(タイトルペーパー)

アメリカ合衆国労働安全衛生法、1970年(Occupational Safety and Health Act of 1970)に基づくホルムアルデヒドに関する労働安全衛生基準(1910.1047)について

本稿は、アメリカ合衆国労働安全衛生法に基づいてがん原性物質の一つとして規制されているホルムアルデヒドについての次の労働安全衛生 基準ほぼ全文(ただし、附属書 A~E については別記1に記載している方針に沿って本稿で紹介します。)について、「英語原文―日本語仮訳」 の形式で紹介するものです。

Part Number: 1910

• Part Number Title:Occupational Safety and Health Standards

• Subpart:1910 Subpart Z

Subpart Title: Toxic and Hazardous Substances

■ Standard Number: 1910.1047

Title: Formaldehyde

GPO Source: e-CFR

• 部番号:1910

• 部番号の標題:労働安全衛生基準

細部番号:1910細部Z

細部標題:有害及び危険物質

• 基準番号:1910.1047

• 標題;ホルムアルデヒド

情報源:

https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-XVIII/part-1910/subtitle-B/chapter-A/dia-B/chapter-A/dia-B/chapter-B/chapter-A/dia-B/chapter-A/dia-B/chapter-B

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(別記1 附属書A~Eについての本稿での掲載方針)

附属書 A~E までの一覧(英語原文)	左欄の日本語仮訳	附属書A~Eまでについての本稿での資料とし
(資料作成者注:この列の英語原文をクリック		ての取扱い
すれば原典の英語原文にアクセスできます。)		
o 1910.1048 App A - Substance	o 1910.1048 附属書 A - ホルマリンに関する	附属書 A については重要と思われる部分のみ
Technical Guidelines for	物質技術指針(Substance Technical	を抜粋して「英語原文―日本語仮訳」として紹
Formalin	Guidelines for Formalin	介しました。
o 1910.1048 App B - Sampling strategy	o 1910.1048 附属書 B - ホルムアルデヒドの	附属書 B については、日本語仮訳を作成せず
and analytical methods for	試料採取方法及び分析方法	に原典の英語原文をそのまま別に掲載してあ
formaldehyde		ります。
o 1910.1048 App C - Medical	o 1910.1048 附属書 C - 医療監視(サーベイ	附属書 C については、原則として原典の英語
surveillance - Formaldehyde	ランス) ホルムアルデヒド	原文について「英語原文―日本語仮訳」として
		紹介しました。
o 1910.1048 App D - Nonmandatory	o 1910.1048 附属書 D - 義務でない医学的疾	附属書 D については、日本語仮訳を作成せず
medical disease questionnaire	患の質問票	に原典の英語原文をそのまま別に掲載してあ
		ります。
1010 1040 A E [D 1]	1010 1040 4 『仏日寺 P 「火川(人) ナンナーフ	地域ないよので、土柱では相撲していよりに
o 1910.1048 App E - [Removed]	ο 1910.1048 A 附属書 E − [削除しました。]。	削除されたので、本稿では掲載していません。

Editorial Note: Nomenclature changes to part 1910 appear at <u>84 FR 21597</u>, May 14, 2019.

原典の編集者注:1910部の命名法の変更は、2019年5月14日、84 FR 21597 に掲載されています。

○ホルムアルデヒドに関する労働安全衛生基準(1910.1047)の全条項(附属書 A~D の掲載方針については別記 1 を参照されたい。)の「英語原文─日本語仮訳」

- (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.
- (a) 範囲及び適用 本基準は、ホルムアルデヒドへのすべての職業的ばく露、すなわちホルムアルデヒドガス、その溶液及びホルムアルデヒドを放出する材料からのばく露に適用される。
- (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.

(b) 定義。本基準では、以下の定義が適用される:

対処濃度とは、8 時間の時間加重平均 (TWA) 濃度として算出される、空気 100 万部当たり 0.5 部のホルムアルデヒド (0.5ppm) の濃度をいう。

次官補とは、米国労働省の労働安全衛生管理局次官補又はその被指名人をいう。

許可された者とはとは、規制区域に存在することが作業上必要な者又は使用者、本節若しくは 1970 年 OSH 法から許可された者をいう。

所長とは、米国保健福祉省労働安全衛生研究所所長又はその被指名人をいう。

緊急事態とは、機器の故障、容器の破裂又は制御機器の故障のような、制御不能なホルムアルデヒドの大量放出につながるあらゆる事象をいう。

被雇用者のばく露とは、使用中の呼吸用保護具による保護を補正することなく発生するホルムアルデヒドの空気中へのばく露を意味します。

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

ホルムアルデヒドとは、化学物質、HCHO、Chemical Abstracts Service Registry No.50-00-0 を意味します。

(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.

(c) 許容ばく露限界値 (PEL) —

- (1) **TWA** (時間荷重平均値。以下同じ。):使用者は、8 時間 **TWA** として 100 万分の 0.75 (0.75pm)を超えるホルムアルデヒドの空気中濃度に被雇用者がさらされないことを保証するものとする。
- (2) 短期間ばく露限界値(STEL。以下同じ。)): 使用者は、15 分間における STE として空気中の 100 万分当たり 2 部のホルムアルデヒド(2ppm) を超えるホルムアルデヒドの空気中濃度に被雇用者がばく露されないことを保証するものとする。
- (d) ばく露モニタリング(資料作成者注:ばく露監視。以下単に「モニタリング」と訳します。) —
- (1) 一般的なこと。
- (i) 本基準の対象となる事業場を有する各使用者は、被雇用者のホルムアルデヒドへのばく露を把握するために、モニタリングを行うこと。
- (ii) **何外。**ホルムアルデヒド又はホルムアルデヒド放出製品が職場に存在して も、予測可能な使用条件下で、被雇用者が対処濃度又は **STEL** 以上のばく露を 受けるようなホルムアルデヒドの空気中濃度にならないことを、使用者が客観的 データを用いて証明する場合には、使用者は被雇用者のホルムアルデヒドへのば く露を測定する必要はない。
- (iii) 被雇用者のばく露が代表試料採取から決定される場合には、使用される測定値は、適宜、被雇用者の全シフト又はホルムアルデヒドへの短期間ばく露を代表するものでなければならないものとする。

- (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

- (iv) 各作業区域の各職種の代表的なサンプルは、使用者が、ある職種のばく露レベルが異なる作業シフトでも同等であることを客観的データで証明できない限り、シフトごとに採取しなければならないものとする。
- (2) 初期モニタリング。使用者は、対処濃度以上又は STEL 以上のばく露を受ける可能性のある全ての被雇用者を特定し、特定された各被雇用者従のばく露量を正確に測定するものとする。
- (i) 使用者がホルムアルデヒドにさらされる可能性のある各被雇用者のばく露を 測定することを選択しない限り、使用者は代表的な試料採取方法を策定し、各ば く露グループ内の被雇用者のばく露を正しく特徴付け、過小評価しないように、 各作業シフトの各職種において十分なばく露を測定するものとするとする。
- (ii) 生産、設備、工程、人員又は管理措置に変更があり、ホルムアルデヒドへの 新たな又は追加の暴露をもたらす可能性がある場合は、最初のモニタリングプロ セスを毎回繰り返すものとする。
- (iii) ホルムアルデヒドばく露に関連する呼吸器若しくは皮膚症状の兆候又は症状の報告を受けた場合には、使用者は、影響を受ける被雇用者のばく露を速やかに監視するものとする。

(3) 定期的なモニタリング

- (i) 使用者は、最初のモニタリングにより、ホルムアルデヒドが対処濃度以上又は STEL 以上であることが示された被雇用者のホルムアルデヒドへのばく露を 定期的に測定し、正確に判断するものとする。
- (ii)最後のモニタリングの結果、被雇用者のばく露が対処濃度以上であることが 判明した場合、使用者は少なくとも 6 ヶ月ごとに被雇用者のモニタリングを繰 り返すものとする。
- (iii) 前回のモニタリングの結果、被雇用者がSTEL以上のばく露を受けた場合、

