SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS IN THE 13 CARCINOGENS STANDARD (29 CFR 1910.1003[1]) OFFICE OF MANAGEMENT BUDGET (OMB) CONTROL NO. 1218-0085 (June 2015)

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 *et seq.*). As one means in achieving this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" to ensure that workers will be furnished "employment and a place of employment which are 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 other technological procedures, suitable protective equipment, labels and other appropriate forms of warning, and precautions for safe use or exposure (29 U.S.C. 655(b)(7)). 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(c)(1) and (c)(3)).

The 13 Carcinogens Standard covers the following carcinogens: 4-Nitrobiphenyl (§1910.1003), alpha-Naphthylamine (§1910.1004), Methyl chloromethyl ether (§1910.1006), 3,3'-Dichlorobenzidine (and its salts) (§1910.1007), bis-Chloromethyl ether (§1910.1008), beta-Naphthylamine (§1910.1009), Benzidine (§1910.1010), 4-Aminodiphenyl (§1910.1011), Ethyleneimine (§1910.1012), beta-Propiolactone (§1910.1013), 2-Acetylaminofluorene (§1910.1014), 4-Dimethylaminoazo-benzene (§1910.1015), and N-Nitrosodimethylamine

[1]Reference to 29 CFR 1910.1003 also incorporates the 13 Carcinogens Standards for Shipyards (29 CFR 1915.1003-.1016) and Construction (29 CFR 1926.1103-.1116), which have requirements identical to those contained in §1910.1003.

(§1910.1016). The standard provides protection for workers from adverse health effects associated with occupational exposure to these substances.

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.

A. General regulated area requirements (§1910.1003(d))

Respirator program §1910.1003(d)(1) - The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b), (c), (d) (except (d)(1)(iii) and (iv), and (d)(3)), and (e) through (m), which covers each employee required by this section to use a respirator.

Purpose: To ensure that employers establish a standardized procedure for selecting, using, and maintaining respirators for each workplace where respirators will be used. Developing written procedures ensures that employers develop a respirator program that meets the needs of their workers.

Emergencies §1910.1003(d)(2) - In an emergency, immediate measures including, but not limited to, the requirements of paragraphs (d)(2)(i) through (v) of this section shall be implemented.

§1910.1003(d)(2)(iii) - Requires employer to provide special medical surveillance by a physician within 24 hours for employees present in the potentially affected area at the time of the emergency.

Purpose: The emergency medical surveillance is necessary to ensure that no worker has suffered adverse effects as a result of the emergency.

Decontamination procedures §1910.1003(d)(4)(iii) - Decontamination procedures shall be established and implemented to remove carcinogens addressed by this section from the surfaces of materials, equipment, and the decontamination facility.

Purpose: Implementation of these procedures will remove carcinogens from materials, equipment, and the decontamination facility.

B. Signs, information, and training (§1910.1003(e))

(e) ***Communication of hazards*****—(1)** ***Hazard communication***. (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§1910.1200) for each carcinogen listed in paragraph (e)(1)(iv) of this section.

(ii) In classifying the hazards of carcinogens listed in paragraph (e)(1)(iv) of this section, at least the hazards listed in paragraph (e)(1)(iv) are to be addressed.

(iii) Employers shall include the carcinogens listed in paragraph (e)(1)(iv) of this section in the hazard communication program established to comply with the HCS (§1910.1200). Employers shall ensure that each employee has access to labels on containers of the carcinogens listed in paragraph (e)(1)(iv) and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (e)(4) of this section.

(iv) List of Carcinogens:

(A) 4-Nitrobiphenyl: Cancer.

(B) alpha-Naphthylamine: Cancer; skin irritation; and acute toxicity effects.

(C) Methyl chloromethyl ether: Cancer; skin, eye and respiratory effects; acute toxicity effects; and flammability.

(D) 3,3′-Dichlorobenzidine (and its salts): Cancer and skin sensitization.

(E) bis-Chloromethyl ether: Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability.

(F) beta-Naphthylamine: Cancer and acute toxicity effects.

(G) Benzidine: Cancer and acute toxicity effects.

(H) 4-Aminodiphenyl: Cancer.

