vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the object to be included in the exhibit, "The Scream by Edvard Munch" (see list[1]) imported from abroad for the temporary exhibition without profit within the United States is of cultural significance. The object is imported pursuant to a loan agreement with the foreign lender. I also determine that the temporary exhibition or display of the listed exhibit object at the National Gallery of Art in Washington, DC, beginning on or about May 29, 1989, to on or about November 30, 1990, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register.**

Date: May 25, 1989.

R. Wallace Stuart,

Acting General Counsel.

[FR Doc. 89–12957 Filed 5–26–89; 8:45 am]

BILLING CODE 8230–01–M

[1] A copy of this list may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202/485–7979, and the address is Room 700, U.S. Information Agency, 301 4th Street SW., Washington, DC 20547.

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The agency responsible for sponsoring the information collection; (2) the title of the information collection; (3) the Department form number(s), if applicable; (4) a description of the need and its use; (5) frequency of the information collection, if applicable; (6) who will be required or asked to respond; (7) an estimate of the number of responses; (8) an estimate of the total number of hours needed to complete the information collection; and (9) an indication of whether section 3504(h) of Public Law 96–511 applies.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Patti Viers, VA Clearance Officer (732), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3172.

Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Joseph Lackey, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395–7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: May 19, 1989.

By direction of the Secretary

Frank E. Lalley,

Director, Office of Information Management and Statistics.

Extension

1. Office of Facilities.
2. Architect-Engineer Fee Proposal.
3. VA Form 08–6298.
4. VA Form 08–6298 is the A/E's proposed fee architect-engineer services based on the scope, complexity and nature of the project. The Office of Facilities uses the form in contract negotiations with A/E firms.
5. On occasion.
6. Business or other for-profit; small businesses or organizations.
7. 200 responses.
8. 4 hours.
9. Not applicable.

[FR Doc. 89–12713 Filed 5–26–89; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 54, No. 102
Tuesday, May 30, 1989

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ENERGY REGULATORY COMMISSION

May 24, 1989.

The following notice of meeting is published pursuant to Section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–49), 5 U.S.C. 552B:

DATE AND TIME: May 31, 1989, 10:00 a.m.

PLACE: 825 North Capitol Street, NE., Room 9306, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 357–8400.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Public Reference Room.

Consent Power Agenda, 897th Meeting—May 31, 1989, Regular Meeting (10:00 a.m.)

CAP–1.
Project No. 2531–009, Central Maine Power Company
CAP–2.
Project No. 9248–003, Town of Telluride, Colorado
CAP–3.
Project No. 10727–001, Robert W. Shaw
CAP–4.
Docket No. EL88–25–001, Illiamna-Newhalen-Nondalton Electric Cooperative, Inc.
CAP–5.
Project No. 6765–005, BMB Enterprises, Inc.
CAP–6.
Project No. 6456–008, Village of Green Island, New York
CAP–7.
Project No. 5223–003, International Falls Power Company
CAP–8.
Project No. 3407–006, Magic Reservoir Hydroelectric, Inc.
Project No. 8909–002, Idaho Renewable Resources, Bonneville Pacific Corp., and Big Wood Canal Company
CAP–9.
Project No. 4204–010, City of Batesville, Arkansas
Project Nos. 4659–0140 and 4660–011, Independence County, Arkansas
CAP–10.
Project No. 9812–001, Clifton Corporation
Project No. 9977–012, City of Augusta, Georgia
CAP–11.
Docket No. UL88–27–001, Consolidated Hydro, Inc.
CAP–12.
Docket Nos. EL86–44–001, 002, Project Nos. 10479–001 and 002, Island Power Company
CAP–13.
Project No. 8361–006, Olsen Power Partners
CAP–14.
Project No. 4939–001, Brownville Power Company
CAP–15.
Docket No. ER82–774–012, Tapoco, Inc.
CAP–16.
Docket No. ER88–142–002, Michigan Power Company
CAP–17.
Docket No. ER84–705–011, Boston Edison Company
CAP–18.
Docket No. ER89–106–001, Duke Power Company
CAP–19.
Docket Nos. EC87–19–000 and 001, Southwestern Public Service Company and Black Mesa Power Company
Docket No. ER87–584–002, Southwestern Public Service Company and Black Mesa Power Company
CAP–20.
Docket No. ER87–180–004, Cincinnati Gas & Electric Company
CAP–21.
Omitted
CAP–22.
Omitted
CAP–23.
Docket Nos. ER88–456–000 and ER88–629–000, Central Vermont Public Service Corporation
CAP–24.
Docket No. EL84–560–012, Union Electric Company
CAP–25.
Docket Nos. ER89–73–000 and ER89–74–000, Orange & Rockland Utilities, Inc.

Consent Miscellaneous Agenda

CAM–1.
Docket No. RM89–13–000, Revision of Formula for Computing Monthly Carrying Charges in PGA Filings
CAM–2.
Docket No. GP89–34–001, Columbia Gas Transmission Corporation
CAM–3.
Docket No. GP89–36–000, Utah Department of Natural Resources
CAM–4.
Docket No. GP89–28–000, Virginia Department of Mines, Minerals and Energy
CAM–5.
Docket No. GP84–23–029 (Phase 2), Stowers Oil & Gas Company, Panhandle Energy Corporation, Prairie Oil Company, Sharon Oil Company, Almac Oil Company, Judy Oil Company, Kim-Petroleum Company, Inc., Komanche Oil & Gas Company, Omega Energy, Tumbleweed Production, Panstar Oil & Gas, Inc., Dennis Mills Enterprises, Wy-Vel Corporation, Walker Operating Corporation, and 3W Oil, Inc.
CAM–6.
Docket No. GP86–51–001, Northern Natural Gas Company, Division of Enron Crop. v. Cabot Pipeline Corporation and Texaco Producing Inc.

Consent Gas Agenda

CAG–1.
Docket No. RP89–163–000, Transcontinental Gas Pipe Line Corporation
CAG–2.
Docket Nos. RP89–165–000 and TM89–2–22–000, CNG Transmission Corporation
CAG–3.
Docket No. TA89–1–55–000, Questar Pipeline Company
CAG–4.
Docket Nos. TA89–1–56–000 and 001, Valero Interstate Transmission Company
CAG–5.
Docket No. TA89–1–25–000, Mississippi River Transmission Corporation
CAG–6.
Docket Nos. TM89–2–26–000 and TM89–3–26–000, Natural Gas Pipeline Company of America
CAG–7.
Docket Nos. TM89–3–25–000 and RP89–12–004, Mississippi River Transmission Corporation
CAG–8.
Docket No. TQ89–4–63–000, Carnegie Natural Gas Company
CAG–9.
Docket No. TQ89–6–4–000, Granite State Gas Transmission, Inc.
CAG–10.
Docket No. TQ89–4–49–000, Williston Basin Interstate Pipeline Company
CAG–11.
Docket Nos. RP89–184–002, 004, 005 and 006, El Paso Natural Gas Company
CAG–12.
Docket No. RP89–164–000, Eastern Shore Natural Gas Company
CAG–13.
Docket No. RP89–161–000, ANR Pipeline Company
CAG–14.
Docket No. RP89–160–000, Trunkline Gas Company
CAG–15.
Docket No. RP89–162–000, Ringwood Gathering Company
CAG–16.
Docket No. RP82–55–041, Transcontinental Gas Pipe Line Corporation
CAG–17.
Docket Nos. RP82–114–015, 016 and 017, Williams Natural Gas Company

CAG–18.
Docket No. RP89–157–000, Valley Gas Transmission Inc.
CAG–19.
Docket Nos. RP89–48–000 and CP89–1126–000, Transwestern Pipeline Company
CAG–20.
Docket Nos. RP89–151–000 and 001, Transwestern Pipeline Company
CAG–21.
Docket No. RP85–47–005, East Tennessee Natural Gas Company
CAG–22.
Docket No. RP89–86–002, Chandeleur Pipe Line Company
CAG–23.
Docket No. RP89–75–002, Black Marlin Pipeline Company
CAG–24.
Docket No. RP86–87–000, Questar Pipeline Company (Formerly Mountain Fuel Resources Inc.)
CAG–25.
Docket No. RP88–221–006, Texas Eastern Transmission Corporation
CAG–26.
Docket Nos. RP89–84–002 and RP88–228–015, Tennessee Gas Pipeline Company
CAG–27.
Docket No. RP89–70–002, Stringray Pipeline Company
CAG–28.
Docket No. RP88–259–012, Northern Natural Gas Company, Division of Enron Corp.
CAG–29.
Docket Nos. RP88–92–012, RP88–263–008, and RP88–265–002, United Gas Pipe Line Company
CAG–30.
Docket Nos. RP89–99–001, 003, RP89–38–001 and 003, U–T Offshore System
CAG–31.
Docket Nos. RP89–82–002, 003, RP89–37–002 and 003, High Island Offshore System
CAG–32.
Docket No. TM89–2–27–003, North Penn Gas Company
CAG–33.
Docket Nos. TQ89–1–46–018, RP86–165–012 and RP86–166–012, Kentucky West Virginia Gas Company
CAG–34.
Docket No. RP88–184–009, El Paso Natural Gas Company
CAG–35.
Docket Nos. RP88–262–005 and CP89–917–002, Panhandle Eastern Pipe Line Company
CAG–36.
Docket No. RP89–53–001, Canadian Petroleum Association
CAG–37.
Docket No. RP88–68–012, Transcontinental Gas Pipe Line Corporation
CAG–38.
Docket Nos. TQ89–1–46–017, RP86–165–011, RP86–166–011, Kentucky West Virginia Gas Company
CAG–39.
Docket No. RP88–198–008 and RP89–59–002, Transwestern Pipeline Company
CAG–40.
Docket No. RP89–73–001, Pelican Interstate Gas System
CAG–41.
Docket No. RP88–68–013 and RP87–7–049, Transcontinental Gas Pipe Line Corporation
CAG–42.
Docket No. RP87–7–050, Transcontinental Gas Pipe Line Corporation
CAG–43.
Docket Nos. ST86–1657–002, ST86–1660–002, ST86–1663–002, ST86–1687–002, ST86–1688–002, ST86–1689–002, ST86–1690–002, ST86–1691–002, ST86–1692–002, ST86–1752–002, ST86–1778–002, ST86–1779–002, ST86–1781–002, ST86–1790–002, ST86–1849–002, ST86–1853–002, ST86–1876–002, ST86–1877–002, ST86–1896–002, ST86–1898–002, ST86–1899–002, ST86–1900–002, ST86–1901–002, ST86–1902–002, ST86–1903–002, ST86–1904–002, ST86–1905–002, ST86–1906–002, ST86–1954–002, ST86–1955–002, ST86–1956–002, ST86–1957–002, ST86–1959–002, ST86–1971–002, ST86–2009–002, ST86–2014–002, ST86–2035–002, ST86–2048–002, ST86–2049–002, ST86–2050–002, ST86–2113–002, ST86–2114–002, ST86–2115–002, ST86–2116–002, ST86–2117–002, ST86–2126–002, ST86–2128–002, ST86–2132–002, ST86–2133–002, ST86–2134–002, ST86–2137–002, ST86–2142–002, ST86–2144–002, ST86–2146–002, ST86–2147–002, ST86–2151–002, ST86–2201–002, ST86–2202–002, ST86–2203–002, ST86–2204–002, ST86–2205–002, ST86–2206–002, ST86–2210–002, ST86–2211–002, ST86–2212–002, ST86–2213–002, ST86–2214–002, ST86–2215–002, ST86–2216–002, ST86–2254–002, ST86–2255–002, ST86–2257–002, ST86–2258–002, ST86–2260–002, ST86–2261–002, ST86–2262–002, ST86–2419–002, ST86–2422–002, ST86–2431–002 and ST86–2432–002, ANR Pipeline Company
CAG–44.
Docket No. RP82–80–028, ANR Pipeline Company
CAG–45
Docket No. RP88–28–000, Northern Illinois Gas Company v. Natural Gas Pipeline Company of America
CAG–46.
Docket No. RP88–232–000, Phillips Gas Pipeline Company
CAG–47.
Docket No. RP88–209–000, Natural Gas Pipeline Company of America
CAG–48.
Docket Nos. ST88–2555–002, ST89–1708–000 and ST89–1775–000, Louisiana Intrastate Gas Corporation
CAG–49.
Docket Nos. ST82–95–000, ST88–1543–000, ST88–2547–000, ST88–5632–000, ST89–15–000 and ST89–1460–000, Red River Corporation
CAG–50.
Docket Nos. ST88–5348–000 and ST83–297–000, Tejas Gas Corporation
CAG–51.
Docket No. CI88–487–000, Union Exploration Partners, Ltd.
CAG–52.
Docket No. CP88–463–001, Placid Oil Company
CAG–53.
Docket No. CP87–480–011, Wyoming–California Pipeline Company
CAG–54.
Docket Nos. CP88–325–001 and CP89–526–001, Alabama-Tennessee Natural Gas Company
CAG–55.
Docket No. CP89–281–001, Panhandle Eastern Pipe Line Company
CAG–56.
Docket No. CP87–471–001, United Gas Pipe Line Company
CAG–57.
Docket No. CP87–205–002, Texas Gas Transmission Corporation
CAG–58.
Docket No. CP88–312–002, Natural Gas Pipeline Company of America
CAG–59.
Docket No. CP89–93–001, Williams Natural Gas Company
CAG–60.
Docket Nos. CP87–5–003, CP87–92–003, CP87–312–002, CP88–197–001 and CP88–388–001, Texas Eastern Transmission Corporation and CNG Transmission Corporation

Docket Nos. CP87–5–002, CP87–312–001, CP87–313–001, CP87–314–001, CP88–197–002, CP88–388–002, CP88–128–000 and 002, CNG Transmission Corporation

Docket Nos. CP87–554–000 and CP87–554–001, Algonquin Gas Transmission Company

Docket No. CP89–6–000, Transcontinental Gas Pipe Line Corporation
CAG–61.
Docket No. CP89–515–000, Green Canyon Pipe Line Company
CAG–62.
Docket Nos. CP87–458–000 and 001, Arkla Energy Resources, a Division of Arkla, Inc.
CAG–63.
Docket No. Docket No. CP89–639–000, Columbia Gas Transmission Company
CAG–64.
Docket No. CP69–687–000, Southern Natural Gas Company
CAG–65.
Docket No. CP89–465–000, Arkansas Oklahoma Gas Corporation
CAG–66.
Docket No. CP88–761–000, El Paso Natural Gas Company
CAG–67.
Docket No. CP89–1231–000, Natural Gas Pipeline Company of America
CAG–68.
Docket No. CP89–1399–000, Columbia Gulf Transmission Company
CAG–69.
Docket No. CP89–1278–000, United Gas Pipe Line Company
CAG–70.
Docket No. CP89–738–000, Interstate Power Company
CAG–71.
Docket No. CP89–655–000, Iowa-Illinois Gas and Electric Company
CAG–72.
Docket No. CP89–485–000, Kansas Power and Light Company

I. Licensed Project Matters

P-1.
Reserved

II. Electric Rate Matters

ER-1.
Docket No. ER86-721-004, Central Power and Light Company. Opinion and Order on Initial Decision.

