3×$900). Annualizing the capital cost at 10% over a 10 year expected equipment lifetime results in an annualized cost of $3,505,536.[3] Total annual costs therefore, are projected to be $5,444,136 (annualized costs plus annual recurring operating costs). It is possible that providing controls for only a portion of the machines would reduce exposures sufficiently to achieve compliance with the proposed PEL, but OSHA conservatively assumes that controls on all three would be necessary.

Hardwood Plywood

In the 1987 RIA [Ex. 206, p. IV–36] it was estimated that forty hardwood plywood establishments had exposures above 1.0 ppm and would lower exposures to 0.75 ppm as a result of the 1.0 ppm PEL. Sixty-six establishments unaffected by the 1.0 ppm PEL were estimated to have exposures between 0.5 ppm and 1.0 ppm. OSHA estimates that half of these establishments, or 33, would be affected by a 0.75 ppm PEL.

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[2] The assumption within the 1987 Regulatory Impact Analysis that establishments previously above 1.0 ppm would be reduced to 0.75 ppm in response to the 1.0 ppm PEL was a conservative assumption in two respects. First, as a technological matter, in a number of industries, the engineering controls described were shown to be capable of lowering exposures by a factor of 10 or more, in many cases to below 0.5 ppm [Ex. 128, p. 6, 15; 1, Chap III]. However, due to difficulties encountered in lowering exposures in some establishments within certain industries [Ex. 206, Chap III], OSHA employed a generic assumption of 0.75 ppm as the exposure level attainable by establishments after implementing engineering controls.

All exposures above 1.0 ppm were projected to drop to 0.75 ppm. Targeting controls to achieve an effective 0.75 ppm limit provided a critical buffer for unforeseen exposure problems that may arise. Thus, in order to insure compliance with the 1.0 ppm PEL, exposures were projected to drop to 0.75 ppm or lower.

In the 1987 RIA, OSHA indicated that for some foundries, complying with a PEL of 0.5 ppm would not be feasible [Ex. 206, p. III–2]. The Agency's position was summarized in the Foundry section of the technological feasibility analysis: "OSHA therefore concludes that achieving a 0.5 ppm is not feasible by the use of engineering controls." However, OSHA believes that achieving a 0.75 ppm TWA in the foundry industry is technologically feasible. Evidence in the existing record indicates that the majority of foundry employees were exposed to formaldehyde levels of 0.5 ppm or less [Ex. 206, p. II–13, IV–55]. The introduction of engineering controls since the 1987 rule should have moved more employees below 0.75 ppm. OSHA has conducted 101 inspections and 94 exposure readings within the foundry industry since the standard took effect. These data indicate that the majority of foundries inspected had exposures below 0.75 ppm and therefore support the conclusion that a PEL of 0.75 ppm is technologically feasible [Ex. 301–1].

[3] The annualized cost is derived by applying a cost recovery factor (of 0.163 based on an equipment life expectancy of 10 years and a 10% cost of capital) to total capital costs.

OSHA assumes that plants with exposures between 0.75 ppm and 1.0 ppm have exposure problems similar to those plants which were out of compliance with the 1.0 ppm PEL. These plants were estimated to require fan replacement at an incremental capital cost of $2,000 and an incremental annual operating cost of $100 per plant [Ex. 206, p. IV-34]. The costs to come into compliance with a 0.75 ppm PEL in this industry are therefore estimated to be $66,000 in capital costs and $3,300 in annual operating costs.

In the 1987 RIA, OSHA stated that some plants could comply with a 1.0 ppm PEL with ventilation alone, others would also need to convert to low-emitting ureaformaldehyde (LEUF) resins [Ex. 206, p. IV-30-35]. While it is possible that some or all of the plants discussed in the previous paragraph could achieve compliance with a 0.75 ppm PEL through increased ventilation alone, OSHA conservatively assumes that these plants would also need to convert to LEUF resins to assure compliance. The 1987 RIA noted a gradual shift to LEUF resins in the hardwood plywood industry [Ex. 206, p. IV-32, 35]. However, establishments with the highest formaldehyde exposures currently are also the least likely to have converted. Due to uncertainty regarding these plants, OSHA is employing the conservative assumption that LEUF resins would be introduced directly as a result of this rule. Using the same method of estimating cost as was used in the 1987 RIA [Ex. 206, p. IV-35], it is estimated that an additional 235 million square feet (MMSF) of board production would need to be converted to LEUF at a cost of $2,750 per MMSF, or an annual operating cost of $646,250 ($2,750×235). The total costs associated with complying with a 0.75 ppm in the hardwood plywood industry are therefore estimated to be $66,000 in capital costs and $649,550 in annual operating costs for the 33 plants affected within this industry. Annualizing the capital cost at 10% over a 10 year expected equipment lifetime results in an annualized cost of $10,741. The total annual costs, therefore, are projected to be $660,291.

Particleboard

In the 1987 RIA [Ex. 206, p. IV-24, 26] it was estimated that 14 out of 46 plants had exposures above 1.0 ppm, and would lower exposures to 0.75 ppm as a result of the standard. An additional 16 plants were estimated to have exposures between 0.5 and 1.0 ppm, 8 of which are estimated to have exposures between 0.75 and 1.0 ppm. Assuming these plants would need to employ ventilation similar to those with exposures previously above 1.0 ppm, these plants would need additional ventilation at a capital cost of $215,320 per plant and annual operating costs of $53,830 per plant [Ex. 206, p. IV-21], or a total capital cost of $1,722,560 and a total annual operating cost of $430,640. Based upon the annualized capital cost of $280,339 and the recurring annual operating cost, total annual costs are $710,979.

Medium Density Fiberboard (MDF)

The 1987 RIA [Ex. 206, p. IV-27, 29, 31] projected that 9 MDF establishments would lower exposures to 0.75 ppm as a result of the 1.0 ppm PEL. It is estimated that 5 additional establishments have exposures between 0.5 and 1.0 ppm. It is estimated that approximately half, or 3 of these establishments would be affected by a 0.75 ppm PEL.

In the 1987 RIA it was estimated that the capital costs of lowering exposures to 0.75 ppm through additional ventilation would be $105,534 per plant, with annual operating costs of $63,486. Applying these costs to the 3 affected plants, OSHA estimates that cost of additional ventilation in this industry would be $316,602 in capital costs, and $190,458 in annual operating costs. The annualized cost of capital is equal to $51,526 using the 10%, 10 year expected equipment lifetime cost recovery value. Thus, the total annualized costs for this industry is projected to be $241,984.

Furniture

In the 1987 RIA, it was estimated that 184 plants had exposures above 1.0 ppm and would lower exposures to 0.75 ppm in response to the 1.0 ppm PEL. These were all facilities producing both furniture and board ("integrated" plants), with hazardous exposures in board production operations rather than furniture operations. There were an additional 2,646 establishments that had exposures estimated between 0.5 and 1.0 ppm, mostly furniture assembly plants with relatively isolated exposures above 0.5 ppm [Ex. 206, p. IV-43-44].

It was assumed that one-half of these, or 1,323 plants, have exposures between 0.75 ppm and 1.0 ppm. However, as noted in the 1987 RIA [Ex. 206, p. IV-44], in many of these plants, the exposure problems were due to improper use of non-use of existing ventilation systems. Poor work practices may also be responsible. In this regard, more training, not additional engineering controls, would remedy the exposure problems.

To the extent that available ventilation is utilized, there would be an increase in operating costs for these furniture plants. One basis for estimating these costs is the cost of annual exhaust ventilation employed by Ashford [Ex. 70-1]. The annual operating cost related to increased usage was estimated to be approximately $864 per establishment. However, OSHA assumes that this additional per plant cost would apply to only half of annual work days, or $432 annually. This cost would be incurred at 1,323 plants and the estimated cost of compliance at these plants would be $571,536 annually.

In approximately 214 plants (one half the integrated plants unaffected by the 1.0 ppm PEL) additional ventilation would likely be necessary to comply with a 0.75 ppm PEL. Based upon the analysis in the 1987 RIA [Ex. 206, p. IV-42], OSHA estimates that capital costs would be $52,000 per plant, or $11,128,000 for all furniture plants. The annual operating costs would be $13,000 per plant, or $2,782,000 for all "integrated" plants, or a total for the industry of $3,353,536. Annualizing the capital cost at 10% over a 10-year expected equipment lifetime results in an annualized cost of $1,811,031; total annual costs, therefore, are projected to be $5,164,567.

Laboratories

In the 1987 RIA analysis of formaldehyde exposures in laboratories [Ex. 206, p. IV-58-59, 61], a clear dichotomy was found between laboratories with functioning fume hoods and good work practices and those without them. High exposure levels were believed to exist in "problem" histology and pathology labs as a result of malfunctioning or misused fume hoods or poor work practices. Engineering controls and good work practices implemented in response to the existing standard, should have largely eliminated exposures above 0.5 ppm [Ex. 128, p. 4, 6, 9]. Exposures in some laboratories also show significant peak periods or episodes [Ex. 128, p. 5]. To the extent that laboratories are in compliance with the existing 2.0 ppm STEL, they should also be in compliance with a 0.75 ppm PEL [Ex. 128, p. 9]. Therefore, no engineering controls are thought to be necessary.

Funeral Services

The 1987 RIA indicated, based upon a study of 44 Iowa funeral homes, that TWA exposures were less of a problem than short-term exposures in this industry sector. TWA exposures were estimated to be below 0.5 ppm for all establishments in compliance with the

present standard [Ex. 206, p. IV-66]. Annual training for employees exposed between 0.1 and 0.5 ppm should improve work practices and help reduce short term exposures. No engineering controls are thought to be necessary for this.

Resins

OSHA's 1987 RIA indicated that 35 of 97 plants had partially open production processes and would need to install engineering controls, lowering exposures to 0.75 ppm. The other 62 plants had a closed production process and were not believed to have exposures above 0.5 ppm [Ex. 206, p. IV-70]. No additional engineering control costs are estimatesd for this industry.

Textile Finishing

At the time of the 1987 rulemaking, OSHA estimated that there were 685 textile finishing plants with formaldehyde exposures between 0.5 and 1.0 ppm [Ex. 206, p. 78, 80]. Approximately half, or 343, were estimated to have exposures between 0.75 and 1.0 ppm.

The Ashford report examined methods [Ex. 70-1] which would be expected to lower exposures in many areas of textile plants. However, the textile industry indicated that as of 1986, they were using the most chemically advanced resins available, and a further reduction of formaldehyde content in cloth would come only at the expense of a significant decrease in fabric quality [Ex. 159].

However, in 1989 OSHA lowered permissible exposure limits (PELs) on about 200 chemicals and instituted first time PELs for about 160 others. Since the textile finishing industry uses a large number of regulated chemicals, OSHA believes that improved ventilation is being introduced in order to limit chemical exposure generally [54 FR 2816, 1/19/89]. Recent OSHA inspection data have indicated no personal exposures to formaldehyde above 0.5 ppm in this industry [Ex. 301-1]. OSHA therefore believes that all textile finishing plants are currently in compliance with a 0.75 ppm PEL.

Apparel

In the 1987 RIA, OSHA estimated that 5,737 establishments had exposures between 0.5 and 1.0 ppm. OSHA estimates that approximately half of these, or 2,869 establishments, may have exposures between 0.75 and 1.0 ppm.

The record indicates that exposure problems in the apparel industry are due to the lack of appropriate exhaust ventilation. That is, the workplace is treated like an office or store and air is recirculated rather than exhausted and replaced, allowing formaldehyde concentrations to build [Ex. 78-24, 78-48]. A relatively simple solution to this problem of air stagnation is to install roof exhaust fans. These fans will also provide the additional benefit of exhausting the excess heat and formaldehyde present within the air. Ashford cited the cost of installing a 2,000 cubic feet per minute (cfm) roof exhaust fan at $1,000, with an annual operating cost of $720 [Ex. 70-1, p. 4-19]. Factoring in inflation, the capital cost is now estimated to be approximately $1,200, and the incremental annual operating cost $864. OSHA, therefore, estimates the cost of compliance with the lower PEL in the apparel industry to be $3,442,800 for capital and $2,478,816 for annual operating costs. Annualizing the capital cost at 10% over a 10 year expected equipment lifetime results in an annualized cost of $560,300; total annual costs, therefore, are projected to be $3,039,116.

Formaldehyde Production

The 1987 RIA estimated that approximately 16 out of 49 establishments would have exposures above 0.5 ppm after promulgation of the standard; the 1987 RIA indicated no exposures above 0.7 ppm [Ex. 206, p. IV-78].

Ashford [Ex. 70-1] developed formaldehyde production engineering control cost estimates in 1981 and indicated costs of compliance to meet all potential exposure limits. (However, Ashford actually had very little information on formaldehyde production operations and based his cost estimates on vinyl chloride monomer production operations.) In 1985 Heiden indicated that such plants were already in compliance with a 1.0 ppm PEL [Ex. 77-19]. Consistent with the above analysis and data, OSHA believes no additional controls would be necessary to achieve compliance with a 0.75 ppm PEL.

Plastic Molding Laminates

In its 1987 RIA, OSHA estimated that approximately 1,000 plants have exposures between 0.5 and 1.0 ppm [Ex. 206, p. IV-75, 76]. OSHA estimates that approximately half, or 500 plants, have exposures between 0.75 and 1.0 ppm. Ashford [Ex. 70-1] estimated that there was one molding machine for every four workers, the capital cost for local ventilation was $425 per machine and the annual operating cost was approximately $133 per machine. Given the estimated 5,000 workers exposed between 0.75 and 1.0 ppm, ventilation would be required for 1,250 machines. OSHA estimates the capital cost would be $510 per machine and the annual operating cost $160. Based upon these unit costs, OSHA estimates $637,500 in capital costs and $200,000 in annual operating costs. The annualized capital cost amounts to $103,750. Therefore, total annual cost of compliance for this industry is expected to be $303,750.

Summary of Engineering Control Costs

OSHA estimates the total capital costs of instituting engineering controls which would be sufficient to comply with a 0.75 ppm PEL to be $38.9 million, with annual operating costs of $9.2 million. The annualized cost of the engineering control capital costs is estimated to be $6.4 million, for a total annual cost of $15.6 million. An annual cost summary for each industry is provided in Table II.