(I) Ethyleneimine: Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability.

(J) beta-Propiolactone: Cancer; skin irritation; eye effects; and acute toxicity effects.

(K) 2-Acetylaminofluorene: Cancer.

(L) 4-Dimethylaminoazo-benzene: Cancer; skin effects; and respiratory tract irritation.

(M) N-Nitrosodimethylamine: Cancer; liver effects; and acute toxicity effects.

(2) *Signs.* (i) The employer shall post entrances to regulated areas with signs bearing the legend:

DANGER

(CHEMICAL IDENTIFICATION)

MAY CAUSE CANCER

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall post signs at entrances to regulated areas containing operations covered in paragraph (c)(5) of this section. The signs shall bear the legend:

DANGER

(CHEMICAL IDENTIFICATION)

MAY CAUSE CANCER

WEAR AIR-SUPPLIED HOODS, IMPERVIOUS SUITS, AND PROTECTIVE EQUIPMENT IN THIS AREA

AUTHORIZED PERSONNEL ONLY

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

CANCER-SUSPECT AGENT

AUTHORIZED PERSONNEL ONLY

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

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA

IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES

AUTHORIZED PERSONNEL ONLY

(v) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(3) *Prohibited statements.* No statement shall appear on or near any required sign, label, or instruction that contradicts or detracts from the effect of any required warning, information, or instruction.

(4) *Training and indoctrination.* (i) Each employee prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to:

(A) The nature of the carcinogenic hazards of a carcinogen addressed by this section, including local and systemic toxicity;

(B) The specific nature of the operation involving a carcinogen addressed by this section that could result in exposure;

(C) The purpose for and application of the medical surveillance program, including, as appropriate, methods of self-examination;

(D) The purpose for and application of decontamination practices and purposes;

(E) The purpose for and significance of emergency practices and procedures;

(F) The employee's specific role in emergency procedures;

(G) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of a carcinogen addressed by this section;

(H) The purpose for and application of specific first aid procedures and practices;

(I) A review of this section at the employee's first training and indoctrination program and annually thereafter.

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

(iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

Purpose: Such signs warn workers that entry is permitted only if they are authorized to do so, and there is a specific need to enter the area. Warning signs also supplement the training workers receive under this standard.

Posting emergency procedures provides a continuing reminder to workers of what actions they need to take if an emergency occurs.

Medical Surveillance (§1910.1003(g))

At no cost to the worker, a program of medical surveillance shall be established and implemented for workers considered for assignment to enter regulated areas, and for authorized workers.

Examinations §1910.1003(g)(1)(i) - Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the worker, family and occupational background, including genetic and environmental factors.

§1910.1003(g)(1)(ii) - Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.

§1910.1003(g)(1)(iii) - In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy, and cigarette smoking.

Purpose: Worker health must be documented periodically so that a physician can determine whether workers have experienced adverse health effects over the course of their exposure to the carcinogenic chemicals regulated by this standard. In addition, if symptoms of organic damage appear, the physician often needs information about the patient's previous medical conditions to make an accurate diagnosis of the new problem, its apparent cause, and the course of treatment required. Further, these medical records will aid workers and their physicians in determining whether treatment or other interventions are needed for occupational exposure to any of the carcinogens.

Records §1910.1003(g)(2)(i) - Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment.

§1910.1003(g)(2)(ii) - Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i). These records shall also be provided upon request to the Director.

§1910.1003(g)(2)(iii) - Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific exposure.

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 burdens.

Employers may use improved information technology as appropriate when making, keeping, and preserving the required records. The standard is written in performance-oriented language, that is, in terms of what data must collected and maintained, rather than how the data must be collected and maintained.

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 information required to be collected and maintained by this standard is specific to each employer and worker involved, and is not available or duplicated by another source. This information is available only from employers. At this time, there is no indication that any alternate source is available.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information collection does not have a significant impact on a substantial number of small entities.

6. Describe the consequences 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 information collection frequencies specified by this standard are the minimum OSHA believes are necessary to ensure that employers and OSHA can effectively monitor the health status of workers working with any of the 13 carcinogens.

