

**SUPPORTING STATEMENT FOR
THE INFORMATION COLLECTION REQUIREMENTS OF
THE 4, 4'-METHYLENEDIANILINE STANDARD FOR
GENERAL INDUSTRY (29 CFR 1910.1050)
(Office of Management and Budget (OMB) Control No. 1218-0184(2006))¹**

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Occupational Safety and Health Act's (OSH Act) main objective is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" (29 U.S.C. 651). As one means in achieving this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" (29 U.S.C. 651) to assure that employees will be furnished "employment and a place of employment . . . free from recognized hazards that are causing or likely to cause death or serious physical harm."

For toxic substances, the OSH Act contains specific statutory language. Thus, as appropriate, health standards must include provisions for monitoring and measuring employee exposure, medical examinations and other tests, control and technological procedures, suitable protective equipment, labels and other appropriate forms of warning, and precautions for safe use or exposure (29 U.S.C. 655 and 657). In addition, the OSH Act specifically mandates issuing "regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or other harmful physical agents which are required to be monitored and measured, " and further requires that employees exposed to concentrations over prescribed limits be notified of this fact, and of the corrective action being taken (29 U.S.C. 657).

Under the authority granted by the OSH Act, the Agency published a standard for general industry that regulated employee exposure to 4,4'-Methylenedianiline (MDA) (29 CFR 1910.1050²; the "Standard"). OSHA based the Standard on a determination that occupational exposure to MDA poses a health risk to employees. This determination showed that MDA exposure results in an increased risk of cancer and liver disease, and poses a dermal hazard as well. Items 2 and 12 below describe in detail the specific information collection requirements of the Standard.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection,

¹The purpose of this supporting statement is to analyze and describe the burden hours and costs associated with provisions of the Standard that contain paperwork requirements; and does not provide information or guidance on how to comply with or to enforce the Standard.

²The Agency regulates occupational exposure to MDA in the Construction Industry under a separate standard (i.e., 29 CFR 1926.60; see the Information Collection Request, OMB Control No. 1218-0183).

indicate the actual use the agency has made of the information received from the current collection.

The following are the collection of information requirements as stated in the Standard, followed by discussions indicating how, by whom, and for what purpose the information is used.

A. Emergency situations (§1910.1050(d))

Written Plan (§1910.1050(d)(1))

§1910.1050(d)(1)(i)

A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

§1910.1050(d)(1)(ii)

The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with the appropriate personal protective equipment and clothing as required in paragraphs (h) and (i) of this section until the emergency is abated.

§1910.1050(d)(1)(iii)

The plan shall specifically include provisions for alerting and evacuating affected employees as well as the elements prescribed in 29 CFR 1910.38 and 29 CFR 1910.39, "Emergency action plans" and "Fire prevention plans," respectively.

Purpose: Emergency plans, including emergency and fire prevention plans, provide employees with information to maximize their personal protection and minimize MDA exposures during an emergency.

B. Exposure monitoring (§1910.1050(e))

§1910.1050(e)(1)(iii)

Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer shall only be required to determine representative employee exposure for that operation during one shift.

Purpose: To assess employee MDA exposures, the employer has the duty to characterize the workplace by performing monitoring, and identifying tasks that exceed the STEL³ and PEL.⁴

³Paragraph (b) of the Standard states that "STEL means short term exposure limit as determined by any 15 minute sample period."

⁴Paragraph (c) of the Standard defines the term "permissible exposure limits" as "an airborne concentration of MDA in excess of ten parts per billion (10 ppb) as an 8-hour time-weighted average (TWA) or a STEL [short-

Initial monitoring (§1910.1050(e)(2))

Each employer who has a workplace or work operation covered by this Standard shall perform initial monitoring to determine accurately the airborne concentrations of MDA to which employees may be exposed.

Purpose: Employers must perform initial monitoring to determine the extent of MDA exposure in their workplace. Initial monitoring allows employers to identify areas and operations that may require additional reduction in airborne MDA to meet the PEL. The results of initial exposure-monitoring also assist employers in determining the need for engineering controls, implementing or modifying work practices, and selecting appropriate respiratory protection to prevent employees from overexposure to MDA.

Periodic monitoring and monitoring frequency (§1910.1050(e)(3))

§1910.1050(e)(3)(i)

If the monitoring required by paragraph (e)(2) of this section reveals employee exposure at or above the action level⁵ but at or below the PELs, the employer shall repeat such representative monitoring for each such employee at least every six (6) months.

§1910.1050(e)(3)(ii)

If the monitoring required by paragraph (e)(2) of this section reveals employee exposure above the PELs, the employer shall repeat such monitoring for each such employee at least every three (3) months.

§1910.1050(e)(3)(iii)

The employer may alter the monitoring schedule from every three months to every six months for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to below the TWA but above the action level.

Purpose: Periodic monitoring allows employers to determine the effects of implemented controls, modifications in process, materials, or environmental conditions on employee exposures to MDA. It also reminds both the employer and employees of the continuing need to protect against the hazards that could result from employee overexposure.

Additional monitoring (§1910.1050(e)(5))

The employer shall institute the exposure monitoring required under paragraphs (e)(2) and (e)(3)

term exposure limit] of 100 ppb.”

⁵Paragraph (b) of the Standard defines “action level” as “a concentration of airborne MDA in excess of 5 ppb as an eight (8)-hour time-weighted average.”

of this section when there has been a change in production process, chemicals present, control equipment, personnel, or work practices which may result in new or additional exposures to MDA, or when the employer has any reason to suspect a change which may result in new or additional exposures.

Purpose: Changes in production process, chemicals present, control equipment, personnel, or work practices may lead to increases in employee exposure levels. Additional monitoring is necessary so that the employer takes action to protect employees, such as providing appropriate respiratory equipment or instituting engineering controls, thereby ensuring that the workplace is safe.

Employee notification of monitoring results (§1910.1050(e)(7))

§1910.1050(e)(7)(i)

The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this standard, notify each employee of these results, in writing, either individually or by posting of results in an appropriate location that is accessible to affected employees.

§1910.1050(e)(7)(ii)

The written notification required by paragraph (e)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce the employee exposure to or below the PELs, wherever the PELs are exceeded.

Purpose: Consistent with Section 8(c)(3) of the Act, every employee has the right to know what their exposure level is and whether it is above or below the action level. Moreover, since the PEL is one that also considers feasibility and, therefore, is not necessarily a “safe” level, it is necessary for the employee to know the level of MDA to which they were exposed.

Additionally, when exposures are above the PEL, the employer must also state in the notification what corrective action the employer is going to take to reduce the exposure level. This requirement is necessary to assure employees that the employer is making every effort to furnish them with a safe and healthy work environment as required by Section 8(c)(3) of the OSH Act.

