SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS IN THE 13 CARCINOGENS STANDARD (29 CFR 1910.1003[1]) (OMB CONTROL NO. 1218-0085(December 2008))

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 employees 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 employee 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 employee exposures to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further requires that employees exposed to concentrations over prescribed limits be notified of this fact, and of the corrective action being taken (29 U.S.C. 657(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 (§1910.1016). The standard provides protection for employees 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))

[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), whose requirements are identical to those contained in §1910.1003.

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).

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 employees.

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)(i) - The potentially affected area shall be evacuated as soon as the emergency has been determined.

§1910.1003(d)(2)(ii) - Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.

§1910.1003(d)(2)(iii) - Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (f)(2) of this section.

§1910.1003(d)(2)(iv) - Where an employee has a known contact with a carcinogen addressed by this section, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

§1910.1003(d)(2)(v) - An incident report on the emergency shall be reported as provided in paragraph (f)(2) of this section.

Purpose: The emergency surveillance is necessary to ensure that no employee 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))

§1910.1003(e)(1)(i) -Entrances to regulated areas shall be posted with signs bearing the legend: CANCER-SUSPECT AGENT - AUTHORIZED PERSONNEL ONLY.

§1910.1003(e)(1)(ii) - Entrances to regulated areas containing operations covered in paragraph (c)(5) of this section shall be posted with signs bearing the legend: CANCER-SUSPECT AGENT EXPOSED IN THIS AREA - IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES - AUTHORIZED PERSONNEL ONLY.

§1910.1003(e)(1)(iii) - 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.

Container contents identification - *§1910.1003(e)(2)(i)* - Containers of a carcinogen addressed by this section and containers required under paragraphs (c)(4)(v) and (c)(6)(vii)(B) and (viii)(B) of this section that are accessible only to and handled only by authorized employees, or by other employees trained in accordance with paragraph (e)(5) of this section, may have contents identification limited to a generic or proprietary name or other proprietary identification of the carcinogen and percent.

§1910.1003(e)(2)(ii) - Containers of a carcinogen addressed by this section and containers required under paragraphs (c)(4)(v) and (c)(6)(vii)(B) and (viii)(B) of this section that are accessible to or handled by employees other than authorized employees or employees trained in accordance with paragraph (e)(5) of this section shall have contents identification that includes the full chemical name and Chemical Abstracts Service Registry number as listed in paragraph (a)(1) of this section.

§1910.1003(e)(2)(iii) - Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

§1910.1003(e)(2)(iv) - Containers whose contents are carcinogens addressed by this section with corrosive or irritating properties shall have label statements warning of such hazards noting, if appropriate, particularly sensitive or affected portions of the body.

Purpose: Such signs warn employees 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 employees receive under this standard.

§1910.1003(e)(5)(ii) - "Specific emergency procedures shall be prescribed, and posted**,** and employees shall be familiarized with their terms, and rehearsed in their application."

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

C. Medical Surveillance (§1910.1003(g))

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

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 employee, 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: Employee health must be documented periodically so that a physician can determine whether employees 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 employees 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. Upon termination of the employee's employment, including retirement or death, or in the event that the employer ceases business without a successor, records, or notarized true copies thereof, shall be forwarded by registered mail to the Director.

§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 burden.

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 2 above.

The information required to be collected and maintained by this standard is specific to each employer and employee 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 (Item 5 of OMB Form 83-I), 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 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 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 employees 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 **Federal Register** notice on September 26, 2008 (73 FR 55870, Docket No. OSHA-2008-0030)) requesting public comment on its extension of the information collection requirements contained in the 13 Carcinogens Standard. This notice was part of a preclearance consultation program intended those interested parties the opportunity to comment on OSHA's request to the Office of Management and Budget (OMB) for an extension of a previous approval of the information collection requirements found in the above standard. The Agency has not received comments in response to its notice.

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

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.

As medical records may contain private information, OSHA and NIOSH have taken steps to assure that the medical records data are kept confidential. Agency practices and procedures governing OSHA access to employee 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 reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons form whom the information is requested, and any steps to be taken to obtain their consent.