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.* The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions 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

使用者は最悪の条件下で少なくとも 1 年に 1 回、被雇用者のモニタリングを繰り返えすものとする。

- (4) *モニタリングの終了。*少なくとも 7 日間の間隔をおいて採取された連続する 2 つの試料採取期間の結果が、被雇用者のばく露が対処濃度及び STEL を下回っていることを示す場合、使用者は被雇用者に対する定期的なモニタリングを中止することができる。この結果は、統計的に代表的なものでなければならず、また、職務及び作業操作に関する使用者の知識と一致するものでなければならない。
- (5) *モニタリングの正確性*。モニタリングは、95%の信頼水準で、TWA及びSTELのホルムアルデヒドの空気中濃度についてはプラスマイナス 25%以内、対処濃度のホルムアルデヒドの空気中濃度についてはプラスマイナス 35%以内の精度を有するものとする。
- (6) モニタリング結果の被雇用者への通知。 使用者は、本節に基づき実施されたモニタリングの結果を受け取ってから 15 営業日以内に、影響を受ける各被雇用者に対し、個別に書面で通知するか、被雇用者が閲覧できる適切な場所に掲示することにより、結果を通知しなければならない。 被雇用者のばく露が PEL を超える場合、影響を受ける被雇用者には、ばく露を減らすために使用者が行っている是正措置の説明を提供するものとする。

(7) モニタリングの観察

- (i) 使用者は、影響を受ける被雇用者又はその指定代理人に、本基準で要求されるホルムアルデヒドへの被雇用者ばく露のモニタリングを観察する機会を提供するものとする。
- (ii)被雇用者 のホルムアルデヒドへのばく露のモニタリングの観察で、保護服又は機器の使用が必要な区域に入る必要がある場合、使用者は観察者にその服及び

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.

機器を提供し、観察者にその服や機器の使用を要求し、観察者が他のすべての該当する安全衛生手順を遵守することを保証するものとする。

(e) Regulated areas—

(1) **Signs.**

(i) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

DANGER

FORMALDEHYDE

MAY CAUSE CANCER

CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION

AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

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

(e)規制された区域―

(1) 標識

(i) 使用者は、空気中のホルムアルデヒド濃度が TWA 又は STEL を超える規制 区域を設定し、すべての入口及び進入路に以下の凡例が記載された標識を掲示するものとする:

危険

ホルムアルデヒド

がんを引き起こす可能性がある。

皮膚、目及び呼吸器に刺激を与える。

許可された人員のみが立ち入れる。

(ii) 2016 年 6 月 1 日以前は、本項(e)(1)(i)に規定される凡例に代えて、使用者は以下の凡例を使用できる:

危険

ホルムアルデヒデド

刺激性及び潜在的ながんの危険性

許可された人員のみが立ち入れる。

- (2) 使用者は、規制区域への立ち入りを、ホルムアルデヒドの危険性を認識するための訓練を受けた許可された者に限定するものとする。
- (3) 規制区域を設定する複数の使用者がいる事業場の使用者は、当該事業場で作業を行う他の使用者に対し、立入制限及びこれらの区域の場所を伝達するものと

(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.

(f) 順守の方法

- (1) 技術的管理及び作業慣行。使用者は、被雇用者のホルムアルデヒドへのばく 露を TWA 及び STEL 以下に低減し、及び維持するために、技術的及び作業的な 管理を実施するものとする。
- (2) **例外**。実現可能な技術的及び作業的管理では、被雇用者のばく露を PEL のいずれかに低減できないことを使用者が立証した場合、使用者はこれらの管理を適用して被雇用者のばく露を実現可能な範囲で低減し、本基準を満たす呼吸用保護具(レスピレーター)で補完するものとする。

(g) Respiratory protection —

- (1) *General.* For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:
- (i) Periods necessary to install or implement feasible engineering and work-practice controls.
- (ii) 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) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

(g) 呼吸器の保護-

- (1) 一般。本節で要求される呼吸用保護具を使用する被雇用者に対して、使用者は、本項の要件に準拠した適切な呼吸用保護具を各被雇用医者に提供するものとする。呼吸用保護具は、以下の期間中に使用されなければならない:
- (i) 実現可能な技術的及び作業的な管理を設置又は実施するために必要な期間
- (ii) 保守及び修理作業又は容器の洗浄のような、使用者が工学的及び作業的管理 が実行不可能であることを証明した作業工程
- (iii) 実現可能な技術的及び作業的管理が、被雇用者のばく露を PELs 以下に低減するのに未だ十分でない作業作業

- (iv) Emergencies.
- (2) Respirator program.
- (i) The employer must implement a respiratory protection program in accordance with § 1910.134(b) through (d) (except (d)(1)(iii), (d)(3)(iii)(b)(1), and (2)), and (f) through (m), which covers each employee required by this section to use a respirator.
- (ii) When employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by <u>paragraphs (d)(3)(iii)(B)(1)</u> and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever
- (3) Respirator selection.
- (i) Employers must:
- (A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.
- (B) Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.
- (C) For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front-or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.
- (ii) Employers may substitute an air-purifying, half mask respirator for an air-purifying, full facepiece respirator when they equip the half mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

- (iv) 緊急時
- (2) 呼吸用保護具 (レスピレーター) プログラム
- (i) 使用者は、本項により呼吸用保護具の使用を必要とする労働者を対象として、 $\$1910.134(b)\sim(d)$ ((d)(1)(iii)、(d)(3)(iii) (b) (1)、(2)を除く。)、(f) \sim (m) に基づいて呼吸保護プログラムを実施しなければならない。
- (ii) 被雇用者が、国立労働安全衛生研究所によって承認された耐用年数指標を含まない化学物質カートリッジ又はキャニスターを備えた空気清浄呼吸用保護具を使用する場合、使用者は、29 CFR 1910.134 の (d)(3)(iii) (B)(1) 及び (B)(2) 項で指定されたとおり、又は交代制勤務 (作業シフト) の終了時にこれらのカートリッジ又はキャニスターを交換しなければならない。
- (3) 呼吸用保護具 (レスピレーター) の選択
- (i) 使用者は、以下のことをしなければならない:
- (A) 29 CFR 1910.134 の(d)(3)(i)(A)に規定する適切な呼吸用保護具を選択し、被雇用者に提供する。
- (B) 各空気浄化用フルフェイスピース型呼吸用保護具に、ホルムアルデヒドに対する保護として承認されたキャニスター又はカートリッジを装備する。
- (C) 避難のために、被雇用者に以下の呼吸用保護具の選択肢の一つを提供する:需要モード又は圧力需要モードで作動する自給式呼吸用保護具又はホルムアルデヒドに対する保護が承認されたあご型又は前面若しくは背面に取り付けられた工業用サイズのキャニスター若しくはカートリッジを有するフルフェイスピース型呼吸用保護具
- (ii) 使用者は、ホルムアルデヒドに対する保護が承認されたカートリッジをハーフマスクレスピレーターに装備し、影響を受ける被雇用者に有効な防毒ゴーグルを提供する場合、空気清浄ハーフマスクレスピレーターを空気清浄フルフェイスピースレスピレーターに代えてもよい。

- (iii) Employers must provide employees who have difficulty using negative pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this standard and that affords adequate protection against formaldehyde exposures.
- (iii) 使用者は、陰圧呼吸用保護具の使用が困難な被雇用者に対し、本基準の(g)(3)(i)(A)の下で使用が許可され、ホルムアルデヒドばく露に対する適切な保護をもたらす動力式空気浄化呼吸用保護具を提供しなければならない。

- (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.