Visual monitoring (§1910.1050(e)(8))

The employer shall make routine inspections of employee hands, face and forearms potentially exposed to MDA. Other potential dermal exposures reported by the employee must be referred to the appropriate medical personnel for observation. If the employer determines that the employee has been exposed to MDA the employer shall:

§1910.1050(e)(8)(i) - Determine the source of exposure;

§1910.1050(e)(8)(ii) - Implement protective measures to correct the hazard; and

§1910.1050(e)(8)(iii) - Maintain records of the corrective actions in accordance with paragraph (n) of this section.

Purpose: Visual monitoring ensures timely recognition and treatment of employees harmed by exposure to MDA, thus reducing the possibility of permanent injury.

C. Methods of compliance (§1910.1050(g))

Compliance program (§1910.1050(g)(2))

§1910.1050(g)(2)(i)

The employer shall establish and implement a written program to reduce employee exposure to or below the PELs by means of engineering and work practice controls, as required by paragraph (g)(1) of this section, and by use of respiratory protection where permitted under this section. The program shall include a schedule for periodic maintenance (e.g., leak detection) and shall include the written plan for emergency situations as specified in paragraph (d) of this section.

§1910.1050(g)(2)(ii)

Upon request this written program shall be furnished for examination and copying to the Assistant Secretary,⁶ the Director,⁵ affected employees, and designated employee representatives. The employer shall review and, as necessary, update such plans at least once every 12 months to make certain they reflect the current status of the program.

Purpose: The purpose of the written program is to encourage employers to achieve the required engineering and work practice controls and provide necessary documentation to OSHA, employers and employees of the compliance methods chosen, and the extent to which controls have been or are planned to be instituted. Revising and updating the written program reminds employers to implement and maintain the exposure-control methods required by the Standard.

D. Respiratory protection (§1910.1050(h))

General (§1910.1050(h)(1))

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⁵“Assistant Secretary” means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

⁷“Director” means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

For employees who use respirators required by this section, the employer must provide respirators that comply with the requirements of this paragraph. Respirators must be used during:

§1910.1050(h)(1)(i) - Periods necessary to install or implement feasible engineering and work-practice controls.

§1910.1050(h)(1)(ii) - Work operations for which the employer establishes that engineering and work-practice controls are not feasible.

§1910.1050(h)(1)(iii) - Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PEL.

§1910.1050(h)(1)(iv) - Emergencies.

Respirator program (§1910.1050(h)(2))

The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

Purpose: OSHA's Respiratory Protection Standard assists employers in protecting the health of employees exposed to airborne contaminants and biological agents that they find infeasible to control at the required levels using work practices and engineering methods.

E. Protective work clothing and equipment (§1910.1050(i))

Removal and storage (§1910.1050(i)(2))

§1910.1050(i)(2)(v)

Containers of MDA-contaminated protective work clothing or equipment which are to be taken out of change rooms or the workplace for cleaning, maintenance, or disposal, shall bear labels warning of the hazards of MDA.

Purpose: This requirement prevents MDA exposure of downstream employees who handle the protective clothing and equipment. Handling includes cleaning, maintaining, repairing, or disposing of clothing and equipment contaminated with MDA.

Cleaning and replacement (§1910.1050(i)(3))

§1910.1050(i)(3)(iv)

Any employer who gives MDA-contaminated clothing to another person for laundering shall inform such person of the requirement to prevent the release of MDA.

§1910.1050(i)(3)(v)

The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with MDA of the potentially harmful effects of exposure.

Purpose: The information provided by employers under this provision will protect personnel who may come in contact with MDA contaminated clothing from the hazards associated with MDA exposure.

F. Communication of hazards to employees (§1910.1050(k))

Signs and labels (§1910.1050(k)(1))

§1910.1050(k)(1)(i)

The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that bear the following legend:

DANGER
MDA
MAY CAUSE CANCER
LIVER TOXIN
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING
MAY BE REQUIRED TO BE WORN IN THIS AREA

Purpose: These signs alert employees that they can enter a regulated area only if they have authority to do so and a specific need exists to enter the area. The signs, therefore, warn employees that they are in or near a hazardous area, and supplement the hazard-recognition training employees receive under the Standard.

§1910.1050(k)(1)(ii)

The employer shall ensure that labels or other appropriate forms of warning are provided for containers of MDA within the workplace. The labels shall comply with the requirements of 29 CFR 1910.1200(f) and shall include the following legend:

§1910.1050(k)(1)(ii)(A) - For pure MDA

DANGER
CONTAINS MDA

MAY CAUSE CANCER
LIVER TOXIN

§1910.1050(k)(1)(ii)(B) - For mixtures containing MDA

DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER
LIVER TOXIN

Purpose: Warning labels inform downstream employers and employees of the hazards associated with MDA, and that they may need to implement special practices to prevent exposure to the substance. Furthermore, hazard labels alert other employers who, in the absence of such labels, may not know that MDA is present in their workplace and, consequently, that they must comply with the Standard.

Material safety data sheets (MSDSs) §1910.1050(k)(2)

§1910.1050 (k)(2)(i)

Employers shall obtain or develop, and shall provide access to their employees, to a material safety data sheet (MSDS) for MDA. In meeting this obligation, employers shall make appropriate use of the information found in Appendices A and B.

§1910.1050 (k)(2)(ii)

Employers who are manufacturers or importers shall:

§1910.1050 (k)(2)(ii)(A) - Comply with paragraph (k)(1)(ii) of this section as appropriate, and

§1910.1050 (k)(2)(ii)(B) - Comply with the requirement in OSHA's Hazard Communication standard, 29 CFR 1910.1200, that they deliver to downstream employers an MSDS for MDA.

Purpose: The purpose of MSDSs is to provide detailed information on each hazardous chemical, including its potential hazardous effects, its physical and chemical characteristics, and recommendations for appropriate protective measures. The MSDS provides information about the hazards of MDA, as well as the means to protect employees (of the chemical producer, as well as employees of downstream employers) from these hazards. The MSDS complements labels by providing detailed information about the ingredients and hazards, as well as the means to properly handle the chemicals and to prevent adverse health effects. In addition, the MSDS serves as the basic source of information on the hazards of MDA essential to the training provisions required in the Standard.

Information and training (§1910.1050(k)(3))

§1910.1050(k)(3)(i)

The employer shall provide employees with information and training on MDA, in accordance with 29 CFR 1910.1200(h), at the time of initial assignment and at least annually thereafter.

§1910.1050(k)(3)(ii)

In addition to the information required under 29 CFR 1910.1200, the employer shall:

§1910.1050(k)(3)(ii)(A) - Provide an explanation of the contents of this section, including appendices A and B, and indicate to employees where a copy of the standard is available;

§1910.1050(k)(3)(ii)(B) - Describe the medical surveillance program required under paragraph (m) of this section, and explain the information contained in appendix C; and

§1910.1050(k)(3)(ii)(C) - Describe the medical removal provision required under paragraph (m) of this section.

