SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS OF THE BLOODBORNE PATHOGENS STANDARD (29 CFR 1910.1030)[1] (Office of Management and Budget (OMB) Control No. 1218-0180(2007))

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 main objective of the Occupational Safety and Health Act (OSH Act) 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). To achieve this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health regulations" (29 U.S.C. 651).

To protect employee health, the OSH Act authorizes the Occupational Safety and Health Administration (OSHA) to develop standards that provide for "monitoring or measuring employee exposure" to occupational hazards and "prescribe the type and frequency of medical examinations and other tests which shall be made available [by the employer] to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure" (29 U.S.C. 655). In addition, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to the Secretary [of Labor] . . . such records regarding [his/her] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses" (29 U.S.C. 657). In addition, the OSH Act directs OSHA to "issue regulations requiring employers to maintain accurate records of employee exposure to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further specifies that such regulations provide "for each employee or former employee to have access to such records as will indicate [their] own exposure to toxic materials or harmful physical agents" (29 U.S.C. 657). The OSH Act states further that "[t]he Secretary . . . shall . . . prescribe such rules and regulations as [he/she] may deem necessary to carry out [his/her] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (29 U.S.C. 651).

Under the authority granted by the OSH Act, the Occupational Safety and Health Act ("OSHA" or "Agency") published a health standard governing employee exposure to Bloodborne Pathogens at 29 CFR 1910.1030, 1915.1030 (the "Standard"). The basis for this standard is a determination by the Assistant Secretary for OSHA that occupational exposure to bloodborne pathogens can

[1] The 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; this supporting statement does not provide information or guidance on how to comply with, or how to enforce the Standard.

result in infections. These pathogens include, but are not limited to, the hepatitis B virus or the human immunodeficiency virus. These infections can lead to serious clinical illness which may result in death. Additionally, on November 6, 2000, the Needlestick Safety and Prevention Act (NSPA), was signed into law (Pub. L. 106-430), as a result of the growing concern over bloodborne pathogens exposures resulting from sharps injuries and in response to technological developments that increase employee protections. On January 18, 2001, OSHA published a Direct Final Rule to conform to the requirements of NSPA. The paperwork requirements resulting from the NSPA include: modifying the existing requirements for revising and updating the exposure control plan; soliciting of employee input for selecting safer medical devices; and recordkeeping. The information collection requirements contained in the Bloodborne Pathogens, including the NSPA requirements, are fully discussed under items 2 and 12.

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.

Collections of information contained in this Standard include a written exposure control plan, documentation of employees' hepatitis B vaccinations and post exposure evaluations and follow-up medical visits, training, related recordkeeping and a sharps injury log. Information generated in accordance with these provisions, provides the employer and the employee with means to provide protection from the adverse health effects associated with occupational exposure to bloodborne pathogens.

A. Exposure control plan (§1910.1030(c)(1))

§1910.1030(c)(1)(i) - Each employer having an employee(s) with occupational exposure[2] as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

§1910.1030(c)(1)(ii) - The Exposure Control Plan shall contain at least the following elements:

§1910.1030(c)(1)(ii)(A) - The exposure determination required by paragraph (c)(2),

§1910.1030(c)(1)(ii)(B) - The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

§1910.1030(c)(1)(ii)(C) - The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

§1910.1030(c)(1)(iii) - Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

[2] "Occupational exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

§1910.1030(c)(1)(iv) - The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

> §1910.1030(c)(1)(iv)(A) – Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
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> §1910.1030(c)(1)(iv)(B) - Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

§1910.1030(c)(1)(v) - An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

Purpose: The purpose of this requirement is to assure that all new tasks and procedures are evaluated in order to determine whether they will result in occupational exposure. Additionally, the exposure control plan identifies those tasks and procedures where occupational exposures may occur and to identify the positions whose duties include those tasks and procedures identified with occupational exposure. The review also assures evaluation and implementation of safer medical devices. Employee input into this process can serve to assist the employer in overcoming obstacles to the successful implementation of control measures.

Exposure determination (§1910.1030(c)(2)) - Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

> §1910.1030(c)(2)(i)(A) - A list of all job classifications in which all employees in those job classifications have occupational exposure;
>
> §1910.1030(c)(2)(i)(B) - A list of job classifications in which some employees have occupational exposure, and
>
> §1910.1030(c)(2)(i)(C) - A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

Purpose: To assure that the employees who hold these job classifications are included in the training program, are provided with personal protective equipment are provided with post-exposure follow-up where appropriate, are included in the HBV vaccination program, and receive all other protection afforded by this standard.

B. Housekeeping (§1910.1030(d)(4))

General (§1910.1030(d)(4)(i)) - Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

Purpose: Assist in ensuring that routine cleaning, as recommended by CDC, is performed and that the method of decontamination deemed appropriate by the employer is followed. Additionally, the employee's can utilize the schedule to determine when such cleaning should be done and what method they should use to properly accomplish the task.

C. Laundry (§1910.1030(d)(4)(iv))

§1910.1030(d)(4)(iv)(A) - Contaminated laundry shall be handled as little as possible with a minimum of agitation.

§1910.1030(d)(4)(iv)(A)(1) - Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

§1910.1030(d)(4)(iv)(A)(2) - Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

§1910.1030(d)(4)(iv)(A)(3) - Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

§1910.1030(d)(4)(iv)(B) - The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

§1910.1030(d)(4)(iv)(C) - When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

Purpose: Placing and transporting contaminated laundry in labeled or color-coded bags or

containers prevents inadvertent exposure by warning employees of the bag/container's contaminated contents.

D. HIV and HBV research laboratories and production facilities (§1910.1030(e))

§1910.1030(e)(2)(ii)(b) - Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

§1910.1030(e)(2)(ii)(M) - A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

Purpose: Placing and transporting contaminated materials in labeled or color-coded container prevents inadvertent exposure by warning employees of the container's contaminated contents. The biosafety manual serves as a reference and assists in preventing exposure by identifying hazards and practices and procedures to be followed. Periodic review and update assures that the manual reflects the work setting's current hazards, practices, and procedures.