- (h) **保護具及び衣服**。使用者は、29 CFR 1910.132 及び 29 CFR 1910.133 の 規定を遵守するものとする。これらの規定により保護具又は衣類が提供される場 合、使用者はこれらの保護具を被雇用者に無償で提供し、被雇用者が着用するこ とを保証するものとする。
- (1) **選定。** 使用者は、遭遇するホルムアルデヒドの形態、使用条件及び防止すべき危険有害性に基づいて、保護衣及び保護具を選択するものとする。
- (i) 1%以上のホルムアルデヒドを含む液体と目及び皮膚との接触は、ホルムアルデヒドを通さない素材でできた化学防護服の使用及び作業に応じてゴーグル及びフェイスシールドのようなその他の個人防護具の使用により、すべて防がなければならないものとする。
- (ii) 刺激性又は感作性のある物質との接触は、危険有害性を除去するために必要な範囲で防止すされるものとする。
- (iii) 顔面シールドを着用する場合、ホルムアルデヒドが目の部分に到達する危険性がある場合は、化学安全ゴーグルも必要である。
- (iv) 濃度が 100ppm を超える区域への立ち入り及び濃度が不明な区域への緊急 再立ち入りの際には、全身保護具を着用するものとする。

- (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 formaldehyde-contaminated clothing and equipment is ventilated, the employer shall establish storage areas so that employee exposure is minimized.
- (A) *Signs.* Storage areas for contaminated clothing and equipment shall have signs bearing the following legend:

DANGER

FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT

MAY CAUSE CANCER

CAUSES SKIN, EYE AND RESPIRATORY IRRITATION

DO NOT BREATHE VAPOR

DO NOT GET ON SKIN

(B) *Labels.* The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, § 1910.1200, and shall, as a minimum, include the following:

FORMALDEHYDE-CONTAMINATED

[CLOTHING]

EQUIPMENT

DANGER

MAY CAUSE CANCER

CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION DO NOT BREATHE VAPOR

(2) 保護具及び衣服の維持管理

- (i) 使用者は、ホルムアルデヒドで汚染された保護具及び衣類が再使用される前 に洗浄又は洗濯されることを保証するものとする。
- (ii) ホルムアルデヒドで汚染された衣類及び機器を換気する場合、使用は被雇用者のばく露が最小限になるように保管場所を設定するものとする。
- (A) 標識。汚染された衣服及び機器の保管場所には、以下の凡例が記載された標識を設置するものとする:

危険

ホルムアルデヒドに汚染された[衣類]機器

がんを引き起こす可能性がある。

皮膚、目及び呼吸器に刺激を与える。

蒸気を吸わないこと。

皮膚に付着させないこと。

(B) ラベル。使用者は、汚染された衣類及び機器の容器に、危険有害性周知基準 (§1910.1200) に沿ったラベルを貼ることを確実にするものとし、最低限、以下を含むものとする:

危険

ホルムアルデヒドで汚染された[衣服]装置

ホルムアルデヒドに汚染された[衣類]機器は、がんを引き起こす可能性がある。

皮膚、目及び呼吸器への刺激の原因となる。

蒸気を吸わないこと。

皮膚に付着させないこと。

DO NOT GET ON SKIN

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

DANGER

FORMALDEHYDE-CONTAMINATED

[CLOTHING]

EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(D) Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(ii)(B) of this section:

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.

(C) 2016 年 6 月 1 日以前は、本節の本項(h)(2)(ii)(A)に規定される凡例に代えて、使用者は以下の凡例を使用できる:

危険

ホルムアルデヒドに汚染された[衣服]機器 吸入及び皮膚接触を避ける。

(D) 2015 年 6 月 1 日以前は、使用者は、本節の本項(h)(2)(ii)(B)の表示要件の代わりに、保護衣及び保護具の容器に以下の情報を含めることができる:

危険

ホルムアルデヒドに汚染された[衣服]機器 吸入と皮膚接触を避ける。

- (iii) 使用者は、ホルムアルデヒドの危険性を認識するよう訓練された者だけが、 洗浄、洗濯又は廃棄の目的で汚染物を保管場所から取り除くよう保証するものと する。
- (iv) 使用者は、ホルムアルデヒドで汚染された機器又は衣類を持ち帰る被雇用者 がいないことを保証するものとする。
- (v) 使用者は、影響を受ける各被雇用者に対して、必要な保護衣や保護具を、その効果を保証するために必要に応じて修理又は交換するものとする。
- (vi) 使用者は、そのような衣類又は機器を洗濯し、洗浄し、又は修理する者に、ホルムアルデヒドの潜在的な有害作用及び衣類及び機器を安全に取り扱うための手順を知らせるものとする。

(i) Hygiene protection.

- (1) The employer shall provide change rooms, as described in <u>29 CFR 1910.141</u> 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.

(i) 衛生保護

- (1) 使用者は、ホルムアルデヒドとの皮膚接触を防ぐため、作業服から保護服に 着替える必要のある被雇用者のために、29 CFR 1910.141 に記載されている更 衣室を提供するものとする。
- (2) 設備の故障又は不適切な作業方法等により、1%以上のホルムアルデヒドを含む溶液が被雇用者の皮膚にかかる可能性がある場合、使用者は便利な場所に緊急洗浄設備を提供し、影響を受ける被雇用者が直ちにこれらの施設を利用するように保証するものとする。
- (3) 0.1%以上のホルムアルデヒドを含む溶液が被雇用者の目にかかる可能性がある場合、使用者は、緊急時に使用できる洗眼施設を直下の作業区域内に提供するものとする。

- (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

- (j) *清掃。*ホルムアルデヒドの液体又はガスを含む作業について、使用者は、定期的な目視検査を含む、漏れ及び流出を検出するプログラムを実施するものとする。
- (1) 漏れの調査を含む機器の予防的メンテナンスは、定期的に実施するものとする。
- (2) 流出するおそれのある作業場では、使用者は、流出の防止、作業場内の汚染除去及び廃棄物の処理のための規定を設けるものとする。
- (3) 使用者は、適切な保護具を着用し、清掃及び除染の適切な方法について教育を受けた被雇用者により、すべての漏出が修理され、流出が速やかに清掃される

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. The employer shall ensure that the labels are in accordance with <u>paragraph</u> (m) of this section.
- よう保証するものとする。
- (4) 漏洩又は流出によって生じたホルムアルデヒドに汚染された廃棄物及び破片は、ホルムアルデヒドの存在及びホルムアルデヒドに関連する危険性を警告するラベルを貼った密閉容器に入れて廃棄されるものとする。使用者は、ラベルが本節の(m)項に従っていることを確認するものとする。

- (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.
- (1) 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.

- (k) *緊急事態。*ホルムアルデヒドが関係する緊急事態が発生する可能性がある各職場において、使用者は、傷害及び人命の損失を最小限に抑えるための適切な手順が採用されていることを保証するものとする。緊急事態が発生した場合は、適切な手順が実施されるものとする。
- (I) 医療監視
- (1) 対象となる被雇用者
- (i) 使用者は、対処濃度以上の濃度又は STEL を超える濃度のホルムアルデヒド にさらされるすべての被雇用者に対して、医療監視プログラムを制定するものとする。
- (ii) 使用は、ホルムアルデヒドへの過剰ばく露の徴候及び症状を発症した被雇用者並びに緊急時にホルムアルデヒドにばく露されるすべての被雇用者に対して、医療監視を実施するものとする。被雇用者がホルムアルデヒドの過剰ばく露の可能性のある兆候及び症状を経験しているかどうかを判断する際、使用者は、ホルムアルデヒドばく露に関連する兆候及び症状は、空気中へのばく露が 0.1ppm 未満で、ホルムアルデヒドが 0.1%未満の濃度で材料中に存在する場合にのみ例外的に発生するという証拠に依拠しても良い。

- (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:

- (2) **医師による診察**。医学的疾患の問診票の管理を含むすべての医療処置は、免許を持つ医師によって、又はその監督下で行われるものとし、被雇用者の費用負担なく、給与の損失なく、合理的な時間及び場所で提供されるものとする。
- (3) **医学的疾患に関する質問票**。使用者は、ホルムアルデヒドのばく露が対処 濃度又は STEL を超える業務に就く前に、被雇用者に対して以下の医学的サー ベイランスを実施し、その後毎年実施するものとする。また、使用者は、被雇用 者がホルムアルデヒドへの過度のばく露の可能性を示す徴候及び症状を経験し ていると判断した場合、速やかに以下の医学的監視を実施するものとする。
- (i) 職歴、喫煙歴、目、鼻若しくは喉の炎症の証拠、慢性気道障害若しくは過敏性気道疾患、アレルギー性皮膚疾患若しくは皮膚炎又は上若しくは下呼吸器疾患に関する情報を引き出すように設計された、附録 D のような医学疾患質問票の管理
- (ii) ホルムアルデヒドへのばく露を減らすために呼吸用保護具を着用する必要 のない被雇用者に対して、健康診断が必要かどうか、医学的疾患質問票の評価に 基づいて医師が判断すること。
- (4) 健康診断。 健康診断は、問診票の情報に基づき、医師がホルムアルデヒドへのばく露によるリスクが高いと感じる被雇用者及びホルムアルデヒドへのばく露を減らすために呼吸用保護具を着用する必要がある全ての被雇用者に対して、初任時及びその後少なくとも年 1 回実施するものとする。健康診断は以下を含むものとする:

- (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 (FEV₁), 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;

- (i) 皮膚及び呼吸器系への刺激又は感作、息切れ又は目の炎症の証拠に重点を置いた身体検査
- (ii) 呼吸用保護具装着者の検査室検査は、ベースライン検査及び毎年の肺機能検査からなる。最低限、これらの検査は強制換気量 (FVC)、1 秒間強制呼気量 (FEV1) 及び強制呼気流量 (FEF) から成るものとする。
- (iii) 診断医が意見書を完成させるために必要と考えるその他の検査
- (iv) ホルムアルデヒドへのばく露により直接的又は間接的に悪化するような病状を持つ被雇用者に対し、健康障害のリスクの増加についてカウンセリングを行うこと。
- (5) *緊急時にばく露された被雇用者に対する検査*。使用者は、緊急時にホルムアルデヒドにばく露された全ての被雇用者に対して、できるだけ早く健康診断を受けさせるものとする。
- (i) 健康診断には、上若しくは下呼吸器の問題、アレルギー状態、皮膚反応又は 過敏症、目、鼻若しくは喉の刺激の証拠に重点を置いた病歴及び作業歴を含める ものとする。
- (ii) その他の検査は、検査医が適切と考える要素で構成されるものとする。
- (6) **医師に提供する情報。** 使用者は、以下の情報を診察医に提供するものとする:
- (i) 本基準及び附属書A、C、D 及び E の写し;
- (ii) ホルムアルデヒドへのばく露に関連する、影響を受ける被雇用者の職務の説明;

- (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) 被雇用者の職務の代表的なばく露レベル:
- (iv) 被雇用者が使用する、又は使用する予定の個人用保護具及び呼吸保護具に関する情報
- (v) 使用者の管理下にある、影響を受ける被雇用者の過去の健康診断の情報
- (vi) 緊急事態のため定期的でない検査を行う場合、使用者は、できるだけ早く医師に提供するものとする: 緊急事態が発生した経緯及び被災者が受けたと思われるばく露について説明すること。

(7) 医師の書面による意見書

- (i) 本基準に基づき必要とされる各検査について、使用者は検査医師から意見書を入手するものとする。この意見書には、ホルムアルデヒドへの職業的ばく露と無関係な特定の所見又は診断を明らかにしないことを除き、健康診断の結果を記載するものとする。意見書には以下の内容が含まれるものとする:
- (A) 被雇用者がホルムアルデヒドへのばく露による健康への重大な障害のリスクが高まるような医学的状態にあるかどうかについての医師の意見;
- (B) 被雇用者のばく露の制限又は呼吸用保護具を含む個人用保護具の使用の変更に関する推奨事項;
- (C) ホルムアルデヒドへのばく露により悪化する医学的状態、これらの状態が過去のホルムアルデヒドばく露又は緊急時のばく露により生じた可能性があるかどうか、さらなる検査又は治療の必要性があるかどうかについて、被雇用者が医師から説明を受けたことを示す文書
- (ii) 使用者は、医師が実施した健康診断及び検査の結果の保存を提供するものと する。

(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 (1)(3). If the physician determines that a medical examination is not necessary under paragraph (1)(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

(iii) 使用者は、医師の意見書の写しを、その受領後 15 日以内に、影響を受ける 被雇用者に提供するものとする。

(8) 医学的作業転換。

- (i) (l)(8)項の規定は、被雇用者が職場におけるホルムアルデヒドばく露に起因する目の粘膜若しくは上気道の著しい刺激、呼吸器感作又は皮膚刺激若しくは皮膚感作を報告した場合に適用されます。皮膚刺激又は皮膚感作の場合、皮膚症状の原因と疑われる製品のホルムアルデヒド含有量が 0.05%未満である場合は、医学的作業転換の規定は適用されない。
- (ii) ホルムアルデヒドへの過度のばく露の可能性がある徴候又は症状に関する被雇用者の報告は、(l)(3)項に従って使用者が選んだ医師によって評価されるものとする。医師が(l)(3)(ii)項に基づき診察が必要ないと判断した場合、兆候若しくは症状が未治療で、又はクリーム、手袋、応急処置若しくは個人保護具の使用で治まるかどうかを使用者が確認できるように、2週間の評価及び改善期間を設けるものとする。この期間中、被雇用者のホルムアルデヒドへのばく露を制限する産業衛生対策も実施することができる。

徴候又は症状が悪化した場合、2週間の期間が経過する前に、被雇用者を直ちに 医師に紹介するものとする。報告により、2週間の期間中、収入、年功序列及び 福利厚生が変更されることはありません。

(iii) 2週間の期間が終了しても徴候や症状が治まらない場合又は徴候若しくは症状がより早まる場合は、使用者が選んだ医師による診察を受けるものとする。医師は、被雇用者がさらされる製品のホルムアルデヒド含有量が 0.1%未満の場合、反対証拠がない限り、観察された皮膚刺激又は皮膚感作がホルムアルデヒドに起

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

因しないことを推定するものとする。

- (iv) 健康診断は、(l)(5) 項 (i) 及び (ii) の要件に従って実施されるものとする。 健康診断の実施に関する追加のガイドラインは、付録 C に記載されている。
- (v) 医師が、職場のホルムアルデヒドばく露により、目の粘膜又は上気道の著しい刺激、呼吸器感作、皮膚刺激若しくは皮膚感作が生じると判断し、作業制限又は作業転換を勧告した場合、使用者は速やかにその作業制限又は作業転換勧告に従うものとする。作業転換の勧告があった場合、使用者は、影響を受けた被雇用者を現在のホルムアルデヒドばく露から解放し、可能であれば、ホルムアルデヒドへのばく露がない、又は著しく少ない仕事に被雇用者を移動させるものとする。
- (vi) (l)(8)(v)項に従って被雇用者が解任された場合、使用者は、被雇用者が資格を有するか、又は短期間 (6ヶ月以内) で訓練できる同等の業務で、ホルムアルデヒドばく露量ができるだけ低く、かつ、対処濃度より高くはないところに、被雇用者を異動させるものとする。

使用者は、被雇用者の現時点での収入、年功序列及びその他の利益を維持するものとする。そのような仕事がない場合、使用者は、そのような仕事ができるようになるまで、被雇用者が職場でのホルムアルデヒドばく露に戻れないと判断されるまで、被雇用者が元の職務状態に戻れると判断されるまで、又は 6 ヶ月間、いずれか早いほうの期間、被雇用者の現在の収入、年功賃金、その他の利益を維持するものよとする。

(vii) 使用者は、被雇用者が本項に従って作業転換された後、6ヶ月以内にフォローアップのための健康診断を手配するものとする。この診察では、被雇用者が元

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.

