4, 4'-METHYLENEDIANILINE STANDARD FOR GENERAL INDUSTRY (29 CFR 1910.1050)
1218-0184
June 2016

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 (May 2016)[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 workers 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 worker 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 worker exposures to potentially toxic materials or other harmful physical agents which are required to be monitored and measured, " and further requires that workers 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 worker exposure to 4,4'-Methylenedianiline (MDA) (29 CFR 1910.1050)[2;] (the "Standard"). OSHA based the Standard on a determination that occupational exposure to
MDA poses a health risk to workers. This determination showed that MDA exposure results in

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).

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, 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 workers 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 workers 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 workers 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 worker exposure for that operation during one shift.

Purpose: To assess worker MDA exposures, the employer has the duty to characterize the workplace by performing monitoring, and identifying tasks that exceed the STEL[3] and PEL.[4]

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 workers 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 workers 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 worker exposure at or above the action level[5] but at or below the PELs, the employer shall repeat such representative monitoring for each such worker at least every six (6) months.

§1910.1050(e)(3)(ii)

If the monitoring required by paragraph (e)(2) of this section reveals worker exposure above the PELs, the employer shall repeat such monitoring for each such worker 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 worker for whom two consecutive measurements taken at least 7 days apart indicate that the worker exposure has decreased to below the TWA but above the action level.

Purpose: Periodic monitoring allows employers to determine the effects of implemented

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-term exposure limit] of 100 ppb."

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

controls, modifications in process, materials, or environmental conditions on worker exposures to MDA. It also reminds both the employer and workers of the continuing need to protect against the hazards that could result from worker overexposure.

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

The employer shall institute the exposure monitoring required under paragraphs (e)(2) and (e)(3) 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 worker exposure levels. Additional monitoring is necessary so that the employer takes action to protect, workers 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 worker.

§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 worker exposure to or below the PELs, wherever the PELs are exceeded.

Purpose: Consistent with Section 8(c)(3) of the Act, every worker 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 worker 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 workers 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 worker hands, face and forearms potentially exposed to MDA. Other potential dermal exposures reported by the worker must be referred to the appropriate medical personnel for observation. If the employer determines that the worker 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 workers 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 worker 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[7] affected workers, and designated worker 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 workers of the compliance methods chosen, and the extent to which controls have

6"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.

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))

For workers who use respirators required by this section, the employer must provide each worker with an appropriate respirator that complies with 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, such as maintenance and repair activities and vessel cleaning , for which 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 worker exposure to or below the TWA.
>
> §*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) which covers each worker required by this section to use a respirator.

Purpose: OSHA's Respiratory Protection Standard assists employers in protecting the health of workers 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 workers 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)(2))

§1910.1050(k)(2)(i)(A)

The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend (A)

DANGER
MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER
AUTHORIZED PERSONNEL ONLY
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING
MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

§1910.1050(k)(2)(i)(B)

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

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 workers 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 workers that they are in or near a hazardous area, and supplement the hazard-recognition training workers receive under the Standard.

§1910.1050(k)(2)(ii) Labels

Prior to June 1, 2015, employers may include the following information workplace labels in lieu of the labeling requirements in paragraph (k)(1) of this section:

§1910.1050(k)(2)(ii)(A) - For pure MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
LIVER TOXIN

§1910.1050(k)(2)(ii)(B) - For mixtures containing MDA:

DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER
LIVER TOXIN

Purpose: Warning labels inform downstream employers and workers 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.

Safety data sheets (SDSs) §1910.1050(k)(3)

In meeting this obligation to provide safety data sheets, employers shall make appropriate use of the information found in Appendices A and B *§1910.1050*.

Purpose: The purpose of SDSs 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 SDS provides information about the hazards of MDA, as well as the means to protect workers (of the chemical producer, as well as workers of downstream employers) from these hazards. The SDS 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 SDS 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)(4)) & Access to training materials (§1910.1050(k)(5))

Upon further analysis, the requirements that employers provide training to workers under paragraph (k)(4) and to provide access to training materials under paragraph (k)(5) are not considered to be collections of information. OSHA is not taking burden for these activities under Item 12 of this Supporting Statement.