Miscellaneous Agenda

M-1.
Reserved
M-2.
Reserved

I. Pipeline Rates Matters

RP-1.
Reserved

II. Producer Matters

CI-1/
Reserved

III. Pipeline Certificate Matters

CP-1.
Docket Nos. CP89-1258-000, CP88-6-001 and RP88-8-007, United Gas Pipe Line Company.
Docket Nos. CP83-232-000 and CP84-196-000, Columbia Gulf Transmission Corporation
Docket No. CP75-104-000, High Island Offshore Systems
Docket No. CP78-433-000, Michigan Consolidated Gas Company
Docket Nos. CP78-124-000 and CP86-395-000, Northern Border Pipeline Company
Docket No. ST88-3071-000, Northern Natural Gas Company
Docket No. CP79-78-000, Panhandle Eastern Pipe Line Company
Docket Nos. CP78-262-000, CP76-418-000, CP76-428-000 and CP77-410-000, Sea Robin Pipeline Company
Docket Nos. CP75-19-000, CP79-374-000 and CP80-509-000, Southern Natural Gas Company
Docket No. CP74-89-000, Stringray Pipeline Company
Docket Nos. CP78-545-000 and CP84-387-000, Tennessee Gas Pipeline Company
Docket Nos. CP80-31-000 and CP81-26-000, Trunkline Gass Company
Docket Nos. CP76-118-000 U-T Offshore System. Order to Show Cause.

Lois D. Cashell,

Secretary.

[FR Doc. 89-12887 Filed 5-25-89; 3:06 p.m.]

BILLING CODE 6717-01-M

FEDERAL COMMUNICATIONS COMMISSION

May 24, 1989.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, May 31, 1989, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Agenda, Item No., and Subject

Private Radio—1—Title: Reorganization of Deregulation of Part 97 of Rules Governing the Amateur Radio Services. Summary: The Commission will consider whether to adopt a Report and Order in PR Docket No. 88-139 concerning a proposal to reorganize and revise the Amateur Radio Services Rules.

General—1—Title: Inquiry into the Compulsory License for Cable Retransmission of Broadcast Signals. Summary: The Commission will consider further action in this proceeding.

General—2—Title: Amendment of Parts 2, 22, and 25 of the Commission's Rules to Allocate Spectrum for, and to Establish Other Rules and Policies Pertaining to the Use of Radio Frequencies in a Mobile Satellite Service for the Provision of Various Common Carrier Services. Summary: In this item the Commission considers a request from certain aviation parties to reconsider the Commission's L-band allocation in light of the 1987 Mobile WARC.

Common Carrier—1—Title: Amendment of Parts 2, 22, and 25 of the Commission's Rules to allocate spectrum for and to establish other rules and policies pertaining to the use of radio frequencies in a land mobile satellite service for the provision of various common carrier services, and applications of Global Land Mobile Satellite, Inc., *et al.* Summary: The Commission will consider petitions for reconsideration and applications for review of the *Second Report and Order* and subsequent orders concerning the establishment of rules and applications for a mobile satellite services, General Docket No. 84-1234.

Common Carrier—2—Title: Amendment of Parts 2, 22, and 25 of the Commission's Rules to allocate spectrum for and to establish other rules and policies pertaining to the use of radio frequencies in a land mobile satellite service for the provision of various common carrier services, and applications of Hughes Communications Mobile Satellite, Inc., *et al.* Summary: The Commission will consider applications seeking authority to construct, launch and operate a domestic mobile satellite system.

Common Carrier—3—Title: In the Matter of Aeronautical Radio, Inc. for authority to construct and operate an aviation satellite system (CSS-87-015(7)). Summary: The Commission will consider the petition of Aeronautical Radio, Inc. for reconsideration and reinstatement of its application *Nunc Pro Tunc.*

Common Carrier—4—Title: Provision of Aeronautical Services via the INMARSAT System (CC Docket No. 87-75; CSS-86-005-M(2). Summary: The Commission will consider whether to adopt a Report and Order regarding the establishment of a domestic structure by which U.S. entities may access INMARSAT space segment to provide aeronautical services.

Mass Media—1—Title: Amendment of Part 74 of the Commission's Rules and Regulations In Regard to the Instructional Television Fixed Service. Summary: The Commission will consider adopting rules in the comparative selection procedure for mutually exclusive ITFS applicants relating to the breaking ties among application that are indistinguishable under the primary selection criteria.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Sarah Lawrence, Office of Public Affairs telephone number (202) 632-5050.

Federal Communications Commission.

Issued: May 24, 1989.

Donna R. Searcy,

Secretary

[FR Doc. 89-12856 Filed 5-25-89; 10:51 am]

BILLING CODE 6712-01-M

NATIONAL MEDIATION BOARD

TIME AND DATE: 2:00 p.m., Wednesday, June 14, 1989.

PLACE: Board Hearing Room 8th Floor, 1425 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Ratification of the Board actions taken by notation voting during the month of May, 1989.
2. Other priority matters which may come before the Board for which notice will be given at the earliest practicable time.

SUPPLEMENTARY INFORMATION: Copies of the monthly report of the Board's notation voting actions will be available from the Executive Director's office following the meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Charles R. Barnes, Executive Director, Tel: (202) 523-5920.

Date of Notice: May 22, 1989.

Charles R. Barnes,

Executive Director, National Mediation Board.

[FR Doc. 89-12908 Filed 5-26-89; 8:45 am]

BILLING CODE 7550-01-M

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE-89-21]

TIME AND DATE: Tuesday, June 6, 1989 at 11:30 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and Complaints.
5. Inv. No. 731-TA-433 (P) (Certain Residential Door Locks from Taiwan)—briefing and vote.
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary, (202) 252-1000.

Kenneth R. Mason,

Secretary.

May 23, 1989.

[FR Doc. 89-12844 Filed 5-25-89; 10:05 am]

BILLING CODE 7020-02-M

Corrections

Federal Register
Vol. 54, No. 102
Tuesday, May 30, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals; Application for Permit; NMFS, Southwest Fisheries Center (P77 #33)

Correction

In notice document 89-10992 appearing on page 19934 in the issue of Tuesday, May 9, 1989, make the following corrections:

1. On page 19934, in the second column, in designated paragraph 5, in the second line, after "Tropical" insert "Pacific".

2. On the same page, in the same column, in the title appearing below the signature, in the second line, remove "*Wildlife*".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-3555-1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

Correction

In proposed rule document 89-8999 beginning on page 14971 in the issue of Friday, April 14, 1989, make the following corrections:

1. On page 14973, in the third column, in Table 2, in the first column, the 11th entry should read "Bis(2-chloroethyl)ether".

2. On page 14974, in the first column, in Table 2, in the first column, the fifth entry should read "4-Nitrophenol".

3. On the same page, in the same column, in Table 3, in the second column, in the sixth entry, remove "<".

4. On the same page, in the third column, in Table 5, in the second column, the third entry should read "0.03".

5. On page 14975, in the 1st column, in the 1st complete paragraph, in the 10th line, "receive" was misspelled.

6. On the same page, in the same column, under "5. Conclusion", in the 12th line, "further" should read "future".

7. On the same page, in the second column, in the first complete paragraph, in the fourth line, "hazard" was misspelled.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Regulations No. 16]

RIN 0960-AC54

Public Emergency Shelters for the Homeless, Exclusion of Underpayments, Increase in Benefit Rate for Individuals in Medical Care Facilities

Correction

In rule document 89-10715 beginning on page 19162 in the issue of Thursday, May 4, 1989, make the following corrections:

1. On page 19162, in the 2nd column, in the **SUMMARY**, in the 23rd line, "supplementary" was misspelled.

§ 416.2097 [Corrected]

2. On page 19165, in the second column, in § 416.2097(d), in the fifth line, "payment" should read "payable".

§ 416.2098 [Corrected]

3. On the same page, in the same column, in § 416.2098(a), in the 11th line, "Statement" should read "State".

4. On the same page, in the same column, in the same paragraph, in the 15th line, "FRB" should read "FBR".

BILLING CODE 1505-01-D

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

Pay Under the General Schedule

Correction

In the proposed rule document beginning on page 13196 in the issue of Friday, March 31, 1989, make the following corrections:

§ 531.203 [Corrected]

1. On page 13197, in the 2nd column, in § 531.203(2)(i), in the 10th through 11th lines remove "the maximum rate for the grade in which pay is being fixed,".

2. On page 13198, in the first column, in the file line, the docket number should read "89-7636".

BILLING CODE 1505-01-D

federal register

Tuesday
May 30, 1989

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Bloodborne Pathogens; Proposed Rule and Notice of Hearing

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-370]

RIN 1218-AB15

Occupational Exposure to Bloodborne Pathogens

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule and notice of hearing

SUMMARY: The Occupational Safety and Health Administration proposes to reduce occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655. Based on a review of the available data, OSHA has made a preliminary determination that certain employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials because they may contain bloodborne pathogens, including hepatitis B virus which causes Hepatitis B, a serious liver disease, and human immunodeficiency virus, which causes Acquired Immunodeficiency Syndrome (AIDS). The Agency preliminarily concludes that this significant health risk can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical follow-up of exposure incidents, vaccination (where applicable), and other provisions.

DATES: Written comments on the proposed standard and Notices of Intention to Appear at one of the informal rulemaking hearings must be postmarked on or before August 14, 1989.

Parties requesting more than 10 minutes for their presentation at the hearings and parties submitting documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than August 31, 1989 for the Washington, DC hearing and no later than September 29, 1989 for the Chicago, IL and San Francisco, CA hearings.

All informal public hearings will begin at 10:00 a.m. on the first day of the hearing and at 9:00 a.m. on each succeeding day. Three informal public rulemaking hearings are scheduled to begin on the following dates:

Washington, DC: September 12, 1989.
Chicago, IL: October 17, 1989.
San Francisco, CA: October 24, 1989.

ADDRESSES: Comments on the proposed standard are to be submitted to the Docket Officer, Docket No. H-370, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-7894. Comments limited to 10 pages or less in length also may be transmitted by facsimile to (202) 523-5046 or (for FTS) to 8-523-5046, provided the original and 4 copies of the comment are sent to the Docket Officer thereafter.

Notices of Intention to Appear at the informal rulemaking hearings, testimony, and documentary evidence for the public hearings are to be sent to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-370, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-8615. All informal public hearings will begin at 10:00 a.m. on the first day of the hearing and at 9:00 a.m. on each succeeding day. The locations of the informal public hearings are as follows:

Washington, DC: The Auditorium, Frances Perkins Department of Labor Building, 200 Constitution Avenue, NW., Washington, DC 20210.

Chicago, IL: Parlor A, Palmer House, 17 East Monroe Street, Chicago, IL 60603.

San Francisco, CA: The Crystal Ballroom, San Franciscan Hotel, 1231 Market Street, San Francisco, CA 94103.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Room N-3647, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

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References to the rulemaking record are in the text of the preamble. References are given as "Ex." followed by a number to designate the reference in the docket. For example, "Ex. 1" means exhibit 1 in Docket H-370. This document is the Advance Notice of Proposed Rulemaking that was published in the **Federal Register** on November 27, 1987 (52 FR 45438).

I. Introduction

The preamble to the proposed standard on bloodborne pathogens discusses the events leading to the proposal, health effects of exposure, degree and significance of the risk, an analysis of the technological and economic feasibility of the proposal's implementation, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard.

Public comment on all matters discussed in this notice and all other relevant issues is requested for the purpose of assisting OSHA in the development of a new standard for occupational exposure to bloodborne pathogens. Persons need not resubmit information already submitted in response to the Advance Notice of Proposed Rulemaking entitled, "Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus" at 52 FR 45438 (November 27, 1987).

This proposed standard represents OSHA's first regulation of occupational exposure to biological hazards. The Agency recognizes the unique nature of both the healthcare industry and other operations covered by this proposed standard. Adequate employee protection must be provided in a manner consistent with a high standard of patient care. OSHA seeks comments and information from interested parties on how this goal can be achieved.

On February 6, 1989 the Department of Health and Human Services forwarded to the Department of Labor a document entitled "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers" (Exhibit 15) in compliance with the requirements of the Health Omnibus Programs Extension of 1988, Pub. L. 100-607. OSHA has placed this document and a companion document, "A Curriculum Guide for Public-Safety and Emergency-Response Workers—Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus" (Exhibit 16) in the public docket for this rulemaking. The Agency invites comments relative to using the information in this rulemaking. In particular, comments should be addressed to issues where these guidelines differ with the proposed requirements of this standard (e.g. which body fluids require the use of precautions in emergency situations).