E. Hepatitis B vaccination and post-exposure evaluation and follow-up (§1910.1030(f))

§1910.1030(f)(1)(i) - The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

§1910.1030(f)(1)(ii) - The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

§1910.1030(f)(1)(ii)(A) - Made available at no cost to the employee;

§1910.1030(f)(1)(ii)(B) - Made available to the employee at a reasonable time and place;

§1910.1030(f)(1)(ii)(C) - Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

§1910.1030(f)(1)(ii)(D) - Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

Hepatitis B vaccination (§1910.1030(f)(2))

§1910.1030(f)(2)(i) - Hepatitis B vaccination shall be made available after the employee has

received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

§1910.1030(f)(2)(ii) - The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

§1910.1030(f)(2)(iii) - If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

§1910.1030(f)(2)(iv) - The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

§1910.1030(f)(2)(v) - If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

Purpose: To eliminate or minimize risk of contracting hepatitis B through exposure, particularly when other controls inadequately protect or the employee is inadvertently or unknowingly exposed. Additionally, assures that employees who are initially reluctant to accept vaccination but who later change their minds as the result of information or experiences are accorded the opportunity to receive vaccination. The declination form encourages greater participation in the vaccination program by reiterating that an employee declining the hepatitis B vaccination remains at risk of acquiring hepatitis B. Also allows employers to easily determine who is not vaccinated so that resources can be directed toward improving the acceptance rate of the vaccination program, and assists compliance officers in enforcing training and vaccination requirements.

Post-exposure evaluation and follow-up (§1910.1030(f)(3)) - Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

§1910.1030(f)(3)(i) - Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

§1910.1030(f)(3)(ii) - Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

> §1910.1030(f)(3)(ii)(A) - The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

§1910.1030(f)(3)(ii)(B) - When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

§1910.1030(f)(3)(ii)(C) - Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

§1910.1030(f)(3)(iii) - Collection and testing of blood for HBV and HIV serological status;

§1910.1030(f)(3)(iii)(A) - The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

§1910.1030(f)(3)(iii)(B) - If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

§1910.1030(f)(3)(iv) - Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

§1910.1030(f)(3)(v) - Counseling; and

§1910.1030(f)(3)(vi) - Evaluation of reported illnesses.

Purpose: This documentation allows the employer to receive feedback regarding the circumstances of employee exposures, and the information collected can then be used to focus efforts on decreasing or elimination specific circumstances or routes of exposure. Testing for the source individual's infectious status provides exposed employees with information that will assist them in decisions regarding testing of their own blood, complying with other elements of post-exposure management, and using precautions to prevent transmission to their sexual partners or, in the case of pregnancy, to their fetuses. Such testing also assists the healthcare professional in deciding on appropriate follow-up. Counseling of exposed employees is a vital component of post-exposure follow up procedures and that counseling concerning infection status, including results of and interpretation of all tests, will assist in the employee in understanding the potential risk of infection and in making decisions regarding the protection personal contacts.

Information provided to the healthcare professional (§1910.1030(f)(4))

§1910.1030(f)(4)(i) - The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

§1910.1030(f)(4)(ii) - The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

§1910.1030(f)(4)(ii)(A) - A copy of this regulation;

§1910.1030(f)(4)(ii)(B) - A description of the exposed employee's duties as they relate to the exposure incident;

§1910.1030(f)(4)(ii)(C) - Documentation of the route(s) of exposure and circumstances under which exposure occurred;

§1910.1030(f)(4)(ii)(D) - Results of the source individual's blood testing, if available; and

§1910.1030(f)(4)(ii)(E) - All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

Purpose: The purpose of providing this information is to inform the Healthcare Professional of the requirements of the standard. This information, which represents the minimum necessary for proper follow-up care, enables the Healthcare Professional to understand the employees duties, the circumstances of the exposure incident, the source individuals infections status, the employees Hepatitis B vaccination status and other employee medical information. This information is essential to follow-up evaluation, so that a determination can be made regarding whether prophylaxis or medical treatment is indicated.

Healthcare professional's written opinion (§1910.1030(f)(5)) - The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

§1910.1030(f)(5)(i) - The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

§1910.1030(f)(5)(ii) - The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

§1910.1030(f)(5)(ii)(A) - That the employee has been informed of the results of the evaluation; and

§1910.1030(f)(5)(ii)(B) - That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

§1910.1030(f)(5)(iii) - All other findings or diagnoses shall remain confidential and shall not be included in the written report.

Purpose: To ensure that the employer is provided with documentation that a medical assessment of the employees ability and indication to receive Hepatitis B vaccination was completed and to inform the employee regarding the employees Hepatitis B vaccination. The purpose of requiring a written opinion is to ensure that the employer is provided with documentation that a post-exposure evaluation has been performed, and that the exposed employee has been informed of the results and any medical conditions from exposure that require further evaluation or treatment.

F. Communication of hazards to employees (§1910.1030(g))

Labels and signs (§1910.1030(g)(1))[3]

§1910.1030(g)(1)(i)(A) - Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

§1910.1030(g)(1)(i)(B) - Labels required by this section shall include the following legend:

§1910.1030(g)(1)(i)(C) - These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

§1910.1030(g)(1)(i)(E) - Red bags or red containers may be substituted for labels.

Signs (§1910.1030(g)(1)(ii))

§1910.1030(g)(1)(ii)(A) - The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

[3] Paragraphs (d)(2)(xiii)(A), *Containers for storage, transportation and shipping;* and (d)(2)(ix)(A), *Contaminated equipment* require labels in accordance with (g)(1)(i) and (g)(1)(i)(H) respectively. Also paragraph (d)(4)(iii), *Regulated Waste*, contains several labeling requirements to be in accordance with (g)(1)(i) of the standard.

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

§1910.1030(g)(1)(ii)(B) - These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

Purpose: The purpose of this requirement is to alert employees to possible exposure since the nature of the material or contents will not always be readily identified as blood ot other potentially infectious materials under these circumstances. Warning labels also would inform employees that appropriate barrier precautions would need to be used if occupational exposure occurs. Posting warning signs serves as a warning to employees who may otherwise not know they are entering a restricted area. Signs would also warn employees not to enter the area unless there is a need, unless the employee have been properly trained, and unless the employee also meets all other appropriate entrance requirements listed on the sign. The signs assure employees are aware of the specific biohazard involved and of any special measures that need to be taken before entering the restricted area.

Information and training (§1910.1030(g)(2))

§1910.1030(g)(2)(i) - Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

§1910.1030(g)(2)(ii) - Training shall be provided as follows:

§1910.1030(g)(2)(ii)(A) - At the time of initial assignment to tasks where occupational exposure may take place;

§1910.1030(g)(2)(ii)(B) - At least annually thereafter.