TABLE II.—ANNUAL COSTS OF ENGINEERING CONTROLS IN COMPLIANCE WITH THE REVISED FORMALDEHYDE STANDARD

[1987 dollars]

SIC	Industry	Capital cost	Annualized capital cost	Annual operating cost	Total annual cost
332,336	Foundries	$21,540,000	$3,505,536	$1,938,600	$5,444,136
2435	Hardwood Plywood	66,000	10,741	649,550	660,291
2492	Particleboard	1,722,560	280,339	430,640	710,979
2499	Fiberboard	316,602	51,526	190,458	241,984
25	Furniture	11,128,000	1,811,031	3,353,536	5,164,567
23	Apparel	3,442,800	560,300	2,478,816	3,039,116
3079	Plastic Molding	637,500	103,750	200,000	303,750
Total		38,853,462	6,323,222	9,241,600	15,564,822

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Medical Removal Protection

The medical removal process begins when an employee reports signs and symptoms of possible overexposure to formaldehyde. OSHA previously estimated that 10 percent of workers exposed between 0.1 and 0.5 ppm would report signs and symptoms [Ex. 206, p. IV-11]. These workers would fill out a medical questionnaire, after which a two week evaluation and remediation period would begin. If the symptoms have not subsided after two weeks, the employee would be immediately referred to a physician. The physician might, in turn recommend transferring the employee to a job with significantly less formaldehyde exposure.

OSHA's medical removal provision is a codified version of plans that already exist in a number of companies [Ex. 159]. Companies with current removal programs have noted that placement in another job because of formaldehyde exposure, is rare. The former medical director of Burlington Industries reported that "clearly less than ten percent" of employees completing medical questionnaires required further medical evaluation. He added that among all exposed employees, only about one percent had symptoms that were clearly "chemically related" [Tr. 160, May 12, 1986]. The American Textile Manufacturers Institute stated that "* * * most companies have a complaint mechanism in place to discover individuals with problems * * *. Corporate medical surveillance programs show absolutely no evidence that contact dermatitis or allergic reaction from formaldehyde is a frequent problem [Ex. 159]." The medical director for the Dan River Clinic, indicated that over a 10 year period he received "no complaints about formaldehyde irritation or formaldehyde induced dermatological problems" [Ex. 159]. This clinic provides medical examinations for 6,000–12,000 company employees, 25 percent of whom are exposed to formaldehyde at levels between 0.15 and 1.0 ppm in textile operations.

There are, however, additional safeguards in the final provision that may increase the frequency of medical removal. The amended standard provides for additional training, which should increase employee awareness of the signs and symptoms of formaldehyde exposure, as well as an understanding of their rights under medical removal protection (MRP) and the proper channels to follow in using it. Additionally, under the final rule, an employee is allowed to appeal the company doctor's decision. Therefore, it is reasonable to expect some increase in the amount of transfer and removal over what is currently reported.

Based upon the discussion above, OSHA estimates that one percent, or 22,000 of all employees exposed to formaldehyde may require medical removal protection as provided for in the final rule. These employees are already provided medical surveillance under the present standard and a large number of employers presently provide for medical removal in one form or another. Thus, the additional burden imposed by this amendment is expected to be small. It is estimated that most sensitized employees will be transferred out of higher exposure areas into other jobs.

However, a potentially significant cost of this provision would be the requirement to provide 6 months compensation to employees for whom alternate jobs would not be available. Although the record on medical removal programs in larger companies suggests that alternate jobs are usually available [Ex. 159], the effect of universal medical removal protection on small firms is uncertain. For the purposes of estimating the impact of this provision, OSHA assumes that 30 percent of 2,200 sensitized employees in smaller establishments, or 660 employees will not be provided alternate positions by their employer and therefore must be provided six months compensation. By this assumption, the cost would be $6.0 million annually.

The existence of current medical removal plans in industry points to the fact that it makes economic sense to have a medical removal program. Workers who suffer adverse health effects from formaldehyde exposure can be moved to positions where they can contribute productively to a firm's operation. OSHA anticipates offsetting cost savings from this provision in the form of reduced absenteeism and reduced medical care costs.

Hazard Communication

In an expansion of the existing standard, workers exposed between 0.1 and 0.5 ppm are now required to receive annual training on the hazards of formaldehyde and ways to avoid them. OSHA estimates the cost of this to be $13.5 million per year.

Based upon the 1987 RIA [Ex. 206, p. I-3], OSHA estimates that there are currently approximately 2 million employees exposed to formaldehyde between 0.1 and 0.5 ppm. OSHA estimates that when current compliance is accounted for, it would take an additional half an hour annually, on average, to provide training specific to formaldehyde for these employees [4]. Employing the data and methodology used in the RIA [Ex. 206, p. 15], OSHA estimates the cost of training as follows:

Employee Training Cost: # of employees between 0.1 and 0.5 ppm × (1 + ½ turnover rate [5]) × (wage × 1.3 fringe rate) × ½ hour

Trainer cost in establishments with 20 employees or more: # of employees exposed between 0.1 and 0.5 ppm × (1 + ½ turnover rate) /20 × $26 [6] × ½ hour

Trainer cost in establishments with 20 or fewer employees: # of affected establishments × $26 × ½ hour

A summary of the compliance costs of these revisions to the standard for each industry are provided in Table III.

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[4] In the 1987 RIA, OSHA estimated that one hour training would be a reasonable estimate of the amount of time required for the annual training in the average establishment [Ex. 206, p. IV-15]. However, the original RIA training costs did not factor in current compliance. In the apparel industry, with almost half of the affected employees, little time would be needed to train employees on these provisions. Moreover, in addition to whatever baseline existed before, the current standard has likely spurred additional training for employees with exposure below 0.5 ppm, in part because some establishments may have chosen to establish training programs for all employees, not just new employees or those exposed above 0.5 ppm.

[5] While the exact turnover rate varies by industry, OSHA has assumed that ½ each industry's turnover rate reflects the percent of employees leaving a job who were already trained in that year. [Ex. 206, p. IV-4]

[6] Trainer hourly compensation [Ex. 206, p. IV-15].

TABLE III.—ANNUAL COSTS OF COMPLYING WITH THE REVISED FORMALDEHYDE STANDARD

[1987 Dollars]

SIC	Industry	Engineering controls	Medical removal protection	Training	Total
2435	Hardwood Plywood	$660,291	$28,451	$50,720	$739,461
2492	Particleboard	710,979	12,834	17,634	741,447
2499	Fiberboard	241,984	3,233	2,011	247,227
25	Furniture	5,164,567	752,527	1,498,668	7,415,761
2821	Resins	0	49,860	81,433	131,293
332,336	Foundries	5,444,136	279,162	397,961	6,121,259
806,807	Laboratories	0	133,827	321,714	455,541
7261	Funeral Services	0	91,962	363,597	455,559
226	Textile Finishing	0	83,423	62,996	146,419
23	Apparel	3,039,116	2,132,891	4,367,703	9,539,710
2869	Formaldehyde Production	0	11,594	25,461	37,055
3079	Plastic Molding	303,750	317,460	630,934	1,252,144
2436	Softwood Plywood	0	100,903	193,398	294,301
2611	Pulp Mills	0	41,529	90,578	132,107
2621	Paper Mills	0	324,772	708,344	1,033,116
2631	Paperboard Mills	0	139,512	304,284	443,796
2642	Envelopes	0	61,645	142,735	204,380
2653	Corrugated & Solid Fiber Boxes	0	218,678	492,770	711,448
2865	Cyclic Crudes, Cyclic Intermediates, Dyes & Organic Pigment	0	51,912	112,685	164,597
2851	Paints, Pigments	0	89,548	203,638	293,186
2879	Agricultural Chemicals, NEC	0	31,471	70,593	102,064
2891	Adhesives & Sealants	0	35,365	79,691	115,056
2899	Chemicals & Chemical Preparations, NEC	0	74,947	168,887	243,834
3291	Abrasive Products	0	55,156	123,149	178,305
3293	Gaskets, Packaging & Sealing Devices	0	70,730	157,920	228,650
3296	Mineral Wool Insulation	0	50,289	112,283	162,572
3634	Electric Housewares & Fans	0	95,063	218,147	313,210
3643	Current-carrying Wiring Devices	0	103,499	235,365	338,863
3644	Noncurrent-carrying Wiring Devices	0	58,725	133,545	192,270
3694	Electrical Equip. For I.C. Engines	0	104,797	231,816	336,613
3792	Mobile Homes Manufacturing	0	36,338	91,275	127,613
7395	Photofinishing Labs	0	232,765	520,050	752,815
806	Hemodialysis	0	102,201	460,368	562,569
822	Biology Instructors	0	93,928	759,151	853,078
822	Veterinary Anatomy	0	123	494	617
Total		15,564,822	6,071,119	13,431,998	35,067,940

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis

Benefits

OSHA expects these final revisions to the standard to produce quantifiable benefits in the form of reduced cancer incidence due to the lowered PEL and increased training, and reduced acute respiratory irritation due to the institution of medical removal protection. In addition, OSHA expects that the lower PEL and increased training would improve worker productivity through a lessening of irritation and an improved understanding of workplace processes.

Cancers Avoided

An estimated 83,818 workers are currently exposed above 0.75 ppm, at an average formaldehyde concentration of 0.875 ppm. This exposure is expected to be reduced to an average of 0.5625 ppm after implementation of the 0.75 ppm PEL. The 1987 RIA employed a cancer risk model developed by the Consumer Product Safety Commission based upon rat studies [Ex. 206, p. V–1–5]. Based upon this model, OSHA estimates that from 0.2 to 72 cancers would be avoided over the next 45 years by lowering the PEL from 1 to 0.75 ppm, depending on whether the Maximum Likelihood Estimate (MLE) or the Upper Confidence Limit (UCL) is used in the risk assessment [7]. Lowering exposure levels should also bring some decrease in respiratory distress and may result in greater worker productivity, as described further below.

OSHA believes that the additional training would also provide health benefits. Annual training ensures that the knowledge and appreciation of the hazard and ways to limit exposure through good work practices are reinforced continually.

The projected benefits of the hazard communication rule were a 20% reduction in all chemically related worker illnesses as the result of labeling, MSDSs and initial training. With the specific exposure reductions noted in the industry discussion, OSHA expects an additional 5% reduction in formaldehyde-related illnesses among the workers exposed between 0.1 and 0.5 ppm. Using the same risk model used to project benefits from lowering the PEL, OSHA estimates that, given a 5% risk reduction from annual training, an additional .004 to 79 cancers would be avoided over the next 45 years as a result of annual training [8].

In sum, OSHA estimates that lowering the PEL and providing additional training could prevent as many as 151 cancers over the next 45 years based upon the upper confidence limit risk assessment model. However, the

[7] Based upon the CPSC five-stage model, the Maximum Likelihood Estimate of Risk (MLE) is expressed as:

$EP(d) = 0.3954763163 \times 10^{-5} \times (\text{dose in ppm})^4 + 0.1597258396 \times 10^{-5} \times (\text{dose in ppm})^5$

where

EP(d) = the excess probability of cancer attributable to formaldehyde

The Upper Confidence Limit (UCL) is approximately linear at low doses and, for the purposes of this analysis, could be expressed as: $EP(d) = 264 \times 10^{-5} \times (\text{dose in ppm})$.

[8] This was estimated by using the MLE and the UCL applied to all employees exposed to formaldehyde between 0.5 and 0.1 ppm, assuming an average exposure of 0.3 ppm, and a 5% reduction in risk.

maximum likelihood estimate of risk, produces only negligible benefits related to the final revisions.

Non-Carcinogenic Benefits

In the 1987 RIA, OSHA estimated that 5,911 cases of respiratory distress would be eased by lowering the PEL to 1.0 ppm [Ex. 206, p. V–9–11]. These same symptoms persist at very low exposure levels for a small percentage of the population. These employees would be directly aided by medical removal protection.

There are approximately 2,156,801 employees exposed to formaldehyde at 0.1 ppm or greater. As discussed in the 1987 RIA, employee exposure to formaldehyde can cause eye, nose, and throat irritation, coughing, headaches, chest discomfort, changes in lung function, impaired physical performance and exacerbation of asthma. OSHA estimates that as many as 1%, or 21,568 workers may be removed annually for respiratory distress. This represents a potential cost savings to society since the protected worker will be more productive when not experiencing health problems.

Economic Impact and Regulatory Flexibility

An analysis of revenue and profit data provided in the 1987 RIA indicates that the costs to comply (without consideration of cost savings) with these amendments would not have a significant adverse impact on a substantial number of small entities nor on the economy as a whole. In only the fiberboard industry are costs expected to be as much as 0.1% of revenue, and costs are expected to be less than 1% of profits in all but a few industries. The greatest potential impact on profits would be in the hardwood plywood industry, where compliance costs are estimated to be 5.4% of profits.

Smaller establishments should not be disproportionately impacted. Although it is possible that a small number of marginal firms may have to cease operations, OSHA estimates that most of these firms should be able to absorb the costs of this standard. Most of the costs in the hardwood plywood industry are attributed to the capital and operating costs associated with the introduction of LEUF resins, and these costs are directly proportional to sales. In the furniture industry, most of the engineering control costs would be absorbed by a minority of larger plants. Human resource costs, such as removal protection and training are generally proportional to the number of employees, and therefore would not have a disproportionate impact on small businesses. The requirement to give employees six month removal compensation might be more burdensome to small businesses due to limited availability of alternate jobs, but this should be a particularly rare event. Since the likelihood of encountering such formaldehyde-sensitive employees is directly related to the number of employees in a business, this provision is not expected to impact a substantial number of small entities. Estimates of average compliance costs per establishment, as a percentage of revenues and profits are provided for all affected industries in Table IV.