The Standard requires that employee pre-assignment medical examinations include a personal history of the employee 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 employee. 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 employees 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 in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. 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 following hourly wage rates for the relevant occupational categories have been derived from the National Compensation Survey (NCS), published by the Bureau of Labor Statistics.[2] These wages have been adjusted to reflect the fact that fringe benefits comprise roughly 29.3 percent of total employee compensation in the private sector.[3] The costs of labor used in this analysis are therefore estimates of total hourly compensation. These hourly wages are:

- Professional/Manager/Supervisor $48.17[4]
- Worker $30.27[5]
- Clerical/Secretary $23.14[6]

[2] Source: Bureau of Labor Statistics, National Compensation Survey: Occupational Wages in the United States, June 2005 Supplementary Tables. Published July 2006. Supplementary Table 1.1: United States, selected occupations: Mean hourly earnings and percentiles, all workers, National Compensation Survey, June 2005.
[3] Source: Bureau of Labor Statistics. *Employer Costs for Employee Compensation – December 2007.* March 12, 2008.
[4] Executive, administrative and managerial
[5] Precision, production, craft and repair
[6] Administrative support, including clerical

Table 1
Summary of Burden Hours and Costs

Information Collection Requirements	Existing Burden Hours	Proposed Burden Hours	Burden Hour Change	Estimated Cost
A. Respirator Program §1910.1003(d)(1)	0	0	0	0
Emergencies §1910.1003(d)(2)	0	0	0	0
Decontamination procedures §1910.1003(d)(4)(iii)	97	93	-4	$4,480
B. Signs, information and training §1910.1003(e)	121	116	-5	$5,588
C. Medical surveillance §1910.1003(g)(1)	1,379	1,337	-42	$43,447
Records (g)(2)	60	58	-2	$1,367
Totals	**1,657**	**1,604**	**-53**	**$ 54,882**

Table 1 summarizes the number of establishments and number of exposed employees 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 of these chemicals are often limited to just a few facilities.[7] 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.

[7] 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.

Table 2 - Establishments and Exposure Data					
Previous CFR Citation	**Title**	**OMB Inventory Number**	**CAS Number**	**Number of Establishments**	**Number of Exposed Employees**
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	1218-0082	92-87-5	0	0
1910.1011	4-Aminodiphenyl	1218-0090	92-67-1	0	0
1910.1012	Ethyleneimine[7]	1218-0080	151-56-4	10	82
1910.1013	β-Propiolactone[8]	1218-0079	57-57-8	10	20
1910.1014	2-Acetylaminofluorene[9]	1218-0088	53-96-3	3	10
1910.1015	4-Dimethylaminoazobenzene	1218-0044	60-11-7	0	0
1910.1016	N-Nitrosodimethylamine	1218-0081	62-75-9	0	0
	TOTALS			**93**	**643**

[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) 2006.

[2] The EPA TRI database lists four facilities reporting α-Naphthylamine releases for RY 2006.

[3] The EPA TRI database lists two facilities reporting Methyl chloromethyl ether releases for RY2006.

[4] The EPA TRI database lists one hazardous waste treatment and disposal site (NAICS 562211) reporting 3,3'-Dichlorobenzidine releases for RY2006. 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 lists one facility reporting bis-Chloromethyl ether (BCME) releases for RY2006. 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).

[7] The EPA TRI database lists two facilities reporting Ethyleneimine releases for RY2006. 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).

[8] The EPA TRI database has no reported data of β-Propiolactone. 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).

[9] The EPA TRI database lists two facilities reporting 2-Acetylaminofluorene releases for RY2006, and 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)

(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) 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 employees 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 (D) 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, with an hourly wage rate of $48.17, would take 1 hour to review and update decontamination procedures.

Burden hours: 93 employers × 1 hour = 93 hours
Costs: 93 hours × $48.17 = $4,480

(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 employees are authorized to be in regulated areas (i.e., authorized employees).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 Agency assumes that no additional facilities are using the 13 carcinogens. Therefore, burden being taken is for reviewing and updating existing emergency procedures and instructions for entering and exiting regulated areas. OSHA assumes a professional would take 1 hour to update and post the procedures and 15 minutes (0.25 hour) to review the signs and instructions on procedures for the entry to and exit from regulated areas.