Purpose: Training is essential to inform employees of the health hazards of MDA exposure, and to provide them with the understanding required to minimize these health hazards. In addition, training provides information to employees that enables them to recognize how and where MDA exposure occurs, and what steps to take, including work practices, to avoid or limit such exposure. Another benefit of training is that it serves to explain and reinforce the information presented to employees on warning signs and labels. In this regard, employees must understand the information, and be aware of the actions they must take to avoid or minimize MDA exposure.

Access to training materials (§1910.1050(k)(4))

§1910.1050(k)(4)(i)

The employer shall make readily available to all affected employees, without cost, all written materials relating to the employee training program, including a copy of this regulation.

§1910.1050(k)(4)(ii)

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

Purpose: Allowing employees to have access to the training materials ensures that the employer provided them with the required information and training, thereby assuring that the employees can minimize or eliminate workplace exposure to MDA. The requirement to provide the training materials to OSHA compliance officers ensures that the training materials are correct and meet the requirements of the provision.

G. Medical surveillance (§1910.1050(m))

General (§1910.1050(m)(1)(i))

§1910.1050(m)(1)(i)

The employer shall make available a medical surveillance program for employees exposed to MDA:

§1910.1050(m)(1)(i)(A) - Employees exposed at or above the action level for 30 or more days per year;

§1910.1050(m)(1)(i)(B) - Employees who are subject to dermal exposure to MDA for 15 or more days per year;

§1910.1050(m)(1)(i)(C) - Employees who have been exposed in an emergency situation;

§1910.1050(m)(1)(i)(D) - Employees whom the employer, based on results from compliance with paragraph (e)(8), has reason to believe are being dermally exposed; and

§1910.1050(m)(1)(i)(E) - Employees who show signs or symptoms of MDA exposure.

Initial examinations (§1910.1050(m)(2))

§1910.1050(m)(2)(i)

Within 150 days of the effective date of this standard, or before the time of initial assignment, the employer shall provide each employee covered by paragraph (m)(1)(i) with a medical examination including the following elements:

§1910.1050(m)(2)(i)(A) - A detailed history which includes:

§1910.1050(m)(2)(i)(A)(1) - Past work exposure to MDA or any other toxic substances;

§1910.1050(m)(2)(i)(A)(2) - A history of drugs, alcohol, tobacco, and medication routinely taken (duration and quantity); and;

§1910.1050(m)(2)(i)(A)(3) - A history of dermatitis, chemical skin sensitization, or previous hepatic disease.

§1910.1050(m)(2)(i)(B) - A physical examination which includes all routine physical examination parameters, skin examination, and signs of liver disease.

§1910.1050(m)(2)(i)(C) - Laboratory tests including:

§1910.1050(m)(2)(i)(C)(1) - Liver function tests and

§1910.1050(m)(2)(i)(C)(2) - Urinalysis.

§1910.1050(m)(2)(i)(D) - Additional tests as necessary in the opinion of the physician.

Periodic examinations (§1910.1050(m)(3))

§1910.1050(m)(3)(i)

The employer shall provide each employee covered by this section with a medical examination at least annually following the initial examination. These periodic examinations shall include at least the following elements:

§1910.1050(m)(3)(i)(A) - A brief history regarding any new exposure to potential liver toxins, changes in drug, tobacco, and alcohol intake, and the appearance of physical signs relating to the liver, and the skin;

§1910.1050(m)(3)(i)(B) - The appropriate tests and examinations including liver function tests and skin examinations; and

§1910.1050(m)(3)(i)(C) - Appropriate additional tests or examinations as deemed necessary by the physician.

Emergency examinations (§1910.1050(m)(4))

If the employer determines that the employee has been exposed to a potentially hazardous amount of MDA in an emergency situation as addressed in paragraph (d) of this section, the employer shall provide medical examinations in accordance with paragraphs (m)(3)(i) and (ii) of this section. If the results of liver function testing indicate an abnormality, the employee shall be removed in accordance with paragraph (m)(9) of this section. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing. If the results of the second set of tests are normal and, on the advice of the physician, no additional testing is required.

Additional examinations (§1910.1050(m)(5))

Where the employee develops signs and symptoms associated with exposure to MDA, the employer shall provide the employee with an additional medical examination including a liver function test. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing.

If the results of the second set of tests are normal and, on the advice of the physician, no additional testing is required.

Purpose: The principal purpose of medical surveillance is the prevention or detection of abnormalities that may occur in some MDA-exposed workers early enough to prevent future or progressive adverse health effects. Documentation and maintenance of the medical-examination results provide a continuous record of employee health. Physicians use these records to determine the extent to which employees, since their last examination, experience health effects related to their MDA exposure. Further, if symptoms of organic damage appear, the physician often needs information about an employee's previous medical conditions to make an accurate diagnosis of the new condition, ascertain its apparent cause, and identify a course of treatment. Medical records also permit employees to determine whether or not they need treatment, or to evaluate the effectiveness of their employer's exposure-reduction program.

Multiple physician review mechanism (§1910.1050(m)(6))

§1910.1050(m)(6)(i)

If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, and the employee has signs or symptoms of occupational exposure to MDA (which could include an abnormal liver function test), and the employee disagrees with the opinion of the examining physician, and this opinion could affect the employee's job status, the employee may designate an appropriate, mutually acceptable second physician:

§1910.1050(m)(6)(i)(A) - To review any findings, determinations, or recommendations of the initial physician; and

§1910.1050(m)(6)(i)(B) - To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

§1910.1050(m)(6)(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 pursuant to this section. 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 foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

§1910.1050(m)(6)(ii)(A) - The employee informing the employer that he or she intends to seek a second medical opinion, and

§1910.1050(m)(6)(ii)(B) - The employee initiating steps to make an appointment with a second physician.

Purpose: It is necessary to require a multiple-physician review mechanism because it provides some assurance that employees will not refuse medical examinations because they fear their jobs could be terminated.

Information provided to the examining and consulting physicians (§1910.1050(m)(7))

§1910.1050(m)(7)(i)

The employer shall provide the following information to the examining physician:

§1910.1050(m)(7)(i)(A) - A copy of this regulation and its appendices;

§1910.1050(m)(7)(i)(B) - A description of the affected employee's duties as they relate to the employee's potential exposure to MDA;

§1910.1050(m)(7)(i)(C) - The employee's current actual or representative MDA exposure level;

§1910.1050(m)(7)(i)(D) - A description of any personal protective equipment used or to be used; and

§1910.1050(m)(7)(i)(E) - Information from previous employment-related medical examinations of the affected employee.

Purpose: Making this information available to the physicians assists them in evaluating the employee's health and fitness for specific job assignments involving MDA exposure. As noted earlier, if signs of organic damage appear, a physician often needs information to make an accurate diagnosis of the new condition, its apparent cause, and the course of treatment required.