TABLE IV.—COST OF PROPOSED AMENDMENTS TO FORMALDEHYDE STANDARD AS A PERCENTAGE OF REVENUES AND PROFIT

SIC	Industry	Annual costs ($)	Cost per establishment	Costs as % of revenue	Cost as % of profits
2435	Hardwood Plywood	739,461	3,697	0.075	5.35
2492	Particleboard	741,447	16,118	0.089	1.78
2499	Fiberboard	247,227	17,659	0.102	2.04
25	Furniture	7,415,761	1,355	0.080	3.09
2821	Resins	131,293	1,354	0.003	0.08
332, 336	Foundries	6,121,259	2,039	0.049	1.63
806; 807	Laboratories	455,541	37	0.000	NA
7261	Funeral Services	455,559	30	0.009	0.10
226	Textile Finishing	146,419	214	0.003	0.16
23	Apparel	9,539,710	416	0.018	0.57
2869	Formaldehyde Production	37,055	756	0.002	0.03
3079	Plastic Molding	1,252,144	250	0.006	NA
2436	Softwood Plywood	294,301	1,177	0.004	0.09
2611	Pulp Mills	132,107	3,072	0.004	0.09
2621	Paper Mills	1,033,116	3,455	0.004	0.09
2631	Paperboard Mills	443,796	1,999	0.004	0.09
2642	Envelopes	204,380	690	0.010	0.26
2653	Corrugated & Solid Fiber Boxes	711,448	477	0.005	0.14
2865	Cyclic Crudes, Cyclic Intermediates, Dyes	164,597	871	0.002	0.04
2851	Paints, Pigments	293,186	203	0.003	0.07
2879	Agricultural Chemicals, NEC	102,064	309	0.002	0.05
2891	Adhesives & Sealants	115,056	168	0.003	0.07
2899	Chemicals & Chemical Preparations, NEC	243,834	169	0.003	0.08
3291	Abrasive Products	178,305	477	0.005	0.27
3293	Gaskets, Packaging & Sealing Devices	228,650	482	0.010	NA
3296	Mineral Wool Insulation	162,572	908	0.005	NA
3634	Electric Houseware & Fans	313,210	1,191	0.010	0.19
3643	Current-carrying Wiring Devices	338,863	817	0.010	0.20
3644	Noncurrent-carrying Wiring Devices	192,270	851	0.008	0.18
3694	Electrical Equip. For I.C. Engines	336,613	777	0.006	0.12
3792	Mobile Homes Manufacturing	127,613	77	0.009	0.32
7395	Photofinishing Labs	752,815	210	0.026	0.60
806	Hemodialysis	562,569	54	0.000	NA
822	Biology Instructors	853,078	38	0.001	NA
822	Veterinary Anatomy	617	32	0.000	NA

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis

Environmental Impact Analysis

The National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et. seq.*, requires OSHA to determine whether this regulatory action would have a significant impact on the environment. These amendments would not increase the amount of formaldehyde found in the general environment and may decrease it as some establishments switch to low-emitting resins. Therefore, the Agency believes that these provisions would not have a significant impact on the environment. No comments made at the public hearing or submitted to the record contradict this conclusion.

Paperwork Reduction

The amended paragraphs of the formaldehyde standard do not have information collection requirements subject to OMB review under the Paperwork Reduction Act. The existing paperwork requirements were approved by OMB under control number 1218–0145.

Federalism and State Plan Applicability

This final standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act, a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of publication of a final rule. The States are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. For New York and Connecticut, plans cover only State and local government employees. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these States.

Authority and Signature

This document was prepared under the direction of Dorothy L. Strunk, Acting Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington DC 20210. Pursuant to the authority of section 4(b)(2), 6(b), and 8(c) of the Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 653, 655, 657), the Construction Safety Act (40 U.S.C. 333), the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), the Secretary of Labor's Order 1–90 (55 FR 9033), 29 CFR part 1911, 29 CFR part 1910 is amended as set forth below. As with the original standard covering occupational exposure to formaldehyde, this final amendment of that standard would also apply to the maritime and construction industries.

List of Subjects in 29 CFR Part 1910

Formaldehyde, Occupational Safety and Health, Chemicals, Cancer.

Signed at Washington, DC this 15th day of May, 1992.

Dorothy L. Strunk,

Acting Assistant Secretary of Labor.

PART 1910—[AMENDED]

Part 1910 of title 29 of the Code Federal Regulations is therefore amended as follows:

1. The authority citation for subpart Z of part 1910 continues to read in part as follows:

Authority: Secs. 6, 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033) as applicable; and 29 CFR part 1911.

* * * * *

Section 1910.1048 also issued under 29 U.S.C. 653.

2. In § 1910.1048, Table 1 is removed from paragraph (g)(3)(ii), and paragraphs (c)(1), (d)(1)(ii), (g)(2)(i) (including Table 1), (g)(3)(iv), (m)(1) introductory text, (m)(1)(i), (m)(3), (m)(4), (n)(1) and (n)(2) are revised; and paragraphs (d)(2)(iii), (1)(8), (1)(9), (m)(5) and (p)(3) are added to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(c) *Permissible Exposure Limit (PEL)*—(1) *TWA*: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8–hour TWA.

* * * * *

(d) *Exposure monitoring*—(1) *General.** * *

* * * * *

(ii) *Exception.* Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

* * * * *

(2) *Initial monitoring.* * * *

(iii) If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

* * * * *

(g) *Respiratory protection.* * * *

(2) *Respiratory selection.* (i) The appropriate respirators as specified in Table 1 shall be selected from those approved by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION AGAINST FORMALDEHYDE

Condition of use or formaldehyde concentration (ppm)	Minimum respirator required[1]
Up to 7.5 ppm. (10 × PEL).	Full facepiece with cartridges or canisters specifically approved for protection against formaldehyde.[2]
Up to 75 ppm. (100 × PEL).	Full-face mask with chin style or chest or back mounted type with industrial size canister specifically approved for protection against formaldehyde. Type C supplied-air respirator, pressure demand or continuous flow type, with full facepiece, hood, or helmet.
Above 75 ppm. or unknown (emergencies). (100 × PEL).	Self-contained breathing apparatus (SCBA) with positive pressure full facepiece.
22	Combination supplied-air, full facepiece positive pressure respirator with auxiliary self-contained air supply.
Firefighting	SCBA with positive pressure in full facepiece.
Escape	SCBA in demand or pressure demand mode. Full-face mask with chin style or front or back mounted type industrial size canister specifically approved for protection against formaldehyde.

[1] Respirators specified for use at higher concentrations may be used at lower concentrations.
[2] A half-mask respirator with cartridges specifically approved for protection against formaldehyde can be substituted for the full facepiece respirator providing that effective gas-proof goggles are provided and used in combination with the half-mask respirator.

* * * * *

(3) *Respirator usage.* * * *

(iv) Unless the canister contains a NIOSH-approved end-of-service-life indicator to show when breakthrough occurs, canisters used in atmospheres up to 7.5 ppm (10 × PEL) shall be replaced every 4 hours and industrial sized canisters used in atmospheres up to 75 ppm (100 × PEL) shall be replaced every two hours or at the end of the workshift, whichever is sooner.

* * * * *

(l) *Medical surveillance.* * * *

(8) *Medical removal.* (i) The provisions of paragraph (l)(8) apply when an employee reports significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal conditon contains less than 0.05% formaldehyde.

(ii) An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (l)(3). If the physician determines that a medical examination is not necessary under paragraph (l)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

(iii) If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1% formaldehyde.

(iv) Medical examinations shall be conducted in compliance with the requirements of paragraph (l)(5)(i) and (ii). Additional guidelines for conducting medical exams are contained in appendix C.

(v) If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the affected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

(vi) When an employee is removed pursuant to paragraph (l)(8)(v), the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The employer shall maintain the employee's current earnings, seniority, and other benefits. If there is no such work available, the employer shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to workplace formaldehyde exposure, until the employee is determined to be able to return to the original job status, or for six months, whichever comes first.

(vii) The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

(viii) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(ix) In making determinations of the formaldehyde content of materials under this paragraph the employer may rely on objective data.

(9) *Multiple physician review.* (i) After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or

recommendations of the initial physician and to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical or consultation for the purpose of medical removal or restriction.

(iii) The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a medical opinion, or receipt of the initial physician's written opinion, whichever is later;

(A) The employee informs the employer of the intention to seek a second medical opinion, and

(B) The employee initiates steps to make an appointment with a second physician.

(iv) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

(A) To review the findings, determinations or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

(vi) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(m) *Hazard communication*—(1) *General.* Communication of the hazards associated with formaldehyde in the workplace shall be governed by the requirements of paragraph (m). The definitions of 29 CFR 1910.1200(c) shall apply under this paragraph.

(i) The following shall be subject to the hazard communication requirements of this paragraph: formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air, under reasonably foreseeable conditions of use, at concentrations reaching or exceeding 0.1 ppm.

* * * * *

(3) *Labels.* (i) The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of materials listed in paragraph (m)(1)(i), except to the extent that 29 CFR 1910.1200(f) is inconsistent with this paragraph.

(ii) *Information on labels.* As a minimum, for all materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from material safety data sheets.

(iii) For materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in 29 CFR 1910.1200(d) and 29 CFR 1910.1200 appendices A and B, including respiratory sensitization, and shall contain the words "Potential Cancer Hazard."

(iv) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

(v) *Substitute warning labels.* The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

(4) *Material safety data sheets.* (i) Any employer who uses formaldehyde-containing materials listed in paragraph (m)(1)(i) shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of material safety data sheets.

(ii) Manufacturers, importers, and distributors of formaldehyde-containing materials listed in paragraph (m)(1)(i) shall assure that material safety data sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

(5) *Written hazard communication program.* The employer shall develop, implement, and maintain at the workplace, a written hazard communication program for formaldehyde exposures in the workplace, which at a minimum describes how the requirements specified in this paragraph for labels and other forms of warning and material safety data sheets, and paragraph (n) for employee information and training, will be met. Employers in multi-employer workplaces shall comply with the requirements of 29 CFR 1910.1200(e)(2).

(n) *Employee information and training*—(1) *Participation.* The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

(2) *Frequency.* Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

* * * * *

(p) *Dates.* * * *

(3) *Start-up dates of amended paragraphs*—(i) *Respiratory protection.* Respiratory protection required to meet the amended PEL of 0.75 ppm TWA shall be provided as soon as possible but no later than September 24, 1992.

(ii) *Engineering and work practice controls.* Engineering and work practice controls required to meet the amended PEL of 0.75 ppm TWA shall be implemented as soon as possible, but no later than June 26, 1993.

(iii) *Medical removal protection.* The medical removal protection provisions including the multiple physician review mechanism shall be implemented no later than December 28, 1992.

(iv) *Hazard communication.* The labeling provisions contained in amended paragraph (m) of this standard shall be implemented no later than December 28, 1992. Labeling of containers of formaldehyde products shall continue to comply with the provisions of 29 CFR 1910.1200 (e)–(j) until that time.

(v) *Training.* The periodic training mandated for all employees exposed to formaldehyde between 0.1 ppm and 0.5 ppm shall begin no later than August 25, 1992.

For the convenience of the public, the Formaldehyde Standard, 29 CFR 1910.1048 as revised is set forth below.

§ 1910.1048 Formaldehyde.

(a) *Scope and application.* This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

(b) *Definitions.* For purposes of this standard, the following definitions shall apply:

Action level means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

Assistant Secretary means the Assistant Secretary of Labor for the Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

Authorized person means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency is any occurrence, such as but not limited to equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde.

Employee exposure means the exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use.

Formaldehyde means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50-00-0.

(c) *Permissible Exposure Limit (PEL)*—(1) *TWA*: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8-hour TWA.

(2) *Short Term Exposure Limit (STEL)*: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15-minute STEL.

(d) *Exposure monitoring*—(1) *General.* (i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(ii) *Exception.* Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

(iii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full shift or short-term exposure to formaldehyde, as appropriate.

(iv) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

(2) *Initial monitoring.* The employer shall identify all employees who may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

(i) Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(ii) The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

(iii) If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

(3) *Periodic monitoring.* (i) The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(iii) If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

(4) *Termination of monitoring.* The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

(5) *Accuracy of monitoring.* Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(6) *Employee notification of monitoring results.* Within 15 days of receiving the results of exposure monitoring conducted under this standard, the employer shall notify the affected employees of these results. Notification shall be in writing, either by distributing copies of the results to the employees or by posting the results. If the employee exposure is over either PEL, the employer shall develop and implement a written plan to reduce employee exposure to or below both PELs, and give written notice to employees. The written notice shall contain a description of the corrective action being taken by the employer to decrease exposure.

(7) *Observation of monitoring.* (i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this standard.

(ii) When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and accessways with signs bearing the following information:

DANGER

FORMALDEHYDE

IRRITANT AND POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(2) The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of formaldehyde.

(3) An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) *Methods of compliance*—(1) *Engineering controls and work practices.* The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

(2) *Exception.* Whenever the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the PELs, the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this standard.

(g) *Respiratory protection*—(1) *General.* Where respiratory protection is required, the employer shall provide the respirators at no cost to the employee and shall assure that they are properly used. The respirators shall comply with the requirements of this standard and shall reduce the concentration of formaldehyde inhaled by the employee to at or below both the TWA and the STEL. Respirators shall be used in the following circumstances:

(i) During the interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PELs; and

(iv) In emergencies.

(2) *Respirator selection.* (i) The appropriate respirators as specified in Table 1 shall be selected from those approved by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION AGAINST FORMALDEHYDE

Condition of use or formaldehyde concentration (ppm)	Minimum respirator required[1]
Up to 7.5 ppm. (10 x PEL).	Full facepiece with cartridges or canisters specifically approved for protection against formaldehyde.[2]
Up to 75 ppm. (100 x PEL).	Full-face mask with chin style or chest or back mounted type with industrial size canister specifically approved for protection against formaldehyde. Type C supplied-air respirator, pressure demand or continuous flow type, with full facepiece, hood, or helmet.
Above 75 ppm or unknown (emergencies). (100 x PEL).	Self-contained breathing apparatus (SCBA) with positive pressure full facepiece. Combination supplied-air, full facepiece positive pressure respirator with auxiliary self-contained air supply.
Firefighting	SCBA with positive pressure in full facepiece.
Escape	SCBA in demand or pressure demand mode. Full-face mask with chin style or front or back mounted type industrial size canister specifically approved for protection against formaldehyde.

[1] Respirators specified for use at higher concentrations may be used at lower concentrations.
[2] A half-mask respirator with cartridges specifically approved for protection against formaldehyde can be substituted for the full facepiece respirator providing that effective gas-proof goggles are provided and used in combination with the half-mask respirator.

(ii) The employer shall make available a powered air-purifying respirator adequate to protect against formaldehyde exposure to any employee who experiences difficulty wearing a negative pressure respirator to reduce exposure to formaldehyde.

(3) *Respirator usage.* (i) whenever respirator use is required by this standard, the employer shall institute a respiratory protection program in accordance with 20 CFR 1910.134(b), (d), (e), and (f).

(ii) The employer shall perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in Appendix E at the time of initial fitting and at least annually thereafter for all employees required by this standard to wear negative pressure respirators.