Burden hours: 93 employers × 1.25 hour = 116 hours
Costs: 116 hours × $48.17 = $5,588

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

OSHA estimates that an employee spends 2 hours away from the job per medical exam, and that a clerk, earning $23.14 an hour, would expend 5 minutes (0.08 hour) to update/maintain the corresponding medical records. OSHA estimates that 643 employees will receive pre-assignment, periodic or emergency medical exams. Of the 643, OSHA estimates that 1 supervisor per plant or 93 supervisors, with a hourly wage rate of

$48.17 per hour, will receive medical examinations. The remaining 550 are employees receiving a medical examination earning $30.27 per hour.

Burden hours: (643 employees × 2 hours) + (643 exams × 0.08 hour) = 1,337 hours
Costs: Clerical: 643 medical exams × .08 hour × $23.14 = $1,190
Supervisors: 93 medical exams × 2 hours × $48.17 = $8,960
Employees: 550 medical exams × 2 hours × $30.27 = $33,297

Records (§1910.1003(g)(2))

Transfer medical records to NIOSH (§1910.1003(g)(2)(i & ii))

Employers must forward, by registered mail, employee medical records (or notarized true copies) to NIOSH when an employee terminates employment, retires or dies. Employee medical records must also be transmitted to NIOSH if the employer ceases business without a successor and or if NIOSH requests them.

OSHA estimates that a clerk, earning $23.14 an hour, spends 2 hours preparing and sending records to NIOSH. Based on the number of records NIOSH received from employers in the past, OSHA estimates that, on average, NIOSH receives 29 records from 3 employers each year.

Burden hours: 3 employers × 2 hours = 6 hours
Costs: 6 hours × $23.14 = $139

Records Access (§1910.1003(g)(2)(ii))

OSHA assumes that all employees 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 employee. Each request will take 5 minutes (0.08 hour) of clerical time to process.

Burden hours: 643 employees × 0.08 hours = 51 hours
Costs: 51 hours × $23.14 = $1,180

Federal Access (§1910.1003(g)(2)(ii))

The 13 Carcinogens Standard requires that employers make available employee medical records and training materials at the request of the Assistant Secretary (usually an OSHA compliance officer). OSHA estimates that a supervisor, earning $48.17 per hour, will spend approximately 5 minutes (0.08 hour) to inform an OSHA compliance officer of the location of the records during an inspection. The Agency estimates that only 1 of the 93 establishments covered by this Standard will be inspected per year, therefore, there will be only one request by OSHA per year to access medical records.[8]

Burden hours: 1 inspection × 0.08 hour = 1 hour (rounded up)
Costs: 1 hour × $48.17 = $48.17

[8] OSHA estimated the number of inspections by determining the inspection rate (1.4%) for all facilities under the jurisdiction of the OSH Act (including both Federal OSHA and approved state-plan agencies), and then multiplied the total number of plants regulated by the 13 Carcinogens Standard (93) by this percentage (i.e., .014 × 93 = 1.3 inspections (rounded to 1)).

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

Based on the final Respiratory Protection economic analysis, OSHA estimates that each employee's medical exam, which includes the physician's written opinion, costs the employer $138.[9] Approximately 643 medical exams will be given annually for a total cost of $88,734.

Costs: 643 exams × $138 = $88,734

Transferring records to NIOSH

Under paragraph (g)(2) of the Standard, employers must forward by register mail, exposure monitoring and medicals records (or notarized true copies) to NIOSH when an employee terminates employment, retires, or dies. Employee medical records must also be transmitted to NIOSH if the employer ceases to do business without a successor and or if NIOSH requests them. OSHA estimates that 3 sets of records, weighing 5 lbs., will cost approximately $12.30 to mail to NIOSH via the United States Postal Service.