On November 1, 1988 the President signed the "Medical Waste Tracking Act of 1988" into effect. The Act is an amendment to the Solid Waste Disposal Act and requires the Environmental Protection Agency (EPA) to promulgate regulations on the management of medical waste by establishing a two-year demonstration program to track medical waste. As part of the tracking program EPA will be investigating, among other things, areas such as segregation, containerization, and labeling of medical waste. These facets of infectious waste management are also dealt with in the proposed OSHA standard for occupational exposure to Bloodborne Pathogens. On March 24, 1989, the Environmental Protection Agency (EPA) published "Standards for the Tracking and Management of Medical Waste; Interim Final Rule and Request for Comments" in the **Federal Register** (FR 54 12326). In general, this EPA document sets forth the criteria and procedures for State participation in the demonstration program, EPA's definition of "medical wastes" for use under the Act, and the regulations and standards to be used in the demonstration program. OSHA has placed a copy of EPA's interim final rule in the record for consideration in development of the final Bloodborne Pathogens Standard (Ex. 6–497).

OSHA requests comments on health effects, risk assessment, significance of risk determination, technological and economic feasibility and provisions which should be included in a final bloodborne pathogens standard. The following list of questions is provided to assist persons in formulating comments, but it is not intended to be all inclusive or to indicate that participants need to respond to all issues or follow this format.

Specific issues of concern to OSHA are the following

1. Are there any bloodborne pathogens, in addition to the ones discussed in section IV *Health Effects* that present a risk to employees with occupational exposure to blood? If so what are these pathogens, and what evidence is available that they present a potential or actual risk to employees?

2. Are there additional studies or case reports on HBV and HIV that should be included in the health effects analysis? If so, what are they? Has OSHA adequately represented the results of available epidemiologic and case studies?

3. For its significance of risk determination, OSHA considered clinical hepatitis B, HBV carrier status, hospitalization, and death to be material impairment of health. Because of the possibility of infecting others (sexual partners, newborns) and the possibility of becoming an HBV carrier, should OSHA consider HBV infection as a material impairment of health?

4. Has OSHA employed the correct methodology for determining the quantitative and qualitative risks of exposure? Are alternative risk assessments available? Are there demographic factors which should be controlled for in estimating the background risk for HBV?

5. OSHA has chosen to protect employees from bloodborne pathogens by requiring that they be protected from exposure to blood and other potentially infectious materials. Is this the correct approach and is it the most protective approach? If not, what other approach should be employed?

6. The scope of the proposed standard would be based on occupational exposure to blood and other potentially infectious materials, whether or not the individual is employed in the healthcare industry. Is this approach the most protective? Will another approach provide greater protection? Should the scope of the standard be limited to one (or a few) industries?

7. In addition to law enforcement personnel, firefighters, and corrections personnel, are there any other occupations with potential for exposure that are predominantly or entirely confined to the public (federal, state or local) sector? If so, do they perform tasks or procedures that are unique and require special protective measures that are not addressed by this standard? If so, what are these protective measures?

8. What circumstances unique to law enforcement and correction officers place these employees at risk of exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any additional training should be required? What can be done to ensure that personal protective equipment is available when and where it is needed?

9. What circumstances unique to firefighters, emergency medical technicians and paramedics place these employees at risk for exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any, additional training should be required? What can be done to ensure that personal protective clothing and equipment is available when and where it is needed?

10. There is evidence that HIV may be transmitted through human breast milk. Are employees at risk of infection due to exposure to human breast milk? If so, what tasks or procedures do they perform that place them at risk? What special protective measures, if any, should be required for these employees?

11. Throughout the proposal, OSHA uses the terms "contaminated" and "decontaminated". Are these terms clearly understood? Should OSHA define these terms? If so, what are the appropriate definitions? Should laundry be considered "contaminated" only when blood or other potentially infectious materials are visible on the laundry? If not, what should indicate "contaminated" laundry?

12. The proprosed standard includes a number of requirements including an infection control plan, engineering and work practice controls, personal protective clothing and equipment, training, signs and labels, provision of HBV vaccination, and medical follow-up for exposure incidents. Are these requirements appropriate? Do they provide adequate protection? Should other provisions be added?

13. The Agency has traditionally preferred engineering and work practice controls over the use of personal protective equipment. Do employees, in nearly every case, need to use a combination of methods that include personal protective equipment, or are there tasks or worksites where exposures can be adequately minimized or eliminated by adherence to engineering or work practice controls alone? How could OSHA best structure the methods of control requirements to reflect actual working conditions?

14. The available evidence indicates that an exposure incident that involves a percutaneous exposure, resulting from an injury with a needle or other sharp object, carries the highest risk of HIV or HBV infection. Many of these injuries result from the need to disassemble the device after use, poorly designed equipment, or other factors that relate to the basic design of the equipment. How can OSHA encourage the development of safer instruments and equipment to further reduce the likelihood of percutaneous exposure?

15. The proposed standard does not require the use of respirators. Do aerosols present a risk for transmission of bloodborne pathogens? Are there instances when these bloodborne pathogens may be transmitted in respirable particles generated during medical procedures such as laser surgery or the use of medical or surgical instruments such as a bone saw? Are there other instances where respirable particles containing (or potentially

containing) bloodborne pathogens may present a risk to employees?

16. Commenters have indicated that some procedures with potential for exposure are performed in locations where handwashing facilities are not available or not located near the work area (e.g., crime scenes or mobile blood collection sites). Is there an acceptable substitute for handwashing that can be used under these circumstances? Does it provide protection that is equivalent to handwashing?

17. In paragraphs (d)(3)(vii) (B), (D), and (E) OSHA has proposed that *fluid-resistant* clothing be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials while *fluid-proof* clothing must be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials. Is the distinction between *fluid-resistant* and *fluid-proof* clear? Should these terms be defined? Are the requirements for two types of protective clothing based on anticipated exposure appropriate? If not, what other approaches will assure employee protection?

18. Should OSHA specify that all non-intact skin be bandaged or otherwise covered before performing tasks or procedures with a potential for occupational exposure?

19. The proposed standard allows the use of utility gloves for housekeeping and laundry workers. Is the decontamination and reuse of these gloves appropriate? Should OSHA require that these gloves be puncture-resistant?

20. Are the requirements for HIV and HBV research laboratories adequate and appropriate? What additional requirements should be included? Is the definition for "research laboratories" clear? Does the definition clearly differentiate between research laboratories and clinical (diagnostic) laboratories?

21. Are the requirements for HIV and HBV production facilities adequate and appropriate? What additional requirements should be included? Is the definition for "production facilities" clear? Does the definition adequately differentiate between research laboratories and production facilities?

22. Some research laboratories use blood and blood components but do not propagate bloodborne pathogens. Are the requirements for clinical laboratories adequate for these research laboratories? If not, what additional provisions should be required?

23. The proposal requires that the HBV vaccine be offered to employees exposed an average of one or more times per month. Should the administration of the HBV vaccine be contingent on the frequency of exposure? Is this frequency appropriate? If this approach is not appropriate, what justification can be provided for an alternative approach?

24. The proposed standard requires that the HBV vaccine be made available 90 days after the effective date of the standard. Are there sufficient quantities of the HBV vaccine to vaccinate all eligible employees? Assuming that sufficient quantities of vaccine are available, will there be a problem with the distribution of the vaccine? If so, should there be a phase-in period?

25. In paragraph (f) Hepatitis B vaccine and post-exposure follow-up, the employer is required to administer the vaccine and provide effective post-exposure prophylaxis according to "standard recommendations for medical practice." Does this approach give sufficient guidance to the employer on what must be done? For example, should the Agency be more specific about the meaning of "* * * accepted safe effective * * * prophylaxis * * *?" Should these recommendations be those of the U.S. Public Health Service?

26. Employees may be reluctant to report exposure incidents if they fear that coworkers or others may gain access to their test results. OSHA has attempted to reduce barriers to the reporting of exposure incidents by requiring that employee medical records, including test results, be kept confidential except as required by law. Has OSHA adequately addressed the issue of confidentiality? If not, what additional measures should be required?

27. The biohazard signs required in paragraph (g)(1)(i) do not require the use of the word "Danger." Is it necessary to require the use of "Danger" or other additional warning words in order to warn individuals who may not understand the meaning of "Biohazard?"

28. OSHA requires that infectious wastes be labelled or "red bagged." If infectious waste is decontaminated prior to disposal, should OSHA allow the label to be removed from the container?

29. OSHA requires that exposed employees be trained. Should OSHA specify minimum qualifications required for the individual who conducts the training program?

30. The standard would require that all employees participate in the training program when they are hired and annually thereafter. Certain individuals, for example, infection control practitioners or some virologists, would be expected to be thoroughly familiar with some of the material in the training program. Is it appropriate to substitute some measure of competency in lieu of training for these individuals? If so, what criteria would be appropriate?

31. In all previous OSHA health standards, the Agency has required the employer to bear the cost for all provisions of the standard. This proposed standard would also require the employer to pay for all the provisions of the standard. OSHA seeks comments on this issue.

32. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries affected by the standard. The following information is requested to aid in that effort. Data should be provided for the last five years. Data already submitted to OSHA or Jack Faucett Associates (JFA) need not be resubmitted.

a. What were total annual revenues for your facility and/or industry sector?

b. What were the total annual investments categorized as replacement, expansion, modernization, and environmental health and safety?

c. What were the retained earnings, after tax income, total assets, stockholders' equity, net worth, depreciation charges, and debt-equity ratios?

d. What were the total annual employment levels and labor turnover for the affected industries for the last 5 years?

33. How would an OSHA standard for occupational exposure to bloodborne pathogens affect competition in the healthcare industry?

34. OSHA and JFA have performed detailed feasibility analyses for all industry sectors. Comments are requested with regard to any other industry segments on additional impacts which should be considered prior to issuing a final standard.

35. Comments are requested on OSHA's Preliminary Regulatory Impact Analysis (PRIA), the report prepared by Jack Faucett Associates, the feasibility of the proposed standard and alternatives.

36. The following information is requested for small businesses in addition to the information OSHA has gathered.

a. What kinds of small businesses or organizations would be affected by regulating exposures to blood and other potentially infectious materials? How many such businesses are there?

b. Which if any, federal rules may duplicate, overlap, or conflict with an OSHA regulation concerning exposure to blood and other potentially infectious materials?

c. Will difficulties be encountered by small entities when attempting to comply with the standard? What requirements, if any, should be deleted or simplified for small entities, while still achieving comparable protection for the health of employees of small entities?

d. What timetable would be appropriate to allow small entities sufficient time to comply?

37. OSHA's PRIA contains estimates of the current level of compliance for various provisions. Are these estimates accurate? If not, by what means and to what extent are employers currently providing protection to their employees?

38. The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them along with supporting documentation to OSHA. Such impacts might include a positive or negative environmental effect that could result should a standard be adopted; as well as any irreversible commitments of natural resources. Also, estimates of the effect on the level of hazardous pathogens in the environment by the proposed OSHA standard and alternatives are requested.

39. As discussed in Section IX—Summary and Explanation of the Proposed Standard and Section X—Public Participation, OSHA plans to devote several days of the public hearing to a discussion of Hepatitis B vaccination. OSHA seeks written comments concerning the elements of a HBV vaccination program that will result in a high degree of compliance of eligible employees.

40. OSHA believes a hepatitis B vaccination program where employers bear the cost of the vaccine, make the vaccine available to employees at a reasonable time and place, and provide information about the benefits of the vaccine is the most appropriate way to assure that a large percentage of eligible employees are vaccinated. The Agency seeks comment on whether this voluntary approach is the correct approach.

In the past, the Agency has not mandated medical examinations or other medical procedures. For example, the final standards for benzene, asbestos, cotton dust, and formaldehyde require the employer to "provide" or "make available" medical procedures (29 CFR 1910.1028; 1910.1001; 1910.1043; and 1910.1048, respectively). In the preamble to the Lead Standard (43 FR 54450), OSHA specifically rejected mandating worker participation in medical surveillance. The Agency noted that medical surveillance was a sensitive area and that: "Attempting to compel workers to subject themselves to detailed medical examinations presents the possibility of clashes with legitimate privacy and religious concerns. Health in general is an intensely personal matter. * * *" In lead, medical surveillance involved effects on male and female reproduction, while in this proposed standard a major concern is that a vaccination is an invasive procedure. Here, as in the lead standard, OSHA prefers to encourage rather than try to force by governmental coercion, employee cooperation in the vaccination program.

The HBV vaccination provision is a significant element in this rule with regard to saving lives from hepatitis B infection. Complete vaccination of the healthcare workers at significant risk would substantially reduce hepatitis B associated illness and death. In addition, once immunized, workers are protected from infection both on the job and off even should other precautions fail. Finally, the vaccine is safe and effective.

OSHA seeks comment on whether the HBV vaccination should be mandated for some or all exposed employees and on what legal, ethical, medical, or other issues would be raised by such a requirement.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et. seq.), and the regulations issued pursuant thereto (5 CFR Part 1320), OSHA certifies that it has submitted the information collection requirements contained in this proposed standard to the Office of Management and Budget (OMB) for review under Section 3504(h) of that Act. Paragraph (c) Infection Control, paragraph (g)(2) Training, and paragraph (h) Recordkeeping are the provisions that make the major contribution to the information collection requirements in the proposed standard. Comments on these information collection requirements may be submitted by interested parties to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for the Occupational Safety and Health Administration, New Executive Office Building, Washington, DC 20503. OSHA requests that copies of such comments also be submitted to the OSHA rulemaking docket, at the following address: Docket Officer, Docket No. H-370, Room N 2625, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210.

Public Reporting Burden

Public reporting burden for this collection of information is estimated to range from 4 to 16 hours for the Infection Control Plan and an average of 7 hours per facility for the remaining information requirements. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the OSHA rulemaking docket, at the address previously set forth; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

Federalism

This proposed standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

Bloodborne pathogens are present wherever blood or other potentially infectious materials are found. Since these potentially infectious materials are present in workplaces in every state of the Union, the occupational hazard of bloodborne pathogens is a national problem.

The Federally proposed bloodborne pathogen standard is drafted so that employees in every State would be protected by general, performance-oriented standards. To the extent that

there are any State or regional peculiarities, States with occupational safety and health plans approved under Section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this proposed standard, of and by itself, allows for flexibility by States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

In short, there is a clear national problem related to occupational safety and health for employees exposed to bloodborne pathogens. Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this proposed regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard. State comments are invited on this proposal and will be fully considered prior to promulgation of a final rule.