(A) Respirators selected shall be from those exhibiting the best facepiece fit.

(B) No respirator shall be chosen that would potentially permit the employee to inhale formaldehyde at concentrations in excess of either the TWA or the STEL.

(iii) Where air purifying chemical cartridge respirators are used, the cartridges shall be replaced after three hours of use or at the end of the workshift, whichever is sooner unless the cartridge contains a NIOSH-approved end-of-service indicator to show when breakthrough occurs.

(iv) Unless the canister contains a NIOSH-approved end-of-service-life indicator to show when breakthrough occurs, canisters used in atmospheres up to 7.5 ppm (10×PEL) shall be replaced every 4 hours and industrial sized canisters used in atmospheres up to 75 ppm (100×PEL) shall be replaced every two hours or at the end of the workshift, whichever is sooner.

(v) Employers shall permit employees to leave the work area to wash their faces and respirator facepieces as needed to prevent skin irritation from respirator use.

(h) *Protective equipment and clothing.* Employers shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the employer shall provide these protective devices at no cost to the employee and assure that the employee wears them.

(1) *Selection.* The employer shall select protective clothing and equipment based upon the form of formaldehyde to be encountered, the conditions of use, and the hazard to be prevented.

(i) All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and face shields, as appropriate to the operation.

(ii) Contact with irritating or sensitizing materials shall be prevented to the extent necessary to eliminate the hazard.

(iii) Where a face shield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

(iv) Full body protection shall be worn for entry into areas where concentrations exceed 100 ppm and for emergency reentry into areas of unknown concentration.

(2) *Maintenance of protective equipment and clothing.* (i) The employer shall assure that protective equipment and clothing that has become contaminated with formaldehyde is cleaned or laundered before its reuse.

(ii) When ventilating formaldehyde-contaminated clothing and equipment, the employer shall establish a storage area so that employee exposure is minimized. Containers for contaminated clothing and equipment and storage areas shall have labels and signs containing the following information:

DANGER

FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(iii) The employer shall assure that only persons trained to recognize the hazards of formaldehyde remove the contaminated material from the storage area for purposes of cleaning, laundering, or disposal.

(iv) The employer shall assure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

(v) The employer shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

(vi) The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(i) *Hygiene protection.* (1) The employer shall provide change rooms, as described in 29 CFR 1910.141 for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

(2) If employees' skin may become spashed with solutions containing 1 percent or greater formaldehyde, for example, because of equipment failure or improper work practices, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

(3) If there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde, the employer shall provide acceptable eyewash facilities within the immediate work area for emergency use.

(j) *Housekeeping.* For operations involving formaldehyde liquids or gas, the employer shall conduct a program to detect leaks and spills, including regular visual inspections.

(1) Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

(2) In work areas where spillage may occur, the employer shall make provisions to contain the spill, to decontaminate the work area, and to dispose of the waste.

(3) The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for cleanup and decontamination.

(4) Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde.

(k) *Emergencies.* For each workplace where there is the possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

(l) *Medical surveillance*—(1) *Employees covered.* (i) The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL.

(ii) The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in material in concentrations less than 0.1 percent.

(2) *Examination by a physician.* All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) *Medical disease questionnaire.* The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde.

(i) Administration of a medical disease questionnaire, such as in appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease: allergic skin conditions or dermatitis; and upper or lower respiratory problems.

(ii) A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

(4) *Medical examinations.* Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

(i) A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

(ii) Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and forced expiratory flow (FEF).

(iii) Any other test which the examining physician deems necessary to complete the written opinion.

(iv) Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the

increased risk of impairment of their health.

(5) *Examinations for employees exposed in an emergency.* The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

(i) The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

(ii) Other examinations shall consist of those elements considered appropriate by the examining physician.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and appendix A, C, D, and E;

(ii) A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;

(iii) The representative exposure level for the employee's job assignment;

(iv) Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and

(v) Information from previous medical examinations of the affected employee within the control of the employer.

(vi) In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: A description of how the emergency occurred and the exposure the victim may have received.

(7) *Physician's written opinion.* (i) For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

(A) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;

(B) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;

(C) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.

(ii) The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

(8) *Medical removal.* (i) The provisions of paragraph (l)(8) apply when an employee reports significant irritation of the mucosa of the eyes or the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal condition contains less than 0.05% formaldehyde.

(ii) An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (l)(3). If the physician determines that a medical examination is not necessary under paragraph (l)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

(iii) If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1% formaldehyde.

(iv) Medical examinations shall be conducted in compliance with the requirements of paragraph (l)(5) (i) and (ii). Additional guidelines for conducting medical exams are contained in Appendix C.

(v) If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the effected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

(vi) When an employee is removed pursuant to paragraph (l)(8)(v), the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The employeer shall maintain the employee's current earnings, seniority, and other benefits. If there is no such work available, the employer shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to workplace formaldehyde exposure, until the employee is determined to be able to return to the original job status, or for six months, whichever comes first.

(vii) The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

(viii) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(ix) In making determinations of the formaldehyde content of materials under this paragraph the employer may rely on objective data.

(9) *Multiple physician review.* (i) After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation for the purpose of medical removal or restriction.

(iii) The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a second medical opinion, or receipt of the initial physician's written opinion, whichever is later;

(A) The employee informs the employer of the intention to seek a second medical opinion, and

(B) The employee initiates steps to make an appointment with a second physician.

(iv) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

(A) To review the findings, determinations or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

(vi) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(m) *Hazard communication*—(1) *General.* Communication of the hazards associated with formaldehyde in the workplace shall be governed by the requirements of paragraph (m). The definitions of 29 CFR 1910.1200(c) shall apply under this paragraph.

(i) The following shall be subject to the hazard communication requirements of this paragraph: Formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air, under reasonably foreseeable conditions of use, at concentrations reaching or exceeding 0.1 ppm.

(ii) As a minimum, specific health hazards that the employer shall address are: Cancer, irritation and sensitization of the skin and respiratory system, eye and throat irritation, and acute toxicity.

(2) Manufacturers and importers who produce or import formaldehyde or formaldehyde-containing products shall provide downstream employers using or handling these products with an objective determination through the required labels and MSDSs if these items may constitute a health hazard within the meaning of 29 CFR 1910.1200(d) under normal conditions of use.

(3) *Labels.* (i) The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of materials listed in paragraph (m)(1)(i), except to the extent that 29 CFR 1910.1200(f) is inconsistent with this paragraph.

(ii) *Information on labels.* As a minimum, for all materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from material safety data sheets.

(iii) For materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in 29 CFR 1910.1200(d) and 29 CFR 1910.1200 appendices A and B, including respiratory sensitization, and shall contain the words "Potential Cancer Hazard."

(iv) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

(v) *Substitute warning labels.* The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

(4) *Material safety data sheets.* (i) Any employer who uses formaldehyde-containing materials listed in paragraph (m)(1)(i) shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of material safety data sheets.

(ii) Manufacturers, importers, and distributors of formaldehyde-containing materials listed in paragraph (m)(1)(i) shall assure that material safety data sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

(5) *Written hazard communication program.* The employer shall develop, implement, and maintain at the workplace, a written hazard communication program for formaldehyde exposures in the workplace, which at a minimum describes how the requirements specified in this paragraph for labels and other forms of warning and material safety data sheets, and paragraph (n) for employee information and training, will be met. Employers in multi-employer workplaces shall comply with the requirements of 29 CFR 1910.1200(e)(2).

(n) *Employee information and training*—(1) *Participation.* The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

(2) *Frequency.* Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

(3) *Training program.* The training program shall be conducted in a manner which the employee is able to understand and shall include:

(i) A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

(ii) The purpose for and a description of the medical surveillance program required by this standard, including:

(A) A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

(B) Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

(iii) Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(iv) The purpose for, proper use of, and limitations of personal protective clothing and equipment;

(v) Instructions for the handling of spills, emergencies, and clean-up procedures;

(vi) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(vii) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

(4) *Access to training materials.* (i) The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(ii) The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

(o) *Recordkeeping*—(1) *Exposure measurements.* The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

(i) The date of measurement;

(ii) The operation being monitored;

(iii) The methods of sampling and analysis and evidence of their accuracy and precision;

(iv) The number, durations, time, and results of samples taken;

(v) The types of protective devices worn; and

(vi) The names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

(2) *Exposure determinations.* Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

(3) *Medical surveillance.* The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

(i) The name and social security number of the employee;

(ii) The physician's written opinion;

(iii) A list of any employee health complaints that may be related to exposure to formaldehyde; and

(iv) A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the standard or mandated by the examining physician.

(4) *Respirator fit testing.* (i) The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this standard.

(ii) This record shall include:

(A) A copy of the protocol selected for respirator fit testing.

(B) A copy of the results of any fit testing performed.

(C) The size and manufacturer of the types of respirators available for selection.

(D) The date of the most recent fit testing, the name and social security number of each tested employee, and the respirator type and facepiece selected.

(5) *Record retention.* The employer shall retain records required by this standard for at least the following periods:

(i) Exposure records and determinations shall be kept for at least 30 years.

(ii) Medical records shall be kept for the duration of employment plus 30 years.

(iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(6) *Availability of records.* (i) Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

(ii) The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i).

(iii) Employee medical records required by this standard shall be provided upon request for examination and coying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i).

(p) *Dates*—(1) *Effective dates*—(i) *General.* This section shall become effective February 2, 1988, except as noted below.

(ii) *Laboratories.* This standard shall become effective for anatomy, histology, and pathology laboratories February 2, 1988, except as noted in the start-up date section. For all other laboratories, paragraphs (a) and (c) of this standard shall become effective February 2, 1988, and paragraphs (b) and (d)–(o) of this standard shall become effective on September 1, 1988 except as noted in the start-up date section.

(2) *Start-up dates*—(i) *Exposure determinations.* Initial monitoring or objective determinations that no monitoring is required by the standard shall be completed by 6 months after the effective date of the standard.

(ii) *Medical surveillance.* The initial medical surveillance of all eligible employees shall be completed by 6 months after the effective date of the standard.

(iii) *Emergencies.* The emergency procedures required by this standard shall be implemented by 6 months after the effective date of the standard.

(iv) *Respiratory protection.* Respiratory protection as required in this standard shall be provided as soon as possible and no later than 9 months after the effective date of the standard.

(v) *Engineering and work practice controls.* Engineering and work practice controls required by this standard shall be implemented as soon as possible, but no later than one year after the effective date of the standard.

(vi) *Employee training.* Written materials for employee training shall be updated as soon as possible, but no later than 2 months after the effective date of the standard.

(3) *Start-up dates of amended paragraphs*—(i) *Respiratory protection.* Respiratory protection required to meet the amended PEL of 0.75 ppm TWA shall be provided as soon as possible but no later than September 24, 1992.

(ii) *Engineering and work practice controls.* Engineering and work practice controls required to meet the amended PEL of 0.75 ppm TWA shall be implemented as soon as possible, but no later than June 26, 1993.

(iii) *Medical removal protection.* The medical removal protection provisions including the multiple physician review mechanism shall be implemented no later than December 28, 1992.

(iv) *Hazard communication.* The labeling provisions contained in

amended paragraph (m) of this standard shall be implemented no later than December 28, 1992. Labeling of containers of formaldehyde products shall continue to comply with the provisions of 29 CFR 1910.1200 (e)-(j) until that time.

(v) *Training.* The periodic training mandated for all employees exposed to formaldehyde between 0.1 ppm and 0.5 ppm shall begin no later than August 25, 1992.

Appendix A to § 1910.1048—Substance Technical Guidelines for Formalin

The following Substance Technical Guideline for Formalin provides information on uninhibited formalin solution (37% formaldehyde, no methanol stabilizer). It is designed to inform employees at the production level of their rights and duties under the formaldehyde standard whether their job title defines them as workers or supervisors. Much of the information provided is general; however, some information is specific for formalin. When employee exposure to formaldehyde is from resins capable of releasing formaldehyde, the resin itself and other impurities or decomposition products may also be toxic, and employers should include this information as well when informing employees of the hazards associated with the materials they handle. The precise hazards associated with exposure to formaldehyde depend both on the form (solid, liquid, or gas) of the material and the concentration of formaldehyde present. For example, 37-50 percent solutions of formaldehyde present a much greater hazard to the skin and eyes from spills or splashes than solutions containing less than 1 percent formaldehyde. Individual Substance Technical Guidelines used by the employer for training employees should be modified to properly give information on the material actually being used.

Substance Identification

Chemical Name: Formaldehyde
Chemical Family: Aldehyde
Chemical Formula: HCHO
Molecular Weight: 30.03
Chemical Abstracts Service Number (CAS Number): 50-00-0

Synonyms: Formalin; Formic Aldehyde; Paraform; Formol; Formalin (Methanol-free); Fyde; Formalith; Methanal; Methyl Aldehyde; Methylene Glycol; Methylene Oxide; Tetraoxymethalene; Oxomethane; Oxymethylene

Components and Contaminants

Percent: 37.0 Formaldehyde
Percent: 63.0 Water

(Note.—Inhibited solutions contain methanol.)

Other Contaminants: Formic acid (alcohol free)
Exposure Limits:

OSHA TWA—1 ppm
OSHA STEL—2 ppm

Physical Data

Description: Colorless liquid, pungent odor
Boiling point: 214 °F (101 °C)
Specific Gravity: 1.08 (H_2O=1 @ 20 °C)
pH: 2.8-4.0
Solubility in Water: Miscible
Solvent Solubility: Soluble in alcohol and acetone
Vapor Density: 1.04 (Air=1 @ 20 °C)
Odor Threshold: 0.8-1 ppm

Fire and Explosion Hazard

Moderate fire and explosion hazard when exposed to heat or flame.

The flash point of 37% formaldehyde solutions is above normal room temperature, but the explosion range is very wide, from 7 to 73% by volume in air.

Reaction of formaldehyde with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid yields explosive compounds.

Flash Point: 185 °F (85 °C) closed cup
Lower Explosion Limit: 7%
Upper Explosion Limit: 73%
Autoignition Temperature: 806 °F (430 °C)
Flammability Class (OSHA): III A

Extinguishing Media: Use dry chemical, "alcohol foam", carbon dioxide, or water in flooding amounts as fog. Solid streams may not be effective. Cool fire-exposed containers with water from side until well after fire is out.

Use of water spray to flush spills can also dilute the spill to produce nonflammable mixtures. Water runoff, however, should be contained for treatment.