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 that can 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.**

No special circumstances exist that require employers to collect information in the manner or using the procedure specified by this item; the paperwork requirements in the Standard conform to the guidelines set forth in 5 CFR 1320.5.

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.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on April 27, 2015 (80 FR 23301) soliciting public comments on its proposed extension of the collection of information requirements contained in the 13 Carcinogens Standard (29 CFR 1910.1003). This notice was part of a preclearance consultation program that provided interested parties with an opportunity to comment on OSHA's request for an extension by the Office of Management and Budget (OMB) of a previous approval of the collection of information requirements found in the Standard. The Agency did not receive any comments in response to its notice.

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

No payments or gifts will be provided to the respondents.

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

Agency files containing personally identifiable employee medical information shall be segregated from other agency files. When not in active use, files containing this information shall be kept secured in a locked cabinet or vault. The OSHA Medical Records Officer and the Principal OSHA Investigator shall each maintain a log of uses and transfers of personally identifiable employee medical information and lists of coded direct personal identifiers, except as to necessary uses by staff under their direct personal supervision.

The photocopying or other duplication of personally identifiable employee medical information shall be kept to the minimum necessary to accomplish the purposes for which the information was obtained. The protective measures established by this section apply to all worksheets, duplicate copies, or other agency documents containing personally identifiable employee medical information. Intra-agency transfers of personally identifiable employee medical information shall be by hand delivery, United States mail, or equally protective means. Inter-office

Consistent with OSHA records disposition programs, personally identifiable employee medical information and lists of coded direct personal identifiers shall be destroyed or returned to the original record holder when no longer needed for the purposes for which they were obtained. Personally identifiable employee medical information which is currently not being used actively but may be needed for future use shall be transferred to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall conduct an annual review of all centrally-held information to determine which information is no longer needed for the purposes for which it was obtained.

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 reasons 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 Standard requires that worker pre-assignment medical examinations include a personal history of the worker and a family background, including "genetic and environmental factors" (§1910.1003(g)(1)(i)). In addition, in all physical examinations (pre-assignment, periodic, emergency) the physician must consider whether conditions exist that pose increased risk to the worker. The Standard specifically mentions the following conditions: reduced immunological competence, pregnancy, cigarette smoking, and treatment involving steroids or cytotoxic agents. This information is necessary to ensure that workers will not be at increased risk of harm if they enter or work in a regulated area or have not been harmed due to a workplace emergency. With regard to pregnant workers, obtaining such information will also help to ensure that entering or working in a regulated area will not result in adverse developmental health effects.

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. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

Wage Rates

The Agency adopted the mean wage rates from *"May 2013 National Occupational Employment and Wage Estimates, United States,"* Bureau of Labor Statistics (BLS), U.S. Department of Labor, http://www.bls.gov/news.release/archives/ocwage_04012014.pdf. Total compensation for these occupational categories includes an adjustment of 31.3 percent ("*Employer Costs for Employee Compensation," Jan 2015*, p. 1, http://www.bls.gov/news.release/archives/ecec_12102014.pdf) 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:

- Professional/Manager/Supervisor $36.71[2]
- Worker $22.05[3]
- Clerical/Secretary $21.47[4]

Table 1 summarizes the number of establishments and number of exposed workers based on previous ICR estimates and updated with new information where possible. In attempting to update these figures, the Agency examined SRI International's *Directory of Chemical Producers*, OSHA docket materials, EPA Toxic Release Inventory data and other information where available. According to the *Directory of Chemical Producers* there currently is no domestic U.S. production of any of the 13 carcinogens, and EPA TRI data indicates that releases

2 Occupation Code: 51-1011, First-line supervisors of production and operating workers.

3 Occupation Code: 51-0000, Production occupations.

4 Occupation Code 43-6014, Secretaries and administrative assistants, except legal, medical and executive.

of these chemicals are often limited to just a few facilities.[5] Given this, OSHA believes the number of facilities may be overestimated, and thus the burden hours and costs are overestimated. However, the *DCP* only includes production facilities, while the TRI database only identifies facilities releasing chemicals in quantities greater than reporting thresholds. Because of these limitations, it is unclear the total number of facilities covered by the Standard that might be engaged in processing, repackaging, releasing, handling, or storing a particular chemical.