Physician's written opinion (§1910.1050(m)(8))

§1910.1050(m)(8)(i)

For each examination under this section, the employer shall obtain, and provide the employee with a copy of, the examining physician's written opinion within 15 days of its receipt. The written opinion shall include the following:

§1910.1050(m)(8)(i)(A) - The occupationally-pertinent results of the medical examination and tests;

§1910.1050(m)(8)(i)(B) - The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to MDA;

§1910.1050(m)(8)(i)(C) - The physician's recommended limitations upon the employee's exposure to MDA or upon the employee's use of protective clothing or equipment and respirators; and

§1910.1050(m)(8)(i)(D) - A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from MDA exposure which require further explanation or treatment.

§1910.1050(m)(8)(ii)

The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

Purpose: The purpose of providing the physician's written opinion to the employer is to aid the employer in determining the initial placement of employees, and to assess the employee's ability to use protective clothing and equipment. The physician's written opinion also informs the employer about whether the employee has a condition indicating overexposure to MDA. The requirement that the physician's opinion be in writing permits retention of the information for later reference. Providing employees with a copy of the physician's written opinion informs them of the medical-examination results so that they can assist in determining the need for, and evaluate the effectiveness of, treatment or other interventions.

Medical removal (§1910.1050(m)(9))

Temporary medical removal of an employee (§1910.1050(m)(9)(i))

§1910.1050(m)(9)(i)(A)

The employee shall be removed from work environments in which exposure to MDA is at or above the action level or where dermal exposure to MDA may occur, following an initial examination (paragraph (m)(2) of this section), periodic examinations (paragraph (m)(3) of this section), an emergency situation (paragraph (m)(4) of this section), or an additional examination (paragraph(m)(5) of this section) in the following circumstances:

§1910.1050(m)(9)(i)(A)(1) - When the employee exhibits signs and/or symptoms indicative of acute exposure to MDA; or

§1910.1050(m)(9)(i)(A)(2) - When the examining physician determines that an

employee's abnormal liver function tests are not associated with MDA exposure but that the abnormalities may be exacerbated as a result of occupational exposure to MDA.

Purpose: Medical removal prevents medical impairments induced or exacerbated by MDA from becoming worse. Moreover, medical removal allows employees who have these impairments an opportunity to recuperate and return to their former jobs.

H. Recordkeeping (§1910.1050(n))

Monitoring data for exempted employers (§1910.1050(n)(1))

§1910.1050(n)(1)(i)

Where as a result of the initial monitoring the processing, use, or handling of products made from or containing MDA are exempted from other requirements of this section under paragraph (a)(2) of this section, the employer shall establish and maintain an accurate record of monitoring relied on in support of the exemption.

§1910.1050(n)(1)(ii)

This record shall include at least the following information:

§1910.1050(n)(1)(ii)(A) - The product qualifying for exemption;

§1910.1050(n)(1)(ii)(B) - The source of the monitoring data (e.g., was monitoring performed by the employer or a private contractor);

§1910.1050(n)(1)(ii)(C) - The testing protocol, results of testing, and/or analysis of the material for the release of MDA;

§1910.1050(n)(1)(ii)(D) - A description of the operation exempted and how the data support the exemption (e.g., are the monitoring data representative of the conditions at the affected facility); and

§1910.1050(n)(1)(ii)(E) - Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

§1910.1050(n)(1)(iii)

The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

Purpose: The information collection requirement discourages abuse of the exemption. Under the recordkeeping provisions of the Standard, employees and their representatives have access to the information and data used by an employer to determine whether the exemption applies to

their workplace. Such access assures employees that the determinations are reasonable and the exemption is warranted. Additionally, maintaining these records permits OSHA to ascertain whether the employer is complying with the requirements of this provision

Objective data for exempted employers (§1910.1050 (n)(2))

§1910.1050(n)(2)(i)

Where the processing, use, or handling of products made from or containing MDA are exempted from other requirements of this section under paragraph (a) of this section, the employer shall establish and maintain an accurate record of objective data relied upon in support of the exemption.

§1910.1050(n)(2)(ii)

This record shall include at least the following information:

§1910.1050(n)(2)(ii)(A) - The product qualifying for exemption;

§1910.1050(n)(2)(ii)(B) - The source of the objective data;

§1910.1050(n)(2)(ii)(C) - The testing protocol, results of testing, and/or analysis of the material for the release of MDA;

§1910.1050(n)(2)(ii)(D) - A description of the operation exempted and how the data support the exemption; and

§1910.1050(n)(2)(ii)(E) - Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

§1910.1050(n)(2)(iii)

The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

Purpose: Documenting and retaining information about the objective data used to support the exemption demonstrate the appropriateness of employer's reliance on objective data in lieu of initial monitoring. Maintaining a record of this information will permit OSHA to ascertain whether the employer is achieving compliance with the Standard.

Exposure measurements (§1910.1050(n)(3))

§1910.1050(n)(3)(i)

The employer shall establish and maintain an accurate record of all measurements required by

paragraph (e) of this section, in accordance with 29 CFR 1910.1020.

§1910.1050(n)(3)(ii)

This record shall include:

§1910.1050(n)(3)(ii)(A) - The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

§1910.1050(n)(3)(ii)(B) - Identification of the sampling and analytical methods used;

§1910.1050(n)(3)(ii)(C) - A description of the type of respiratory protective devices worn, if any; and

§1910.1050(n)(3)(ii)(D) - The name, social security number, job classification and exposure levels of the employee monitored and all other employees whose exposure the measurement is intended to represent.

§1910.1050(n)(3)(iii)

The employer shall maintain this record for at least 30 years, in accordance with 29 CFR 1910.1020.

Purpose: This requirement enables employers, and employees and their designated representatives, to identify the levels, durations, and extent of MDA exposures (including overexposures). Additionally, this requirement allows the employers to determine if existing controls are protecting employees or whether additional controls are necessary to provide the required protection. Lastly, it enables the employer to assess the relationship between MDA exposure and the subsequent development of medical diseases. Retaining these records for 30 years is necessary to document any association that may exist between MDA exposures and the development of long-latency illnesses caused by these exposures.

Medical surveillance (§1910.1050(n)(4))

§1910.1050(n)(4)(i)

The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (m) of this section, in accordance with 29 CFR 1910.1020.