§1910.1030(g)(2)(iv) - Annual training for all employees shall be provided within one year of their previous training.

§1910.1030(g)(2)(v) - Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

§1910.1030(g)(2)(vii) - The training program shall contain at a minimum the following elements:

§1910.1030(g)(2)(vii)(A) - An accessible copy of the regulatory text of this standard and an explanation of its contents;

§1910.1030(g)(2)(vii)(B) - A general explanation of the epidemiology and symptoms of bloodborne diseases;

§1910.1030(g)(2)(vii)(C) - An explanation of the modes of transmission of bloodborne pathogens;

§1910.1030(g)(2)(vii)(D) - An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

§1910.1030(g)(2)(vii)(E) - An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

§1910.1030(g)(2)(vii)(F) - An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

§1910.1030(g)(2)(vii)(G) - Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

§1910.1030(g)(2)(vii)(H) - An explanation of the basis for selection of personal protective equipment;

§1910.1030(g)(2)(vii)(I) - Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

§1910.1030(g)(2)(vii)(J) - Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

§1910.1030(g)(2)(vii)(K) - An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

§1910.1030(g)(2)(vii)(L) - Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

§1910.1030(g)(2)(vii)(M) - An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

§1910.1030(g)(2)(vii)(N) - An opportunity for interactive questions and answers with the person conducting the training session.

Purpose: Effective training is a critical element of an overall exposure control program. It will ensure that employees understand hazards associated with bloodborne pathogens, the modes of transmission, the exposure control plan, and the use of engineering controls, work practices, and personal protective clothing. The training also informs employees of the appropriate actions to take in an emergency involving exposure to blood or other potentially infectious materials, and the reasons why they should participate in hepatitis B vaccination and post-exposure evaluation and follow-up. Additionally, because of the severity of the diseases and the potential to contract them from a single event, it is also important to retrain occupationally exposed employees on an annual basis. Annual retraining reinforces initial training and provides an opportunity to present new information that was not available at the time of initial training.

G. Recordkeeping (§1910.1030(h))

Medical records (§1910.1030(h)(1))

§1910.1030(h)(1)(i) - The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

§1910.1030(h)(1)(ii) - This record shall include:

§1910.1030(h)(1)(ii)(A) - The name and social security number of the employee;

§1910.1030(h)(1)(ii)(B) - A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

§1910.1030(h)(1)(ii)(C) - A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

§1910.1030(h)(1)(ii)(D) - The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

§1910.1030(h)(1)(ii)(E) - A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

§1910.1030(h)(1)(iv) - The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

Training records (§1910.1030(h)(2))

§1910.1030(h)(2)(i) - Training records shall include the following information:

§1910.1030(h)(2)(i)(A) - The dates of the training sessions;

§1910.1030(h)(2)(i)(B) - The contents or a summary of the training sessions;

§1910.1030(h)(2)(i)(C) - The names and qualifications of persons conducting the training; and

§1910.1030(h)(2)(i)(D) - The names and job titles of all persons attending the training sessions.

§1910.1030(h)(2)(ii) - Training records shall be maintained for 3 years from the date on which the training occurred.

Purpose: Medical and training records are necessary to assure that employees receive appropriate information on the hazards and effective prevention and treatment measures, as well as to aid in the general development of information on the causes of occupational illnesses and injuries involving bloodborne pathogens. Maintenance of medical records is essential because documentation is necessary to ensure proper evaluation of the employees immune status and for proper healthcare management following an exposure incident. Training records assure that training has taken place and can be used in determining the need to perform training in the future. They also enable the employer to assess the content and completeness of the training program in order to ensure that his or her employees have received the required training.

Availability (§1910.1030(h)(3))

§1910.1030(h)(3)(i) - The employer shall ensure that all 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.

§1910.1030(h)(3)(ii) - Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

§1910.1030(h)(3)(iii) - Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

Purpose: Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease.

Transfer of records (§1910.1030(h)(4))

§1910.1030(h)(4)(i) - The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

§1910.1030(h)(4)(ii) - If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

Purpose: To assure an employee retains access to his or her historical records, particularly since a diseases like liver cancer, which can result from hepatitis B infection, can take 20 to 30 years to develop.

Sharps injury log (§1910.1030(i)(5))

§1910.1030(h)(5)(i) - The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

§1910.1030(h)(5)(i)(A) - The type and brand of device involved in the incident,

§1910.1030(h)(5)(i)(B) - The department or work area where the exposure incident occurred, and

§1910.1030(h)(5)(i)(C) - An explanation of how the incident occurred.

§1910.1030(h)(5)(ii) - The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

§1910.1030(h)(5)(iii) - The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

Purpose: The sharps injury log serves as a tool for identifying tasks, areas, and devices that have a high risk for sharps injuries. The information allows the employer to focus efforts toward eliminating these high risks and in device evaluation.

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 whenever appropriate when establishing and maintaining the required records. OSHA wrote the paperwork requirements of the Standard in performance-oriented language (i.e., in terms of what data to maintain, not how to maintain the data). The employer may also contract the services of a healthcare professional located offsite to

maintain and retain medical records.

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 is specific to each employer and employee involved and is not available or duplicated by another source. The information required by this Standard is available only from employers. At this time, there is no indication that any alternative 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 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 information collection frequencies specified by this Standard are the minimum that OSHA believes are necessary to ensure that the employer and OSHA can effectively monitor the exposure and health status of employees exposed to bloodborne pathogens**.**

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.**

The Standard requires that employers must obtain and provide the employee with a copy of the evaluating healthcare professional’s written opinion within 15 days of the completion of the

evaluation (§1910.1030(f)(5)). The 15 day provision assures that the employee is informed in a timely manner regarding information received by the employer and is consistent with other OSHA health standards.

8. If applicable, provide a copy and identify the data 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 July 27, 2007 (72 FR 41357, Docket No. OSHA-2007-0063) requesting public comment on its proposed extension of the information collection requirements specified by the Bloodborne Pathogen Standard (29 CFR 1910.1030). The notice was part of a preclearance consultation program intended to provide interested parties the opportunity to comment on OSHA's request for an extension by the Office of Management and Budget (OMB) of a previous approval of the information collection requirements found in the above Bloodborne Pathogen Standard. The Agency received no comments in response to its notice to comment on this request.