National Fire Protection Association Section 325M Designation:

Health: 2—Materials hazardous to health, but areas may be entered with full-faced mask self-contained breathing apparatus which provides eye protection.

Flammability: 2—Materials which must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity: D—Materials which (in themselves) are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

Reactivity

Stability: Formaldehyde solutions may self-polymerize to form paraformaldehyde which precipitates.

Incompatibility (Materials to Avoid): Strong oxidizing agents, caustics, strong alkalies, isocyanates, anhydrides, oxides, and inorganic acids. Formaldehyde reacts with hydrochloric acid to form the potent carcinogen, bis-chloromethyl ether. Formaldehyde reacts with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid to yield explosive compounds. A violent reaction occurs when formaldehyde is mixed with strong oxidizers.

Hazardous Combustion or Decomposition Products: Oxygen from the air can oxidize formaldehyde to formic acid, especially when heated. Formic acid is corrosive.

Health Hazard Data

Acute Effects of Exposure

Ingestion (Swallowing): Liquids containing 10 to 40% formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04%) may cause discomfort in the stomach and pharynx.

Inhalation (Breathing): Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. Concentrations of 10 to 20 ppm cause difficulty in breathing, burning of the nose and throat, cough, and heavy tearing of the eyes, and 25 to 30 ppm causes severe respiratory tract injury leading to pulmonary edema and pneumonitis. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

Skin (Dermal): Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

Eye Contact: Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent corneal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Note.—The perception of formaldehyde by odor and eye irritation becomes less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on formaldehyde's warning properties to alert him or her to the potential for exposure.

Acute Animal Toxicity:
Oral, rats: LD50=800 mg/kg
Oral, mouse: LD50=42 mg/kg
Inhalation, rats: LCLo=250 mg/kg
Inhalation, mouse: LCLo=900 mg/kg
Inhalation, rats: LC50=590 mg/kg

Chronic Effects of Exposure

Carcinogenicity: Formaldehyde has the potential to cause cancer in humans. Repeated and prolonged exposure increases the risk. Various animal experiments have conclusively shown formaldehyde to be a carcinogen in rats. In humans, formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx, and nasal passages.

Mutagenicity: Formaldehyde is genotoxic in several *in vitro* test systems showing properties of both an initiator and a promoter.

Toxicity: Prolonged or repeated exposure to formaldehyde may result in respiratory impairment. Rats exposed to formaldehyde at 2 ppm developed benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Structural changes in the epithelial cells in the human nose have also been observed. Some persons have developed asthma or bronchitis following exposure to formaldehyde, most often as the result of an accidental spill involving a single exposure to a high concentration of formaldehyde.

Emergency and First Aid Procedures

Ingestion (Swallowing): If the victim is conscious, dilute, inactivate, or absorb the ingested formaldehyde by giving milk, activated charcoal, or water. Any organic material will inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

Inhalation (Breathing): Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim, and medical personnel should be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first-aid or medical personnel should administer oxygen, if available, and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the worker should be hospitalized for observation and treatment.

Skin Contact: Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with soap or mild detergent and large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, get first aid to cover the area with sterile, dry dressing, and bandages. Get medical attention if you experience appreciable eye or respiratory irritation.

Eye Contact: Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). In case of burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you should be referred promptly to an opthamologist for evaluation.

Emergency Procedures

Emergencies: If you work in an area where a large amount of formaldehyde could be released in an accident or from equipment failure, your employer must develop procedures to be followed in event of an emergency. You should be trained in your specific duties in the event of an emergency, and it is important that you clearly understand these duties. Emergency equipment must be accessible and you should be trained to use any equipment that you might need. Formaldehyde contaminated equipment must be cleaned before reuse.

If a spill of appreciable quantity occurs, leave the area quickly unless you have specific emergency duties. Do not touch spilled material. Designated persons may stop the leak and shut off ignition sources if these procedures can be done without risk. Designated persons should isolate the hazard area and deny entry except for necessary people protected by suitable protective clothing and respirators adequate for the exposure. Use water spray to reduce vapors. Do not smoke, and prohibit all flames or flares in the hazard area.

Special Firefighting Procedures: Learn procedures and responsibilities in the event of a fire in your workplace. Become familiar with the appropriate equipment and supplies and their location. In firefighting, withdraw immediately in case of rising sound from venting safety device or any discoloration of storage tank due to fire.

Spill, Leak, and Disposal Procedures

Occupational Spill: For small containers, place the leaking container in a well ventilated area. Take up small spills with absorbent material and place the waste into properly labeled containers for later disposal. For larger spills, dike the spill to minimize contamination and facilitate salvage or disposal. You may be able to neutralize the spill with sodium hydroxide or sodium sulfite. Your employer must comply with EPA rules regarding the clean-up of toxic waste and notify state and local authorities, if required. If the spill is greater than 1,000 lb/day, it is reportable under EPA's Superfund legislation.

Waste Disposal: Your employer must dispose of waste containing formaldehyde in accordance with applicable local, state, and Federal law and in a manner that minimizes exposure of employees at the site and of the clean-up crew.

Monitoring and Measurement Procedures

Monitoring Requirements: If your exposure to formaldehyde exceeds the 0.5 ppm action level or the 2 ppm STEL, your employer must monitor your exposure. Your employer need not measure every exposure if a "high exposure" employee can be identified. This person usually spends the greatest amount of time nearest the process equipment. If you are a "representative employee", you will be asked to wear a sampling device to collect formaldehyde. This device may be a passive badge, a sorbent tube attached to a pump, or an impinger containing liquid. You should perform your work as usual, but inform the person who is conducting the monitoring of any difficulties you are having wearing the device.

Evaluation of 8-hour Exposure: Measurements taken for the purpose of determining time-weighted average (TWA) exposures are best taken with samples covering the full shift. Samples collected must be taken from the employee's breathing zone air.

Short-term Exposure Evaluation: If there are tasks that involve brief but intense exposure to formaldehyde, employee exposure must be measured to assure compliance with the STEL. Sample collections are for brief periods, only 15 minutes, but several samples may be needed to identify the peak exposure.

Monitoring Techniques: OSHA's only requirement for selecting a method for sampling and analysis is that the methods used accurately evaluate the concentration of formaldehyde in employees' breathing zones. Sampling and analysis may be performed by collection of formaldehyde on liquid or solid sorbents with subsequent chemical analysis. Sampling and analysis may also be performed by passive diffusion monitors and short-term exposure may be measured by instruments such as real-time continuous monitoring systems and portable direct reading instruments.

Notification of Results: Your employer must inform you of the results of exposure monitoring representative of your job. You may be informed in writing, but posting the results where you have ready access to them constitutes compliance with the standard.

Protective Equipment and Clothing

[Material impervious to formaldehyde is needed if the employee handles formaldehyde solutions of 1% or more. Other employees may also require protective clothing or equipment to prevent dermatitis.]

Respiratory Protection: Use NIOSH-approved full facepiece negative pressure respirators equipped with approved cartridges or canisters within the use limitations of these devices. (Present restrictions on cartridges and canisters do not permit them to be used for a full workshift.) In all other situations, use positive pressure respirators such as the positive-pressure air purifying respirator or the self-contained breathing apparatus (SCBA). If you use a negative pressure respirator, your employer must provide you with fit testing of the respirator at least once a year in accordance with the procedures outlined in Appendix E.

Protective Gloves: Wear protective (impervious) gloves provided by your employer, at no cost, to prevent contact with formalin. Your employer should select these gloves based on the results of permeation testing and in accordance with the ACGIH Guidelines for Selection of Chemical Protective Clothing.

Eye Protection: If you might be splashed in the eyes with formalin, it is essential that you wear goggles or some other type of complete protection for the eye. You may also need a face shield if your face is likely to be splashed with formalin, but you must not substitute face shields for eye protection. (This section pertains to formaldehyde solutions of 1% or more.)

Other Protective Equipment: You must wear protective (impervious) clothing and equipment provided by your employer at no cost to prevent repeated or prolonged contact with formaldehyde liquids. If you are required to change into whole-body chemical protective clothing, your employer must provide a change room for your privacy and for storage of your normal clothing.

If you are splashed with formaldehyde, use the emergency showers and eyewash fountains provided by your employer

immediately to prevent serious injury. Report the incident to your supervisor and obtain necessary medical support.

Entry Into an IDLH Atmosphere

Enter areas where the formaldehyde concentration might be 100 ppm or more only with complete body protection including a self-contained breathing apparatus with a full facepiece operated in a positive pressure mode or a supplied air respirator with full facepiece and operated in a positive pressure mode. This equipment is essential to protect your life and health under such extreme conditions.

Engineering Controls

Ventilation is the most widely applied engineering control method for reducing the concentration of airborne substances in the breathing zones of workers. There are two distinct types of ventilation.

Local Exhaust: Local exhaust ventilation is designed to capture airborne contaminants as near to the point of generation as possible. To protect you, the direction of contaminant flow must always be toward the local exhaust system inlet and away from you.

General (Mechanical): General dilution ventilation involves continuous introduction of fresh air into the workroom to mix with the contaminated air and lower your breathing zone concentration of formaldehyde. Effectiveness depends on the number of air changes per hour. Where devices emitting formaldehyde are spread out over a large area, general dilution ventilation may be the only practical method of control.

Work Practices: Work practices and administrative procedures are an important part of a control system. If you are asked to perform a task in a certain manner to limit your exposure to formaldehyde, it is extremely important that you follow these procedures.

Medical Surveillance

Medical surveillance helps to protect employees' health. You are encouraged strongly to participate in the medical surveillance program.

Your employer must make a medical surveillance program available at no expense to you and at a reasonable time and place if you are exposed to formaldehyde at concentrations above 0.5 ppm as an 8-hour average or 2 ppm over any 15-minute period. You will be offered medical surveillance at the time of your initial assignment and once a year afterward as long as your exposure is at least 0.5 ppm (TWA) or 2 ppm (STEL). Even if your exposure is below these levels, you should inform your employer if you have signs and symptoms that you suspect, through your training, are related to your formaldehyde exposure because you may need medical surveillance to determine if your health is being impaired by your exposure.

The surveillance plan includes:

(a) A medical disease questionnaire.

(b) A physical examination if the physician determines this is necessary.

If you are required to wear a respirator, your employer must offer you a physical examination and a pulmonary function test every year.

The physician must collect all information needed to determine if you are at increased risk from your exposure to formaldehyde. At the physician's discretion, the medical examination may include other tests, such as a chest x-ray, to make this determination.

After a medical examination the physician will provide your employer with a written opinion which includes any special protective measures recommended and any restrictions on your exposure. The physician must inform you of any medical conditions you have which would be aggravated by exposure to formaldehyde.

All records from your medical examinations, including disease surveys, must be retained at your employer's expense.

Emergencies

If you are exposed to formaldehyde in an emergency and develop signs or symptoms associated with acute toxicity from formaldehyde exposure, your employer must provide you with a medical examination as soon as possible. This medical examination will include all steps necessary to stabilize your health. You may be kept in the hospital for observation if your symptoms are severe to ensure that any delayed effects are recognized and treated.

Appendix B to § 1910.1048—Sampling Strategy and Analytical Methods for Formaldehyde

To protect the health of employees, exposure measurements must be unbiased and representative of employee exposure. The proper measurement of employee exposure requires more than a token commitment on the part of the employer. OSHA's mandatory requirements establish a baseline; under the best of circumstances all questions regarding employee exposure will be answered. Many employers, however, will wish to conduct more extensive monitoring before undertaking expensive commitments, such as engineering controls, to assure that the modifications are truly necessary. The following sampling strategy, which was developed at NIOSH by Nelson A. Leidel, Kenneth A. Busch, and Jeremiah R. Lynch and described in NIOSH publication No. 77-173 (Occupational Exposure Sampling Strategy Manual) will assist the employer in developing a strategy for determining the exposure of his or her employees.

There is no one correct way to determine employee exposure. Obviously, measuring the exposure of every employee exposed to formaldehyde will provide the most information on any given day. Where few employees are exposed, this may be a practical solution. For most employers, however, use of the following strategy will give just as much information at less cost.

Exposure data collected on a single day will not automatically guarantee the employer that his or her workplace is always in compliance with the formaldehyde standard. This does not imply, however, that it is impossible for an employer to be sure that his or her worksite is in compliance with the standard. Indeed, a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved provided that measurements are conducted using valid sampling strategy and approved analytical methods.

There are two PELs, the TWA concentration and the STEL. Most employers will find that one of these two limits is more critical in the control of their operations, and OSHA expects that the employer will concentrate monitoring efforts on the critical component. If the more difficult exposure is controlled, this information, along with calculations to support the assumptions, should be adequate to show that the other exposure limit is also being achieved.

Sampling Strategy

Determination of the Need for Exposure Measurements

The employer must determine whether employees may be exposed to concentrations in excess of the action level. This determination becomes the first step in an employee exposure monitoring program that minimizes employer sampling burdens while providing adequate employee protection. If employees may be exposed above the action level, the employer must measure exposure. Otherwise, an objective determination that employee exposure is low provides adequate evidence that exposure potential has been examined.

The employer should examine all available relevant information, *eg.* insurance company and trade association data and information from suppliers or exposure data collected from similar operations. The employer may also use previously-conducted sampling including area monitoring. The employer must make a determination relevant to each operation although this need not be on a separate piece of paper. If the employer can demonstrate conclusively that no employee is exposed above the action level or the STEL through the use of objective data, the employer need proceed no further on employee exposure monitoring until such time that conditions have changed and the determination is no longer valid.

If the employer cannot determine that employee exposure is less than the action level and the STEL, employee exposure monitoring will have to be conducted.

Workplace Material Survey

The primary purpose of a survey of raw material is to determine if formaldehyde is being used in the work environment and if so, the conditions under which formaldehyde is being used.

The first step is to tabulate all situations where formaldehyde is used in a manner such that it may be released into the workplace atmosphere or contaminate the skin. This information should be available through analysis of company records and information on the MSDSs available through provisions of this standard and the Hazard Communication standard.

If there is an indication from materials handling records and accompanying MSDSs that formaldehyde is being used in the following types of processes or work operations, there may be a potential for releasing formaldehyde into the workplace atmosphere:

(1) Any operation that involves grinding, sanding, sawing, cutting, crushing, screening, sieving, or any other manipulation of material that generates formaldehyde-bearing dust

(2) Any processes where there have been employee complaints or symptoms indicative of exposure to formaldehyde

(3) Any liquid or spray process involving formaldehyde

(4) Any process that uses formaldehyde in preserved tissue

(5) Any process that involves the heating of a formaldehyde-bearing resin.