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 workers exposed to MDA:

> *§1910.1050(m)(1)(i)(A)* – Workers exposed at or above the action level for 30 or more days per year;
>
> *§1910.1050(m)(1)(i)(B)* - Workers who are subject to dermal exposure to MDA for 15 or more days per year;
>
> *§1910.1050(m)(1)(i)(C)* – Workers who have been exposed in an emergency situation;
>
> *§1910.1050(m)(1)(i)(D*) – Workers 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)* – Workers 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 worker 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 worker 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 worker 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 worker 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 worker develops signs and symptoms associated with exposure to MDA, the employer shall provide the worker 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 the liver function tests are normal, than 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 worker health. Physicians use these records to determine the extent to which, 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 a worker'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 workers 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 worker under this section, and the worker has signs or symptoms of occupational exposure to MDA (which could include an abnormal liver function test), and the worker disagrees with the opinion of the examining physician, and this opinion could affect the worker's job status, the worker 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 a worker 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 worker 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 workers 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 worker's duties as they relate to the worker'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 worker.

Purpose: Making this information available to the physicians assists them in evaluating the worker'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 worker 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 worker has any detected medical conditions which would place the worker 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 worker's exposure to MDA or upon the worker's use of protective clothing or equipment and respirators; and *§1910.1050(m)(8)(i)(D)* - A statement that the worker 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 workers, and to assess the worker's ability to use protective clothing and equipment. The physician's written opinion also informs the worker about whether the worker 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 workers 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 worker 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 worker 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 worker'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 workers 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, workers 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 workers 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 worker 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 worker 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 worker monitored and all other workers 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 workers 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 workers 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 worker 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 worker;

§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 worker and the representative exposure levels supplied to the physician; and

§1910.1050(n)(4)(ii)(D) - Any worker 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 workers provided the employer references the standard and its appendices in the medical surveillance record of each worker;

§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 worker'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 workers and their designated representatives, with access to useful medical information. These records assist workers and their physicians in determining the need for treatment or other interventions as a result of the workers' 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 worker 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 worker;

§1910.1050(n)(5)(ii)(B) - The date of each occasion that the worker was removed from current exposure to MDA as well as the corresponding date on which the worker 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 worker's employment plus 30 years.

Purpose:

These records assist workers 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)

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

§1910.1050(n)(6)(iii)

Worker medical records required by this section shall be provided upon request for examination and copying, to the subject worker, to anyone having the specific written consent of the subject worker, 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. Worker and worker representatives use exposure-monitoring and medical-surveillance records to assess worker medical status over the course of employment and to evaluate the effectiveness of the employer's exposure-reduction program.

Records Transfer (§1910.1050 (n)(7)

The standard requires employers ceasing to do business to transfer records to a successor employer. Employers must comply with the transfer requirements in §1910.1020(h).

Paragraph (h) of § 1910.1020 requires employers who cease to do business to transfer medical and exposure-monitoring records to the successor employer, who then must receive and maintain the records. If no successor employer is available, the employer must, at least three months before ceasing business, notify current workers who have records of their right to access these records.

OSHA considers the employer's transfer of records to a successor employer to be usual and customary communications during the transition from one employer to a successor employer. In this regard, the employer would communicate the location of all records, including worker exposure-monitoring and medical records, at the facility to the successor employer during the transfer of business operations, as a matter of usual and customary business practice.
In addition, OSHA accounts for the burden hours and costs resulting from the worker notification requirements under the Information Collection Request (ICR) for its Access to Worker Exposure and Medical Records Standard (§1910.1020), OMB Control No. 1218-0065.

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 A.2 above.