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.

To ensure that the personal information contained in medical records remains confidential, OSHA developed 29 CFR 1913.10 to regulate access to these records.

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.

None of the provisions in the Standard require the collection of sensitive information.

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

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Table A
Number of Establishments

Establishment Type	**Total Affected**
*Office of Physicians	199,100[4]
*Office of Dentists	114,908[5]

[4] Source; U.S. Bureau of the Census (1997) County Business Patterns, Offices of Osteopathic (SIC Code 8030) has been added.
[5] Ibid

*Nursing Homes	15,980[6]
*Hospitals	6,985[7]
*Medical and Dental Labs	19,853
*Home Health	6,437
*Hospices	651
*Hemodialysis	782
*Drug Rehabilitation	744
*Government Clinics	10,893
*Blood/Plasma/Tissue Centers	730
*Residential Care	11,220[8]
Personnel Services	1,348
Funeral Services	19,890
Health Units in Industry	202,540
Research Labs	1,453
Linen Services	1,250
Medical Equipment Repair	1,076
Law Enforcement	4,946
Fire and Rescue	3,174
Correctional Facilities	1,895
Lifesaving	100
Schools	6,321
Waste Removal	50
	632,326

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis
*Industries that are included in SIC 80 Health care.

Classification of Employees

In order to prepare its regulatory impact analysis, OSHA chose to group employees into four groups depending upon their duties. Group A employees are those who have direct patient health care responsibilities, such as physicians and nurses. Group B employees are those employed in laboratories or who have emergency response duties, such as emergency medical technicians, fire fighters, and law enforcement officers. Group C employees are housekeepers and janitors. Group D employees are other workers, such as drivers, service workers, and social workers.

Many of the Tables in Appendix A, "Bloodborne Pathogens Standard Burden Hour Calculation Tables" use these Groups to calculate burden hours and costs.

[6] Source; American Health Care Association Comment (Docket Number, ICR 1218-0180 (2002)). OSHA assumed 6% of the 17,000 nursing homes do not have employees exposed to blood or other potentially infectious materials
[7] Source; U.S. Bureau of the Census (1997) County Business Patterns
[8] Source; American Health Care Association Comment (Docket Number ICR 1218-0180(2002)).

TABLE B
Number of Affected Employees, Job Turnover Rates, and Occupational Turnover Rates by Industry and Job Classification

`	Number of Affected Employees	Job Turnover Rate	Occupational Turnover Rate
Offices of Physicians			
Category A	967,626	22.8	6.9%
C	6,969	31.6	9.8%
D	69,685	21.8	12.9%
Office of Dentists			
Category A	359,662	26.8	1.6%
C	3,447	31.6	9.8%
Nursing Homes			
Category A	594,456	49.9	24.8%
C	38,352	31.6	9.8%
D	6,392	31.6	9.8%
Hospitals			
Category A	2,207,260	27.2	14.7%
B	188,595	21.8	12.9%
C	293,370	31.6	9.8%
Medical and Dental Labs			
Category A	227,773	21.7	12.9%
C	1,754	31.6	9.8%
D	197,766	31.6	9.8%
Home Health			
Category A	202,946	36.3	22.3%
C	3,000	31.6	9.8%
D	6,300	36.3	22.5%
Hospices			
Category A	10,565	36.3	22.5%
C	154	31.6	9.8%
D	27	36.3	22.5%
Hemodialysis			
Category A	11,926	25.5	15.4%
C	209	31.6	22.5%
D	553	21.8	12.9%
Drug Rehabilitation			
Category A	6,067	25.5	15.4%
C	149	31.6	22.5%
D	506	21.8	12.9%
Government Clinics			
Category A	52,156	22.8	13.5%
C	381	31.6	9.8%
D	3,808	21.8	12.9%
Blood/Plasma/Tissue Cntrs.			
Category A	18,198	21.8	12.9%
C	200	31.6	9.8%
D	390	36.3	22.5%
Residential Care			
Category A	41,211	49.6	24.3%
C	1,138	31.6	9.8%
D	6,753	36.3	9.8%
Personnel Services			
Category A	61,387	100.0	8.7%

D	102,090	31.6	9.8%
Funeral Services			
Category A	51,054	21.8	12.9%
C	2,721	31.6	9.8%
D	3,238	31.6	9.8%
Health Units in Industry			
Category A	34,184	31.7	19.5%
B	141,051	21.8	9.8%
D	3,497	31.6	12.9%
Research Labs			
Category A	87,484	21.8	12.9%
C	1,315	31.6	9.8%
D	352	21.8	12.9%
Linen Services			
Category D	50,000	54.0	9.8%
Medical Equipment Repair			
Category A	473	38.3	22.5%
B	200	38.3	12.9%
C	5,152	21.8	12.9%
D	360	21.8	22.5%
Law Enforcement			
Category A	306,769	10.1	7.8%
B	1,137	21.8	9.8%
C	2,617	31.6	7.8%
D	31,022	10.1	12.9%
Fire and Rescue			
Category A	113,866	21.8	12.9%
B	136,412	8.5	22.5%
D	1,770	38.3	7.8%
Correctional Facilities			
Category A	8,381	31.7	19.5%
B	82,883	41.0	12.9%
C	7,273	31.6	17.7%
D	21,687	29.1	7.8%
Lifesaving			
Category A	5,000	21.8	12.9%
Schools			
Category A	23,514	25.0	15.0%
D	17,848	36.3	22.5%
Waste Removal			
Category A	13,300	36.3	22.5%

To update the number of affected employees, the Agency, using the original RIA estimates, determined the number of employees per category, per establishment. The number of employees per category, per establishment, was multiplied by the number of establishments as listed in Table A to determine the total number of affected employees in the various job categories.