Processes and work operations that use formaldehyde in these manners will probably require further investigation at the worksite to determine the extent of employee monitoring that should be conducted.

Workplace Observations

To this point, the only intention has been to provide an indication as to the existence of potentially exposed employees. With this information, a visit to the workplace is needed to observe work operations, to identify potential health hazards, and to determine whether any employees may be exposed to hazardous concentrations of formaldehyde.

In many circumstances, sources of formaldehyde can be identified through the sense of smell. However, this method of detection should be used with caution because of olfactory fatigue.

Employee location in relation to source of formaldehyde is important in determining if an employee may be significantly exposed to formaldehyde. In most instances, the closer a worker is to the source, the higher the probability that a significant exposure will occur.

Other characteristics should be considered. Certain high temperature operations give rise to higher evaporation rates. Locations of open doors and windows provide natural ventilation that tend to dilute formaldehyde emissions. General room ventilation also provides a measure of control.

Calculation of Potential Exposure Concentrations

By knowing the ventilation rate in a workplace and the quantity of formaldehyde generated, the employer may be able to determine by calculation if the PELs might be exceeded. To account for poor mixing of formaldehyde into the entire room, locations of fans and proximity of employees to the work operation, the employer must include a safety factor. If an employee is relatively close to a source, particularly if he or she is located downwind, a safety factor of 100 may be necessary. For other situations, a factor of 10 may be acceptable. If the employer can demonstrate through such calculations that employee exposure does not exceed the action level or the STEL, the employer may use this information as objective data to demonstrate compliance with the standard.

Sampling Strategy

Once the employer determines that there is a possibility of substantial employee exposure to formaldehyde, the employer is obligated to measure employee exposure.

The next step is selection of a maximum risk employee. When there are different processes where employees may be exposed to formaldehyde, a maximum risk employee should be selected for each work operation.

Selection of the maximum risk employee requires professional judgment. The best procedure for selecting the maximum risk employee is to observe employees and select the person closest to the source of formaldehyde. Employee mobility may affect this selection; *eg.* if the closest employee is mobile in his tasks, he may not be the maximum risk employee. Air movement patterns and differences in work habits will also affect selection of the maximum risk employee.

When many employees perform essentially the same task, a maximum risk employee cannot be selected. In this circumstance, it is necessary to resort to random sampling of the group of workers. The objective is to select a subgroup of adequate size so that there is a high probability that the random sample will contain at least one worker with high exposure if one exists. The number of persons in the group influences the number that need to be sampled to ensure that at least one individual from the highest 10 percent exposure group is contained in the sample. For example, to have 90 percent confidence in the results, if the group size is 10, nine should be sampled; for 50, only 18 need to be sampled.

If measurement shows exposure to formaldehyde at or above the action level or the STEL, the employer needs to identify all other employees who may be exposed at or above the action level or STEL and measure or otherwise accurately characterize the exposure of these employees.

Whether representative monitoring or random sampling are conducted, the purpose remains the same—to determine if the exposure of any employee is above the action level. If the exposure of the most exposed employee is less than the action level and the STEL, regardless of how the employee is identified, then it is reasonable to assume that measurements of exposure of the other employees in that operation would be below the action level and the STEL.

Exposure Measurements

There is no "best" measurement strategy for all situations. Some elements to consider in developing a strategy are:

(1) Availability and cost of sampling equipment

(2) Availability and cost of analytic facilities

(3) Availability and cost of personnel to take samples

(4) Location of employees and work operations

(5) Intraday and interday variations in the process

(6) Precision and accuracy of sampling and analytic methods, and

(7) Number of samples needed.

Samples taken for determining compliance with the STEL differ from those that measure the TWA concentration in important ways. STEL samples are best taken in a nonrandom fashion using all available knowledge relating to the area, the individual, and the process to obtain samples during periods of maximum expected concentrations. At least three measurements on a shift are generally needed to spot gross errors or mistakes; however, only the highest value represents the STEL.

If an operation remains constant throughout the workshift, a much greater number of samples would need to be taken over the 32 discrete nonoverlapping periods in an 8-hour workshift to verify compliance with a STEL. If employee exposure is truly uniform throughout the workshift, however, an employer in compliance with the 1 ppm TWA would be in compliance with the 2 ppm STEL, and this determination can probably be made using objective data.

Need to Repeat the Monitoring Strategy

Interday and intraday fluctuations in employee exposure are mostly influenced by the physical processes that generate formaldehyde and the work habits of the employee. Hence, in-plant process variations influence the employer's determination of whether or not additional controls need to be imposed. Measurements that employee exposure is low on a day that is not representative of worst conditions may not provide sufficient information to determine whether or not additional engineering controls should be installed to achieve the PELs.

The person responsible for conducting sampling must be aware of systematic changes which will negate the validity of the sampling results. Systematic changes in formaldehyde exposure concentration for an employee can occur due to:

(1) The employee changing patterns of movement in the workplace

(2) Closing of plant doors and windows

(3) Changes in ventilation from season to season

(4) Decreases in ventilation efficiency or abrupt failure of engineering control equipment

(5) Changes in the production process or work habits of the employee.

Any of these changes, if they may result in additional exposure that reaches the next level of action (*i.e.* 0.5 or 1.0 ppm as an 8-hr average or 2 ppm over 15 minutes) require the employer to perform additional monitoring to reassess employee exposure.

A number of methods are suitable for measuring employee exposure to formaldehyde or for characterizing emissions within the worksite. The preamble to this standard describes some methods that have been widely used or subjected to validation testing. A detailed analytical procedure derived from the OSHA Method 52 for acrolein and formaldehyde is presented below for informational purposes.

Inclusion of OSHA's method in this appendix in no way implies that it is the only acceptable way to measure employee exposure to formaldehyde. Other methods that are free from significant interferences and that can determine formaldehyde at the permissible exposure limits within ±25 percent of the "true" value at the 95 percent confidence level are also acceptable. Where applicable, the method should also be capable of measuring formaldehyde at the action level to ±35 percent of the "true" value with a 95 percent confidence level.

OSHA encourages employers to choose methods that will be best for their individual needs. The employer must exercise caution, however, in choosing an appropriate method since some techniques suffer from interferences that are likely to be present in workplaces of certain industry sectors where formaldehyde is used.

OSHA's Analytical Laboratory Method

Method No: 52
Matrix: Air
Target Concentration: 1 ppm (1.2 mg/m ^{3})
Procedures: Air samples are collected by drawing known volumes of air through sampling tubes containing XAD-2 adsorbent which have been coated with 2-(hydroxymethyl) piperidine. The samples are desorbed with toluene and then analyzed by gas chromatography using a nitrogen selective detector.
Recommended Sampling Rate and Air Volumes: 0.1 L/min and 24 L
Reliable Quantitation Limit: 16 ppb (20 μg/m^3)
Standard Error of Estimate at the Target Concentration: 7.3%
Status of the Method: A sampling and analytical method that has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.
Date: March 1985

1. General Discussion

1.1 *Background:* The current OSHA method for collecting acrolein vapor recommends the use of activated 13X molecular sieves. The samples must be stored in an ice bath during and after sampling and also they must be analyzed within 48 hours of collection. The current OSHA method for collecting formaldehyde vapor recommends the use of bubblers containing 10% methanol in water as the trapping solution.

This work was undertaken to resolve the sample stability problems associated with acrolein and also to eliminate the need to use bubblers to sample formaldehyde. A goal of this work was to develop and/or to evaluate a common sampling and analytical procedure for acrolein and formaldehyde.

NIOSH has developed independent methodologies for acrolein and formaldehyde which recommend the use of reagent-coated adsorbent tubes to collect the aldehydes as stable derivatives. The formaldehyde sampling tubes contain Chromosorb 102 adsorbent coated with N-benzylethanolamine (BEA) which reacts with formaldehyde vapor to form a stable oxazolidine compound. The acrolein sampling tubes contain XAD-2 adsorbent coated with 2-(hydroxymethyl)piperidine (2-HMP) which reacts with acrolein vapor to form a different, stable oxazolidine derivative. Acrolein does not appear to react with BEA to give a suitable reaction product. Therefore, the formaldehyde procedure cannot provide a common method for both aldehydes. However, formaldehyde does react with 2-HMP to form a very suitable reaction product. It is the quantitative reaction of acrolein and formaldehyde with 2-HMP that provides the basis for this evaluation.

This sampling and analytical procedure is very similar to the method recommended by NIOSH for acrolein. Some changes in the NIOSH methodology were necessary to permit the simultaneous determination of both aldehydes and also to accommodate OSHA laboratory equipment and analytical techniques.

1.2 *Limit-defining parameters:* The analyte air concentrations reported in this method are based on the recommended air volume for each analyte collected separately and a desorption volume of 1 mL. The amounts are presented as acrolein and/or formaldehyde, even though the derivatives are the actual species analyzed.

1.2.1 *Detection limits of the analytical procedure:* The detection limit of the analytical procedure was 386 pg per injection for formaldehyde. This was the amount of analyte which gave a peak whose height was about five times the height of the peak given by the residual formaldehyde derivative in a typical blank front section of the recommended sampling tube.

1.2.2 *Detection limits of the overall procedure:* The detection limits of the overall procedure were 482 ng per sample (16 ppb or 20 μg/m^3 for formaldehyde). This was the amount of analyte spiked on the sampling device which allowed recoveries approximately equal to the detection limit of the analytical procedure.

1.2.3 *Reliable quantitation limits:* The reliable quantitation limit was 482 ng per sample (16 ppb or 20 μg/m^3) for formaldehyde. These were the smallest amounts of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (±1.96 SD) of ±25% or better.

The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters.

1.2.4 *Sensitivity:* The sensitivity of the analytical procedure over concentration ranges representing 0.4 to 2 times the target concentration, based on the recommended air volumes, was 7,589 area units per μg/mL for formaldehyde. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5 *Recovery:* The recovery of formaldehyde from samples used in an 18-day storage test remained above 92% when the samples were stored at ambient temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6 *Precision (analytical method only):* The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.4 to 2 times the target concentration was 0.0052 for formaldehyde (Section 4.3).

1.2.7 *Precision (overall procedure):* The precision at the 95% confidence level for the ambient temperature storage tests was ±14.3% for formaldehyde. These values each include an additional ±5% for sampling error. The overall procedure must provide results at the target concentrations that are ±25% at the 95% confidence level.

1.2.8 *Reproducibility:* Samples collected from controlled test atmospheres and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The formaldehyde samples were analyzed following 15 days storage. The average recovery was 96.3% and the standard deviation was 1.7%.

1.3 *Advantages:*

1.3.1 The sampling and analytical procedures permit the simultaneous determination of acrolein and formaldehyde.

1.3.2 Samples are stable following storage at ambient temperature for at least 18 days.

1.4 *Disadvantages:* None.

2. Sampling Procedure

2.1 *Apparatus:*

2.1.1 Samples are collected by use of a personal sampling pump that can be calibrated to within ±5% of the recommended 0.1 L/min sampling rate with the sampling tube in line.

2.1.2 Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane treated glass and is about 8-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with a 75-mg backup section, located nearest the tapered end and a 150-mg sampling section of pretreated XAD-2 adsorbent which has been coated with 2-HMP. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and the coating of XAD-2 adsorbent are presented in Section 4 of this method.

2.1.3 Sampling tubes, similar to those recommended in this method, are marketed by Supelco, Inc. These tubes were not available when this work was initiated; therefore, they were not evaluated.

2.2 *Reagents:* None required.

2.3 *Technique:*

2.3.1 Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2 Attach the sampling tube to the pump using a section of flexible plastic tubing such that the large, front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3 After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps.

2.3.4 Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5 List any potential interferences on the sample data sheet.

2.4 *Breakthrough:*

2.4.1 Breakthrough was defined as the relative amount of analyte found on a backup sample in relation to the total amount of analyte collected on the sampling train.

2.4.2 For formaldehyde collected from test atmospheres containing 6 times the PEL, the average 5% breakthrough air volume was 41 L. The sampling rate was 0.1 L/min and the average mass of formaldehyde collected was 250 μg.

2.5 *Desorption Efficiency:* No desorption efficiency corrections are necessary to compute air sample results because analytical standards are prepared using coated adsorbent. Desorption efficiencies were determined, however, to investigate the recoveries of the analytes from the sampling device. The average recovery over the range of 0.4 to 2 times the target concentration, based on the recommended air volumes, was 96.2% for formaldehyde. Desorption efficiencies were essentially constant over the ranges studied.

2.6 *Recommended Air Volume and Sampling Rate:*

2.6.1 The recommended air volume for formaldehyde is 24 L.

2.6.2 The recommended sampling rate is 0.1 L/min.

2.7 *Interferences:*

2.7.1 Any collected substance that is capable of reacting 2-HMP and thereby depleting the derivatizing agent is a potential interference. Chemicals which contain a carbonyl group, such as acetone, may be capable or reacting with 2-HMP.

2.7.2 There are no other known interferences to the sampling method.

2.8 *Safety Precautions:*

2.8.1 Attach the sampling equipment to the worker in such a manner that it well not interfere with work performance or safety.

2.8.2 Follow all safety practices that apply to the work area being sampled.

3. Analytical Procedure

3.1 *Apparatus:*

3.1.1 A gas chromatograph (GC), equipped with a nitrogen selective detector. A Hewlett-Packard Model 5840A GC fitted with a nitrogen-phosphorus flame ionization detector (NPD) was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

3.1.2 A GC column capable of resolving the analytes from any interference. A 6 ft x ¼ in OD (2mm ID) glass GC column containing 10% UCON 50–HB–5100 + 2% KOH on 80/100 mesh Chromosorb W–AW was used for the evaluation. Injections were performed on-column.

3.1.3 Vials, glass 2-mL with Teflon-lined caps.

3.1.4 Volumetric flasks, pipets, and syringes for preparing standards, making dilutions, and performing injections.

3.2 *Reagents:*

3.2.1 Toluene and dimethylformamide. Burdick and Jackson solvents were used in this evaluation.

3.2.2 Helium, hydrogen, and air, GC grade.

3.2.3 Formaldehyde, 37%, by weight, in water. Aldrich Chemical, ACS Reagent Grade formaldehyde was used in this evaluation.