State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months after the publication of a final standard for occupational exposure to bloodborne pathogens or amend their existing standard if it is not "at least as effective" as the final Federal standard. OSHA anticipates that this proposed standard will have a substantial impact on state and local employees. The states and territories with occupational safety and health state plans are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees.)

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (the Act) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically directed that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practical, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 6(b)(5)].

Where appropriate, standards are required to include provisions for labels or other appropriate forms of warning to apprise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and training and education. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for the development of information regarding occupational accidents and illnesses [Section 8(c)].

In vacating OSHA's 1978 revision to its benzene standard, the Supreme Court required in *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 601, 64 L. Ed. 2d 1010, 100 S. Ct. 2844 (1980), that before the issuance of a new or revised standard pursuant to section 6(b)(5) of the Act, OSHA must make two threshold findings: that a place of employment is unsafe in that significant risks are present; and that the risks can be reduced or eliminated by a change in practices (448 U.S. at 642).

The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" (448 U.S. at 644, n. 49). The Court indicated, however, that the significant risk determination is "not a mathematical straitjacket," and that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge" [and that] . . . the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656). The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." (448 U.S. at 655, 656, n. 62).

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the regulatory action, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employees will suffer material impairment of health" [Section 6(b)(5)]. The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility *American Textile Manufacture's Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." (452 U.S. at 509). The Court stated that the Agency could use cost-effectiveness analysis and choose the least costly of two equally effective standards. (452 U.S. 531, n. 32).

Authority for this action is also found in section 8(c)(3) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6."

The Secretary's authority to issue this proposed standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as [she] may deem necessary to carry out [her] responsibilities under the Act"—in this case as part of a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

> Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new

and to perfect existing programs for providing safe and healthful working conditions [29 U.S.C. 651(b)(1)];

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce [29 U.S.C. 651(b)(4)];

Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions [29 U.S.C. 651(b)(a)];

Providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health program [29 U.S.C. 651(b)(12)];

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions [29 U.S.C. 651(b)(6)];

Encouraging joint labor-management efforts to reduce injuries and disease arising out of employment [29 U.S.C. 651(b)(13)]; and developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems [29 U.S.C. 651(b)(5)].

The Agency's preliminary judgment is that the bloodborne pathogens standard is reasonably related to these statutory goals, and that the evidence satisfies the statutory requirements, and that the standard will reduce a significant risk of hepatitis B and other adverse health effects, including but not limited to AIDS and non-A/non-B hepatitis. Thus, the Secretary preliminarily finds that the proposed standard is necessary and appropriate to carry out her responsibilities under the Act.

III. Events Leading to the Proposed Standard

Hepatitis B virus (HBV) has long been recognized as a pathogen capable of causing serious illness and death. Because the virus is transmitted through blood and certain body fluids, persons who handle these as part of their jobs have been at increased risk of contracting HBV. The human immunodeficiency virus (HIV), the virus that causes AIDS, has only been recognized in the last decade. Because the transmission of HIV is considerably less efficient than HBV, the risk of HIV infection to employees who must handle blood and other potentially infectious materials is less than for HBV infection (i.e., HIV results in fewer seroconversions following exposure incidents.) The consequences of HIV infection are grave, however, because HIV causes the fatal disease AIDS.

Although OSHA has no standard that was designed specifically to reduce occupational exposure to these viruses, the Agency has a number of existing regulations that apply to this hazard. For example, 29 CFR 1910.132 requires employers to provide personal protective equipment and 29 CFR 1910.145(f) requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1) the General Duty Clause of the Act requires that each employer:

> furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

In 1983, OSHA issued a set of voluntary guidelines designed to reduce the risk of occupational exposure to hepatitis B virus (Ex. 4–25). The voluntary guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices, and recommendations for use of immune globulins and the hepatitis B vaccine.

On September 19, 1986, the American Federation of State, County and Municipal Employees (AFSCME) petitioned OSHA to take action to reduce the risk to employees from exposure to certain infectious agents (Ex. 2A). They requested that OSHA issue an emergency temporary standard (ETS) under section 6(c) of the Act. The petitioners also requested that OSHA immediately initiate a section 6(b) rulemaking that would require employers to provide the HBV vaccine at no cost to employees at risk for HBV infection and would require employers to follow work practice guidelines such as those issued by the Centers for Disease Control. AFSCME also requested that OSHA amend the Hazard Communication Standard (48 FR 53280) to require a training program for employees exposed to infectious diseases, require counseling for pregnant employees about diseases that have reproductive effects, and mandate posting of isolation precautions in patient areas and in contaminated areas.

On September 22, 1986, the Service Employees International Union, the National Union of Hospital and Healthcare Employees, and RWDSU Local 1199—Drug, Hospital and Healthcare union petitioned the Agency to promulgate a standard to protect healthcare employees from the hazard posed by occupational exposure to hepatitis B virus (Ex. 3). They requested that, as a minimum, the standard should contain all of the provisions in OSHA's 1983 guidelines with special emphasis on making workers aware of the benefits of vaccination. In addition, they asked OSHA to immediately issue a directive stating that employers must provide the HBV vaccine free of charge to all high risk healthcare workers.

Having determined that the available data did not meet the criteria for an ETS as set forth in section 6(c) of the Act, Assistant Secretary John A. Pendergrass denied the petitions by letter dated October 22, 1987. OSHA further determined that the appropriate course of action was to publish an Advance Notice of Proposed Rulemaking (ANPR) to initiate rulemaking under section 6(b) of the Act and to collect further information. Concurrently with the collection of this information, the Agency committed to enforcing existing regulations and section 5(a)(1) of the Act in healthcare settings and to undertaking an educational program in cooperation with the Department of Health and Human Services.

On October 30, 1987, the Departments of Labor and Health and Human Services published a Joint Advisory Notice entitled, "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)" (52 FR 4181). In the cover letter to employers, Secretaries Brock and Bowen urged the "* * * widest possible adherence to the appropriate precautions as exemplified by the CDC guidelines and the Joint Advisory Notice." The letter, notice and a pamphlet written by OSHA for healthcare workers were mailed to more than 600,000 employers, employee representatives and trade and professional associations.

On November 27, 1987, OSHA published in the **Federal Register** an ANPR announcing the initiation of the rulemaking process (52 FR 45438). The Agency requested information relevant to reducing occupational exposure to HBV and HIV under section 6(b) of the OSH Act. The public was asked to comment on the scope, the modes of controlling exposure, personal protective equipment, vaccination programs, management of exposure incidents, medical surveillance, training and education, generic standards, advances in hazard control, effectiveness of alternative approaches and the environmental effects. A sixty day period was set for comments, and these comments were to be submitted to the OSHA docket by January 26, 1988, as noted in a correction published in the **Federal Register** December 11, 1987 (52 FR 47097).

OSHA received an overwhelming response to the ANPR. Over 350 comments were filed by interested parties including employers, unions, health professionals, trade representatives, professional

associations, manufacturers, and federal, state and local government agencies, among others. The comments have been analyzed and the data were used in preparing this proposal.

IV. Health Effects

A. Introduction

Certain pathogenic microorganisms can be found in the blood of infected individuals. For the purposes of this standard, OSHA is referring to these microoganisms as "bloodborne pathogens" and to the diseases that they cause as "bloodborne diseases." These bloodborne pathogens may be transmitted from the infected individual to other individuals when blood or certain other body fluids are exchanged, for example, when blood-contaminated needles are shared by intravenous drug users. Because it is the exposure to the blood or body fluid that carries the risk of infection, individuals whose occupational duties place them at risk of blood exposure are also at risk of becoming infected with these bloodborne pathogens, developing the disease and, in some cases, dying. Infected employees may also transmit the pathogens to others.

A complete discussion of two of the most significant bloodborne pathogens, hepatitis B virus and human immunodeficiency virus, follows. This includes a discussion of each of the viruses, the disease each causes, modes of transmission, and documented risk of infection resulting from occupational exposure. In addition, a discussion of other bloodborne diseases, including non-A, non-B hepatitis, delta hepatitis, syphilis, and malaria, are included. There is also a discussion of cytomegalovirus with a review of the literature concerning transmission of the virus and risks to pregnant women.

B. Hepatitis Viruses

Introduction

Hepatitis means "inflammation of the liver," and can be caused by a number of agents including drugs, toxins, autoimmune disease, and infectious agents including viruses. The most common causes of hepatitis are viruses. There are four types of viral hepatitis which are important in the U.S. (Ex. 6–449, Ex. 6–430, Ex. 6–199). Hepatitis A, formerly called "infectious" hepatitis, is spread by fecal contamination and is not generally considered to be a significant risk to healthcare workers, although episodes of transmission to healthcare workers in hospitals have been reported (Ex. 6–430, Ex. 6–472; Ex. 6–449, Ex. 6–456). Hepatitis B, formerly called "serum" hepatitis, is the major risk to healthcare workers and is extensively discussed in this document. Delta hepatitis affects persons already infected with HBV and can increase the severity of acute and chronic liver disease in these individuals (Ex. 6–470). Non-A, non-B hepatitis is the name given to a group of diseases caused by viral agents. The "post transfusion" type of non-A, non-B hepatitis is caused by a bloodborne virus that is efficiently transmitted by blood transfusion and by needle sharing among IV drugs users (Ex. 6–430, Ex. 6–449). There are occasional reports of transmission to healthcare workers (Ex. 6–39, Ex. 6–455). Although it is not thought to be a major occupational hazard to health workers, serological tests for this disease are not currently available, and the actual risk of transmission to health workers is unknown.

Hepatitis B virus (HBV) infection is the major infectious occupational hazard to healthcare workers. The Hepatitis Branch of the Centers for Disease Control (CDC) estimates that there are approximately 18,000 infections in healthcare workers each year in the United States. Approximately 12,000 of these infections occur in employees who have occupational exposure to blood, causing 2500–3000 cases of clinical acute hepatitis and 500–600 hospitalizations and over 200 deaths. Approximately 1000 health care workers annually become HBV carriers, at risk of long-term sequellae including disabling chronic liver disease, cirrhosis and liver cancer. Death may result from both acute and chronic hepatitis. Infected healthcare workers can spread the infection to family members or rarely, to their patients. [For a detailed discussion, see Section V, Preliminary Quantitative Risk Assessment.] The use of Hepatitis B (HB) vaccine and appropriate environmental controls will prevent almost all of these occupational infections. Efforts to reduce blood exposure and minimize puncture injuries in the healthcare setting will reduce the risk of transmission of all bloodborne hepatitis viruses.

Biology

Hepatitis B is caused by the hepatitis B virus (HBV), formerly called the Dane particle, that attacks and replicates in liver cells (Ex. 6–430, Ex. 6–449). The virus has an inner core and an outer shell structure. The inner core contains DNA, enzymes, and various proteins, the most important of which is called the hepatitis B core antigen (HBcAg). The outer shell is composed of a lipoprotein called hepatitis B surface antigen (HBsAg), formerly called the Australia Antigen. The HBsAg is produced in great excess by liver cells replicating the virus, and is found, along with complete virus, in the form of small spheres and larger tubular particles in the blood of infected persons. The small spherical forms of HBsAg are important because the plasma derived hepatitis B vaccines are composed of a highly purified preparation of these particles. There is a readily available laboratory test for HBsAg, and its presence in blood indicates that an individual is currently infected with the HBV, and is potentially infectious to others.

Disease Outcomes

Infection with the hepatitis B virus in a susceptible person can produce two types of outcomes: self-limited acute hepatitis B and chronic HBV infection (Ex. 6–430, Ex. 6–449). Similarly, the human body can mount two types of response to HBV infection. The most frequent response seen in healthy adults is development of self-limited acute hepatitis and the production of an antibody against HBsAg, called anti-HBs. The production of this antibody coincides with the destruction of liver cells containing the virus, elimination of the virus from the body, and signifies lifetime immunity against reinfection. Persons having this response also develop an antibody against the core protein, call anti-HBc, and usually maintain both anti-HBc and anti-HBs in their blood for life.

Unfortunately, the destruction of liver cells in an attempt to rid the body of this infection often leads to clinically apparent acute hepatitis B. About one third of infected individuals have no symptoms when infected with the virus, one third have a relatively mild clinical course of a flu-like illness which is usually not diagnosed as hepatitis, and one third have a much more severe clinical course with jaundice (yellowing of the eyes and skin), dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. These symptoms require hospitalization in about 20% of jaundiced cases, and often cause several weeks to months of work loss even in those cases that do not require hospitalization. Fulminant hepatitis, which is about 85% fatal with even the most advanced medical care, develops in about 1–2% of reported acute hepatitis B cases, and an estimated 1 per 1000 HBV infections (Ex. 6–217).

The second type of response—development of chronic HBV infection—has more severe consequences (Ex. 6–430, Ex. 6–449). About 6% to 10% of newly-infected adults cannot clear the

virus from their liver cells and become chronic HBV carriers. These individuals continue to produce HBsAg for many years, usually for life. They do not develop anti-HBs, but do produce anti-HBc antibody. HBV carriers are at high risk of developing chronic persistent hepatitis, chronic active hepatitis, cirrhosis of the liver, and primary liver cancer. About 25% of carriers develop chronic persistent hepatitis, a relatively mild, non-progressive form of chronic liver disease, and 25% develop chronic active hepatitis. The latter is a progressive, debilitating disease that often leads to cirrhosis of the liver after 5–10 years (Ex. 5–5, Ex. 6–448). Patients with end-stage cirrhosis may develop ascites (fluid accumulation in the abdomen), esophageal bleeding from distended veins (causing patients to vomit large volumes of blood), coma, and death. Chronic HBV infection has been estimated to cause 10% of the 25,000–30,000 deaths that occur due to cirrhosis in the U.S. each year (Ex.6–199).