The requirements to collect and maintain information are specific to each employer and worker 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 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 workers 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, workers 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 worker of the exposure-monitoring results within 15 working days after receiving these results. Employers may notify workers either individually in writing, or by posting the monitoring results in an appropriate location that is accessible to the exposed workers. Paragraph (m)(6)(ii) requires employers to promptly notify workers of their right to seek a second medical opinion after each initial medical examination or consultation. Workers 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 workers 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 worker within 15 days after the employer receives the opinion. In addition, under OSHA's Access to Employee Exposure and Medical Records Standard (§1910.1020), employers must maintain exposure monitoring results for at least 30 years. The retention of worker exposure records are necessary to assess the relationship between worker exposure and subsequent development of medical diseases.

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.

4, 4'-METHYLENEDIANILINE STANDARD FOR GENERAL INDUSTRY (29 CFR 1910.1050)
1218-0184
June 2016

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 2506 (c)(2)(A)), OSHA published a notice in the Federal Register on March 11, 2016 (81 FR 12966) requesting public comments on its proposed extension of the information collection requirements contained in the Standard on 4,4'-Methylenedianiline (MDA) in General Industry (29 CFR 1910.1050). The notice was a part of a preclearance consultation program that provided the general public and government with an opportunity to comment. The Agency did not receive any comments in response to this notice.

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

The Agency will not provide 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.

The paperwork requirements specified by the Standard do not involve confidential information. 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 worker medical records are contained in 29 CFR 1913.10.

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.

The paperwork requirements specified by the Standard do not involve 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.**

- **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 five commercial-production plants manufacture MDA as an intermediate

product within an enclosed system[8]. MDA is produced commercially by the condensation on aniline and formaldehyde. In the United States, most of the MDA produced is used directly in the manufacturing of methylene diphenyl diisocyanate. Since enclosed systems do not expose workers to MDA, paragraph (a)(3) of the Standard exempts these five facilities from many of the Standard's requirements, such as initial and periodic monitoring. The remaining MDA is used as a precursor for the manufacturing of plastic fibers, antioxidants, dyestuff intermediates, corrosion preventives and special polymers such as polymides.[9]

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; thereby, significantly reducing this source of exposure. OSHA has identified that there are 10 secondary-use plants currently using MDA in the production of polymides and other Imide epoxy resins, and other chemicals.[10]

The Agency adopted the mean hourly wage rates from *Occupational Employment Statistics, May 2014 - National Occupational Employment and Wage Estimates – United States*, Bureau of Labor Statistics, U.S. Department of Labor. Total compensation for these occupational categories includes an adjustment of 31.4 percent (*Employer Costs for Worker Compensation News Release (September 2015)*, Bureau of Labor Statistics, U.S. Department of Labor (htttp://www.bls.gov/schedule/archives/ecec_nr.htm) for fringe benefits; this figure represents the average level of fringe benefits in the private sector. The costs of labor used in this analysis are, therefore, estimates of total hourly compensation. These hourly wages are:

First Line-Supervisor of Production Worker (51-1011): $37.30
Occupational Health and Safety Technician (29-9012): $32.39
Secretary (43-6014): $22.00
Chemical Plant System Operator (51-8091): $35.50

OSHA is using a 23.8% hire rate taken from the manufacturing hires rate, *Job Opening and Labor Turnover Survey (JOLT), 2014*, Bureau of Labor Statistics, U.S. Department of Labor.

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

8"4,4 Methylenedianiline" Toxic Release Inventory (TRI), U.S. National Library of Medicine, 2013.

9Chemical Economics Handbook SRI International, January 2010, pp.580.

10"4,4 Methylenedianiline" Toxic Release Inventory (TRI), U.S. National Library of Medicine, 2013.