I. Explanation of Method of Estimating Annual Burden Hours

The Agency determined average wage rates using hourly earnings, including benefits, to represent the cost of employee time. For the relevant occupational categories, mean hourly earnings from June 2005 National Compensation Survey by the Bureau of Labor Statistics have been adjusted to reflect the fact that fringe benefits comprise about 29.5% of total compensation

in the private sector. Since wages are the remaining 70.5% of employee compensation wages are multiplied by 1.42 (1/0.705) to estimate full employee hourly compensation. The costs of labor used in this analysis are therefore estimates of total hourly compensation. These hourly wages are:

Manager/Supervisor	$50.78
Employee	$30.00
Clerical employee	$24.32
Personnel Training and Labor Relations Specialist	$36.82

Table C

Summary of Burden Hours, Costs and Responses

Collection of Information	**Existing Burden Hours**	**Requested Burden Hours**	**Change in Burden Hours**	**Cost Item #12**	**Responses**
(A) Exposure control plan					
(1) Written Plan *(Table 1*)	1,350,824	1,350,824	0	$47,278,840	632,326
(2) Documentation required by the Needlestick Prevention Act	96,495	97,071	576	$4,929,265	388,283
(3) Employee Solicitation	96,495	97,071	576	$4,929,265	388,283
(4) Employee Response	902,747	902,747		$27,082,410	3,610,986
(B) Housekeeping	0	0	0	0	0
(C) Laundry	0	0	0	0	0
(D) HIV/HBV research laboratories and production facilities.	0	0	**0**	0	0
(E) Hepatitis B Vaccination and post-exposure evaluation and follow-up					
(1) Hepatitis B Vaccination *Table 2 (Employee time*)	206,812	206,812	0	$3,367,341	260,649
Table 3 (Health Care Professional Time)	6,610,935	6,608,360	-2,575	$3,650,303	221,275
(2) Antibody Testing Source Individuals *Table 4 HIV Source Testing Health Care Time*	39,650	39,650	0	$1,387,755	477,713
Table 4 Cont'd HBV Source Testing	5,267	5,310	43	$124,517	63,985
(3) HBV Antibody Testing for workers *Table 5 HBV Antibody Testing for Vaccinated Worker (Employee Time)*	11,402	11,402	0	$213,180	41,445
Table 6 HBV Testing for	3,390	3,397	7	$117,730	40,788

Vaccinated Workers (Health Care Professional Time)					
Table 7 HBV Antibody Testing for Non-Vaccinated Workers (Employee Time)	1,622	1,622	0	$26,254	5,809
Table 8 HBV Antibody Testing for Non-vaccinated Workers (Health Care Professional Time)	282	282	0	$9,792	3,401
Table 9 Hepatitis B Immune Globulin (HBIG) Vaccinated Workers (Employee Time)	103	12	-91	$347	58
Table 10 HBIG: Vaccinated Workers (Health Professional Time)	34	34		$761	63,319
Table 11 HBIG Non Vaccinated Workers (Employee Time)	336	336		$26,254	1,271
Table 12: HBIG Non-vaccinated Workers (Health Care Professional Time)	59	59		$1,159	1,260
Table 13 HIV Antibody Tests (Employee Time)	280,366	280,370	4	$7,997,988	1,292,506
Table 14 (HIV Antibody Tests Health Care Professional Time)	82,118	82,118		$2,874,140	162,777
(4) HIV serologic testing and Post-exposure prophylaxis (PEP) exposed workers	17,704	17,704		619,640	8,852
(5) Counseling for exposed Workers (Table 15)	551,584	551,729	145	$15,984,943	631,370
(6) Information provided to the healthcare professional	118,968	118,968		$2,893,302	1,189,681
(7) Healthcare professionals written opinion	118,968	118,968		$2,893,302	1,189,681
(F) Communication of hazards to employees					
(1) Labels and signs	0	0		0	0
(2) Information and Training					
Table 16 (Training new hires)	1,316,785	1,316,768	-17	$48,506,814	1,286,040
Table 17 Retraining in – service employees	1,203,669	1,203,667	-2	$42,128,418	1,462,875
(G) Recordkeeping					
(1) Medical records (Table 18: Medical records)	870,452	870,457	5	$16,312,878	3,662,666
(2) Training Records (Table 19: Updating or creating training records)	124,329	124,329		$2,359,759	7,313,453
(3) Employee Access	1,903	1,903		$46,281	1,903
(4) Federal access	252	252		$12,797	3,151

(5) Transfer of records	0	0		0	
(6) Sharps injury log	47,213	47,213		$1,738,383	590,164
TOTALS	**14,060,764**	**14,059,435**	-1,329	**$324,726,900**	**24,995,970**

A. Exposure control plan

(1) Exposure control plan (§1910.1030(c)(1)-(2))

There are four key elements that constitute the exposure control plan: the exposure determination, the schedule and method of implementation of the provisions of the Standard, employee solicitation and the procedure for evaluating exposure incidents.

The exposure determination is the identification and documentation of those tasks and procedures where occupational exposures may take place and the employees who perform those tasks and procedures. This includes a list of all job classifications where all employees have occupational exposure and a list of job classifications in which some but not all employees have occupational exposure and the tasks and procedures that they perform that place them at risk for occupational exposure. The employer must provide a schedule and method of implementation of the provisions of the Standard.

Paragraph (c)(1)(iv) requires the employer to annually review and update their exposure control plan. When employers review and update their exposure control plans, employers must ensure that the plan: (A) reflects changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) includes documentation of consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

The burden hours associated with the development of the exposure control plan are for new employers to develop their exposure control plan and existing employers to update their exposure control plan. To develop plans, hospitals take 16 hours; medical and dental labs take 8 hours; and, physicians, dentists and residential care 4 hours. OSHA estimates that hospitals will require 8 hours annually to review and update their plans. All other sectors take 2 hours to review and update their exposure control plans. The total burden hours for the exposure control plan are 1,350,824. The assumptions made and the breakdown by type of facility are found in Table 1 in the appendix to this document.

(2) Exposure control plan – Documentation required by the Needlestick Prevention Act

Employers must document consideration and implementation of appropriate commercially available and effective safer medical devices designated to eliminate or minimize occupational exposure and employee solicitation in the exposure plan. These employers are likely to be in SIC Code 80, as noted in Table A. The effort for this documentation is 15 minutes (.25 hour) of managerial time earning $50.78 an hour.

Burden hours: 388,283 establishments x .25 hour = 97,071 hours
Cost: 97,071 hours x $50.78 = $4,929,265

(3) Employee Solicitation (c)(1)(v)

Employers who are required to establish an exposure control plan must solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the "Exposure control plan."

The overwhelming majority of establishments that have employees who are responsible for direct patient care and who are potentially exposed to injuries from contaminated sharps are in SIC code 80[9], Health Services (*1997 County Business Patterns (SIC), U.S. Census Bureau).* The 1997 data is the most recent data available using the SIC reporting system. The Agency estimates there are 388,283 establishments that must solicit input from non-managerial employees.