The HBV in chronic carriers can integrate into the DNA of the host liver cell. This integration may lead to malignant transformation of the liver cell, and development of primary hepatocellular carcinoma (PHC) (Ex. 6–419, Ex. 6–443). PHC is almost uniformly fatal if diagnosed after symptoms appear. Patients with PHC usually die within four to six months after diagnosis. PHC usually develops in HBV carriers after a latency period of 20 to 60 years. In parts of the world where HBV infection is a common childhood infection, PHC is one of the leading causes of cancer death. In Taiwan, for example, Beasley and colleagues have found that 5 per 1000 adult male HBV carriers develop PHC each year, and estimate that approximately 25% of all HBV carriers, and 40% of male HBV carriers, will die from either PHC or cirrhosis (Ex. 6–419). The relative risk of developing PHC in an HBV carrier compared to a non-carrier in his studies is 100. Studies in the United States and in Great Britain, where HBV infection usually occurs in adulthood, have shown 13 to 40 fold increased risk of developing PHC among HBV carriers (Ex. 6–460, Ex. 6–444). This may be compared to the relative risk of lung cancer in smokers vs non-smokers of 10–20. Studies in many other populations worldwide have confirmed this extremely high relative risk.

The causal link between HBV carriage and PHC is not only based on epidemiologic studies, but is confirmed by both animal and molecular biological studies (Ex. 6–449, Ex. 6–443). Other animal species can become infected with HBV-like viruses (which belong to the same virus family—Hepadna viruses), and woodchucks, Pekin ducks, ground squirrels, and other species that become infected may develop a carrier state. These carrier animals develop primary liver cancers at very high rates. Molecular biological studies have shown that PHC tumor cells contain integrated HBV DNA in virtually all human and animal cases of PHC (Ex. 6–443).

There is likely a higher risk of developing PHC if infection occurs from perinatal (mother to child) transmission, or from infection during childhood than from infection in adulthood. Although persons who develop HBV carriage during adulthood are at increased risk of developing PHC, the exact risk of developing PHC following adult infection has not been established. The risk observed in blood donors in the United States is probably an underestimate, as PHC is most likely in persons with chronic liver disease or cirrhosis who are excluded from such studies. In addition, many carriers will die of other causes before they develop PHC because of the long latency of this cancer. Nevertheless, it has been estimated that, in the U.S., about 25%–33% of all PCH cases, or 750–1000 PHC cases annually, result from HBV infection.

Modes of Transmission

Workplace. HBV is spread via several routes: parenteral (by direct inoculation through the skin), mucous membranes (blood contamination of the eye or mouth), sexual, and perinatal (from infected mother to newborn infant) (Ex. 6–430, Ex. 6–449). The most efficient mode of transmission is direct inoculation of infectious blood, such as might occur during blood transfusion, needle sharing by IV drug users, or needlestick or other sharp instrument injury in health care workers. One milliliter of HBsAg positive blood may contain 100 million infectious doses of virus; thus, exposure to extremely small inocula of HBV-positive blood may transmit infection. In different studies, 7% to 30% of health care workers sustaining needlestick puncture injuries from HBsAg positive patients become infected (Ex. 4–27, Ex. 4–28). Since 1972, all units of blood collected for transfusion in the U.S. have been screened for HBsAg, greatly decreasing the incidence of transfusion related HBV infection.

Blood and blood-derived body fluids (serous exudates and fluids from internal body cavities) contain the highest quantities of virus and are the most likely vehicles for HBV transmission (Ex. 6–430, Ex. 6–449). Certain other body fluids such as saliva and semen contain infectious virus but at 1000-fold lower concentration (Ex. 6–445). Other body fluids such as urine or feces contain only small quantities of virus unless they are visibly contaminated with blood.

Direct inoculation of infectious blood may occur in less apparent ways. Preexisting lesions on hands from injuries incurred at the workplace or at home or from dermatitis may provide a route of entry for the virus (Ex. 6–427). In addition, transfer of contaminated blood via inanimate objects or environmental surfaces has been shown to cause infection in the healthcare workplace (Ex. 6–464, Ex. 6–433, Ex. 6–461). In general, fewer than 20% of infected healthcare workers report discrete needlestick injuries from a known infected patient (Ex. 6–427). The importance of this route of transmission in these less apparent ways should not be underestimated. Although gloving will not stop direct puncture injuries, it could prevent the virus from contacting preexisting lesions.

Infectious sera placed in both the eye and mouth of experimental animals has induced HBV infection (Ex. 6–430, Ex. 6–449). Splashes of blood or serum into the individual's eye or mouth in clinical settings or in the laboratory must be regarded as potentially serious exposures. While there has been concern about the potential infectivity of aerosols generated by dental, medical, and laboratory equipment, and although HBsAg may be found in large particles of "spatter" that travel short distances, OSHA is not aware of any data that link HBV transmission with the production of aerosols.

Secondary transmission in other settings. Sexual transmission of HBV infection is an efficient mode of viral spread as HBsAg has been found in both semen and vaginal secretions (Ex. 6–430, Ex. 6–445). Deposition of virus onto mucous membranes and trauma to tissue causing small lesions may both play roles in transmission. Approximately 30% of spouses or regular sexual partners of acutely infected HB patients become infected. Spouses of chronic carriers, who have a much longer duration of infectivity, escape infection less frequently. Preventing secondary transmission of HBV infection to the spouse or sexual partners of infected healthcare workers is an additional benefit derived from and reason for controlling this disease (Ex. 6–425).

Non-sexual family contacts of HBV carriers are also at risk of infection.

Although the relative importance of various transmission modes has not been determined in families, in various studies about 40–60% of household contacts of carriers identified by blood donation had markers of HBV infection (Ex. 6–420, Ex. 6–430). Daily exposure to the carrier for many years presents occasions for sharing razors or toothbrushes, exposure to blood and other events that could result in infection. Adopted carrier children have been shown to transmit infection to other family contacts.

Perinatal infection with the HBV is an efficient mode of transmission with particularly severe consequences. Highly infectious HBV carriers and persons with acute hepatitis B have an antigen present in their blood called the hepatitis B "e" antigen (HBeAg), in addition to the previously discussed HBsAg. Mothers positive for both HBeAg and HBsAg will infect 70% to 90% of their newborns, most of whom will become chronic HBV carriers (Ex. 6–199, Ex. 6–419). These carriers have a 25% chance of dying from cirrhosis or PHC. They also remain infectious to others and can perpetuate the cycle of perinatal transmission. Fortunately, treatment of newborns at birth with Hepatitis B immune globulin (HBIG) and HB vaccine is 85% to 95% effective in preventing these infants from becoming carriers (Ex. 6–419, Ex. 6–199). To be able to treat these infants at birth, their mothers must be recognized as carriers before delivery. The Immunization Practices Advisory Committee of the CDC has recommended that all pregnant women in the U.S. be screened for HBsAg during an early prenatal visit (Ex. 6–424). Because pregnant healthcare workers may, if infected, transmit HBV to their newborn infants, prevention of HBV infection is critical in women who work in occupations where they are at risk for exposure.

Epidemiology

HBV infection does not occur uniformly in the U.S. population. The infection is more prevalent in certain ethnic and racial groups, and is especially prevalent in certain "high risk" groups defined by occupation and lifestyle (Exs. 6–430, 6–449, 6–199). The prevalence of HBV antibodies in the general population, reflecting the percentage of the population ever infected, is 3% to 4% for whites and 13% to 14% for blacks (Ex. 6–390). Foreign born Asians have a prevalence of antibody of greater than 50%. The HBsAg prevalence, reflecting the percentage of the population who are HBV carriers, is 0.2% for whites, 0.7% for blacks, and up to 13% for foreign born Asians. The high prevalence in Asians is a reflection of the fact that most HBV infections in Asia occur in childhood.

The ACIP has listed a number of groups who are at substantial risk for HBV infection and should receive the HBV vaccine (Ex. 6–199). Healthcare workers and staff of institutions for the mentally retarded are included on this list.

Transmission To Healthcare Workers

Although outbreaks of clinical hepatitis had been reported for many years (Ex. 6–438, Ex. 6–459), it was not until the 1970's that the risk to healthcare workers from HBV infection was well defined. The first studies noted that dentists were more likely than attorneys to have had clinical hepatitis (Ex. 6–441). When HBsAg and antibody testing became available, it was possible to show that the type of hepatitis that occurred in health workers was hepatitis B, that dentists and physicians were 4 to 10 times more likely to have serologic markers indicating previous HBV infection than first time blood donors (Ex. 4–15, Ex. 6–68), and that the prevalence of markers increased significantly with years in practice (Ex. 6–440, Ex. 6–65, Ex. 4–13, Ex. 4–16, Ex. 4–12).

During the next decade, dozens of studies were published measuring the prevalence of HBV markers in various healthcare occupational groups, and in various healthcare settings (Ex. 6–427, Ex. 6–88, Ex. 6–72, Ex. 6–54, Ex. 6–53, Ex. 6–440, Ex. 6–40, Ex. 4–14). The prevalence of markers was studied in hospitals of all sizes and types, in various sized communities, serving all types of populations. Studies were also done on a wide variety of individual occupational groups at meetings and through special studies. The most useful studies showed that risk of HBV infection in hospital personnel was increased several-fold over that in blood donors (Ex. 6–440), that risk was closely related to frequency of contact with blood and not related to contact with patients per se (Ex. 6–65; Ex. 4–13; Ex. 4–16), and that risk was directly related to duration in the occupation (Ex. 4–15, Ex. 4–12, Ex. 4–16). Certain studies attempted to quantitate the frequency of blood and needle exposure in various categories of healthcare workers, and relate this to risk of infection (Ex. 4–16).

The following general observations can be made from these studies:

(1) These studies revealed that workers exposed to blood on the job had a prevalence of HBV markers several times that of non-exposed workers and the general population. The prevalence of markers increased with years on the job.

(2) The prevalence of HBV markers was related to the degree of blood exposure or frequency of needle exposure, and not to patient contact per se. Persons working in operating rooms, emergency rooms labs, and dialysis units had a higher marker prevalence than persons working on medical or pediatric wards, who in turn had a higher prevalence than clerical workers, social workers, and administrators.

(3) Groups shown to be at high risk include (but are not limited to): medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, oncology and dialysis unit staff, emergency room staff, nursing personnel, staff physicians, dental professionals, laboratory and blood bank technicians, emergency medical technicians, and morticians (Ex. 6–199).

Most infected healthcare workers are unaware that they have been exposed to the HBV. Approximately 1% (or more) of hospitalized patients are HBV carriers; most HBV carrier patients seen in the healthcare setting are not symptomatic, are unaware that they are carriers, and their medical charts do not contain this information (Ex. 6–427). Health care workers may take extraordinary precautions when dealing with a known carrier, but are often unaware that they may treat five carriers for each one they recognize. This is a key point in understanding the rationale for the concept of "universal precautions," and for use of HB vaccine in workers with exposure to blood. Although the risk of encountering HBV carriers may vary in the hospital setting, being highest in inner city referral hospitals dealing with high risk groups such as drug abusers and homosexual men, risk will be present in any work setting where human blood is encountered. The risk of HBV carriage in the general population is uniform (does not markedly vary with region of this country) (Ex. 6–390), and high risk groups such as Southeast Asian refugees, mentally retarded individuals, and occult drug abusers may be found in rural as well as urban settings.

Percutaneous exposure to blood through needlesticks and cuts with other sharp instruments are visible and efficient modes of transmission, but reported injuries do not account for the majority of infections in healthcare workers (Ex. 6–65, Ex. 6–427). This fact often goes unrecognized by workman's compensation boards, which sometimes deny coverage to infected workers unless they had reported a discrete needlestick or similar injury from a HBsAg positive patient. Some workers doing traumatic procedures get cuts, needlesticks or large blood exposures so frequently that they do not bother to

report them; other workers become infected when the blood of an unsuspected HBV carrier gets into a small preexisting skin lesion or is rubbed into the eye. Prevention of these occupational infections is the goal of this proposed standard.

Transmission from HCWs to Patients

Transmission of HBV from healthcare workers to patients is an uncommon but extremely serious consequence of healthcare worker infection. Fewer than twenty episodes of this type of transmission have been reported, although instances involving only a few patients may go unrecognized or unreported (Ex. 6–103, F. 6–446, Ex. 6–476, Ex. 4–471 Ex. 6–144). Most instances have involved oral surgeons, dentists, gynecologists, or surgeons, occupations where significant blood exposure, trauma, and use of sharp instruments occur routinely. Some episodes have involved transmission to between 20 and 55 patients, with deaths and secondary transmission to family members of patients occurring (Ex. 6–103, Ex. 6–144).

Most healthcare workers who have transmitted to patients have several factors in common (Ex. 6–476, Ex. 6–471):

(1) The dentists and surgeons were chronic HBV carriers, had high titers of virus in their blood (HBeAg positive), and were unaware that they were infected.

(2) Transmission occurred most frequently during the most traumatic procedures.

(3) The dental personnel who transmitted did not routinely wear gloves.

(4) The dentists and surgeons often had a personal medical problem (such as exudative dermatitis on the hands), or used techniques that made transmission more likely. Several of the gynecologists used their index fingers to feel for the tip of the suture needle when they were performing deep abdominal surgery.

It is important to differentiate between HBV carrier personnel who have and have not transmitted to patients (Ex. 6–476, Ex. 6–471, Ex. 6–418). Among HBV carrier healthcare workers, few ever transmit HBV to patient contacts; when patients who have been treated by known HBV carriers have been followed prospectively, HBV transmission has not been observed (Ex. 6–418, Fv 6–432). The CDC has stated that HBV carrier healthcare workers may work in any occupation as long as they understand the modes of transmission of hepatitis B and take the measures necessary to prevent transmission (Ex. 6–471, Ex. 6–162, Ex. 6–70). These measures are the same measures all healthcare workers performing the same tasks should follow.