の職務状態に戻ることができるかどうか、又は作業転換が永久的なものとなるかどうかを判断するものとする。医師は、被雇用者が作業転換された日から6ヶ月以内に、被雇用者を元の職務に復帰させることができるかどうか、又は作業転換を永久に続けるかどうかについての決定を下すものとする。

- (viii) 作業転換された被雇用者に対して利益、年功序列、その他の給付を提供する使用者の義務は、被雇用者が公費又は使用者が出資する補償制度から、又は被雇用者の作業転換によって可能となった他の使用者との雇用から、作業転換期間中に失った利益の補償を受ける範囲内で、軽減することができる。
- (ix) 本項に基づき材料のホルムアルデヒド含有量を決定する際、使用者は客観的 データに依拠することができる。

(9) 複数の医師による審査

(i) 使用者が医学的作業転換又は作業制限が適切かどうかを判断するために医学的検査又は診察を行う最初の医師を選択した後、被雇用者は、最初の医師の所見、判断又は勧告を検討し、ホルムアルデヒドばく露の影響を評価してこの検討を容易にするために、第2の医師が必要かつ適切と考える検査、診察及び実験室検査を行う第2の医師を指定することができる。

(ii) 使用者は、最初の医師が医学的作業転換又は作業制限を目的とした診察又は協議を行うたびに、第 2 の医学的意見を求める権利を被雇用者に速やかに通知するものとする。

- (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 動するものとする。

- (iii) 使用者は、セカンドメディカルオピニオン (第2回目の医師の意見)を求める権利の通知を受け取った後又は最初の医師の意見書を受け取った後のいずれか遅い方の日から 15 日以内に、被雇用者が以下のことを行うことを条件に、複数医師の診察方式への参加及びその支払いを行うことができる;
- (A) 被雇用者が、セカンドメディカルオピニオンを求める意思を使用者に伝える。
- (B) 被雇用者が第二の医師との予約を取るための手続きを開始する。
- (iv) 第二の医師の所見、判断又は勧告が最初の医師のものと異なる場合、使用者及び被雇用者は、二人の医師が意見の相違を解決するための努力をすることを保証するものとする。2人の医師が意見の相違を速やかに解決できない場合、使用者及び被雇用者は、それぞれの医師を通じて、問題となっている次の分野の専門家である第3の医師を指名するものとする:
- (A) 先行医師の所見、判断又は勧告を検討すること。
- (B) 先行医師の意見の相違を解決するために必要であると第三の医師が考える 検査、協議、実験室検査及び先行医師との協議を行うこと。
- (v) 代替案として、使用者及び被雇用者又は権限を有する被雇用医者代表は、共同で当該第3の医師を指定することができる。
- (vi) 使用者は、使用者及び被雇用者が 3 人の医師のうち少なくとも 1 人の勧告と一致する合意に至らない限り、第 3 の医師の所見、判断及び勧告に一致して行動するものとする。

(m) Communication of hazards—

(2)

- (1) Hazard communication—General.
- (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for formaldehyde.
- (ii) In classifying the hazards of formaldehyde at least the following hazards are to be addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.
- (iii) Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.
- (iv) Paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this section apply to chemicals associated with 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.
- (v) 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.

- (m) 危険有害性の教育 (コミュニケーション)
- (1) 危険有害性の教育。一般。
- (i) 化学物質の製造者、輸入者、販売者及び使用者は、ホルムアルデヒドに関する危険有害性教育基準 (HCS) (§1910.1200) のすべての要求事項を遵守するものとする。
- (ii) ホルムアルデヒドの危険有害性を分類する際、少なくとも以下の危険有害性に対処されるものとする: がん、皮膚・呼吸器感作性、眼・皮膚・呼吸器刺激性、急性毒性作用及び引火性
- (iii) 使用者は、HCS (§1910.1200) に準拠するために策定された危険有害性周知プログラムにホルムアルデヒドを含めるものとする。使用者は、各被雇用者がホルムアルデヒドの容器のラベルや安全データシートを閲覧できるようにし、HCS 及び本節(n)項の要求事項に従って訓練を受けるように保証するものとする。
- (iv) 本項(m)(1)(i)、(m)(1)(ii)、(m)(1)(iii)は、ホルムアルデヒドガスに関連する化学物質、0.1%を超えるホルムアルデヒドからなるすべての混合物又は溶液及び0.1 ppm 以上の濃度でホルムアルデヒドを大気中に放出できる物質にも適用する。
- (v) ホルムアルデヒドの放出が予想されるレベルの判定を行う際、使用者は、合理的に予見できる使用条件下での潜在的なホルムアルデヒド放出の程度を示す 客観的データに依拠してもよい。

(2)

- (i) In addition to the requirements in <u>paragraphs (m)(1)</u> through <u>(m)(1)(iv)</u> of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in <u>paragraph (d) of § 1910.1200</u> and Appendices A and B to <u>§ 1910.1200</u>, including cancer and respiratory sensitization, and shall contain the hazard statement "May Cause Cancer."
- (ii) As a minimum, for all materials listed in <u>paragraph (m)(1)(i)</u> and <u>(iv)</u> of this section 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 safety data sheets.
- (iii) Prior to June 1, 2015, employers may include the phrase "Potential Cancer Hazard" in lieu of "May Cause Cancer" as specified in <u>paragraph (m)(2)(i)</u> of this section.

- (i) 本項の(m)(1)~(m)(1)(iv)項の要件に加え、0.5 ppm を超える水準でホルムアルデヒドを放出できる(m)(1)(iv)の項に記載されている材料については、ラベルは、がん及び呼吸器感作性を含め、基準 1910.1200(d)、同基準附録 A 及び B で定義されているすべての危険有害性について適切に記載し、「がんに至ることがある」のハザード声明を含むものとします。
- (ii) 少なくとも、0.1ppm から 0.5ppm のレベルでホルムアルデヒドを放出することができる本項(m)(1)(i)及び本節(iv)に記載されたすべての材料について、ラベルは、製品がホルムアルデヒドを含むことを特定し、責任者の名前及び住所を記載し、物理的及び健康上の危険情報は使用者及び安全データシートから容易に入手できることを記載する。
- (iii) 2015 年 6 月 1 日以前は、本節(m)(2)(i)項に規定する「がんを引き起こす可能性がある」の代わりに「がんの危険性がある」という表現を使用者は含めることができる。

(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

(n)被雇用者情報及び訓練(トレーニング)—

- (1) **参加すること**。使用者は、ホルムアルデヒドにさらされる職場に配属されたすべての被雇用者が、研修プログラムに参加することを保証するものとする。ただし、被雇用者が 0.1ppm 以上のホルムアルデヒドにさらされないことを客観的なデータで示すことができる場合、使用者は研修を行う必要はない。
- (2) *頻度*。使用者は、最初の配属時及びホルムアルデヒドへの新たなばく露が作業区域に導入されるたびに、被雇用者にこのような情報及び訓練を提供するものとする。また、研修は少なくとも年1回繰り返されるものとする。

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.