OSHA estimates that the initial solicitation requires 15 minutes (.25 hour) of managerial time.

Burden hours: 388,283 establishments x .25 hour = 97,071 hours
Costs: 97,071 hours x $50.78 = $4,929,265

(4) Employee Response (c)(1)(v)

The burden hours and costs associated with the employee response will vary with the number of employees and the response rate to the initial solicitation. According to the *County Business Patterns,* there were 10,942,382 individuals employed in SIC 80 in 1997 OSHA estimates that it takes 15 minutes (.25 hour) of employee time to respond to the solicitation and that approximately 33% or 3,610,986 individuals will respond. OSHA uses a wage rate of $30.00.

Burden hours: 3,610,986 individuals x .25 hour = 902,747 hours
Costs: 902,747 hours x $30.00 = $27,082,410

B. Housekeeping (§1910.1030(d)(4)(i)) **Burden hours: 0**

The employer must determine and implement an appropriate written schedule for cleaning and method of disinfection based on the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed. Since it is customary for facilities to have a written housekeeping plan, the Bloodborne Pathogens Standard would not impose a

[9] The Offices of Other Practioners was not included in SIC 80.

significant paperwork burden.

C. Laundry (§1910.1030(d)(4)(iv)(A)(2)) Burden hours: 0

Labeling requirements required by this paragraph are currently in place and are being followed by the facilities covered by Bloodborne Pathogens Standard; therefore, there is no additional burden from the labeling procedures.

D. HIV/HBV research laboratories and production facilities (§1910.1030(e)(2)(ii)(M))

Burden hours: 0

The employer must adopt or prepare a biosafety manual. The biosafety manual is a usual and customary part of any viral research program where harmful microorganisms are used on a routine basis or in any production facility where large quantities of these microorganisms are being cultured (grown), for example, in the production of viral vaccines. Therefore, there are no additional burden hours.

E. Hepatitis B Vaccine; Post exposure follow-up (§1910.1030(f))

(1) Hepatitis B Vaccination **Burden hours: 6,815,172**

The Standard requires employers to make available the hepatitis B vaccine to all employees who have occupational exposure unless: the employee has previously received the complete hepatitis B vaccination series, antibody testing reveals that the employee is immune, or the vaccine is contraindicated for medical reasons. Since the Standard has been in effect since December, 1991, most employees with occupational exposure have already been offered the vaccine. The Agency expects that most vaccinations would be offered to employees who are newly entering the field. All newly hired employees who have contact with patients or blood and are at an ongoing risk for injuries with sharp instruments or needle sticks must be tested for the antibody to hepatitis B surface antigen, one to two months after completion of the 3-dose vaccination series. Since this procedure would require employee time to be vaccinated and health care professional time to administer the vaccine, we have prepared two tables. The assumptions made and the breakdown by type of facility are found in Table 2, for employee's time and Table 3 for the healthcare worker time. Table 2 estimates the total burden for all employees to receive HBV vaccinations and to be tested for hepatitis B surface antigen is 206,812. The total burden hours for health care professional, in Table 3, is 6,608,360.

(2) Antibody testing of source individuals **Burden hours: 44,960**

The Standard requires that if an exposure incident occurs then the employer is to contact the individual whose blood is the source of the exposure (source individual) and, after legal consent is obtained, test the source individual to determine HIV and HBV

infectivity. The assumptions for determining the burden hours for the health care professional to provide source testing for both HIV and HBV are in Table 4. Burden hours for the healthcare professional to provide HIV source testing is estimated to be 39,650 hours, while source testing for HBV is estimated to be 5,310 hours (Table 4, Cont'd).

(3) HBV antibody testing for workers **Burden hours: 17,137**

The Standard requires that the employer provide post exposure evaluation and follow up according to the recommendations of the US Public Health Service current at the time the evaluation and follow up takes place. The employer must obtain consent of the exposed employee to collect and test the exposed employee's blood to establish a baseline sample (HBV). The current CDC guideline states that within 24 hours, post exposure prophylaxis with hepatitis B immune globulin (HBIG) and/or vaccine should be administered when indicated (e.g., after percutaneous or mucous membrane exposure to blood known or suspected to be HbsAg (hepatitis B surface antigen) positive). The assumptions made and the breakdown by type of facility are found in Tables 5 - 12 in the appendix to this document.

Tables 5 and 7 estimate that it will take 11,402 hours for vaccinated workers, and 1,622 hours for non-vaccinated workers, respectively, to receive HBV post exposure blood tests. Table 6 estimates that it takes health care professionals 3,397 hours to administer the HBV post exposure blood tests to vaccinated workers and Table 8 estimates that health care workers will take 282 hours to administer the HBV post exposure blood tests to non-vaccinated workers.

Tables 9 through 12 determine burden hours and costs for administering the Hepatitis B Immune Globulin (HBIG). Table 9 estimates a total of 12 hours for vaccinated workers to received HBIG and Table 10 estimates it takes health care professionals a total of 34 hours to administer HBIG to vaccinated workers. Table 11 estimates a total of 336 hours for non-vaccinated workers to receive HBIG and Table 12 estimates it takes health care professionals a total of 59 hours to administer HBIG to non-vaccinated workers.

(4) HIV serologic testing and Postexposure prophylaxis (PEP) for exposed workers

Burden hours: 380,192

The Standard requires that the employer provide post exposure evaluation and follow up according the current recommendations of the US Public Health Service at the time the evaluation and follow up takes place. The employer must obtain the exposed employee's consent to collect and test the exposed employee's blood to establish a baseline sample. The current Center for Disease Control (CDC) recommendation for healthcare workers[10]

[10]HCW is defined by CDC as any person (e.g., an employee, student, contractor, attending clinician, public safety worker,

(HCW) who have occupational exposure to blood or other body fluids that may contain HIV virus includes postexposure prophylaxis (PEP) that includes a basic regimen of two drugs for four weeks and in most cases an "expanded" regimen that includes a third drug.

Tables 13 and 14 calculate the burden hours for workers and healthcare professionals respectively. The hours for administration of HIV antibody test for workers is 280,370 hours and for the health care professionals is 82,118 hours.