Transmission Via Environment

Transmission of HBV infection from exposure to contaminated environmental surfaces has been documented to be a major mode of HBV spread in certain settings, particularly hemodialysis units (Ex. 6–56, Ex. 6–446, Ex. 6–480, Ex. 6–461). The virus can survive for at least one week dried at room temperature on environmental surfaces, and medical procedures as well as disinfection and sterilization techniques must be adequate to prevent the spread of this virus (Ex. 6–422, Ex. 6–458). HBV contaminated blood from the surface of dialysis machines and carried on the hands of medical personnel to patients has been postulated as the mechanism of transmission in dialysis units. Unsterilized or improperly sterilized acupuncture needles have been implicated as the cause of large outbreaks of HBV infection (Ex. 6–439). Potential problems of environmental contamination in the dental operatory have been discussed in the CDC guidelines for dental operations (Ex. 6–490).

HBV is thought to be far less resistant to sterilization and disinfection procedures than microbial endospores or mycobacteria used as reference criteria (Ex. 6–421). Any sterilization or disinfection procedure or product approved by the Environmental Protection Agency as a sterilizing agent or high level disinfectant will kill the virus if used as directed. Dilute solutions of sodium hypochlorite (household bleach) are particularly effective and inexpensive, although they may be corrosive or damaging to certain materials. Certain low-level "germicides" such as quaternary ammonium compounds are not considered to be effective against the virus (Ex. 6–422). Unfortunately, soaking medical and dental instruments in these solutions is a common and potentially dangerous procedure, since health workers may handle the sharp instruments soaked in these solutions with a false sense of security.

Methods Of Control

Hepatitis B Vaccine. In 1982 a safe, immunogenic and effective HB vaccine was licensed in the U.S. and was recommended for use in healthcare workers with blood or needle exposure in the workplace (Ex. 6–199). A second vaccine, produced in yeast by recombinant technology was licensed in 1987, and additional vaccine licenses are expected in the near future (Ex. 6–200). In 1988, CDC estimated that 1.4 million persons have received these vaccine in the U.S., and an estimated 85% of them have been healthcare workers. It is estimated that 30% to 40% of high-risk healthcare workers have been vaccinated in this country (Ex. 6–200). HB vaccination is the most important part of any HBV control program. Gloving and other protective devices cannot prevent puncture injuries from needles and other sharp instruments. Only virtually complete immunization of workers at risk of HBV infection will provide acceptable control of this occupational hazard.

Early efforts to immunize healthcare workers were hindered by fear that the plasma derived vaccine might be unsafe. The AIDS epidemic was just being recognized, and there was concern that the plasma derived HB vaccine might contain the infectious agent causing AIDS. Concerns about the safety of the plasma derived vaccine have been adequately studied and addressed (Ex. 6–199). The procedures used to manufacture the vaccine were shown to inactivate HIV virus and representatives of all known viral groups. The vaccine was shown not to contain HIV DNA, and those receiving vaccine do not develop anti-HIV antibodies. Finally, intensive surveillance of reported AIDS cases revealed that all of those cases who had received vaccine were also members of known AIDS high risk groups, such as homosexually active men or IV drug users. The yeast-derived vaccines contain no human plasma and there is no possibility that they could be infectious for HIV (Ex. 6–200).

The currently licensed HB vaccines are given in three doses over a six month period. These vaccines induce protective antibody levels in 85% to 97% of healthy adults. Protection against both the illness and the development of the carrier state lasts at least seven years (the duration of follow-up studies), although antibody in many individuals will decay below detectable levels within seven years after immunization. (Ex. 6–200, Ex. 6–435). If these individuals are exposed to HBV, they develop a rapid (anamnestic) antibody response and do not become ill or develop the HBV carrier state. The ACIP has not currently recommended that a booster dose of HB vaccine be given after the initial series but may do so in the future if significant breakthrough infections occur in vaccinated individuals.

Persons planning HB vaccine programs may consider the need for prevaccination and post-vaccination testing for antibody (Ex. 6–200, Ex. 6–199). Prevaccination testing for antibody to identify previously infected individuals who do not need vaccine is

a requirement of the proposed standard. This prescreening is often cost-effective, depending on the likelihood of prior HBV infection and the costs of testing and vaccination. An algorithm to assist with this determination has been published by the ACIP (6–199). Discussions on the issues surrounding the option of post-vaccination testing have also been published; and at this time post-vaccination testing is not considered necessary unless poor response to vaccine is anticipated.

Post-Exposure Prophylaxis

Percutaneous and mucous membrane exposures to blood occur and will continue to occur in the healthcare setting (Ex. 6–431, 6–468). HBV infection is the major infectious risk that occurs from these exposures, and needlesticks from HBsAg positive individuals will infect 7% to 30% of susceptible healthcare workers (Ex. 6–27, Ex. 4–28). Fortunately, effective post-exposure prophylaxis exists for HBV exposures if appropriate protocols are followed. Hepatitis B Immune Globulin given in two injections one month apart is about 75% effective in preventing clinical hepatitis B if it can be given within seven days of an HBsAg positive needlestick. The addition of HB vaccine may substantially increase the post-exposure efficacy over that of HBIG alone and will also provide long term protection (Ex. 6–199). HB vaccine is recommended for any previously unvaccinated healthcare worker who has a needlestick or other percutaneous accident with a sharp instrument.

Non-A, non-B Hepatitis. Non-A, non-B hepatitis in the United States is caused by more than one viral agent, and remains a diagnosis of exclusion (Ex. 6–437, Ex. 6–429, Ex. 6–449). Despite intensive research over the last decade, little progress was made in identifying the causative agents, and no serologic (blood) test is available to detect or study this infection directly. Nevertheless, in the past year, a candidate virus has been detected, and intensive work to verify this as the major non-A, non-B virus and to develop serologic tests is underway. Availability of direct tests will help in clearly defining the importance of bloodborne transmission of this virus in the workplace (Ex. 6–502, Ex. 6–503).

Non-A, non-B viruses cause between 15–35% of acute hepatitis cases in the United States, primarily in adults (Ex. 6–47, Ex. 6–39). The principal mode of transmission in the United States is bloodborne; major risk groups are IV drug users and transfusion recipients, who account for 40% of cases. Over 90% of post-transfusion hepatitis is due to the non-A, non-B virus(es), and an estimated 3–8% of healthy blood donors appear to chronically carry this virus (Ex. 6–429, Ex. 6–449). Non-A, non-B hepatitis viruses cause not only acute hepatitis, but also chronic hepatitis; 40–60% of infections lead to development of chronic hepatitis, with potential for progression to cirrhosis and for infectivity to others for the duration of life (Ex. 6–429, Ex. 6–449). The amount of virus present in the blood of acutely or chronically infected persons is modest, usually < 1000 infectious doses per milliliter, although occasionally up to 1000 times higher (Ex. 6–423). Thus, relative infectivity of blood is 100 to 100,000 fold lower than with hepatitis B virus. Relative infectivity of other body fluids is not known.

The predominant mode of non-A, non-B transmission in the U.S. is, like that of HBV, bloodborne, and some evidence indicates that non-A, non-B hepatitis also presents an occupational risk to healthcare workers. About 5–9% of non-A, non-B cases occur in persons who work in healthcare professions, and in one study such persons were at significantly elevated risk of infection (Ex. 6–39, Ex. 6–47; Ex. 6–217). In addition, at least one episode of transmission of non-A, non-B hepatitis from an acutely infected patient to a nurse by needlestick has been reported (Ex. 6–455). Furthermore, non-A, non-B hepatitis transmission from infected patients to other patients and to staff has been reported from hemodialysis units; several outbreaks have been observed in this setting, and an incidence of 1.8% of non-A, non-B hepatitis among hemodialysis patients nationwide was observed in 1983 (Ex. 6–462, Ex. 6–386). While pathways of transmission in this setting have not been rigorously documented, bloodborne transmission by environmental contamination, similar to that of HBV, can be presumed to occur.

Given the facts that non-A, non-B hepatitis in the United States is largely due to a bloodborne virus, that between 3–8% of healthy persons likely are virus carriers, and that up to 50% of infections may progress to chronic liver disease, non-A, non-B hepatitis must be considered a potentially important risk in the workplace. The evidence of lower concentration of virus in blood of infected persons, and paucity of data clearly demonstrating this as an occupational illness of healthcare workers suggest it is likely to be less important than HBV; nevertheless, availability of specific tests in the next few years may better address the magnitude of risk.

Because the primary mode of transmission is bloodborne, and a large asymptomatic carrier reservoir exists, precautions to prevent non-A, non-B hepatitis transmission in the workplace are identical for those of other bloodborne viruses such as HBV (Ex. 6–461, Ex. 6–74, Ex. 6–426). Several studies have evaluated the efficacy of immunoglobulin (IG) prophylaxis following parenteral exposure, but results have been equivocal (Ex. 6–447, Ex. 6–436). Nevertheless, the CDC considers it reasonable to give IG as treatment to a healthcare worker after percutaneous exposure to blood from a known non-A, non-B infected patient (Ex. 6–199).

C. Human Immunodeficiency Virus

Introduction

In June of 1981, the first cases were reported in the United States of what was to become known as Acquired Immunodeficiency Syndrome (AIDS) (Ex. 6–382). Investigators described a new clinical entity characterized by *Pneumocystis carinii* pneumonia (PCP) and Kaposi's sarcoma (KS) that had developed in young, homosexual men without a known underlying disease or a history of immunosuppressive therapy (Ex. 6–359, Ex. 6–380).

By early 1982, 159 AIDS cases had been identified in 15 states, the District of Columbia and 2 foreign countries. All but 1 of these were men, over 92% of whom were homosexual or bisexual (Ex. 6–359). By the end of 1982, cases of AIDS were reported among children (Ex. 6–380), intravenous (IV) drug users (Ex. 6–380), blood transfusion recipients (Ex. 6–380), hemophilia patients treated with clotting factor concentrates (Ex. 6–380), and Haitians (Ex. 6–349). In 1983 the disease was also documented among female sexual partners of male IV drug users in the U.S. and among Africans (Ex. 6–349). By the close of 1985, all 50 states, the District of Columbia and three U.S. territories had reported AIDS cases (Ex. 6–359).

During 1983 and 1984, French and American scientists independently isolated a human virus associated with AIDS. Dr. Luc Montagnier and co-workers, of the Institut Pasteur in Paris, called it lymphadenopahty associated virus (LAV). Dr. Robert Gallo and co-workers at the National Cancer Institute identified this virus as human T-cell lymphotropic virus type III (HTLV–1) (Ex. 6–380). Eventually human immunodeficiency virus type 1 (HIV–1) became the universally accepted term for the virus (Ex. 6–383). (In this

document, unless specifically noted, HIV refers to HIV–1.)

The Centers for Disease Control estimates that in the United States, between 1 million and 1.5 million persons are infected with HIV–1 (Ex. 6–356). As of February, 1989, 88,096 cases of AIDS had been reported to the CDC, at least 50,670 (57.5%) of whom had died (Ex. 6–478). Although the rate of spread of HIV–1 in the future is unknown, scientists with the U.S. Public Health Service (Ex. 6–356) have estimated that in the United States alone, a cumulative total of more than 365,000 cases of AIDS will have been reported by 1992 with 80,000 new cases diagnosed during that year. It is projected that there will be 66,000 deaths that year and 263,000 cumulative deaths. It is expected that a total of 172,000 AIDS patients will require medical care in 1992.

Of perhaps greater importance for healthcare workers is the 1 million-1.5 million persons who are infected with HIV, often unknowingly so, and who require medical treatment for unrelated conditions. For example, in a study examining 203 anonymous serum samples from a group of critically ill or severely injured patients treated at the Johns Hopkins University Hospital Department of Emergency Medicine (serving many indigent patients in an urban area), Baker and co-workers (Ex. 6–111) found HIV antibody in 3% as detected by both enzyme-linked immunoassay (EIA) and Western blot. In a subgroup of this population, trauma victims between the ages of 25 and 34, 16% were seropositive for HIV. These individuals were bleeding and their treatment involved multiple invasive procedures. In a more recent study at an inner city emergency department, Kelen and co-workers tested blood samples from 2,302 consecutive adult patients for the presence of HIV antibodies. One hundred and nineteen patients (5.2%) were seropositive for HIV, 92 (4%) of whom had "unrecognized HIV infection" (Ex. 6–370).

There are published reports of 25 healthcare workers who apparently were infected with HIV through occupational exposure to blood or other potentially infectious materials. Some infections are likely to go unrecognized for several years until the HIV-infected individual develops AIDS. The number of documented HIV seroconversions among healthcare workers is low at present. However, if effective preventive procedures are not instituted, it is likely to increase as the number of infected individuals requiring healthcare increases.

The increasing number of individuals with AIDS, the large number of unidentified HIV infections, and the reports of occupational infection all indicate that healthcare workers are at risk for occupationally acquired HIV infection.

The Virus

HIV is a member of a group of viruses known as human retroviruses. Its genetic material is ribonucleic acid (RNA) rather than deoxyribonucleic acid (DNA), the genetic material found in most living organisms. The virus particle is comprised of a core containing the RNA and viral enzymes surrounded by an envelope consisting of lipids and proteins (Ex. 6–380, pp. 131–154).

Because they lack the cellular machinery necessary to reproduce, all viruses must reproduce intracellularly, that is, within the host cell. HIV replicates in human macrophages and T4 lymphocytes, two types of human cells that are vital components of the immune system. T4 lymphocytes and a few other cell types have protein molecules on their surfaces called CD4 antigens or receptors. HIV particles bind with the CD4 receptor sites of the hosts' cells and then release their viral RNA. The RNA is then transcribed by viral enzymes into double-stranded DNA that is incorporated into the DNA of the host cell. The viral DNA then serves as a template to produce more virus particles. The transcription of RNA to DNA is the reverse of what occurs in most organisms and thus HIV is called a retrovirus. The process occurs with the aid of the viral enzyme reverse transcriptase, which is considered to be a marker for retrovirus production (Ex. 6–384; Ex. 6–175; Ex. 6–380, pp. 186–249).

HIV gradually depletes the number of cells which are essential for host immune function, rendering the infected individual increasingly susceptible to opportunistic infections (Ex. 6–360; Ex. 6–380, pp. 131–154).