4, 4'-METHYLENEDIANILINE STANDARD FOR GENERAL INDUSTRY (29 CFR 1910.1050)
1218-0184
June 2016

Table 1 - Summary of Annual Burden Hour and Cost Estimates

Information Collection Requirement	Current Burden Hours	Proposed Burden Hours	Adjustment (Hours)	Estimated Cost	Responses
A. Emergency situations					
Written plan	0	0	0	$0	0
B. Exposure monitoring					
Initial monitoring	2	0	-2	$0	0
Periodic monitoring and monitoring frequency, and additional monitoring	88	80	-8	$2,591	40
Worker notification of monitoring results	4	3	-1	$66	40
Visual monitoring	6	5	-1	$162	10
C. Methods of compliance					
Initial	33	30	-3	$966	10
Periodic	17	15	-2	$486	10
D. Respiratory protection					
Respiratory program	0	0	0	$0	0
E. Protective work clothing and equipment					0
Removal and storage	0	0	0	$0	0
Cleaning and replacement	1	1	0	$32	1
F. Communication of hazards to workers					
Signs and labels	0	0	0	$0	0
Safety Data Sheets	0	0	0	$0	0
G. Medical Surveillance					
Initial examinations	47	47	0	$1,065	20
Periodic examinations	132	120	-12	$4,260	80
Emergency examinations, and additional examinations	2	2	0	$71	1
Multiple physician review mechanism	2	2	0	$71	1
Information provided to the examining and consulting physicians	10	8	-2	$176	102
Physician's written opinion	10	8	-2	$176	102
Medical removal	0	0	0	$0	0
H. Recordkeeping					
Monitoring data for exempted employers, and objective data for exempted employers	1	1	0	$22	5
Exposure measurements	4	3	-1	$66	40
Medical surveillance, and medical removals	10	8	-2	$176	100
Availability	1	1	0	$22	12
TOTALS	**0**	**334**	**-36**	**0**	**0**

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 hours) to distribute and attach portable air-sampling pumps to each worker, record sampling information (e.g., the worker's identification, job classification, start-up time), and collect the pumps after monitoring is complete.

Initial monitoring (§1910.1050(e)(2))

The Agency has not identified any new facilities since the last ICR was prepared, therefore, no burden hours are being taken for this provision.

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

Based on available worker 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 hours = 80 hours
Cost: 80 hours x $32.39 = $2,591

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 the 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 x .08 hour = 3 hours
Cost: 3 hours x $22.00 = $66

Visual monitoring (§1910.1050(e)(8))

The Agency believes that each of the 10 secondary-use plants visually inspects workers for MDA exposure once a year, and that an occupational health and safety 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 $32.39 = $162

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

Compliance program (§1910.1050(g)(2))

Initial

It is estimated that 2 hours of supervisory time and 1 hour of clerical time would be needed to develop this program including an emergency plan for each facility.

Burden hours: 10 plants x (2 supervisory hours and 1 clerical hour) = 30 hours
Cost: 20 hours x $37.30 = $746
Cost: 10 hours x $22.00 = $220
Total cost: $966

Periodic

OSHA estimates that all 10 secondary-use plants have established compliance plans. For these plants, OSHA estimates an occupational health and safety 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 technician time) = 15 hours
Cost: 15 hours x $32.39 = $486

D. Respiratory protection (§1910.1050(h))

Respirator program (§1910.1050(h)(1))

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 for this requirement under 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 an occupational safety and health technician will spend 15 minutes (.25 hour) to inform the cleaning establishment of the possible contamination of the protective work clothing and equipment. The Agency estimates that one plant may need to be informed.

Burden hours: 1 secondary-use plant x .25 hours = 1 hour (rounded)
Cost: 1 hour x $32.39 = $32

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

Signs and labels (§1910.1050(k)(2))

The provisions containing the paperwork requirements associated with signs and labels provide 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)).

Safety Data sheets (SDS)(§1910.1052(k)(3))

This paragraph of the Standard requires employers to develop, obtain and provide workers access to an SDS 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 Control Number 1218-0072).