§1910.1050(n)(4)(ii)

This record shall include:

§1910.1050(n)(4)(ii)(A) - The name, social security number and description of the duties of the employee;

§1910.1050(n)(4)(ii)(B) - The employer's copy of the physician's written opinion on the initial, periodic, and any special examinations, including results of medical examination and all tests, opinions, and recommendations;

§1910.1050(n)(4)(ii)(C) - Results of any airborne exposure monitoring done for that employee and the representative exposure levels supplied to the physician; and

§1910.1050(n)(4)(ii)(D) - Any employee medical complaints related to exposure to MDA;

§1910.1050(n)(4)(iii)

The employer shall keep, or assure that the examining physician keeps, the following medical records:

§1910.1050(n)(4)(iii)(A) - A copy of this standard and its appendices, except that the employer may keep one copy of the standard and its appendices for all employees provided the employer references the standard and its appendices in the medical surveillance record of each employee;

§1910.1050(n)(4)(iii)(B) - A copy of the information provided to the physician as required by any paragraphs in the regulatory text;

§1910.1050(n)(4)(iii)(C) - A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to the information;

§1910.1050(n)(4)(iii)(D) - A copy of the employee's medical and work history related to exposure to MDA; and

§1910.1050(n)(4)(iv)

The employer shall maintain this record for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020.

Purpose: This requirement provides employers, as well as employees and their designated representatives, with access to useful medical information. These records assist employees and their physicians in determining the need for treatment or other interventions as a result of the employees' exposure to MDA. Maintaining these records for extended periods is necessary because of the long latency associated with the development of MDA-related illnesses.

Medical removals (§1910.1050(n)(5))

§1910.1050(n)(5)(i)

The employer shall establish and maintain an accurate record for each employee removed from current exposure to MDA pursuant to paragraph (m) of this section.

§1910.1050(n)(5)(ii)

Each record shall include:

§1910.1050(n)(5)(ii)(A) - The name and social security number of the employee;

§1910.1050(n)(5)(ii)(B) - The date of each occasion that the employee was removed from current exposure to MDA as well as the corresponding date on which the employee was returned to his or her former job status;

§1910.1050(n)(5)(ii)(C) - A brief explanation of how each removal was or is being accomplished; and

§1910.1050(n)(5)(ii)(D) - A statement with respect to each removal indicating the reason for the removal.

§1910.1050(n)(5)(iii)

The employer shall maintain each medical removal record for at least the duration of an employee's employment plus 30 years.

Purpose: These records assist employees and their representatives to evaluate the effectiveness exposure controls, as well as the medical-removal program. Maintaining these records for extended periods is necessary because of the long latency associated with the development of MDA-related illnesses.

Availability (§1910.1050(n)(6))

§1910.1050(n)(6)(i)

The employer shall assure that records required to be maintained by this section shall be made available, upon request, to the Assistant Secretary and the Director for examination and copying.

§1910.1050(n)(6)(ii)

Employee exposure monitoring records required by this section shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

§1910.1050(n)(6)(iii)

Employee medical records required by this section shall be provided upon request for examination and copying, to the subject employee, to anyone having the specific written consent of the subject employee, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

Purpose: The OSHA compliance officer uses these records to assess employer compliance with the major requirements of the Standard, while NIOSH may compile these records for research purposes. Employees and employee representatives use exposure-monitoring and medical-surveillance records to assess employee medical status over the course of employment and to evaluate the effectiveness of the employer's exposure-reduction program.

Transfer of records (§1910.1050(n)(7))

§1910.1050(n)(7)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

§1910.1050(n)(7)(ii)

If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least 90 days prior to disposal, and transmit the records to the Director if so requested by the Director within that period.

Purpose: Transferring records to successor employers and NIOSH ensures that employees will have access to their historical records of exposure monitoring and medical surveillance to assess their medical status over the course of their employment and to evaluate the effectiveness of their employer's exposure-reduction program.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Employers may use automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology (e.g., electronic submission of responses), when establishing and maintaining the required records. The Agency wrote the paperwork requirements of the Standard in performance-oriented language, i.e., in terms of what data to collect, not how to record the data.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The requirements to collect and maintain information are specific to each employer and

employee involved, and no other source or agency duplicates these requirements or can make the required information available to OSHA (i.e., the required information is available only from employers).

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

The information collection requirements of the Standard do not have a significant impact on a substantial number of small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The Agency believes that the information collection frequencies required by the Standard are the minimum frequencies necessary to effectively monitor the exposure and health status of employees exposed to MDA, and thereby fulfill its mandate “to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources” as specified by the OSH Act at 29 U.S.C. 651. Accordingly, if employers do not perform the required information collections, or delay in providing this information, employees will have an increased probability of developing cancer, liver dysfunction, and dermal injuries because of their MDA exposures.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **Requiring respondents to report information to the agency more often than quarterly;**
- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **Requiring respondents to submit more than an original and two copies of any document;**
- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **In connection with a statistical survey, that is not designed to produce valid and reliable results be generalized to the universe of study;**
- **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Under paragraph (e)(7) of the Standard, employers must notify each employee of the exposure-monitoring results within 15 working days after receiving these results. Employers may notify employees either individually in writing, or by posting the monitoring results in an appropriate location that is accessible to the exposed employees. Paragraph (m)(6)(ii) requires employer's to promptly notify employees of their right to seek a second medical opinion after each initial medical examination or consultation. Employees may be required to fulfill certain conditions within 15 days to participate in the second opinion. Also, if the exposure-monitoring results exceed the PELs, the employer must inform the exposed employees of the corrective action the employer is taking to prevent overexposure to MDA. Moreover, paragraph (m)(8)(i) of the Standard requires employers to provide a copy of the physician's written opinion to the covered employee within 15 days after the employer receives the opinion.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years, even if the collection-of-information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on August 30, 2006 (71 FR 51639, Docket No. ICR-1218-0184(2006)) requesting public comment on its proposal to extend the Office of Management and Budget's approval of the information collection requirements specified by the Standard on 4,4'-Methylenedianiline (MDA) (29 CFR 1910.1050). This notice was part of a preclearance consultation program that provided the general public and government agencies with an opportunity to comment. The Agency received no comments in response to its notice.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

The Agency will provide no payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

As medical records contain personal information, OSHA and NIOSH have taken steps to assure that the medical data in these records are kept confidential. Agency practices and procedures governing access to employee medical records are contained in 29 CFR 1913.10 (attached).

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reason why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

None of the provisions in the Standard require sensitive information.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage-rate categories.**

Burden-Hour and Cost Determinations

OSHA estimates that three commercial-production plants manufacture MDA as an intermediate product within an enclosed system. MDA is produced commercially by the condensation on aniline and formaldehyde. In the United State, about 98% of the MDA produced is used directly in the manufacturing of methylene diphenyl diisocyanate. Since enclosed systems do not expose employees to MDA, paragraph (a)(3) of the Standard exempts these three facilities from many of the Standard's requirements, such as initial and periodic monitoring. The remaining 2% of MDA is used as a precursor for the manufacturing of plastic fibers, antioxidants, dyestuff intermediates, corrosion preventives and special polymers such as polyimides.⁸

Research conducted by the Agency disclosed significant changes in coatings technology in recent years. In response to the Clean Air Act amendments addressing hazardous air pollutants, as well as to the toxic effects of MDA, manufacturers are substituting other aromatic amines for MDA. Indeed, MDA-based coatings are essentially largely unavailable from U.S. coatings producers. Nevertheless, OSHA is taking a conservative approach in this ICR by assuming that 10 secondary-use plants currently use MDA in the production of polyimides and epoxy resins.