To estimate the burden hours and costs for PEP, OSHA estimated 8,852 healthcare workers[11] would be eligible for the PEP, and it will take one hour initially and at least one hour for follow-up visits. This includes travel time. The total burden hours for health care worker's PEP is 17,704 hours. OSHA estimates that HCP earns $35.00 an hour, resulting in a wage hour cost of $619,640.

(5) Counseling for exposed workers **Burden hours: 551,729**

The Standard requires that post exposure counseling be provided to employees who have had an exposure incident. This information is presented in a single table that accounts for both employee and counselor time. The assumptions made and the breakdown by type of facility are found in Table 15 in the appendix of this document.

F. Communication of hazards to employees **Burden hours: 118,968**

Information concerning the nature of the exposure incident must be provided to the physician so that the health care professional will know what actions to take in the follow up care. We have determined the hours by multiplying the number of exposure incidents (1,189,681) by 6 minutes.

OSHA assumes a clerk earning $24.32 will provide the information to the physician; therefore the total cost is $2,893,302.

Healthcare professionals written opinion **Burden hours: 118,968**

The standard requires the employer to obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. We have determined the hours by multiplying the number of exposure incidents (1,189,681) by 6 minutes. OSHA assumes a clerk earning $24.32 will provide the information to the physician; therefore the total cost is $ 2,893,302.

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or volunteer) whose activities involve contact with patients or with blood or other body fluids from patients in a health-care or laboratory setting.

[11] OSHA has adopted the International Health Care Worker Safety Center (IHCSWS) estimate of 590,164 needlestick and sharp injuries occur annually. Of these about 1-2% of these involve source patients who are HIV positive. For purposes of calculating burden hours and costs OSHA has assumed 1.5%.

Labels and signs (§1910.1030 (e)(2)(ii) and (g)(1)(i) and (g)(1)(ii)) **Burden hours: 0**

Paragraph (e)(2)(ii), requires that HIV and HBV research laboratories and production facilities that send contaminated materials to a site away from the work area, place the materials in a durable, leakproof container that is labeled or color coded. When infectious materials or infected animals are in the work area, a hazard warning sign, with the universal biohazard symbol, must be posted on all access doors. Paragraph (g)(1)(ii) requires the sign contain the biohazard symbol, the word "biohazard", the name of the infectious agent, special requirements for entering the area, and the name and telephone number of the laboratory director or other responsible person. They must be fluorescent orange-red or predominantly so, with lettering and symbol in a contrasting color. Since these signs have been permanently mounted there is no additional burden.

Paragraph (g)(1)(i) requires that employers place warning labels on containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G). The requirements for the color of the labels are identical for those for the signs except that red bags or red containers may be substituted for labeled containers for regulated wastes. There are no burden hours unique for labeling since containers used to transport or store blood or regulated wastes are now manufactured and widely available with labels and symbols already affixed to them.

Training (§1910.1030(g)(2)) **Burden hours: 2,520,435**

The Standard requires that all employees with occupational exposure participate in an initial training program. The training program must explain: the contents of this Standard and appendices; the epidemiology and symptoms of bloodborne diseases: the modes of transmission of bloodborne pathogens; the provisions of the exposure control plan; ways to recognize tasks that may involve exposure to blood and other potentially infectious material; the use (and limitations) of engineering controls, work practices, and personal protective clothing/equipment in preventing exposure; information on the types, proper use, location, removal, handling, decontamination of protective clothing and equipment; and explanation of the basis for selection of protective clothing and equipment; signs and labels and color coding; and the procedure to follow if an occupational exposure occurs; information on the hepatitis B vaccine, including the efficacy and safety of the vaccine; information on the appropriate actions to take in case of an emergency, information post exposure evaluation and follow-up; an explanation of signs and labels.

Since the Standard has been in effect since March 6, 1992, the only initial training that would be required would be for new hires. The total burden for initial training of new hires is 1,316,768 hours. The assumptions made and the breakdown by facility are found in Table 16 of the appendix to this document. The Standard requires that employees receive training at least annually and whenever there are changes that affect the employee's occupational exposure. The total burden for retraining is 1,203,667. The assumptions made and the breakdown by facility are

found in Table 17 of the appendix to this document.

G. Recordkeeping (§1910.1030 (h) (1) - (4)) **Total hours: 923,794**

(1) Medical Records **Burden hours: 870,457**

The Standard requires the employer to maintain medical surveillance records for each employee in accordance with 29 CFR 1910.1020. These confidential records must contain the employee's name and social security number, a copy of each employee's hepatitis B vaccination record, the circumstances of any occupational exposure incident, results of medical testing as they relate to the employee's ability to receive vaccination or postexposure evaluation following an exposure incident; a copy of the physician's written opinion; and a copy of the information provided to the physician. The records must be maintained for at least the duration of each employee's period of employment plus 30 years. The time required for medical recordkeeping is based on the need to establish medical records for new hires and to update existing medical records for current employees. The assumptions and breakdown by facility type are found in Table 18 in the appendix to this document.

(2) Training Records **Burden hours: 124,329**

The Standard requires the employer to maintain training records. These records must contain the following information: the dates of the training sessions; the contents or a summary of the contents of the training sessions; the names and qualifications of persons conducting the training; and the names and job titles of all persons attending the training. These records do not have to be individual records kept in each employee's personnel folder but can be created and maintained for each training session that may provide training for many employees. These records must be maintained for 3 years. The assumptions and breakdown by facility type are found in Table 19 in the appendix to this document.

(3) Employee Access **Burden hours: 1,903**

The Standard requires that employee medical records also be made available to anyone having the written consent of the employee. OSHA assumes that the records that will be requested by 2% of employees who have had an exposure incident, and that it would take a clerical, earning $24.32 per hour 5 minutes (.08 hour) to provide access. The calculation of burden hours is based on number of exposures per year (1,189,681) x 2% x 0.08 hours.

Costs then equals 1,903 hours x $24.32 = $ 46,281

(4) Federal Access **Burden hours: 252**

The Standard states that the exposure control plan must be made available to the Assistant

Secretary and the Director for examination and copying §1910.1030(c)(1)(v). Similarly, section (h)(3)(i) states "the employer shall ensure that all 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." Also, medical records (§1910.1030(h)(3)(iii)), and training records (§1910.1030 (h)(3)(ii)), shall be made available to the Assistant Secretary and the Director for examination and copying in accordance with 29 CFR 1910.1020.