Table 1 - Establishments and Exposure Data

Previous CFR Citation	Title	OMB Inventory Number	CAS Number	Number of Establishments	Number of Exposed Workers
1910.1003	4-Nitrobiphenyl[1]	1218-0085	92-93-3	0	0
1910.1004	α-Naphthylamine[2]	1218-0084	134-32-7	38	200
1910.1006	Methyl chloromethyl ether[3]	1218-0086	107-30-2	12	169
1910.1007	3,3'-Dichlorobenzidine (and its salts)[4]	1218-0083	91-94-1	12	127
1910.1008	bis-Chloromethyl ether[5]	1218-0087	542-88-1	1	8
1910.1009	β-Naphthylamine[6]	1218-0089	91-59-8	7	27
1910.1010	Benzidine[7]	1218-0082	92-87-5	3	14
1910.1011	4-Aminodiphenyl[8]	1218-0090	92-67-1	0	0
1910.1012	Ethyleneimine[9]	1218-0080	151-56-4	10	82
1910.1013	β-Propiolactone[10]	1218-0079	57-57-8	10	20
1910.1014	2-Acetylaminofluorene[11]	1218-0088	53-96-3	3	10
1910.1015	4-Dimethylaminoazobenzene[12]	1218-0044	60-11-7	1	10
1910.1016	N-Nitrosodimethylamine[13]	1218-0081	62-75-9	0	0
	TOTALS			**97**	**667**

[1] EPA reports that 4-Nitrobiphenyl is no longer manufactured, imported, used, or sold in the United States (http://www.epa.gov/ttn/atw/hlthef/nitrobip.html). Additionally, the EPA TRI database reported no releases of 4-Nitrobiphenyl for Reporting Year (RY) 2012.

[2] EPA TRI database reported no release of α-Naphthylamine for RY2009.

[3] The EPA TRI database reported no release of Methyl chloromethyl ether for RY2012. EPA reports different uses for Methyl chloromethyl but does not provide current usage statistics (http://www.epa.gov/ttn/atw/hlthef/chlo-eth.html).

5 The Agency searched the *Directory of Chemical Producers* by chemical name listed in the Standard, commonly used alternate names, and Chemical Abstract Service (CAS) Registry Numbers (http://www.sriconsulting.com/DCP/Public/index.html). EPA TRI data for each chemical is discussed below in Table 1.

[4]The EPA TRI database reported no release of 3,3'-Dichlorobenzidine for RY2012. EPA reports that, while this chemical was used in the past in the production of dyes and pigments, it is no longer used to manufacture dyes in the United States (http://www.epa.gov/ttn/uatw/hlthef/di-benzi.html).

[5]The EPA TRI database reported no release of bis-Chloromethyl ether (BCME) for RY2012. EPA reports that BCME is used only as a research chemical and lab reagent and is no longer used commercially in the United States (http://www.epa.gov/ttn/uatw/hlthef/chlorome.html).

[6]Department of Health and Human Services, National Toxicology Program reports that the commercial manufacture and use of β-Naphthylamine was banned in the early 1970s. Today, this chemical is available in small quantities for laboratory research; as of 2003, there were six U.S. suppliers of β-Naphthylamine (http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s117naph.pdf). EPA TRI database reported one facility reporting β-Naphthylamine for RY2012.

[7]EPA TRI database reported three facilities reporting Benzidine for RY2012. Two of the three facilities reported also appeared on the TRI database for RY2009. EPA also reports that "Benzidine is no longer produced in the United States, although benzidine-based dyes maybe imported into this country" (http://www.epa.gov/ttn/atw/hlthef/benzidin.html). For the 2011 ICR, OSHA has included two new facilities and estimates 14 new workers, based on an average of seven workers per establishment.

[8]EPA TRI database reported no release of 4-Aminodiphenyl for RY2012. EPA also reports that 4-Aminodiphenyl is no longer produced commercially (http://www.epa.gov/ttn/atw/hlthef/aminobip.html).