Circulating macrophages are also considered a reservoir as well as another target for HIV infection. Since some macrophages can circulate freely throughout the body, they may actually transport HIV to the brain which may lead to neurologic complications (Ex. 6–384).

Serologic Testing

Infection with HIV may be identified through testing the blood for the presence of HIV antibodies. Tests were first licensed for use in the United States in 1985 (Ex. 6–380, pp. 1–17) and have been used routinely to screen donated blood, blood components and blood products, and by physicians and clinics to diagnose HIV infection in patients. The military also uses the antibody tests to screen recruit applicants and active duty personnel for HIV infection (Ex. 6–380, pp. 1–17). Although the antibodies do not appear to defend or protect the host against HIV, they serve as markers of viral infection. Most people infected with HIV have detectable antibodies within 6 months of infection, with the majority generating detectable antibodies between 6 and 12 weeks (Ex. 6–204). There have been a few reports of seroconversion as late as 14 months after infection (Ex. 6–183).

The enzyme-linked immunosorbent assay (ELISA or EIA) technique used to detect HIV antibodies is sensitive, economical and easy to perform. However, as with all laboratory determinations, this test can produce a false positive result, that is, the test gives a positive result when HIV antibody is not present. Therefore, current recommendations include repeating the ELISA test if the first test was positive. If the second test is also positive, a more specific test, usually employing the Western blot technique, is used to validate the ELISA results. A positive ELISA test and a positive Western blot result indicate the presence of HIV antibodies and HIV infection (Ex. 6–345).

Although many new tests are still in the experimental stages, one that is being developed uses the polymerase chain reaction (PCR) technique. This test detects integrated viral DNA rather than antibody and it may have the potential to detect the HIV infection earlier than currently available antibody tests (Ex. 6–329).

Transmission

HIV has been isolated from human blood, semen, breast milk, vaginal secretions, saliva, tears, urine, cerebrospinal fluid, and amniotic fluid; however, epidemiologic evidence implicates only blood, semen, vaginal secretions and breast milk in the transmission of the virus (Ex. 6–317).

Documented modes of HIV transmission include: engaging in sexual intercourse with an HIV-infected person; using needles contaminated with the virus; having parenteral, mucous membrane or non-intact skin contact with HIV-infected blood, blood components or blood products (Ex. 6–349); receiving transplants of HIV-infected organs and tissues including bone (Ex. 6–327, Ex. 6–310), or transfusions of HIV-infected blood (Ex. 6–349); and perinatal transmission (from mother to child around the time of birth) (Ex. 6–349).

HIV is not transmitted by casual contact. Studies evaluating nearly 500 household contacts of individuals diagnosed with AIDS reveal no cases of HIV infection of household members who had no other risk factors for the virus (including no sexual contact with or exposure to blood from the infected person) (Ex. 6–349). Friedland and Klein (Ex. 6–349) examined household members who lived with a person with AIDS for at least 3 months and within an 18-month period prior to the onset of symptoms in the infected person (during which time infection was presumably present.) Other household members had been unaware of the infected individual's HIV status, and had not taken precautions during this time period. This study produced no evidence that HIV was transmitted by shaking hands or talking, by sharing food, eating utensils, plates, drinking glasses or towels, by sharing the same house or household facilities or by "personal interactions expected of family members" including hugging and kissing on the cheek or lips. Other studies have shown that HIV is not transmitted by mosquitoes or other animals (Ex. 6–328).

The vast majority of people with AIDS in the United States can be placed in known transmission categories and the proportion of infected persons associated with each group has remained relatively stable since reporting began in this country in 1981. For adults and adolescents, the transmission categories are shown in Table 1.

TABLE 1 [1].— AIDS TRANSMISSION CATEGORIES

Transmission Group	Percent of cumulative total AIDS cases
Homosexual/bisexual men	62%
Intravenous drug users	20%
Homosexual/bisexual men who are also IV drug users	7%
[2] Heterosexual persons	4%
Transfusion recipients	3%
Persons with hemophilia/coagulation disorders	1%
[3] Undetermined	3%

[1] AIDS Weekly Surveillance Report U.S., November 14, 1988 (Ex. 6–379).

[2] Includes persons who have had heterosexual contact with a person with AIDS or at risk for AIDS or who have no other identified risks but were born in countries in which heterosexual transmission is believed to play a major role although the precise means of transmission have not been fully defined.

[3] Includes persons for whom risk information is incomplete due to death, refusal to be interviewed or loss to follow-up, patients still under investigation, men reported only to have had heterosexual contact with a prostitute, interviewed patients for whom no specific risk was identified and one healthcare worker who seroconverted to HIV and developed AIDS after a documented needlestick exposure to blood.

In the U.S., more than 1,000 cases of AIDS have been reported in children (Ex. 6–364). Most (78%) of the cases are children born to mothers infected with the virus (Ex. 6–364, Ex. 6–349). These mothers transmit the virus to their children prenatally, during birth or during infancy through breast-feeding although the latter is rare (Ex. 6–349). Other cases in children are in hemophiliacs (6%) and transfusion recipients (13%) (Ex. 6–349).

Although the efficiency for most routes of HIV transmission is unknown, some routes of transmission are clearly more efficient than others. The risk of infection from receipt of transfused blood from an HIV-infected donor is approximately 90% (Ex. 6–371). The risk of perinatal transmission from an HIV infected mother is estimated to be 30–50% or higher (Ex. 6–384, Ex. 6–349). Besides the particular route of transmission, other variables contributing to transmissibility may include susceptibility of the host, the virulence of the particular "HIV isolate" or strain, the stage of infection of the source, and the dose of virus and the size of inoculum transmitted (Ex. 6–348, Ex. 6–349). This last factor, the actual amount of virus, may be very important in the likelihood of transmission since it appears there is a greater probability of infection from HIV contaminated blood transfusions (890 infections per 1,000 persons transfused with contaminated blood) than from accidental needlesticks with needles that have been contaminated with HIV (3–5 infections per 1,000 persons injured with contaminated needles) (Ex. 6–384; Ex. 6–349; Ex. 6–371).

Human Immunodeficiency Virus Type–2

A case of AIDS in a person from Africa, caused by another human retrovirus, human immunodeficiency virus type 2 (HIV–2), was diagnosed and reported in the United States in December, 1987 (Ex. 6–308). HIV–2 appears to be similar to HIV–1 in modes of transmission and natural history but has not yet been studied in as much detail. Although HIV–2 is unquestionably pathogenic, there is still much to be learned regarding its epidemiology, pathogenesis and efficiency of transmission. Although only one case of HIV–2 has been reported in the United States, the infection is endemic in West Africa, where it was first linked with AIDS in 1986. There have also been cases of HIV–2 infection reported among West Africans living in Europe.

Serologic tests licensed for detecting HIV–1 can detect only 42–92% of HIV–2 infections, but HIV–2 surveillance is being conducted in the United States to monitor the frequency of occurrence using specific tests not yet available commercially (Ex. 6–308).

Clinical Manifestations of Disease

HIV adversely affects the immune system, rendering the infected individual vulnerable to a wide range of clinical disorders. These conditions, some of which tend to recur, can be aggressive, rapidly progressive, difficult to treat, and less responsive to traditional modes of treatment. They usually lead to the death of the HIV-infected patient (Ex. 6–361). The CDC has divided the disease progression into several stages, depending on the type of signs or symptoms of infection. The order of groups appears to follow a basic pattern or chronology of disease regardless of mode of transmission (Ex. 6–270).

Group I: Within a month after exposure, an individual may experience acute retroviral syndrome, the first clinical evidence of HIV infection. This is a mononucleosis-like syndrome with signs and symptoms that can include fever, lymphadenopathy, myalgias, arthralgias, diarrhea, fatigue, and rash. Acute retroviral syndrome is usually self-limiting and followed or accompanied by the development of antibodies (Ex. 6–270).

Group II: Although most persons infected with HIV develop antibodies to the virus within 6–12 weeks after exposure, most of these individuals are asymptomatic for months to years following infection. However, they can transmit the virus to others throughout this time (Ex. 6–270).

Group III: Although no other signs or symptoms are experienced, some HIV-infected patients will develop a persistent, generalized lymphadenopathy (PGL) that lasts more than 3 months (Ex. 6–270).

Group IV: The clinical manifestations of patients in this group may vary extensively. Some of these HIV-infected patients may experience "constitutional disease," also known as HIV "wasting syndrome," which may be characterized by severe, involuntary weight loss, chronic diarrhea, constant or intermittent weakness, and fever for 30 days or longer (Ex. 6–270). This syndrome in and of itself may result in death.

Epidemiologic information indicates that most persons who are infected with HIV will eventually develop AIDS (Ex. 6–384). AIDS can result in severe opportunistic infections that an individual with a normal immune

system would only rarely experience, as well as a wide range of neurologic and oncogenic or neoplastic processes (Ex. 6–270). Individuals with AIDS may develop HIV encephalopathy, dementia, myelopathy or peripheral neuropathy. This may occur when HIV infects mononuclear cells present in the cerebrospinal fluid surrounding the brain and spinal cord or infects these cells within the brain or spinal cord. Persons with dementia experience varying degrees of cognitive disability or impairment of intellectual function and motor disability or dysfunction. Effects ranging from apathy and depression to memory loss and severe dementia may interfere with a person's occupation as well as activities of daily living and can ultimately be fatal (Ex. 6–380, pp. 548–578; Ex. 6–270). In addition, the virus is capable of affecting the peripheral nervous system causing severe pain and weakness or numbness in the limbs (peripheral neuropathy) (Ex. 6–270).

According to CDC's case definition (Ex. 6–157), there are specific diseases that are considered indicators of AIDS if laboratory tests for HIV were not performed or gave inconclusive results and no other known causes of immunodeficiency are present. Among these are parasitic diseases such as *Pneumocystis carinii* pneumonia, the most common opportunistic infection and cause of death in AIDS patients; fungal diseases such as candidiasis of the esophagus, trachea, bronchi or lungs; viral diseases such as cytomegalovirus disease of an organ other than the liver, spleen or lymph nodes; cancer/neoplastic diseases such as Kaposi's sarcoma affecting persons under 60 years of age; and bacterial infections such as *Mycobacterium avium* complex (Ex. 6–157; Ex. 6–361).

In addition to the diseases listed above there are diseases caused by organisms such as disseminated or extra-pulmonary *Mycobacterium tuberculosis* (TB) which may be considered indicative of AIDS if substantiated by reactive HIV-antibody tests (Ex. 6–157).

Unlike adults, children under 13 years of age can be classified as having AIDS if they experience lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia (LIP–PLH complex). Children who are seropositive for HIV can be classified as having AIDS if they experience recurring serious bacterial infections such as septicemia, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity caused by *Haemophilus, Streptococcus* or other pyogenic bacteria (Ex. 6–157).

AIDS is primarily managed by treating clinical disease symptoms, but conventional therapy cannot reverse the immunodeficiency (Ex. 6–361). Currently, researchers are testing experimental drugs and conducting a number of treatment protocols on patients at various stages of infection or disease. At this time, only one antiviral drug, Zidovudine or Retrovir TM, (formerly known as azidothymidine or AZT) has been approved by the FDA for some patients, specifically those who have experienced *Pneumocystis carinii* pneumonia (PCP), or are symptomatic for AIDS-related illness and have less than 200 T4 cells/ml (Ex. 6–479). Although some patients have had to discontinue the drug due to severe side effects, clinical trials have shown the drug to prolong the life of AIDS patients (Ex. 6–383, pp. 153–165). There is no vaccine to prevent HIV infection (Ex. 6–384).

Occupational Exposure And HIV Infections

Occupational transmission of HIV has been documented in healthcare workers. Twenty-five cases of HIV infection associated with occupational exposure are summarized below. These cases represent a spectrum of healthcare personnel including, among others, nurses, laboratory workers and a dentist. In 16 of these cases exposure to the blood of HIV infected individuals occurred by needlestick. Two infections were believed to have resulted from cuts with sharp, HIV-contaminated objects. In 7 cases, exposure occurred via mucous membrane or non-intact skin. Two workers were exposed to highly concentrated volumes of HIV; 1 by a cut with a sharp, HIV-contaminated object and 1 through skin exposure.

For the 25 cases, HIV status was determined by HIV-antibody testing. Baseline serologic data indicating a non-reactive HIV-antibody status post-exposure was available for at least 18 of the individuals, all of whom were later determined to have seroconverted to an HIV-antibody-positive status. All 25 denied other known risk factors for HIV infection, but in cases where the baseline serologic data were unknown, other modes of transmission cannot be ruled out. Nevertheless, all cases were investigated for risk factors and none were identified. In addition to these cases, as of September 1988 there were at least 44 healthcare workers with AIDS for whom no risk factors have been identified after thorough investigation (Ex. 6–378), providing further, though not as strong, evidence of occupational transmission .

Case Reports

Case 1: A hospital healthcare worker sustained an accidental self-inflicted injection of "several milliliters of blood while obtaining blood in a vacuum collection tube from an AIDS patient" (Ex. 6–365). The healthcare worker subsequently seroconverted to an HIV-antibody-positive status and has since developed AIDS. Having determined there were no other HIV risk factors for this individual, investigators concluded the worker acquired the infection occupationally.

Case 2: In November 1985, a previously healthy, 33 year old United States Navy hospital corpsman punctured his fingertip while disposing of a phlebotomy needle used to draw blood from a patient who was later diagnosed with *Pneumocystis carinii* pneumonia and serologically tested HIV-positive (Ex. 6–337). Upon learning of this diagnosis two weeks after the incident, the corpsman submitted to HIV serology testing on a monthly basis and was HIV-negative for 3 months. Five months after the incident, he experienced a characteristic acute retroviral syndrome, which was self-limiting. Six months after the incident he tested HIV-positive. He reported a negative history of other risk factors for HIV, and his wife was seronegative.