The Agency adopted the following mean wage rates from the *Occupational Employment Statistics, May 2004 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325100 – Basic Chemical Manufacturing*. Total compensation for these occupational categories includes an adjustment of 29.6 percent for fringe benefits; this figure represents the

⁸Chemical Economics Handbook SRI International, March 2004, pp. 580.1400P-580.1400X

average level of fringe benefits in the private sector. The costs of labor used in this analysis are, therefore, estimates of total hourly compensation. The Agency determined average wage rates for MDA in general industry using average hourly earnings, including benefits, to represent the cost of employee time. These hourly wages are:

- First-Line Supervisor/Manager of Production and Operating Workers 51-1011: \$40.40
- Occupational Health and Safety Specialist and Technician 29-9012: \$33.82
- Chemical Plant and System Operator 51-8091: \$31.33
- Secretary 43-6014: \$21.66

Table 1 below provides a summary of the burden-hour and cost estimates for the information collection requirements specified by the Standard.

Table 1
Summary of Annual Burden-Hour and Cost Estimates

Information Collection Requirement	Current Burden Hours	Proposed Burden Hours	Adjustment (Hours)	Estimated Cost
A. Emergency situations				
Written plan	0	0	0	\$0
B. Exposure monitoring				
Initial monitoring	0	0	0	0
Periodic monitoring and monitoring frequency, and additional monitoring	80	80	0	\$2,706
Employee notification of monitoring results	3	3	0	\$65
Visual monitoring	5	5	0	\$169
C. Methods of compliance				
Compliance program	15	15	0	\$507
D. Respiratory protection				
Respiratory program	0	0	0	\$0
E. Protective work clothing and equipment				
Removal and storage	0	0	0	\$0
Cleaning and replacement	0	0	0	\$0
F. Communication of hazards to employees				
Signs and labels	0	0	0	\$0
Material Safety Data Sheets	0	0	0	\$0
Information and training, and access to training materials	6	6	0	\$242
G. Medical Surveillance				
Initial examinations	15	15	0	\$470
Periodic examinations	135	135	0	\$4,230
Emergency examinations, and additional examinations	2	2	0	\$63

Information Collection Requirement	Current Burden Hours	Proposed Burden Hours	Adjustment (Hours)	Estimated Cost
Multiple physician review mechanism	2	2	0	\$63
Information provided to the examining and consulting physicians	8	8	0	\$173
Physician's written opinion	8	8	0	\$173
Medical removal	0	0	0	\$0
H. Recordkeeping				
Monitoring data for exempted employers, and objective data for exempted employers	1	1	0	\$22
Exposure measurements	3	3	0	\$65
Medical surveillance, and medical removals	8	8	0	\$173
Availability	1	1	0	\$5
Transfer of records	3	1	-2	\$22
TOTALS	295	293	-2	\$9,148

The following sections summarize the methodology used for estimating the number of burden hours and cost resulting from the information collection requirements of the Standard.

A. Emergency situations (§1910.1050(d))

Written plan (§1910.1050(d)(1))

As the emergency plan is part of the compliance program, the Agency included the burden hours and cost for this requirement under the determinations made under “Compliance program (§ 1910.1050 (g)(2))” below.

B. Exposure monitoring (§1910.1050(e))

To estimate burden hours, OSHA assumes that an occupational health and safety specialist and technician takes two hours (2.00 hours) to distribute and attach portable air-sampling pumps to employees, record sampling information (e.g., the employee's identification, job classification, start-up time), and collect the pumps after monitoring is complete.

Initial monitoring (§1910.1050(e)(2))

The Agency assumes there are no new facilities. Therefore, there are no burden hours or costs associated with this information collection requirement.

Periodic monitoring and monitoring frequency, and additional monitoring (§1910.1050(e)(3) and (e)(5))

The Agency has anecdotal data on employee exposures to MDA. Based on these data, the

Agency assumes that each secondary-use plant conducts representative periodic sampling every three months. Therefore, the total annual burden-hour and cost estimates for this requirement are:

Burden hours: 10 secondary-use plants x 4 samples per year x 2.00 hours = 80 hours
Cost: 80 hours x \$33.82 = \$2,706

Employee notification of monitoring results (§1910.1050(e)(7))

OSHA assumes that a secretary takes five minutes (.08 hour) to compile and post the written monitoring results obtained from initial, periodic, and additional monitoring at secondary-use plants. Accordingly, the total yearly burden-hour and cost estimates resulting from this requirement are:

Burden hours: (10 secondary-use plants x 4 periodic-/additional-monitoring postings per year) x .08 hour = 3 hours
Cost: 3 hours x \$21.66 = \$65

Visual monitoring (§1910.1050(e)(8))

The Agency believes that each of the 10 secondary-use plants visually inspects employees for MDA exposure once a year, and that an occupational health and safety specialist and technician requires one-half hour (.50 hour) to conduct an inspection, and to establish and maintain a record of corrective actions. Thus, the total annual burden hours and cost estimated for this requirement are:

Burden hours: 10 plants x .50 hour = 5 hours
Cost: 5 hours x \$33.82 = \$169

C. Methods of compliance (§1910.1050(g))

Compliance program (§1910.1050(g)(2))

OSHA estimates all 10 secondary-use plants have established compliance plans. For these plants, OSHA estimates an occupational health and safety specialist and technician spends one and one-half hours (1.50 hours) once a year to review and maintain these plans.

Burden hours: 10 plants x 1.50 hours (occupational health and safety specialist and technician time) = 15 hours
Cost: 15 hours x \$33.82 = \$507

D. Respiratory protection (§1910.1050(h))

Respirator program (§1910.1050(h)(2))

The Standard requires employers to implement a respiratory-protection program in accordance with the provisions of OSHA's Respiratory protection Standard (29 CFR 1910.134). OSHA takes the burden hours and costs for this requirement in the ICR for the Respiratory Protection Standard for General Industry (29 CFR 1910.134), OMB control number 1218-0099.

E. Protective work clothing and equipment (§1910.1050(i))

Removal and storage (§1910.1050(i)(2))

OSHA is taking no burden for this requirement because employers can use the language specified for labels under paragraph (k)(1)(ii) of the Standard for this purpose. (See "Signs and labels (29 CFR 1910.1050 (k)(1))" under Item 2.)