- (3) **訓練プログラム。** 研修プログラムは、被雇用者が理解できる方法で実施されるものとし、以下を含むものとする:
- (i) 本規則の内容及び製品安全データシートの内容に関する説明
- (ii) 本基準で要求される医学的監視プログラムの目的及び説明(以下を含む):
- (A) ホルムアルデヒドへのばく露に関連する潜在的な健康被害の説明並びにホルムアルデヒドへのばく露の兆候及び症状の説明
- (B) ホルムアルデヒドへのばく露に起因すると思われる有害な徴候及び症状が現れた場合、直ちに使用者に報告するよう指示すること。
- (iii) ホルムアルデヒドが存在する作業場での作業の説明及び各作業におけるホルムアルデヒドへのばく露を制限するために適切な安全作業方法の説明;
- (iv) 個人用保護衣及び保護具の目的、適切な使用方法及び制限;
- (v) 流出物、緊急事態の取り扱い及び清掃手順に関する指示;
- (vi) 被雇用者保護のための工学的及び作業慣行的管理の重要性の説明及びこれらの管理の使用に関する必要な指導
- (vii) 緊急事態が発生した場合の各被雇用者の具体的な任務又は分担を含む、緊急時の手順の確認
- (4) 研修資料の閲覧

- (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.
- (i) 使用者は、影響を受けるすべての被雇用者に対し、書面による研修資料の所在を通知し、これらの資料を無償で容易に入手できるようにするものとする。
- (ii) 使用者は、要請に応じて、被雇用者研修プログラムに関するすべての研修資料を次官補及び所長に提供するものとする。

(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, 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:

(o) **記録保存**—

- (1) ばく露量の測定。使用者は、被雇用者のホルムアルデヒドへのばく露を監視するために行ったすべての測定の正確な記録を作成し、維持するものとする。この記録には以下を含めること:
- (i) 測定日;
- (ii) 監視される作業;
- (iii) 試料採取及び分析の方法並びにその正確性及び精度の証拠;
- (iv) 採取した試料の数、期間、時間及び結果;
- (v) 着用する保護具の種類
- (vi) 実際のモニタリング結果によってばく露が表現される被雇用者の氏名、職務 分類及びばく露の推定値
- (2) ばく露の判定。本基準に基づくモニタリングが不要と判断した場合、使用者は、対処濃度以上のホルムアルデヒドにさらされる被雇用者がいないとの判断を裏付けるために依拠した客観的データの記録を保持するものとする。
- (3) **医学的監視**。使用者は、本基準に基づく医療監視の対象となる各被雇用者について、正確な記録を作成し、維持するものとする。この記録には、以下を含むものとする:

- (i) The name 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 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

- (i) 被雇用者の氏名:
- (ii) 医師の意見書;
- (iii) ホルムアルデヒドへのばく露に関連すると思われる被雇用者の健康上の苦情のリスト
- (iv) 健康診断結果のコピー(医学的疾患の質問票、本基準で要求される、又は診察医が義務付ける医学的検査の結果を含む。)

(4) 呼吸用保護具 (レスピレーター) の適合試験

- (i) 使用者は、本基準で要求される陰圧呼吸用保護具の適合試験の対象となる被雇用者について、正確な記録を作成し、維持するものとする。
- (ii) この記録には、以下を含むものとする:
- (A) 呼吸用保護具適合性検査に選択された規格のコピー
- (B) 実施されたフィットテストの結果のコピー
- (C) 選択可能なタイプの呼吸用保護具 (レスピレータ) のサイズ及び製造者
- (D) 直近のフィットテストの日付、テストを受けた各被雇用者の氏名、選択された呼吸用保護具(レスピレータ)のタイプ及びフェイスピース

(5) 記録の保持.

使用者は、本基準で必要とされる記録を少なくとも以下の期間保持するものと する:

- (i) ばく露の記録及び判定は、少なくとも 30 年間保存されるもおとする。
- (ii) 医療記録は、雇用期間プラス 30 年間保管されるものとする。
- (iii) 呼吸用保護具の適合性試験の記録は、より新しい記録に置き換わるまで保管するものとする。
- (6) 記録の利用可能性
- (i) 使用者は、要請があれば、本基準の要求事項として維持されているすべての

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 1910.1020 (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 1910.1020 (a)—(e) and (g)—(i).

記録を、次官補及び所長の調査及び複写に供するものとする。

- (ii) 使用者は、代表的なモニタリングから作成された推定値を含む被雇用者のばく露記録を、29 CFR 1910.1020 (a)-(e) 及び (g)-(i) に従って、対象被雇用者又は元被雇用者並びに被雇用者代表の要求に応じて調査及び複写のために利用できるようにしておくものとする。
- (iii) 本基準で要求される被雇用者の医療記録は、29 CFR 1910.1020 (a)-(e) 及び (g)-(i) に従って、対象被雇用者若しくは元従業員又は対象被雇用者若しくは元被雇用者の書面による同意がある者に、調査及びコピーの要求に応じて提供するものとします。

Appendix A to § 1910.1048—Substance Technical Guidelines for Formalin

1910.1048-ホルマリンに関する物質技術指針の附録 A

(資料作成者注:この附録Aについては、主として健康被害のデータ、ばく露による慢性的な影響、医療用サーベイランス等の部分に限って、原典から抜粋して「英語原文-日本語仮訳」の形式で紹介しています。)

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.

健康被害データ

ばく露による急性影響

摂取(飲み込み): $10\sim40\%$ のホルムアルデヒドを含む液体は、口、喉及び胃に激しい刺激と炎症を引き起こす。摂取後、激しい腹痛が起こり、意識を失い死亡する可能性がある。希薄なホルムアルデヒド溶液($0.03\sim0.04\%$)を摂取すると、胃及び咽頭に不快感を感じることがある。

吸入(呼吸): ホルムアルデヒドは上気道と目に強い刺激を与える。 $0.5\sim2.0\,\mathrm{ppm}$

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:

の濃度は、一部の人の目、鼻及び喉を刺激することがある。また、 $3\sim5ppm$ の 濃度は、目の涙を引き起こし、一部の人には耐えられない。 $10\sim20ppm$ の濃度では、呼吸困難、鼻と喉の火傷、咳及び激しい目の涙が起こり、 $25\sim30ppm$ では、肺水腫及び肺炎につながる重度の呼吸器系障害を引き起こす。

100ppm の濃度は、生命と健康に直ちに危険を及ぼす。高濃度のホルムアルデヒドに誤ってさらされたことによる死亡例も報告されています。

皮膚(経皮): ホルマリンは重度の皮膚刺激性及び感作性物質である。ホルマリンに接触すると、白色変色、ヒリヒリ感、乾燥、ひび割れ及び鱗屑が生じます。 長時間、繰り返し接触すると、しびれ、皮膚の硬化や日焼けを引き起こす可能性があります。過去にばく露された者は、今後ばく露された場合、アレルギー性湿疹性皮膚炎又はじんましんを起こす可能性がある。

目に入った場合: 目に入ったホルムアルデヒド溶液は、一過性の不快感から重度の永久的な角膜の混濁さらには視力喪失に至るまで、様々な傷害を引き起こす可能性があります。影響の程度は、溶液中のホルムアルデヒドの濃度と、事故直後に目を水で洗い流したかどうかによって異なります。

注意してください。

ホルムアルデヒドの臭気及び眼刺激による知覚は、ホルムアルデヒドに適応するにつれて、時間の経過とともに敏感でなくなる。このため、作業者がホルムアルデヒドの警告特性に頼ってばく露の可能性を知らせている場合、過度のばく露につながる可能性がある。

急性動物毒性

<i>Oral,</i> rats: LD50 = 800 mg/kg	経口、ラット LD50 = 800 mg/kg
Oral, mouse: LD50 = 42 mg/kg	経口、マウス LD50 = 42 mg/kg
Inhalation, rats: LCLo = 250 mg/kg	吸入、ラット LCLo = 250 mg/kg
Inhalation, mouse: LCLo = 900 mg/kg	吸入、マウス LCLo = 900 mg/kg
Inhalation, rats: LC50 = 590 mg/kg	吸入、ラット 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.

ばく露による慢性的な影響

発がん性がある: ホルムアルデヒドは、ヒトにがんを引き起こす可能性がある。 繰り返し、長期間のばく露はリスクを高める。様々な動物実験により、ホルムア ルデヒドはラットにおいて発がん性物質であることが決定的に示されている。ヒ トでは、ホルムアルデヒドのばく露は、肺、鼻咽頭並びに中咽頭及び鼻腔のがん と関連している。

変異原性: ホルムアルデヒドは、いくつかの in vitro 試験系において、イニシエーター及びプロモーターの両方の性質を示す遺伝毒性を示します。

毒性: ホルムアルデヒドに長期間又は繰り返しばく露されると、呼吸器系に障害をもたらす可能性がある。ホルムアルデヒドを 2ppm でばく露したラットは、良性の鼻腔腫瘍及び鼻の細胞構造の変化並びに鼻の粘膜の炎症を発症した。また、ヒトの鼻の上皮細胞の構造変化も観察されている。

ホルムアルデヒドにばく露した後、喘息又は気管支炎を発症した者もいますが、 その多くは高濃度のホルムアルデヒドに一度だけばく露した事故によるもので す。

Medical Surveillance

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

医療監視(サーベイランス)

医療監視(サーベイランス)は、被雇用者の健康保護に役立ちます。医療監視プログラムに参加することが強く推奨されます。

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.