G. Medical surveillance (§1910.1050(m))

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

It is estimated that each of the 10 plants will replace 2 workers each year.[11] OSHA believes that workers 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:

11See "Information and training ((*§1910.1050(k)(4))" above.*

Burden hours: 20 replacement workers x 1.50 hours = 30 hours
Cost: 30 hours x $35.50 = $1,065

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

OSHA estimates that 80 of the 100 covered workers receive a periodic examination once a year,[12] and that each examination takes one and one-half hours (1.50 hours) of a worker's time. The resulting total annual burden hour and cost estimates for this provision are:

Burden hours: 80 workers x 1.50 hours per examination = 120 hours
Cost: 120 hours x $35.50 = $4,260

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

The Agency believes that 1% (1) of the 122 covered workers require an emergency or additional medical examination each year, and that a worker 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 worker x 1.50 hours = 2 hours (rounded)
Cost: 2 hours x $35.50 = $71

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

OSHA assumes that 1% (1) of the covered workers undergo multiple-physician review yearly, either because of emergency MDA exposure or the worker has signs or symptoms of MDA exposure, and that this worker 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 $35.50 = $71

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 a worker, 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 20 initial examinations, 80 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:

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Burden hours: 102 examinations/reviews x .08 hour = 8 hours
Cost: 8 hours x $22.00 = $176

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 worker 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 $22.00 = $176

Medical removal (§1910.1050(m)(9))

An employer bases the decision to medically remove a worker 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 five 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: 5 commercial-production plants x .08 hour = 1 hour
Cost: 1 hour x $22.00 = $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: 10 plants x 4 exposure-monitoring samples x .08 hour = 3 hours
Cost: 3 hours x $22.00 = $66

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 100 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: 100 records x .08 hour = 8 hours
Cost: 8 hours x $22.00 = $176

Availability (§1910.1050(n)(6)) + 1910.1050(k)(5)(i) and (ii)

The Agency assumes that 10% of workers [100 existing workers plus 24 (resulting from turnover) x 10% = 12 workers] or their designated representatives request access to medical records, exposure-monitoring records, written compliance plans, and training records and materials (workers only) each year. OSHA estimates that a secretary takes five minutes (.08 hour) to make the requested record available to the worker/designated representative. Therefore, the estimated total yearly burden hours and cost for this availability requirement are:

Burden hours: 12 **w**orker-related requests x .08 hour
= 1 hour (rounded)
Cost: 12 worker-related requests x $22.00 (secretary)) = $264

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.**

- **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 offer 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 $24,180. This total consists of $3,480 to analyze exposure-monitoring samples, $20,700 to administer medical examinations.

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

Based on information obtained from the Agency', the average cost for an OSHA-accredited laboratory to analyze a sample of airborne MDA is $87.[13] The annual cost for the 4 monitoring samples collected by the10 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 $87.00 = $ 3,480

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

Consistent with recent ICRs and regulatory analyses, the Agency estimates that each medical examination costs $207.[14] 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 100 medical examinations each year, resulting in the following annual cost:

Cost: 100 examinations x $207.00 = $20,700

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.

There is no cost to the Federal Government associated with this information collection request.

15. Explain the reasons for any program changes or adjustments.

The Agency is requesting an adjustment decrease in burden hours from 370 hours to 334 hours.

13Galson Laboratories, 2015.

14 The Consumer Price Index (CPI) indicated a 13.03% increase in the price of medical care services from 2010 to 2014; it is assumed that the cost of medical examinations increased by 13.03% as well. (Source: Consumer Price Index – CPI, All Urban Consumers, http://www.bls.gov/data/, (accessed June 11, 2015).

The decrease is the result of a slight decrease in the number of impacted secondary-use plants and a reduction in workers receiving initial medical examinations, receiving exposure monitoring training, and requesting access to records.

There is an overall adjustment decrease in capital costs of $3,802 (from $27,982 to $24,180) resulting from a decrease in the cost to analyze a sample of airborne MDA from $119 to $87 each. However, the cost of a medical exam increased from $187 to $207.

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.

OSHA lists current valid control numbers in §§1910.8, 1915.8, 1917.4, 1918.4 and 1926.5 and publishes the expiration date in a Federal Register notice announcing OMB approval of the information collection requirement (see 5 CFR 1320.3(f)(3)). OSHA believes that this is the most appropriate and accurate mechanism to inform interested parties of these expiration dates.

18. Explain each exception to the certification statement.

OSHA is not seeking an exception to the certification statement.