Most often OSHA will request access to records during compliance inspections. Based on previous estimates, OSHA may inspect 3,151 establishments. The Agency estimates a health care professional, earning $50.78 per hour, will expend 5 minutes (.08 hour) to show OSHA the location of their records.

3,151 inspections x .08 hours = 252 hours
252 hours x $50.78 = $ 12,797

(5) Transfer of Records **Burden hours: 0**

OSHA does not anticipate that any employers will either cease business operations without a successor or be required to transfer records to NIOSH during the period covered by the clearance; therefore, there is no additional burden from the transfer of record requirement of this Standard.

(6) Sharps Injury Log **Burden hours: 47,213**

Employers, who are required to maintain an occupational injuries and illness log under 29 CFR 1904, must establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log must be recorded and maintained in a manner as to protect the confidentiality of the injured employee. The sharps injury log must contain the following: (A) the type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred.

The burden hours and costs attributable to the log are based on the number of needlestick and sharp injuries and the time to record the required information. OSHA estimates there are 590,164 needlestick and sharps injuries annually[12], and it takes a staff member with a skill level of a Personnel Training and Labor Specialist, with an hourly wage rate of $36.82, five minutes (.08 hour) to collect the data and enter it onto a separate log.

[12] OSHA uses The International Health Care Worker Safety Center estimate of 590,164 annual needlestick and sharps injuries.

The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (e.g. paper or electronic), and may include information in addition to that required by the standard, so long as the privacy of the injured workers is protected. Many employers already compile reports of percutaneous exposure incidents in a variety of ways. Existing mechanisms for collecting this information will be considered sufficient to meet the requirements of the standard for maintaining a sharps injury log, provided that the information gathered meets the minimum requirements specified in the standard, and the confidentiality of the injured employee is protected.

Burden hours: 590,164 cases x .08 hour = 47,213 hours
Cost: 47,213 hours x $36.82 = $ 1,738,383

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.**

Certain employers will incur costs for the various medical requirements contained in the Standard. The costs to respondents are reflected in Tables 3, 4, 6, 8, 10, 12, and 14. The table below summarizes the costs.

In addition, employers will incur the cost of providing post exposure prophylaxis (PEP) to employees who have had occupational exposure to blood, and other body fluids, that may contain HIV.

There are a host of drugs that can be prescribed by the doctors depending on the employee's personal health and drug tolerance. Since the costs of these drugs can vary significantly, the

Agency based the cost estimate on the most frequently used drugs.[13]

OSHA estimates it cost $662 per employee to provide the 4-week PEP. For purposes of estimating costs, OSHA assumes each employee will receive an expanded regiment which consists of Combivier and a protease inhibitor. OSHA estimates one tablet of Combivier costs $2.15, which must be taken twice a day for 28 days resulting in a cost of $120. One tablet protease inhibitor costs $2.15. Three tablets must be taken three times a day for 28 days, costing $542. OSHA estimated that 8,852 employees may be provided PEP at a cost of $662 per employee, totaling $5,860,024.

CHANGES IN COSTS

Medical Provision	Existing Costs	Proposed Costs
Hepatitis B Vaccination[14] (Table 3)	$8,125,235	$7,391,790
HIV Testing - (Table 4)	$2,603,427	$2,603,427
HBV Source Testing - (Table 4 (Cont'd))	$1,201,382	$1,201,382
HBV Antibody Testing for Vaccinated Workers (Table 6)	$370,913	$371,183
HBV Antibody Testing for Non Vaccinated Workers (Table 8)	$65,210	$65,367
Hepatitis B Immune Globulin Vaccinated Workers (Table 10)	$21,338	$21,338
Hepatitis B Immune Globulin Non Vaccinated Workers (Table 12)	$99,024	$99,024
HIV Antibody Tests (Table 14)	$6,161,339	$6,161,339
PEP to Employees	$5,860,024	$5,860,024
TOTAL COST	$24,507,892	$23,774,874

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.

[13] National Clinician's Postexposure Hotline, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC).

[14] The cost for antibody to hepatitis B surface antigen is estimated to be $80.00 to $100.00 per person. For purposes of estimating burden hours and costs, OSHA estimated the cost to be $90.00.

Transfer of Records to NIOSH **Cost: $15**

The Bloodborne Pathogens Standard requires that if an employer ceases to do business and there is no successor to preserve and maintain employee records for the required periods of time, the records must be transmitted to NIOSH. Also, at the expiration of the retention period for the records required to be maintained, employers must notify NIOSH at least three months prior to the disposal of such records and transmit those records to NIOSH if requested within the period. The cost to the Federal government consists of the costs associated with NIOSH processing records from employers who cease to do business and have no successor to preserve and maintain employee records, or when the retention period for those records has expired and NIOSH has requested the records be transmitted to them. OSHA is contacting NIOSH to learn how many records NIOSH has received from employers in the past year. OSHA will then use this figure to estimate the number of records NIOSH will receive in the future.

Previously, no records were transmitted to NIOSH. To account for any future costs for transferring records to NIOSH during the period covered by this clearance, we have allocated a burden of 1 hour for the request. NIOSH estimated that 15 records can be processed in one hour at a cost $15.00 per hour. Therefore, the Federal cost for records transfer is estimated to be $15.00 per year.

Programmed Inspections **Cost: $17,640**

During an inspection an OSHA representative may request to see medical records required by the Bloodborne Pathogen Standard. It is estimated that an OSHA inspector earning approximately $36.26 per hour will expend approximately 10 minutes (.17 hour) reviewing such records during an inspection.

Cost: OSHA Inspector Salary: $36.26 x 10 minutes (.17 hour) x 3,151 inspections = $19,423

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

The Agency is requesting an adjustment reduction of 1,329 burden hours, from 14,060,764 hours to 14,059,435 hours. When conducting a thorough review of the numerous complex tables, several administrative errors were identified.

Administrative corrections made to Table 3, *Hepatitis B Vaccination*, resulted in an overall cost decrease (adjustment) of $733,018 from $24,507,892 to $23,774,874.

Note: The ROCIS system rounded the previous cost estimate to $24,508,000. Therefore in the ROCIS system, the Agency will report a decrease of $733,126.

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.

This collection of information will not have results that will be published for statistical use.

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.

The Collection of Information will display a currently valid OMB control number.

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

The Collection of Information does not request any exemptions from the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions," OMB Form 83-I.