ホルムアルデヒドの濃度が 8 時間平均で 0.5 ppm、15 分平均で 2 ppm を超える場合、使用者は、合理的な時間及び場所で、あなたに費用をかけずに医療監視プログラムを提供しなければなりません。ばく露量が 0.5 ppm (TWA) 又は 2 ppm (STEL) 以上である限り、最初の配属時及びその後 1 年に 1 回、医療監視が提供されます。

ばく露量がこれらのレベル以下であっても、ばく露によって健康が損なわれているかどうかを判断するために医療監視が必要な場合があるため、トレーニングを通じてホルムアルデヒドばく露に関連すると思われる兆候や症状がある場合は、使用者に報告する必要があります。

監視計画には以下のものがあります:

- (a) 医学的疾患に関する質問票
- (b) 医師が必要であると判断した場合の身体検査

呼吸用保護具の着用が義務付けられている場合、使用者は毎年、身体検査及び肺機能検査を受けさせなければなりません。

医師は、あなたがホルムアルデヒドへのばく露によってリスクが高まっているかどうかを判断するために必要なすべての情報を収集しなければなりません。医師の判断で、健康診断に胸部X線のような他の検査を加えて、この判定を行うことができます。

健康診断後、医師はあなたの使用者に、推奨される特別な保護措置及びばく露に 関する作業制限を含む意見書を提出します。医師は、ホルムアルデヒドへのばく 露によって悪化するような病状がある場合、それを知らせなければなりません。

疾病調査を含む健康診断のすべての記録は、使用者の費用負担で保管しなければなりません。

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.

緊急時

緊急時にホルムアルデヒドにばく露され、ホルムアルデヒドばく露による急性毒性に関連する徴候及び症状が現れた場合、使用者はできるだけ早く健康診断を受けさせなければなりません。この健康診断には、あなたの健康を安定させるために必要なすべての手順が含まれます。症状が重い場合は、遅発性の影響を確実に認識し治療するために、入院して観察することもあります。

Appendix B to § 1910.1048—Sampling Strategy and Methods for FormaldehydeAnalytical1910.1048-ホルムアルデヒドの試料採取方法及び分析方法」の付録 B(資料作成者注:この附録 B については、その内容が大部になります

「資料作成者注:この附録Bについては、その内容が大部になりますので、「原典の英文-その日本語仮訳」の形式ではなく、別途資料とて原典の英語原文のみを収載してあります。)

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

I. 健康被害

ホルムアルデヒドの職業上の健康被害は、主に吸入後、液体又は蒸気状のホルム アルデヒドが皮膚又は目に直接接触した後及び摂取後の毒性作用に起因するも のです。

II. 毒性学

A. ばく露による急性影響

1. 吸入 (呼吸): ホルムアルデヒドは、上気道に対して強い刺激性がある。生命及び健康に直ちに危険を及ぼすホルムアルデヒドの濃度は 100 ppm である。 50ppm を超える濃度は、数分以内に重度の肺反応を引き起こす可能性があります。これには、肺水腫、肺炎及び気管支の炎症が含まれ、死に至ることもあります。5ppm 以上の濃度は、咳、胸のつかえ及び喘鳴を特徴とする下気道への刺激を容易に引き起こします。ホルムアルデヒドガスが肺感作性であり、それまで正常であった人に職業性喘息を引き起こす可能性があるかどうかについては、いくつかの論争がある。ホルムアルデヒドは、ヒトに気管支喘息の症状をもたらすことがあります。

そのメカニズムは、ホルムアルデヒドへのばく露による個体の感作か、喘息の既往のある人のホルムアルデヒドによる直接的な刺激のいずれかであると考えられる。上気道刺激は、労働者から報告された最も一般的な呼吸器系の影響であり、広い濃度範囲で発生する可能性があり、最も頻繁に起こる濃度は 1ppm を超えます。しかし、気道刺激は、0.1ppm という低いホルムアルデヒドへのばく露を持つ一部の労働者で発生している。

上気道刺激性の症状には、喉の乾燥や痛み、鼻のかゆみや灼熱感さらには鼻づまり等がある。このレベルのばく露に対する耐性は、1~2 時間以内に発現する可能性があります。この耐性により、ホルムアルデヒド濃度が徐々に上昇する環境

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

にいる労働者は、ますます危険な状態にあることに気づかないことがあります。

2. 目に入ったとき: ホルムアルデヒドの濃度が 0.05 ppm から 0.5 ppm の間は、灼熱感、かゆみ、充血及び涙を伴う目の刺激感を生じます。まばたき及び閉眼の回数が増えることで、一般的にこのような低濃度での損傷から目を保護しますが、これらの保護機構は一部の作業者の作業能力を妨げる可能性があります。この範囲の濃度のホルムアルデヒドに継続的にさらされる作業者では、耐性が生じる可能性がある。

ホルムアルデヒド (ホルマリン) 水溶液による人間の目の偶発的な飛沫損傷は、 角膜混濁及び失明を含む広範な眼球損傷を引き起こしています。

反応の重症度は、溶液中のホルムアルデヒドの濃度と並びに緊急及び医療介入までの経過時間に直接依存しています。

- 3. 皮膚に接触する: ホルムアルデヒド溶液にさらされると、皮膚の刺激及びアレルギー性接触皮膚炎を引き起こす可能性がある。これらの皮膚疾患や障害は、多くのホルムアルデヒド作業者が遭遇するレベルよりかなり低いレベルで発生する可能性がある。症状としては、紅斑、浮腫、小水疱又はじんましんがある。液体ホルマリン又はホルムアルデヒドの蒸気にさらされると、ホルムアルデヒドの空気中濃度が 1ppm よりかなり低い場合でも、感作された人に皮膚反応を引き起こすことがあります。
- 4. 摂取すること: ホルムアルデヒド (ホルマリン) の 37%溶液をわずか 30ml でも摂取すると、死に至ることがある。摂取後の胃腸毒性は胃で最も重く、吐き 気、嘔吐及び激しい腹痛を含む症状が出ることがある。

ホルムアルデヒドの摂取による急性反応で、肝臓、腎臓、脾臓、膵臓、脳及び中枢神経系を含む他の臓器系に多様な障害が起こる可能性があります。

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

B. ばく露による慢性的な影響

ホルムアルデヒドへの長期ばく露は、ヒトにおける鼻及び副鼻腔のがん、鼻咽頭がん及び口腔咽頭がんさらには肺がんのリスク上昇に関連することが示されている。動物実験では、ラットの鼻腔がんとホルムアルデヒドばく露との因果関係の決定的な証拠が示されています。

発がん性の一致した証拠としては、DNA結合、短期試験における遺伝毒性、前腫瘍性変化及び線量率効果の両方を示唆する標的器官の細胞の細胞毒性変化等がある。

ホルムアルデヒドは完全な発がん物質であり、発がん過程の少なくとも 2 つの 段階に影響を及ぼすと考えられる。

III. 医療監視(サーベイランス)に関する考察

A. 病歷

- 1. 病歴及び職歴: ホルムアルデヒドは、その急性刺激性作用とともに、アレルギー感作及びがんを引き起こす可能性がある。職務経歴書の目的の1つは、職業的又は非職業的な環境におけるホルムアルデヒドへの過去又は追加のばく露に関する情報を引き出すことであるべきである。
- 2. *呼吸器系の履歴*。上述のように、ホルムアルデヒドは気道刺激物としての特性が認められており、職業性喘息の原因として一部の著者から報告されている。 また、ホルムアルデヒドは、ヒトの呼吸器系全体のがんと関連している。
- これらの理由から、病歴に呼吸器系の包括的なレビューを含めることが適切である。