[9]The EPA TRI database reported two facilities reporting release of Ethyleneimine for RY2012. EPA also reports a number of uses for Ethyleneimine, but does not provide current usage statistics (http://www.epa.gov/ttn/atw/hlthef/ethyl-mi.html).

[10]The EPA TRI database has no reported data of β-Propiolactone for RY2012. EPA reports a number of uses for β-Propiolactone, but does not provide current usage statistics (http://www.epa.gov/ttn/uatw/hlthef/propiola.html); other sources indicate continued current usage in at least some applications (http://www.iom.edu/Object.File/Master/43/434/BETAPROPIOLACTONE.pdf).

[11]The EPA TRI database lists one facility reporting 2-Acetylaminofluorene releases for RY2012; however, this facility already appears in the EPA TRI for 2009. EPA reports that 2-Acetylaminofluorene is "frequently used in the laboratory by biochemists and technicians as a positive control in the study of liver enzymes and the carcinogenesis and mutagenicity of aromatic amines." (http://www.epa.gov/ttn/uatw/hlthef/acetylam.html).

[12]EPA TRI database lists one facility reporting 4-Dimethylaminoazobenzene for RY2012. This facility is different from the facility that was reported in the EPA TRI for RY2009. EPA reports that the chemical was "used as a dye for coloring polishes and other wax products, polystyrene, soap, and as a pH indicator." EPA also reports that "4-Dimethylaminoazobenzeneis not currently produced or used commercially in the U.S (http://www.epa.gov/ttnatw01/hlthef/di-benze.html).

[13]EPA TRI database reports no release of N-Nitrosodimethylamine for RY2012. EPA also reports that "NDMA is not produced in pure form or commercially used, except for research purposes"

(A) General regulated areas (§1910.1003(d))

Respirator Program (§1910.1003(d)(1))

The information collection requirements pertaining to the respiratory protection requirements in the 13 Carcinogens Standard and burden associated with those requirements are included in the Respiratory Protection standard (29 CFR 1910.134) (OMB Control Number 1218-0099) and, therefore, are not included in this ICR.

Emergencies (§1910.1003(d)(2))

The standard requires that employers implement certain measures in an emergency, including providing special medical surveillance for workers present in the potentially affected area at the time of the emergency. The burden hours and costs associated with emergency medical surveillance is included in the medical surveillance provision discussed in (C) below.

Decontamination Procedures (§1910.1003(d)(4))

Employers must establish decontamination procedures to remove carcinogens regulated by the standard from the surfaces of materials, equipment, and the decontamination facility. OSHA assumes that a professional would take 15 minutes (.25 hour) to review and update decontamination procedures. In addition, the Agency identified two new establishments covered by this ICR. For these new establishments, OSHA assumes that a professional would take 1 hour to develop the decontamination procedures.

Burden hours: 95 existing employers × .25 hour = 24 hours
Costs: 24 hours × $36.71 = $881

Burden hours: 2 new employers x 1 hour = 2 hours
Costs: 2 hours x $36.71 = $73

(B) Signs, information, and training (§1910.1003(e))

The standard requires that employers post signs and instructions at regulated area entrances and exits. The standard also specifies how containers must be labeled. Labeling requirements for containers vary depending whether workers are authorized to be in regulated areas (i.e., authorized workers). In addition, the standard requires specific emergency procedures to be posted.

The standard provides specific language for many of the required signs and labels; therefore, no burden has been taken for this requirement since the government is providing information. (See the final rule on Controlling Paperwork Burden on the Public (5 CFR 1320.3(c)(2)). Burden associated with generating any other required label or sign is attributed to the Information Collection Request for OSHA's Hazard Communication Standard, OMB Control Number 1218-0072.

The training required under §1910.1003(e)(4) is not considered to be subject to the PRA, therefore, no burden is associated with this requirement.

The Agency assumes that 95 existing establishments and 2 new establishments are using the 13 carcinogens. The Agency identified two new establishments covered by this ICR. For these new establishments, OSHA assumes that a professional would take 30 minutes (.5 hour) to develop

and post the instructions for the entry and exit procedures for regulated areas and 1 hour to develop and post emergency procedures. For existing establishments, OSHA assumes a professional would take 15 minutes (.25 hour) to review, update and post existing instructions for the entry and exit procedures for regulated areas, and existing emergency procedures.