Cleaning and replacement (§1910.1050(i)(3)(iv) and (i)(3)(v))

OSHA assumes that employers have protective clothing and equipment laundered and cleaned under contract, and that they change laundries infrequently. Accordingly, because the need to provide new contractors with the required information is minimal, the Agency is taking no burden hours or cost for this requirement.

F. Communication of hazards to employees (§1910.1050(k))

Signs and labels (§1910.1050(k)(1)(i) and (k)(1)(ii))

The provisions containing the paperwork requirements associated with signs and labels provides specific language for these materials. Therefore, OSHA is taking no burden for these provisions because it is providing the information needed by employers to meet these requirements (See "Controlling Paperwork Burden on the Public" 5 CFR 1320.3(c)(2)).

Material safety data sheets (MSDS)(§1910.1052(k)(2))

This paragraph of the Standard requires employers to develop, obtain and provide employees access to an MSDS for MDA. Employers who are manufacturers or importers of MDA must comply with OSHA's Hazard communication Standard (29 CFR 1910.1200). Accordingly, the Agency takes the burden hours and costs for this provision in the ICR for the Hazard Communication Standard (OMB number 1218-0072).

Information and training, and access to training materials (§1910.1050(k)(3) and (k)(4))⁹

OSHA estimates that each of the 10 secondary-use plants provides training for 10 employees (for

⁹The Agency is accounting for the burden hours and cost associated with providing employees with access to written training materials, and OSHA compliance officers and NIOSH representatives with access to information and training materials, under "Training records (§1910.1050(k)(3) and (k)(4))" below.

a total of 100 covered employees), and that each of the 10 secondary-use plants holds a single training session each year (for the total of 10 training sessions). OSHA assumes that replacement employees receive initial training on an individual basis; if the annual turnover rate among employees is 10%, then a supervisor conducts initial training for 10 replacement employees each year for the 10 plants combined (i.e., 10% x 100 covered employees = 10 replacement employees).

The Agency also believes that a supervisor takes 20 minutes (.33 hour) to prepare and deliver the training to each session. Moreover, OSHA estimates that a supervisor spends 15 minutes (.25 hour) providing each new employee with the required training.¹⁰ This requirement results in total annual burden-hour and cost estimates of:

Burden hours: (10 annual training sessions x .33 hour) +
(10 initial training sessions x .25 hour) = 6 hours
Cost: 6 hours x \$40.40 = \$242

G. Medical surveillance (§1910.1050(m))

Initial examinations (§1910.1050(m)(2))

Each of the 10 plants must replace one employee each year.¹¹ OSHA believes that employees remain away from the job for one and one-half hours (1.50 hours) to take an initial medical examination. Accordingly, the total annual burden-hour and cost estimates for this requirement are:

Burden hours: (10 replacement employees) x 1.50 hours = 15 hours
Cost: 15 hours x \$31.33 = \$470

Periodic examinations (§1910.1050(m)(3))

OSHA estimates that 90 of the 100 covered employees receive a periodic examination once a year,¹² and that each examination takes one and one-half hours (1.50 hours) of employee time. The resulting total annual burden-hour and cost estimates for this provision are:

Burden hours: 90 employees x 1.50 hours per examination = 135 hours
Cost: 135 hours x \$31.33 = \$4,230

¹⁰ OSHA assumes that supervisors require no preparation because they use the training materials prepared for the annual training sessions.

¹¹ See “Information and training (§1910.1050(k)(3))” above.

¹² The discussion under “Information and training (§1910.1050(k)(3))” above describes the procedure for determining 100 covered employees. The Agency adjusted this figure to 90 by subtracting the number of replacement employees hired each year (i.e., 10) who receive an initial examination instead of a periodic examination.)

Emergency examinations, and additional examinations (§1910.1050 (m)(4) and (m)(5))

The Agency believes that 1% (1) of the 100 covered employees requires an emergency or additional medical examination each year, and that employee remains away from the job one and one-half hours (1.50 hours) to receive the medical examination. Thus, the total annual burden-hour and cost estimates for this requirement are:

Burden hours: 1 employee x 1.50 hours = 2 hours (rounded)
Cost: 2 hours x \$31.33 = \$63

Multiple physician review mechanism (§1910.1050(m)(6))

OSHA assumes that 1% (1) of the covered employees undergo multiple-physician review yearly, either because of emergency MDA exposure or the employee has signs or symptoms of MDA exposure, and that this employee spends one and one-half hours (1.50 hours) taking the examination. Accordingly, the estimated total annual burden hours and cost for these examinations are:

Burden hours: 1 examination x 1.50 hours = 2 hours (rounded)
Cost: 2 hours x \$31.33 = \$63

Information provided to the examining and consulting physicians (§1910.1050(m)(7))

The Agency believes that, for each medical examination or multiple-physician review administered to an employee, a secretary takes five minutes (.08 hour) to compile the required information and provide it to the physician. Based on the determinations made above, this Standard requires 10 initial examinations, 90 periodic examinations, one emergency examination and/or additional examinations, and one multiple-physician review each year, for a total of 102 examinations/reviews. These examinations/reviews result in the following total annual burden-hour and cost estimates:

Burden hours: 102 examinations/reviews x .08 hour = 8 hours
Cost: 8 hours x \$21.66 = \$173

Physician's written opinion (§1910.1050(m)(8))

OSHA assumes a secretary spends five minutes (.08 hour) delivering a copy of the physician's written opinion to each employee receiving an examination/review. This requirement results in the following estimated total burden hours and cost each year:

Burden hours: 102 examinations/reviews x .08 hour = 8 hours
Cost: 8 hours x \$21.66 = \$173

Medical removal (§1910.1050(m)(9))

An employer bases the decision to medically remove an employee from a job on a written recommendation provided by the examining physician. The physician makes the written recommendation following a medical examination required under the medical-surveillance program; the recommendation is, therefore, the same as a physician's written opinion. Accordingly, the Agency included no additional burden hours or costs for this requirement.