3.2.4 Amberlite XAD-2 adsorbent coated with 2-(hydroxymethyl—piperidine (2-HMP), 10% by weight (Section 4).

3.2.5 Desorbing solution with internal standard. This solution was prepared by adding 20 μL of dimethylformamide to 100 mL of toluene.

3.3 *Standard preparation:*

3.3.1 *Formaldehyde:* Prepare stock standards by diluting known volumes of 37% formaldehyde solution with methanol. A procedure to determine the formaldehyde content of these standards is presented in Section 4. A standard containing 7.7 mg/mL formaldehyde was prepared by diluting 1 mL of the 37% reagent to 50 mL with methanol.

3.3.2 It is recommended that analytical standards be prepared about 16 hours before the air samples are to be analyzed in order to ensure the complete reaction of the analytes with 2-HMP. However, rate studies have shown the reaction to be greater than 95% complete after 4 hours. Therefore, one or two standards can be analyzed after this reduced time if sample results are outside the concentration range of the prepared standards.

3.3.3 Place 150-mg portions of coated XAD-2 adsorbent, from the same lot number as used to collect the air samples, into each of several glass 2-mL vials. Seal each vial with a Teflon-lined cap.

3.3.4 Prepare fresh analytical standards each day by injecting appropriate amounts of the diluted analyte directly onto 150-mg portions of coated adsorbent. It is permissible to inject both acrolein and formaldehyde on the same adsorbent portion. Allow the standards to stand at room temperature. A standard, approximately the target levels, was prepared by injecting 11 μL of the acrolein and 12 μL of the formaldehyde stock standards onto a single coated XAD-2 adsorbent portion.

3.3.5 Prepare a sufficient number of standards to generate the calibration curves. Analytical standard concentrations should bracket sample concentrations. Thus, if samples are not in the concentration range of the prepared standards, additional standards must be prepared to determine detector response.

3.3.7 Desorb the standards in the same manner as the samples following the 16-hour reaction time.

3.4 *Sample preparation:*

3.4.1 Transfer the 150-mg section of the sampling tube to a 2-mL vial. Place the 75-mg section in a separate vial. If the glass wool plugs contain a significant number of adsorbent beads, place them with the appropriate sampling tube section. Discard the glass wool plugs if they do not contain a significant number of adsorbent beads.

3.4.2 Add 1 mL of desorbing solution to each vial.

3.4.3 Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand with vigorous force several times during the desorption time.

3.4.4 Save the used sampling tubes to be cleaned and recycled.

3.5 *Analysis:*

3.5.1 GC *Conditions*

Column Temperature:

Bi-level temperature program—First level: 100 to 140 °C at 4 °C/min following completion of the first level.

Second level: 140 to 180 °C at 20 °C/min following completion of the first level.

Isothermal period: Hold column at 180 °C until the recorder pen returns to baseline (usually about 25 min after injection).

Injector temperature: 180 °C

Helium flow rate: 30 mL/min (detector response will be reduced if nitrogen is substituted for helium carrier gas).

Injection volume: 0.8 μL

GC column: Six-ft x ¼-in OD (2 mm ID) glass GC column containing 10% UCON 50–HB–5100+2% KOH on 80/100 Chromosorb W-AW.

NPD conditions:

Hydrogen flow rate: 3 mL/min

Air flow rate: 50 mL/min

Detector temperature: 275 °C

3.5.2 *Chromatogram:* For an example of a typical chromatogram, see Figure 4.11 in OSHA Method 52.

3.5.3 Use a suitable method, such as electronic integration, to measure detector response.

3.5.4 Use an internal standard method to prepare the calibration curve with several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report results in μg/mL.

3.5.5 Bracket sample concentrations with standards.

3.6 *Interferences (Analytical)*

3.6.1 Any compound with the same general retention time as the analytes and which also gives a detector response is a potential interference. Possible interferences should be reported to the laboratory with submitted samples by the industrial hygienist.

3.6.2 GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3 A useful means of structure designation is GC/MS. It is recommended this procedure be used to confirm samples whenever possible.

3.6.4 The coated adsorbent usually contains a very small amount of residual formaldehyde derivative (Section 4.8).

3.7 *Calculations:*

3.7.1 Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2 The concentration, in μg/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If either of the analytes is found on the backup section, it is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3 The acrolein and/or formaldehyde air concentration can be expressed using the following equation:

$mg/m^3 = (A)(B)/C$

where A = μg/mL from 3.7.2, B = desorption volume, and C = L of air sampled.

No desorption efficiency corrections are required.

3.7.4 The following equation can be used to convert results in mg/m^3 to ppm.

$ppm = (mg/m^3)(24.45)/MW$

where mg/m^3 = result from 3.7.3, 24.45 = molar volume of an ideal gas at 760 mm Hg and 25 °C, MW = molecular weight (30.0).

4. Backup Data

4.1 Backup data on detection limits, reliable quantitation limits, sensitivity and precision of the analytical method, breakthrough, desorption efficiency, storage, reproducibility, and generation of test atmospheres are available in OSHA Method 52, developed by the Organics Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah.

4.2 *Procedure to Coat XAD-2 Adsorbent with 2-HMP:*

4.2.1 *Apparatus:* Soxhlet extraction apparatus, rotary evaporation apparatus, vacuum dessicator, 1-L vacuum flask, 1-L round-bottomed evaporative flask, 1-L Erlenmeyer flask, 250-mL Buchner funnel with a coarse fritted disc, etc.

4.2.2 *Reagents:*

4.2.2.1 Methanol, isooctane, and toluene.

4.2.2.2 2-(Hydroxymethyl)piperidine.

4.2.2.3 Amberlite XAD-2 non-ionic polymeric adsorbent, 20 to 60 mesh, Aldrich Chemical XAD-2 was used in this evaluation.

4.2.3 *Procedure:* Weigh 125 g of crude XAD-2 adsorbent into a 1-L Erlenmeyer flask. Add about 200 mL of water to the flask and then swirl the mixture to wash the adsorbent. Discard any adsorbent that floats to the top of the water and then filter the mixture using a fritted Buchner funnel. Air dry the adsorbent for 2 minutes. Transfer the adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent to a 1-L round-bottomed evaporative flask, add 13 g of 2-HMP and then 200 mL of methanol, swirl the mixture and then allow it to stand for one hour. Remove the methanol at about 40 °C and reduced pressure using a rotary evaporation apparatus. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator at room temperature overnight. Transfer the coated adsorbent to a Soxhlet extractor and then extract the material with toluene for about 24 hours. Discard the contaminated toluene, add methanol in its place and then continue the Soxhlet extraction for an additional 4 hours. Transfer the adsorbent to a weighted 1-L round-bottom evaporative flask and remove the methanol using the rotary evaporation apparatus. Determine the weight of the adsorbent and then add an amount of 2-HMP, which is 10% by weight of the adsorbent. Add 200 mL of methanol and then swirl the mixture. Allow the mixture to stand for one hour. Remove the methanol by rotary evaporation. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator until all traces of solvents are gone. Typically, this will take 2-3 days. The coated adsorbent should be protected from contamination. XAD-2 adsorbent treated in this manner will probably not contain residual acrolein derivative. However, this adsorbent will often contain residual formaldehyde derivative levels of about 0.1 µg per 150 mg of adsorbent. If the blank values for a batch of coated adsorbent are too high, then the batch should be returned to the Soxhlet extractor, extracted with toluene again and then recoated. This process can be repeated until the desired blank levels are attained.

The coated adsorbent is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number. A sufficient amount of each lot number of coated adsorbent should be retained to prepare analytical standards for use with air samples from that lot number.

4.3 *A Procedure to Determine Formaldehyde by Acid Titration:* Standardize the 0.1 N HCl solution using sodium carbonate and methyl orange indicator.

Place 50 mL of 0.1 M sodium sulfite and three drops of thymophthalein indicator into a 250-mL Erlenmeyer flask. Titrate the contents of the flask to a colorless endpoint with 0.1 N HCl (usually one or two drops is sufficient). Transfer 10 mL of the formaldehyde/methanol solution (prepared in 3.3.1) into the same flask and titrate the mixture with 0.1 N HCl, again, to a colorless endpoint. The formaldehyde concentration of the standard may be calculated by the following equation:

$$\text{Formaldehyde, mg/mL} = \frac{\text{acid titer} \times \text{acid normality} \times 30.0}{\text{mL of sample}}$$

This method is based on the quantitative liberation of sodium hydroxide when formaldehyde reacts with sodium sulfite to form the formaldehyde-bisulfite addition product. The volume of sample may be varied depending on the formaldehyde content but the solution to be titrated must contain excess sodium sulfite. Formaldehyde solutions containing substantial amounts of acid or base must be neutralized before analysis.

Appendix C to § 1910.1048—Medical Surveillance—Formaldehyde

I. Health Hazards

The occupational health hazards of formaldehyde are primarily due to its toxic effects after inhalation, after direct contact with the skin or eyes by formaldehyde in liquid or vapor form, and after ingestion.

II. Toxicology

A. Acute Effects of Exposure

1. *Inhalation (breathing):* Formaldehyde is highly irritating to the upper airways. The concentration of formaldehyde that is immediately dangerous to life and health is 100 ppm. Concentrations above 50 ppm can cause severe pulmonary reactions within minutes. These include pulmonary edema, pneumonia, and bronchial irritation which can result in death. Concentrations above 5 ppm readily cause lower airway irritation characterized by cough, chest tightness and wheezing. There is some controversy regarding whether formaldehyde gas is a pulmonary sensitizer which can cause occupational asthma in a previously normal individual. Formaldehyde can produce symptoms of bronchial asthma in humans. The mechanism may be either sensitization of the individual by exposure to formaldehyde or direct irritation by formaldehyde in persons with pre-existing asthma. Upper airway irritation is the most common respiratory effect reported by workers and can occur over a wide range of concentrations, most frequently above 1 ppm. However, airway irritation has occurred in some workers with exposures to formaldehyde as low as 0.1 ppm. Symptoms of upper airway irritation include dry or sore throat, itching and burning sensations of the nose, and nasal congestion. Tolerance to this level of exposure may develop within 1-2 hours. This tolerance can permit workers remaining in an environment of gradually increasing formaldehyde concentrations to be unaware of their increasingly hazardous exposure.

2. *Eye contact:* Concentrations of formaldehyde between 0.05 ppm and 0.5 ppm produce a sensation of irritation in the eyes with burning, itching, redness, and tearing. Increased rate of blinking and eye closure generally protects the eye from damage at these low levels, but these protective mechanisms may interfere with some workers' work abilities. Tolerance can occur in workers continuously exposed to concentrations of formaldehyde in this range. Accidental splash injuries of human eyes to aqueous solutions of formaldehyde (formalin) have resulted in a wide range of ocular injuries including corneal opacities and blindness. The severity of the reactions have been directly dependent on the concentration of formaldehyde in solution and the amount of time lapsed before emergency and medical intervention.

3. *Skin contact:* Exposure to formaldehyde solutions can cause irritation of the skin and allergic contact dermatitis. These skin

diseases and disorders can occur at levels well below those encountered by many formaldehyde workers. Symptoms include erythema, edema, and vesiculation or hives. Exposure to liquid formalin or formaldehyde vapor can provoke skin reactions in sensitized individuals even when airborne concentrations of formaldehyde are well below 1 ppm.

4. *Ingestion:* Ingestion of as little as 30 ml of a 37 percent solution of formaldehyde (formalin) can result in death. Gastrointestinal toxicity after ingestion is most severe in the stomach and results in symptoms which can include nausea, vomiting, and servere abdominal pain. Diverse damage to other organ systems including the liver, kidney, spleen, pancreas, brain, and central nervous systems can occur from the acute response to ingestion of formaldehyde.

B. Chronic Effects of Exposure

Long term exposure to formaldehyde has been shown to be associated with an increased risk of cancer of the nose and accessory sinuses, nasopharyngeal and oropharyngeal cancer, and lung cancer in humans. Animal experiments provide conclusive evidence of a causal relationship between nasal cancer in rats and formaldehyde exposure. Concordant evidence of carcinogenicity includes DNA binding, genotoxicity in short-term tests, and cytotoxic changes in the cells of the target organ suggesting both preneoplastic changes and a dose-rate effect. Formaldehyde is a complete carcinogen and appears to exert an effect on at least two stages of the carcinogenic process.

III. Surveillance considerations

A. History

1. *Medical and occupational history:* Along with its acute irritative effects, formaldehyde can cause allergic sensitization and cancer. One of the goals of the work history should be to elicit information on any prior or additional exposure to formaldehyde in either the occupational or the non-occupational setting.

2. *Respiratory history:* As noted above, formaldehyde has recognized properties as an airway irritant and has been reported by some authors as a cause of occupational asthma. In addition, formaldehyde has been associated with cancer of the entire respiratory system of humans. For these reasons, it is appropriate to include a comprehensive review of the respiratory system in the medical history. Components of this history might include questions regarding dyspnea on exertion, shortness of breath, chronic airway complaints, hyperreactive airway disease, rhinitis, bronchitis, bronchiolitis, asthma, emphysema, respiratory allergic reaction, or other preexisting pulmonary disease.

In addition, generalized airway hypersensitivity can result from exposures to a single sensitizing agent. The examiner should, therefore, elicit any prior history of exposure to pulmonary irritants, and any short- or long-term effects of that exposure.

Smoking is known to decrease mucociliary clearance of materials deposited during respiration in the nose and upper airways. This may increase a worker's exposure to inhaled materials such as formaldehyde vapor. In addition, smoking is a potential confounding factor in the investigation of any chronic respiratory disease, including cancer. For these reasons, a complete smoking history should be obtained.

3. *Skin Disorders:* Because of the dermal irritant and sensitizing effects of formaldehyde, a history of skin disorders should be obtained. Such a history might include the existence of skin irritation, previously documented skin sensitivity, and other dermatologic disorders. Previous exposure to formaldehyde and other dermal sensitizers should be recorded.

4. *History of atopic or allergic diseases:* Since formaldehyde can cause allergic sensitization of the skin and airways, it might be useful to identify individuals with prior allergen sensitization. A history of atopic disease and allergies to formaldehyde or any other substances should also be obtained. It is not definitely known at this time whether atopic diseases and allergies to formaldehyde or any other substances should also be obtained. Also it is not definitely known at this time whether atopic individuals have a greater propensity to develop formaldehyde sensitivity than the general population, but identification of these individuals may be useful for ongoing surveillance.