Burden hours: 95 existing employers × .25 hour = 24 hours
Costs: 24 hours × $36.71 = $881

Burden hours: 2 new employers × 1.5 hour = 3 hours
Costs: 3 hours × $36.71 = $110

(C) Medical surveillance (§1910.1003(g)(2)(i))

OSHA estimates that a worker spends 2 hours away from the job per medical exam, and that a clerk would expend 5 minutes (0.08 hour) to update/maintain the corresponding medical records. In addition, OSHA estimates that 667 workers will receive pre-assignment, periodic or emergency medical exams. Of the 667, OSHA estimates that 1 supervisor per plant or 97 supervisors will receive medical examinations. The remaining 570 are workers receiving a medical examination.

Burden hours: (667 workers × 2 hours) + (667 exams × 0.08 hour) = 1,387 hours
Costs: Clerical: 667 medical exams × .08 hour × $21.47 = $1,146
Supervisors: 97 medical exams × 2 hours × $36.71= $7,122
Workers: 570 medical exams × 2 hours × $22.05 = $25,137

(D) Records Access (§1910.1003(g)(2)(ii))

OSHA assumes that all workers who receive medical examinations will request records access to their medical records since the standard does not require employers to provide a physician's written opinion to the worker. Each request will take 5 minutes (0.08 hour) of clerical time to process.

Burden hours: 667 workers × 0.08 hour = 53 hours
Costs: 53 hours × $21.47 = $1,138

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 other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

Medical exams

OSHA estimates that each worker's medical exam, which includes the physician's written opinion, costs the employer $160.[6] Approximately 667 medical exams will be given annually for a total cost of $106,720.

Costs: 667 exams x $160 = $106,720

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.

OSHA does not take cost for other occupational expenses, such as equipment, overhead, and support staff expenses, since these costs are normal expenses and would have occurred without these collections of information requirements.

15. Explain the reasons for any program changes or adjustments reporting in Item 12 or 13 of this Supporting Statement.

6The previous ICR assumed that each medical examination would include the following: basic medical examination costing $151 dollars. The Consumer Price Index indicated an 5.83% increase in the price of professional medical services from March 2011 to March 2014; the cost of a medical examination was assumed to have increased by 5.83% as well. The costs are now $160.

OSHA is requesting an adjustment increase of 21 hours (from 1,472 hours to 1,493 hours). The increase is a result of a slight growth in the number of establishments affected by the Standards from 95 to 97. This increase is offset by a one hour decrease for removing the burden hour for employers to disclose records to an OSHA compliance officer during an inspection. OSHA determined that disclosure of records during an inspection is not covered by the PRA. The Agency is also requesting an adjustment cost increase of $7,513. The increase is a result of an increase in the number of workers receiving medical examinations, from 657 to 667, and an increase in the cost of the medical examination from $151 to $160.

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 of information, completion of report, publication dates, and other actions.

The collection of information will not 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 inappropriate.

OSHA lists current valid control numbers in §§1910.8, 1915.8, 1917.4, 1918.4, and 1926.5 and publishes the expiration date in the 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 such exceptions.

B. **COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS.**

This collection of information does not employ statistical methods.

Table 2					
Summary of Burden Hours and Costs					
Information Collection Requirements	**Existing Burden Hours**	**Proposed Burden Hours**	**Burden Hour Change**	**Estimated Cost**	**Responses**
A. Respirator Program §1910.1003(d)(1)	0	0	0	$0.00	0
Emergencies §1910.1003(d)(2)	0	0	0	$0.00	0
Decontamination procedures §1910.1003(d)(4)(iii)	25	26	1	$954	97
B. Signs, information and training §1910.1003(e)	25	27	2	$991	97
C. Medical surveillance §1910.1003(g)(1) and (g)(2)(i)	1,367	1,387	20	$33,405	1,314
D. Access to records §1910.1003(g)(2)(ii)	54	53	-1	$1,138	667
Totals	**1,472**	**1,493**	**21**	**$36,488**	**2,195**