この病歴の構成要素として、労作時呼吸困難、息切れ、慢性気道愁訴、過敏性気道疾患、鼻炎、気管支炎、気管支炎、喘息、肺気腫、呼吸アレルギー反応又はそ

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,

の他の既存の肺疾患に関する質問を含むことができる。

さらに、単一の感作性物質へのばく露によって、全身性の気道過敏症が生じることもある。したがって、検査者は、肺刺激性物質へのばく露の既往歴及びそのばく露による短期的又は長期的な影響を聴取する必要がある。

喫煙は、呼吸中に鼻や上気道に沈着した物質の粘液による除去機能を低下させることが知られている。これにより、ホルムアルデヒド蒸気のような吸入物質に対する労働者のばく露が増加する可能性がある。さらに、喫煙は、がんを含むあらゆる慢性呼吸器疾患の調査において、交絡因子となる可能性がある。これらの理由から、完全な喫煙歴を取得する必要があります。

- 3. 皮膚障害:皮膚障害:ホルムアルデヒドは皮膚刺激性及び感作性を有するため、皮膚障害の病歴を聴取する必要がある。そのような病歴には、皮膚刺激の有無、以前に記録された皮膚過敏症及びその他の皮膚障害が含まれるかもしれない。ホルムアルデヒド及び他の皮膚感作性物質への過去のばく露を記録する必要がある。
- 4. アトピー性疾患又はアレルギー性疾患の既往歴。: ホルムアルデヒドは皮膚及び気道のアレルギー感作を引き起こす可能性があるため、アレルゲン感作の既往がある人を特定することが有用である場合がある。また、ホルムアルデヒド又はその他の物質に対するアトピー性疾患及びアレルギーの既往歴も確認する必要がある。

また、アトピー患者が一般集団よりもホルムアルデヒド過敏症を発症する傾向が 強いかどうかは、現時点では明確には分かっていないが、これらの個人を特定す ることは継続的な監視に役立つと思われる。 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

5. 病気に関する質問票の使用。 有毒な兆候及び症状を主観的に測定する場合、過去の結果と現在の結果とを比較することが、健康状態の全般的な悪化を検出するための最良の方法となります。この方法では、想起バイアスが分析結果に影響することはない。

従って、OSHAは、病歴及び作業歴の所見を、年ごとの結果を比較するために標準的な形で保管することを決定した。

B. 身体検査

1. 目及び気道の粘膜: ホルムアルデヒドの刺激作用のため、診察医はこの刺激の証拠に注意する必要がある。鼻粘膜の鏡検は、鏡検による後咽頭の間接検査と同様に、刺激及び細胞毒性変化の可能性を評価するのに役立つかもしれない。

2. 肺系: 胸郭の検査、肺野の聴診及び打診を含む通常の呼吸器系検査は、定期的な健康診断の一部として実施されるべきである。定期的な肺機能検査は、TWA濃度限界を超えるばく露を受けた者について、基準では1年に1回のみ必要とされるが、これらの検査は、考えられる呼吸機能障害を調査する上で明らかな価値があり、医師が適切と考える場合には、どこでも使用されるべきである。

ホルムアルデヒドによる気道疾患が疑われる場合、肺機能障害の他の可能性のある原因(他の物質へのばく露を含む。)を除外する必要がある。

このような状況では、胸部X線写真が有用である。

気道過敏症又はアレルギーが疑われる場合、障害の性質を判断するために、ホルムアルデヒド又はメタコリンを用いた気管支負荷検査を行うことが適切である

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

場合がある。このような検査は、関連する処置に精通した医師が行うか、又はその監督下で行う必要がある。

3. 皮膚: 医師は、発赤、炎症、蕁麻疹、水疱、鱗屑、皮膚亀裂の形成及びその他の症状を含む感作性の皮膚刺激性の証拠に注意する必要がある。皮膚バリアの完全性は、他の皮膚疾患によって損なわれるため、そのような疾患の存在に注意する必要がある。皮膚過敏症検査は過敏症を誘発する危険性があるため、ホルムアルデヒド過敏症の皮膚検査は、日常的なスクリーニング検査として使用すべきではない。感受性の検査は、既存の感受性の疑いがある場合の調査として適応されることがある。

このような検査に関するガイドラインは、北米接触皮膚炎グループによって作成 されています。

C. 追加の検査又は試験

医師は、指示された他の医学的検査又は試験を行うことが必要であると考えることができる。本基準は、これらの追加検査がホルムアルデヒドへの職業的ばく露に関する基準の対象となる仕組みを提供している。

D. 緊急時

緊急時にばく露された労働者の検査は、最も影響を受けやすい臓器系に向けられるべきである。深刻な結果を防ぐために直ちに注意を払う必要がある重度の急性ばく露を受けた場合を除き、検査内容の多くは定期検査と同様である。

医療介入又は入院を必要とする重度の過剰ばく露が発生した場合、医師は遅発性症状の可能性に注意する必要がある。患者の健康を保証するために、定期的でないフォローアップ検査が必要な場合がある。

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

E. 使用者の義務

使用者は、以下の情報を医師に提供することが義務付けられています: 本基準 および付属書 A、C、D、E のコピー、ばく露濃度に関連する影響を受ける被雇 用者の職務の説明、期間を含む被雇用者のばく露の推定値(例:15 時間/週、8 時間シフト3回、常勤);被雇用者が使用する呼吸用保護具を含む個人用保護具の説明及びこの情報が使用者の管理下にある限りにおいてホルムアルデヒドへのばく露に関連する被雇用者の過去の医学的判断の結果

F. 医師の義務

本基準では、使用者が医師から書面による診断結果を入手することを義務付けています。この診断結果には、被雇用者がホルムアルデヒドへのばく露又は呼吸用保護具の使用により健康を損なう危険性が高まるような医学的状態にあるかどうかについての医師の意見が含まれていなければなりません (適切な場合)。

また、医師は、被雇用者のホルムアルデヒドへのばく露又は呼吸用保護具のような保護服若しくは保護具の使用に制限を加えるべきことについても意見を述べなければなりません。

ホルムアルデヒドへのばく露の結果、被雇用者が呼吸用保護具を着用する場合、 医師の意見には、指定されたタイプの呼吸用保護具を着用する被雇用者の適性に 関する記述も含まれなければならない。

最後に、医師は、被雇用者が健康診断の結果、さらなる説明及び治療が必要な病 状を告げられたことを使用者に伝えなければならない。

この意見書には、ホルムアルデヒドへの職業的ばく露とは無関係な特定の所見又は診断に関する情報を記載してはならない。

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.

診察医が使用者に意見書を提出することを要求する目的は、使用者が被雇用者を 最初に配置する際、被雇用者の健康がホルムアルデヒドによって損なわれていな いことを保証し、被雇用者が必要な保護具を使用する能力を評価するのに役立つ 医学的根拠を使用者に提供することである。

別記2 (再掲)

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

1910.1048-ホルムアルデヒドの試料採取方法及び分析方法」の附録 B の原典の英語全文

(資料作成者注:この附録Bについては、その内容が大部になりますので、「原典の英文-その日本語仮訳」の形式ではなく、別途資料とて原典の英語原文のみを収載してあります。)

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/m³)

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/m³)

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 bubb1ers 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/m³ 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 μ g/m³) 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 $\pm 14.3\%$ for formaldehyde. These values each include an additional $\pm 5\%$ for sampling error. The overall procedure must provide results at the target concentrations that are $\pm 25\%$ 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 $\pm 5\%$ 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 × 1/4 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 μ L of the acrolein and 12 μ L 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 × 1/4-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 $\mu g/mL$.

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 μ g/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 $A = \mu g/mL$ 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/m³ to ppm.

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

where mg/m³ = 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 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 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:

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.