Costs: 3 sets of records × $12.30 = $37

Access to records

During an inspection, OSHA may request access to records required by this standard. The Agency estimates that a compliance officer will make a request for records during 1 inspection annually. OSHA, as a general

[9] The Consumer Price Index (CPI) indicated a 6.3% increase in the price of professional medical services from 2005 to 2007. The previous ICR estimated that the cost of each medical examination was $130; given the 6.3% increase in the price of professional medical services, it was assumed that the cost of a medical examination increased by 6.3% as well.

rule, bases the cost on the average time (5 minutes .08 hour)) that a compliance officer (GS-12, step 5), with an hourly wage rate of $36.91, spends reviewing information at the time of an inspection.[10]

Costs: 1 inspection × 0.08 hour × $36.91 = $3

Transfer of records to NIOSH

The 13 Carcinogens Standard requires that employers transmit employee records to NIOSH after an employee terminates employment, retires or dies, or if an employer ceases business without a successor. Employers must also provide employee medical records if NIOSH requests them.

The cost of this provision to the Federal government consists of the costs required to process the following records: records transmitted by employers who cease to do business and have no successor to preserve and maintain employee records; records obtained when the retention period for the records has expired; and, records NIOSH requests from the employer. Regarding these costs, NIOSH estimated that: it receives or requests about 29 sets of records a year from 3 employers; and that it takes a NIOSH secretary (GS-7-5, at a wage rate of $20.81 per hour) about 4 minutes (0.07 hour) to process each record.[11]

Costs: 29 records × 0.07 hour × $20.81 = $42

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.

The cost to the Federal government is as follows:

Cost Summary:

Accessing records during inspection (OSHA):	$ 3
Processing medical records (NIOSH):	$ 42
Total	$ 45

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.

Access to Records

Cost: $3

During an inspection, OSHA may request access to records required by this standard. The Agency estimates that a compliance officer will make a request for records during 1 inspection annually.

[10] This rate represents the average 2008 General Schedule (GS) hourly wage rate for a compliance officer (GS-12, Step 5) in each of the 32 geographic regions as specified by the U.S. Office of Personnel Management.

[11] Source: Office of Personnel Management, Salary Table 2008 – Cincinnati http://www.opm.gov/oca/08tables/pdf/cin_h.pdf.

OSHA, as a general rule, bases the cost on the average time (5 minutes .08 hour)) that a compliance officer (GS-12, step 5), with an hour wage rate of $36.91, spends reviewing information at the time of an inspection.

Costs: 1 inspection x 0.08 hour x $36.91 = $3

Transfer of Records to NIOSH

Cost: $42

The 13 Carcinogens Standard requires that employers transmit employee records to NIOSH after an employee terminates employment, retires or dies, or if an employer ceases business without a successor. Employers must also provide employee medical records if NIOSH requests them.

The cost of this provision to the Federal government consists of the costs required to process the following records: Records transmitted by employers who cease to do business and have no successor to preserve and maintain employee records; records obtained when the retention period for the records has expired, and records NIOSH requests from the employer. Regarding these costs, NIOSH estimated that: It receives or requests about 29 sets of records a year from 3 employers; and that it takes a NIOSH secretary (GS-7-5, at a wage rate of $20.81[12] per hour) about 4 minutes (0.07 hour) to process each record.

Costs: 29 records x 0.07 hour x $20.81 = $42

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

OSHA is requesting a net burden hour decrease from 1,657 hours to 1,604 hours, a total reduction of 53 hours. According to the Environmental Protection Agency (EPA) 4- Nitrobiphenyl is no longer manufactured, imported, used, or sold in the United States and therefore the number of establishments has decreased from 97 to 93 establishments. Further, based on the deletion of 4-Nitrobiphenyl the number of exposed employees has also decreased from 663 to 643.

Due to the increase in the cost to perform medical exams (from $130 to $138) there is a cost increase of $2,539 (from $86,277 to $88,816).

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.

[12] Source: Office of Personnel Management, Salary Table 2008- Cincinnati, (http://www.opm.gov/oca/08tables/pdf/cin_h.pdf)

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.

There are no forms associated with this collection of information on which to display an expiration date.

18. Explain each exception to the certification statement in ROCIS.

OSHA is not seeking such exceptions.