H. Recordkeeping (§1910.1050(n))

Monitoring data for exempted employers, and objective data for exempted employers (§1910.1050(n)(1) and (n)(2))

OSHA believes that the three commercial-production plants continue to rely on objective data to exempt them from many of the Standard's requirements. Accordingly, the Agency estimates a secretary takes five minutes (.08 hour) to maintain the necessary objective data, resulting in total annual burden-hour and cost estimates of:

Burden hours: 3 commercial-production plants x .08 hour = 1 hour

Cost: 1 hour x \$21.66 = \$22

Exposure measurements (§1910.1050(n)(3))

The Agency assumes that a secretary takes five minutes (.08 hour) to establish, maintain, and update each exposure-monitoring record. As noted above under "Employee notification of monitoring results (§1910.1050 (e)(7)),” each year the 10 secondary-use plants obtain a total of 40 exposure-monitoring samples. Thus, the estimated annual burden hours and cost estimated for this recordkeeping requirement are:

Burden hours: 40 exposure-monitoring records x .08 hour = 3 hours

Cost: 3 hours x \$21.66 = \$65

Medical surveillance, and medical removals (§1910.1050(n)(4) and (n)(5))

The determinations made under "Information provided to examining and consulting physicians (§1910.1050(m)(7))” above show that employers provide a total of 102 medical examinations/reviews yearly, each of which requires a written record. The Agency assumes that a secretary spends five minutes (.08 hour) a year establishing, maintaining, and updating each of these records, resulting in the following total annual burden-hour and cost estimates:

Burden hours: 102 records x .08 hour = 8 hours

Cost: 8 hours x \$21.66 = \$173

Availability (§1910.1050(n)(6))

OSHA estimates that its compliance officers request records maintained under the Standard during one inspection annually,¹³ and that a supervisor spends five minutes (.08 hour) informing the compliance officer of the location of training materials and information, as well as other required records.¹⁴ In addition, the Agency assumes that 10% (10) of the covered employees or their designated representatives request access to medical records, exposure-monitoring records, written compliance plans, and training records and materials (employees only) each year. OSHA estimates that a secretary takes five minutes (.08 hour) to make the requested record available to the employee/designated representative. Therefore, the estimated total yearly burden hours and cost for this availability requirement are:

Burden hours: (1 inspection-related request + 10 employee-related requests) x .08 hour
= 1 hour
Cost: (1 hour x .08 hour x \$40.40 (supervisor)) + (1 hour x .08 hour x \$21.66
(secretary)) = \$5

Transfer of records (§1910.1050(n)(7))

NIOSH did not receive any MDA-related exposure-monitoring or medical-surveillance records during the past three years. For the purposes of calculating burden hours and costs, it is assumed that one employer may submit one set of records to NIOSH each year, and that a secretary, earning \$21.66 per hour, would spend one hour preparing these records. Therefore, the Agency estimates that this provision requires employers to expend the following hours and cost each year:

Burden hours: 1 employer x 1.00 hour = 1 hour
Cost: 1 hour x \$21.66 per hour = \$22

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14.)

- **The cost estimate should be split into two components: (a) A total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

¹³The Agency estimated the number of inspections by determining the inspection rate (1.4%) for all establishments under the jurisdiction of the OSH Act (including both Federal OSHA and approved state-plan agencies), and then multiplied the total number of establishments covered by the Standard (13) by this percentage (i.e., 13 establishments x 1.4% = 1 inspection).

¹⁴The Agency assumes, based on previous history, that no NIOSH representative will request these records.

If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

- Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) Prior to October 1, 1995; (2) to achieve regulatory compliance with requirements not associated with the information collection; (3) for reasons other than to provide information or keep records for the government; or (4) as part of customary and usual business or private practices.

Capital-Cost Determinations

From these determinations (described below), the Agency estimates that the total capital cost of these requirements each year is \$19,312. This total consists of \$4,000 to analyze exposure-monitoring samples, \$15,300 to administer medical examinations, and \$12 transferring records to NIOSH by mail.

(A) Exposure Monitoring (§1910.1050(e))

Based on information obtained from the Agency's Salt Lake City Technical Center, the average cost for an OSHA-accredited laboratory to analyze a sample of airborne MDA is \$100. The annual cost for the 40 monitoring samples collected by the 10 secondary-use plants covered by the Standard (see the determinations made in Item 12 above under "Exposure monitoring" (§1910.1050(e)) is:

Cost: 40 exposure-monitoring samples x \$100 = \$4,000

(B) Medical Surveillance (§1910.1050(m))

Consistent with recent ICRs and regulatory analyses, the Agency estimates that each medical examination costs \$150. As noted above under "Information provided to examining and consulting physicians (§1910.1050(m)(7))" in Item 12 above, the 10 plants covered by the Standard administer a total of 102 medical examinations each year, resulting in the following annual cost:

Cost: 102 examinations x \$150 = \$15,300

(C) Transfer of Records (§1910.1050(n)(7))

Under paragraph (n)(7) of the Standard, employers who cease to do business and have no successor employer must notify NIOSH before disposing of exposure-monitoring and medical records, and transfer these records to NIOSH if so requested. For purposes of estimating cost,

OSHA estimates that one set of records, weighing 5 lbs., will cost approximately \$12.30 to mail to NIOSH via the United States Postal Service. Therefore, the annual cost of transferring this set of records to NIOSH is:

Cost: 1 set of records x \$12.30 = \$12

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

(A) Availability (§1910.1050(n)(6))

OSHA determines that it conducts one inspection each year (see footnote 14 above). The Agency estimates that a compliance officer (GS-12, step 5), with an hourly wage rate of \$34.15 spends 10 minutes (.17 hour) during each inspection reviewing records maintained by employers covered by the Standard. Other costs, such as equipment, overhead, and support staff expenses, would occur without these collection-of-information requirements, and OSHA considers these costs to be normal operating expenses. Accordingly, the Agency estimates that the Federal government expends the following hours and cost on this requirement each year:

Burden hours: 1 inspection x .17 hour = 1 hour

Cost: 1 hour x \$34.15 = \$34

(B) Transfer of records (§1910.1050(n)(7))

The cost of this provision to the Federal government consists of the costs required to process the following records: Records requested by NIOSH from employers who cease to do business and have no successor to receive and retain the employee records; and records obtained when the retention period for the records has expired. NIOSH has received one record from one employer since 1999. To account for a possible transfer burden during this clearance period, OSHA assumes that NIOSH will receive one record annually, and that a (federal government) secretary, earning \$19.26 per hour, will take four minutes (0.07 hour) to process each record.

Burden hours: 1 employer x .07 hour = 1 hour (rounded)

Cost: 1 hour x \$19.26 = \$19

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

The Agency is requesting an adjustment decrease of two hours from 295 hours to 293 hours. The two-hour reduction is the result of decreasing the number of employers submitting records (from three sets of records to one set of records) to NIOSH under “Transfer of records (§1910.1050(n)(7)).”

There is an overall increase in capitol costs of \$312 (from \$19,000 to \$19,312) resulting from the following:

- There is an increase of \$300 to account for two additional medical examinations inadvertently not counted in previous ICR,
- The Agency added \$37 because the previous Notice of Action rounded the total cost to \$19,000, and the previous ICR exact total was \$19,037; and
- There is a reduction in the number employers mailing records to NIOSH, from \$37.00 to \$12.00 (see paragraph (C) (“Transfer of records (§1910.1050(n)(7)”) under Item 15 above for an explanation).

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection information, completion of report, publication dates, and other actions.

No collection of information will be published.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be appropriate.

No forms are available for the Agency to display the expiration date.

18. Explain each exception to the certification statement identified in Item 19 per "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

OSHA is not seeking an exception to the certification statement specified by Item 19 of OMB 83-I.