5. *Use of disease questionnaires:* Comparison of the results from previous years with present results provides the best method for detecting a general deterioration in health when toxic signs and symptoms are measured subjectively. In this way recall bias does not affect the results of the analysis. Consequently, OSHA has determined that the findings of the medical and work histories should be kept in a standardized form for comparison of the year-to-year results.

B. Physical Examination

1. *Mucosa of eyes and airways:* Because of the irritant effects of formaldehyde, the examining physician should be alert to evidence of this irritation. A speculum examination of the nasal mucosa may be helpful in assessing possible irritation and cytotoxic changes, as may be indirect inspection of the posterior pharynx by mirror.

2. *Pulmonary system:* A conventional respiratory examination, including inspection of the thorax and auscultation and percussion of the lung fields should be performed as part of the periodic medical examination. Although routine pulmonary function testing is only required by the standard once every year for persons who are exposed over the TWA concentration limit, these tests have an obvious value in investigating possible respiratory dysfunction and should be used wherever deemed appropriate by the physician. In cases of alleged formaldehyde-induced airway disease, other possible causes of pulmonary disfunction (including exposures to other substances) should be ruled out. A chest radiograph may be useful in these circumstances. In cases of suspected airway hypersensitivity or allergy, it may be appropriate to use bronchial challenge testing with formaldehyde or methacholine to determine the nature of the disorder. Such testing should be performed by or under the supervision of a physician experienced in the procedures involved.

3. *Skin:* The physician should be alert to evidence of dermal irritation of sensitization, including reddening and inflammation, urticaria, blistering, scaling, formation of skin fissures, or other symptoms. Since the integrity of the skin barrier is compromised by other dermal diseases, the presence of such disease should be noted. Skin sensitivity testing carries with it some risk of inducing sensitivity, and therefore, skin testing for formaldehyde sensitivity should not be used as a routine screening test. Sensitivity testing may be indicated in the investigation of a suspected existing sensitivity. Guidelines for such testing have been prepared by the North American Contact Dermatitis Group.

C. Additional Examinations or Tests

The physician may deem it necessary to perform other medical examinations or tests as indicated. The standard provides a mechanism whereby these additional investigations are covered under the standard for occupational exposure to formaldehyde.

D. Emergencies

The examination of workers exposed in an emergency should be directed at the organ systems most likely to be affected. Much of the content of the examination will be similar to the periodic examination unless the patient has received a severe acute exposure requiring immediate attention to prevent serious consequences. If a severe overexposure requiring medical intervention or hospitalization has occurred, the physician must be alert to the possibility of delayed symptoms. Followup nonroutine examinations may be necessary to assure the patient's well-being.

E. Employer Obligations

The employer is required to provide the physician with the following information: A copy of this standard and appendices A, C, D, and E; a description of the affected employee's duties as they relate to his or her exposure concentration; an estimate of the employee's exposure including duration (*e.g.* 15 hr/wk, three 8-hour shifts, full-time); a description of any personal protective equipment, including respirators, used by the employee; and the results of any previous medical determinations for the affected employee related to formaldehyde exposure to the extent that this information is within the employer's control.

F. Physician's Obligations

The standard requires the employer to obtain a written statement from the physician. This statement must contain the physician's opinion as to whether the employee has any medical condition which would place him or her at increased risk of impaired health from exposure to formaldehyde or use of respirators, as appropriate. The physician must also state his opinion regarding any restrictions that should be placed on the employee's exposure to formaldehyde or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to formaldehyde, the

physician's opinion must also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician must inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure to formaldehyde.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being inpaired by formaldehyde, and to assess the employee's ability to use any required protective equipment.

Appendix D to § 1910.1048—Nonmandatory Medical Disease Questionnaire

A. Identification

Plant Name _____
Date _____
Employee Name _____
S.S. # _____
Job Title _____
Birthdate: _____
Age: _____
Sex: _____
Height: _____
Weight: _____

B. Medical History

1. Have you ever been in the hospital as a patient?
Yes ☐ No ☐
If yes, what kind of problem were you having? _____

2. Have you ever had any kind of operation?
Yes ☐ No ☐
If yes, what kind? _____

3. Do you take any kind of medicine regularly?
Yes ☐ No ☐
If yes, what kind? _____

4. Are you allergic to any drugs, foods, or chemicals?
Yes ☐ No ☐
If yes, what kind of allergy is it? _____
What causes the allergy? _____

5. Have you ever been told that you have asthma, hayfever, or sinusitis?
Yes ☐ No ☐

6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems?
Yes ☐ No ☐

7. Have you ever been told you had hepatitis?
Yes ☐ No ☐

8. Have you ever been told that you had cirrhosis?
Yes ☐ No ☐

9. Have you ever been told that you had cancer?
Yes ☐ No ☐

10. Have you ever had arthritis or joint pain?
Yes ☐ No ☐

11. Have you ever been told that you had high blood pressure?
Yes ☐ No ☐

12. Have you ever had a heart attack or heart trouble?
Yes ☐ No ☐

B-1. Medical History Update

1. Have you been in the hospital as a patient any time within the past year?
Yes ☐ No ☐
If so, for what condition? _____

2. Have you been under the care of a physician during the past year?
Yes ☐ No ☐
If so, for what condition? _____

3. Is there any change in your breathing since last year?
Yes ☐ No ☐
Better? _____
Worse? _____
No change? _____
If change, do you know why? _____

4. Is your general health different this year from last year?
Yes ☐ No ☐
If different, in what way? _____

5. Have you in the past year or are you now taking any medication on a regular basis?
Yes ☐ No ☐
Name Rx _____
Condition being treated _____

C. Occupational History

1. How long have you worked for your present employer?

2. What jobs have you held with this employer? Include job title and length of time in each job.

3. In each of these jobs, how many hours a day were you exposed to chemicals?

4. What chemicals have you worked with most of the time?

5. Have you ever noticed any type of skin rash you feel was related to your work?
Yes ☐ No ☐

6. Have you ever noticed that any kind of chemical makes you cough?
Yes ☐ No ☐
Wheeze?
Yes ☐ No ☐
Become short of breath or cause your chest to become tight?
Yes ☐ No ☐

7. Are you exposed to any dust or chemicals at home?
Yes ☐ No ☐
If yes, explain: _____

8. In other jobs, have you ever had exposure to:
Wood dust?
Yes ☐ No ☐
Nickel or chromium?
Yes ☐ No ☐
Silica (foundry, sand blasting)?
Yes ☐ No ☐
Arsenic or asbestos?
Yes ☐ No ☐
Organic solvents?
Yes ☐ No ☐
Urethane foams?
Yes ☐ No ☐

C-1. Occupational History Update

1. Are you working on the same job this year as you were last year?
Yes ☐ No ☐
If not, how has your job changed? _____

2. What chemicals are you exposed to on your job?

3. How many hours a day are you exposed to chemicals?

4. Have you noticed any skin rash within the past year you feel was related to your work?
Yes ☐ No ☐
If so, explain circumstances: _____

5. Have you noticed that any chemical makes you cough, be short of breath, or wheeze?
Yes ☐ No ☐
If so, can you identify it? _____

D. Miscellaneous

1. Do you smoke?
Yes ☐ No ☐
If so, how much and for how long? _____
Pipe _____
Cigars _____
Cigarettes _____

2. Do you drink alcohol in any form?
Yes ☐ No ☐
If so, how much, how long, and how often?

3. Do you wear glasses or contact lenses?
Yes ☐ No ☐

4. Do you get any physical exercise other than that required to do your job?
Yes ☐ No ☐
If so, explain: _____

5. Do you have any hobbies or "side jobs" that require you to use chemicals, such as furniture stripping, sand blasting, insulation or manufacture of urethane foam, furniture, etc?
Yes ☐ No ☐
If so, please describe, giving type of business or hobby, chemicals used and length of exposures.

E. Symptoms Questionnaire

1. Do you ever have any shortness of breath?
Yes ☐ No ☐
If yes, do you have to rest after climbing several flights of stairs?
Yes ☐ No ☐
If yes, if you walk on the level with people your own age, do you walk slower than they do?
Yes ☐ No ☐
If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk?
Yes ☐ No ☐
If yes, do you have to stop and rest while bathing or dressing?

Yes ☐ No ☐
2. Do you cough as much as three months out of the year?
Yes ☐ No ☐
If yes, have you had this cough for more than two years?
Yes ☐ No ☐
If yes, do you ever cough anything up from chest?
Yes ☐ No ☐
3. Do you ever have a feeling of smothering, unable to take a deep breath, or tightness in your chest?
Yes ☐ No ☐
If yes, do you notice that this on any particular day of the week?
Yes ☐ No ☐
If yes, what day or the week?
Yes ☐ No ☐
If yes, do you notice that this occurs at any particular place?
Yes ☐ No ☐
If yes, do you notice that this is worse after you have returned to work after being off for several days?
Yes ☐ No ☐
4. Have you ever noticed any wheezing in your chest?
Yes ☐ No ☐
If yes, is this only with colds or other infections?
Yes ☐ No ☐
Is this caused by exposure to any kind of dust or other material?
Yes ☐ No ☐
If yes, what kind? _____
5. Have you noticed any burning, tearing, or redness of your eyes when you are at work?
Yes ☐ No ☐
If so, explain circumstances: _____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work?
Yes ☐ No ☐
If so, explain circumstances: _____

7. Have you noticed any stuffiness or dryness of your nose?
Yes ☐ No ☐
8. Do you ever have swelling of the eyelids or face?
Yes ☐ No ☐
9. Have you ever been jaundiced?
Yes ☐ No ☐
If yes, was this accompanied by any pain?
Yes ☐ No ☐
10. Have you ever had a tendency to bruise easily or bleed excessively?
Yes ☐ No ☐
11. Do you have frequent headaches that are not relieved by aspirin or tylenol?
Yes ☐ No ☐
If yes, do they occur at any particular time of the day or week?
Yes ☐ No ☐
If yes, when do they occur? _____

12. Do you have frequent episodes of nervousness or irritability?
Yes ☐ No ☐
13. Do you tend to have trouble concentrating or remembering?
Yes ☐ No ☐
14. Do you ever feel dizzy, light-headed, excessively drowsy or like you have been drugged?
Yes ☐ No ☐
15. Does your vision ever become blurred?
Yes ☐ No ☐
16. Do you have numbness or tingling of the hands or feet or other parts of your body?
Yes ☐ No ☐
17. Have you ever had chronic weakness or fatigue?
Yes ☐ No ☐
18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes?
Yes ☐ No ☐
19. Are you bothered by heartburn or indigestion?
Yes ☐ No ☐
20. Do you ever have itching, dryness, or peeling and scaling of the hands?
Yes ☐ No ☐
21. Do you ever have a burning sensation in the hands, or reddening of the skin?
Yes ☐ No ☐
22. Do you ever have cracking or bleeding of the skin on your hands?
Yes ☐ No ☐
23. Are you under a physician's care?
Yes ☐ No ☐
If yes, for what are you being treated? _____

24. Do you have any physical complaints today?
Yes ☐ No ☐
If yes, explain? _____

25. Do you have other health conditions not covered by these questions?
Yes ☐ No ☐
If yes, explain: _____

Appendix E to § 1910.1048—Qualitative and Quantitative Fit Testing Procedures

I. FIT Test Protocols

Because exposure to formaldehyde can affect the employee's ability to detect common odorants, fit test results from the isoamyl acetate test must be augmented by results from either the saccharin or irritant smoke test.

A. The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT).

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece; and units from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) position of the mask on the nose.
(b) room for eye protection.
(c) room to talk.
(d) position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) chin properly placed;
(b) adequate strap tension, not overly tightened;
(c) fit across nose bridge;
(d) respirator of proper size to span distance from nose to chin;
(e) tendency of respirator to slip;
(f) self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or ANSI Z88.2-1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

(a) *Positive pressure test.* Close off the exhalation valve and exhale gently onto the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

(b) *Negative pressure test.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which

cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respiratory disease or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

11. The test subject shall be given the opportunity to wear the successfully fitted respirator for a period of two weeks. If at any time during this period the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall certify that a successful fit test has been administered to the employee. The certification shall include the following information:

(a) Name of employee;

(b) Type, brand and size of respirator; and

(c) Date of test;

Where QNFT is used, the fit factor, strip chart, or other recording of the results of the test, shall be retained with the certification. The certification shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure.

The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(a) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally.

(b) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) *Turning head side to side.* Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) *Moving head up and down.* Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

(f) *Grimace.* The test subject shall grimace by smiling or frowning.

(g) *Bending over.* The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) *Normal breathing.* Same as exercise 1.

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. *General.* (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that tese equipment is in proper working order.

(c) The employer shall assure the QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Isoamyl Acetate Protocol*—(a) *Odor threshold screening.* The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1-liter glass jars with metal lids are required.

(2) Odor free water (e.g., distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clear dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contain a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA ordor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) *Isoamyl acetate fit test.* (1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall ware it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so

there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. *Saccharin Solution Aerosol Protocol.* The saccharin solution aerosol QLFT protocol is the only currently available, validated test protocol for use with particulate disposable dust respirators not equipped with high-efficiency filters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) *Taste threshold screening.* The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) Threshold screening as well as fit testing subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) *Saccharin solution aerosol fit test procedure.* (1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particular filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeeezes as initially.

(10) The test subject shall indicate to the test conductor if any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. *Irritant Fume Protocol.* (a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristric odor.

(c) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(d) If a half-mask is being fitted, advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocol

1. *General.* (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Definitions.* (a) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agency is a gas or vapor.

(b) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(c) Test subject means the person wearing the respirator for quantitative fit testing.

(d) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(e) Maximum peak penetration method means the method of determing test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(f) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(g) "Fit Factor" means the ratio of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. *Apparatus.* (a) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitiative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively

isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(d) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(g) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(i) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-effciency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies sush as cracks, missing valves and gaskets, etc.

4. *Procedural Requirements.* (a) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(b) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(h) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g., half mask respirator, full facepiece respirator).

(i) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(2) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak concentration

(ii) Maximum peak concentration

(iii) Integration by calculation of the area under the individual peak for each exercise. This includes computerized integration.

(j) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(k) The test subject shall not be permitted to wear a half mask, or full facepiece respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(l) Filters used for quantitative fit testing shall be replaced at least weekly, or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

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