Case 3: Weiss and co-workers (Ex. 6–187) reported that a laboratory worker, who worked with concentrated HIV–1, tested seropositive for the virus (See EPIDEMIOLOGIC STUDIES). Clinical evaluation revealed no signs or symptoms of HIV-related illness. As part of routine laboratory duties, this individual was involved in several possible exposure circumstances such as decontaminating equipment, cleaning up spills or touching potentially contaminated surfaces with gloved hands. Virus-positive culture fluid had occasionally leaked from equipment and contaminated centrifuge rotors. Although reportedly using Biosafety level 3 precautions, the subject was not fully knowledgeable with and did not strictly follow these practices all of the time.

The subject did not recall any direct skin exposure but did report having had a nonspecific dermatitis on the arm, although the "affected area was always covered by a cloth laboratory gown." The individual also reported incidents where he had pinholes or tears in his gloves and had to change them immediately.

Strains of HIV–1 isolated from different individuals generally differ significantly, but the HIV–1 isolated from this subject was indistinguishable from 1 of the 2 predominant HIV genotypes this individual worked with in the laboratory.

Although no specific exposure incident had been identified, the investigators concluded that the subject acquired the HIV infection in the laboratory, most likely through undetected skin contact with the concentrated virus.

Case 4: A female phlebotomist reported that blood splattered on her face and in her mouth when the top of a 10-ml vacuum blood collection tube flew off while she was collecting a patient's blood (which subsequently tested HIV-positive) (Ex. 6–109). The HCW was wearing gloves and glasses and reported that no blood got in her eyes. She reported no open wounds but did have facial acne. She washed off the blood immediately after exposure. Her blood tested HIV-negative one day post-exposure and 8 weeks later. However, when donating blood 9 months after exposure, she was HIV-antibody positive. She denied having other known risk factors for HIV.

Case 5: A female medical technologist was exposed to a blood spill that covered most of her hands and forearms while she was manipulating an apheresis machine (Ex. 6–109), a machine that separates blood components, retains some, and returns the remainder to the donor. Although she was not wearing gloves, she did not report any open wounds on her hands or any mucous membrane exposure. However, she did have dermatitis on her ear and may have touched that ear. Eight weeks after the incident she experienced symptoms of acute retroviral syndrome. She was HIV-negative 5 days post exposure; however, 3 months after exposure she was HIV-antibody positive. She denied having other known risk factors for AIDS. Her husband also denied any risk factors for AIDS and tested HIV-seronegative.

Case 6: Neisson-Vernant and co-workers (Ex. 6–93) reported that a "24-year-old female student nurse pricked the fleshy part of her index finger with a needle used to draw blood from an AIDS patient." She did not recall injecting blood. Two months later signs and symptoms of acute retroviral illness appeared, including fever and a macular eruption lasting 3 days. Although she tested HIV-negative 1 month after the incident, she tested positive 6 months after exposure. She denied all other risk factors for HIV and her husband tested HIV negative 6 and 9 months after her exposure.

Case 7: Michelet and co-workers (Ex. 6–369) reported a case of occupationally acquired HIV infection in a female nurse in France. Having drawn a blood sample in a vacuum tube from an individual with AIDS, she stuck her finger with the large-bore needle of the adapter, but reportedly did not inject any blood. Immediately after the incident, she placed her finger in 0.5% sodium hypochlorite solution in accordance with the hospital's guidelines. Twenty-three days after exposure, she developed signs and symptoms of acute retroviral syndrome, including abdominal cramps, nausea, vomiting, and diarrhea. She later experienced anorexia, fatigue and facial palsy. Clinical evaluation found generalized lymphadenopathy. Although she tested HIV-antibody negative 13 days after the incident she was HIV-antibody positive 71 days post-exposure. Investigators failed to identify any risk factor for HIV for the nurse or her husband, who tested HIV-antibody negative 62 days after his wife's exposure incident.

Case 8: An NIH clinical laboratory worker sustained a cut that penetrated through a glove and the skin when a vial of HIV-infected blood broke in the worker's hand (Ex. 6–348). Although initially testing negative, the individual subsequently tested positive and investigators have linked the infection with the accident.

Case 9: Oksenhendler and co-workers (Ex. 6–18) reported that a female nurse in France stuck her finger superficially while recapping a needle contaminated by bloody pleural fluid from a patient positive for both HBsAg and HIV. Immediately post-exposure she received the HBV vaccine and specific immunoglobulins. She experienced acute retroviral syndrome including fever, fatigue and vomiting 25 days after the incident. Fifty-three days after exposure, she developed an acute "anicteric" hepatitis (possibly related to the primary HIV infection.) Although she tested HIV-negative after the exposure (days 1 and 13), she tested HIV-positive on day 68. She and her husband denied other known risk factors for HIV and her husband tested seronegative for HIV 110 days after the incident.

Case 10: A nurse from England received a needlestick injury to a finger while resheathing a hypodermic needle on a syringe containing an AIDS patient's blood from an arterial line (Ex. 4–41). A small amount of blood may have been injected as well. Signs and symptoms of acute retroviral syndrome presented 13 days after exposure with a rash developing 17 days after the incident.

Although she tested HIV-negative 27 days post injury, she was determined to be HIV-positive on day 49. She denied other known risk factors for HIV.

Cases 11, 12 and 13: Marcus and co-workers (Ex. 6–372) reported 3 cases of healthcare workers who seroconverted to an HIV-antibody-positive status. One healthcare worker sustained a deep needlestick injury inflicted by a co-worker with a 21-gauge needle while attempting to resuscitate an AIDS patient. The healthcare worker was HIV-antibody and antigen negative the day after the exposure. Four weeks after the incident the worker experienced fever, "shaking chills," night sweats, lymphadenopathy, and malaise which lasted about 4 days. One hundred twenty-one days after the exposure the worker tested HIV-seropositive. The healthcare worker denied other known risk factors for HIV and a recent sex partner tested HIV-seronegative.

A second healthcare worker accidentally stuck herself on two occasions with needles that had been used on HIV-infected patients. The first exposure occurred while recapping a needle that had been used on a patient with AIDS. Ten days later the worker stuck herself with a needle that had been used to draw blood from a symptomatic HIV-infected individual. "After removing the tube of blood from the plastic needle holder, the healthcare worker placed the needle holder upright on its base, such that the needle was pointed vertically into the air. The healthcare worker then turned away and subsequently injured herself on the exposed needle." The worker tested positive for HIV-antibody and antigen 21 after the first exposure (11 days after the second.) She developed an acute viral illness four weeks after the first incident, characterized by shaking chills, dehydration, nausea, malaise, bilateral lymphadenopathy and a weight loss of more than 10 pounds. During this illness she was HIV-antibody negative; however, lymphocyte cultures were positive for HIV-antigen and reverse transcriptase, an enzyme which serves as a marker for HIV. The healthcare worker tested HIV-antibody positive on day 121 after the first exposure (111 days after the second exposure.) Four months after the exposure incidents, the worker's spouse tested HIV-antibody negative (See EPIDEMIOLOGIC STUDIES).

A third case, a healthcare worker, received a deep intramuscular needlestick injury with a large bore needle and syringe unit visibly contaminated with blood from an AIDS patient (Ex. 4–39, Ex. 6–367). Fourteen days after the incident, acute retroviral syndrome developed. Although HIV-antibody negative 9 days post-exposure, the healthcare worker was determined HIV-antibody positive on day 184. The worker and the worker's spouse denied

any other risk factors for AIDS and the spouse tested HIV-antibody negative 239 days after the incident (See EPIDEMIOLOGIC STUDIES).

Case 14: Marcus and co-workers (Ex. 6–372) and McCray and co-workers (Ex. 4–39) reported a case where a female nurse received a puncture wound from a colonic biopsy needle (visibly contaminated with blood and feces) used in an AIDS patient. She tested HIV-positive approximately 10 months after exposure although there were no serologic baseline data before or immediately after the incident. She denied other risk factors for AIDS; however, her sexual partner also tested HIV-positive and heterosexual transmission therefore cannot be ruled out.

Case 15: Gerberding and co-workers (Ex. 6–375) reported a case of a healthcare worker who acquired HIV infection after sustaining a deep needlestick injury with an HIV-contaminated needle (See EPIDEMIOLOGIC STUDIES).

Case 16: Ramsey and co-workers (Ex. 6–373), conducted a prospective evaluation of 44 healthcare workers exposed to HIV and reported that one healthcare worker seroconverted to an HIV-antibody positive status after sustaining a needlestick from an HIV-contaminated needle. The worker had been followed for at least 90 days after the exposure incident and had not reported any signs or symptoms of acute-retroviral illness.

Case 17: Gioannini and co-workers (Ex. 6–334) reported that a 37-year-old intensive care nurse in Italy "had her hands, eyes and mouth heavily splashed" with blood from an HIV-infected hemophiliac. Beginning 11 days post-exposure, the nurse developed signs and symptoms of acute retroviral illness including fever, fatigue, chills, arthralgias, cervical and axillary lymphadenopathy and arthritis. She was hospitalized 18 days after the incident due to the severity of her symptoms plus progressive increases of aminotransferase levels. During her 55 day hospital stay the worker developed an acute, anicteric nonA-nonB hepatitis, which may have been associated with HIV infection. HIV antigen was detected in her blood on day 21 and by day 43 she had seroconverted to an HIV-antibody-positive status.

Case 18: A 32-year-old mother tested HIV-positive subsequent to providing extensive healthcare to her male child with a "congenital intestinal abnormality" (Ex. 4–37). Having received multiple blood transfusions (one of which was from an HIV-positive source) the child was tested and determined HIV-positive at 24 months of age. Although the mother did not report any needlestick or other parenteral exposure to the child's blood, she recalled having had frequent hand contact with the child's blood and body fluids. She did not wear gloves and did not wash her hands immediately after exposure. She did not report having open wounds or exudative dermatitis on her hands. One month after the child tested HIV-positive, the mother was determined to be seronegative for HIV. However, 4 months later she was determined to be HIV-antibody-positive. She reported a negative history for other risk factors for HIV for herself and the child. The child's father was seronegative for HIV. Investigators concluded the mother most probably acquired the infection by providing her infected child healthcare that involved extensive exposure to blood and body fluids without using infection control practices.

Case 19: A laboratory worker apparently became infected in a laboratory accident (Ex. 6–187, Ex. 6–368, Ex. 6–312). He handled large volumes of HIV in a high containment laboratory under contract with NIH, performed techniques to concentrate the virus as part of a commercial process and reportedly followed biosafety guidelines. He was tested and found to be HIV-seropositive. The lab worker was not informed of his HIV status until 16 weeks after he tested HIV-positive. At that time, he recalled having cut his finger with a blunt stainless steel needle while cleaning a piece of contaminated equipment. He had tested HIV-negative 4 to 6 months prior to the laboratory incident but tested HIV-positive 6 to 9 months post exposure. Biosafety officials were of the opinion that the accident probably caused the infection. The laboratory worker has not participated in any studies that could determine whether he is infected with a laboratory strain of HIV.

Case 20: Klein and co-workers (Ex. 6–366) reported a male dentist who had tested HIV-seropositive (See EPIDEMIOLOGIC STUDIES.). He denied having other risk factors for the virus. Although he did not recall treating a patient with AIDS, he had treated patients at high risk for HIV infection. He reported having frequent open lesions or "obvious breaks in the skin" on his hands; however, he only intermittently used personal protective equipment. His wife, although refusing to be tested for HIV, denied other HIV-risk factors. There was no report of baseline or convalescent serology and exposure to HIV-positive blood cannot be documented (See EPIDEMIOLOGIC STUDIES).

Case 21: A healthcare worker applied pressure to an HIV-infected patient's arterial catheter insertion site to stop bleeding (Ex. 6–109). During the procedure, she may have had a small amount of blood on her index finger for 20 minutes before washing her hand. She did not wear gloves during this procedure and although she reported no open wounds, her hands were chapped. Twenty days after exposure, she developed symptoms of acute retroviral syndrome lasting 3 weeks. Blood she had donated 8 months prior to the exposure was HIV-negative. However, blood donated 16 weeks after the incident was HIV-positive. She denied having other known risk factors for HIV. No baseline data or serologic testing results were obtained immediately following exposure for this case.

Case 22: A female healthcare worker received accidental needlestick injuries when drawing blood from AIDS patients in two incidents separated in time by 4 months (Ex. 6–258). She had her first blood test for HIV 8 months after the second exposure and was found HIV-positive. Although previously healthy, she developed a persistent mild lymphadenopathy 3 months after the second incident and intermittent diarrhea which started 5 months after that incident. She denied other HIV risk factors. Her long-term sex partner also denied any HIV risk factors, and he repeatedly tested HIV-antibody-negative over an 8-month period following the healthcare worker's positive test result. HIV was obtained from the man's peripheral lymphocytes within 13 months after the second incident but could not be obtained several months later. Heterosexual transmission could not be ruled out for the healthcare worker but seems less likely than parenteral transmission in this case.

Case 23: A male laboratory worker, was found to be HIV-positive when first tested (Ex. 6–258). The worker recalled having received 2 parenteral exposures to blood from persons of unknown HIV status. He sustained an accidental needlestick and a cut on the hand while processing blood 8 and 16 months respectively prior to being tested. Although asymptomatic when tested, he has experienced transient cervical lymphadenopathy. He denied all known risk factors for HIV, but heterosexual transmission could not be ruled out in this case as no serologic data were available immediately after the exposures.

Case 24: Grint and co-workers (Ex. 6–333) reported that a 44-year-old woman from England, although not a healthcare worker, developed AIDS after providing healthcare services for a Ghanaian man with a postmortem diagnosis of AIDS. She recalled having small cuts on her hands, an exacerbation of chronic eczema, and frequent skin contact with body secretions and excretions. There was no report of baseline or convalescent serology.

Case 25: Ponce de Leon and co-workers (Ex. 6–326) reported that a 39-year-old male laboratory technician in Mexico acquired AIDS occupationally and died as a consequence of this disease. From 1971 to 1986 he worked as a laboratory technician in a company that processed blood and blood products and where infection control procedures were not "customary." He reported experiencing many accidental punctures and blood contact with his "teguments and mucosa". The worker also recalled a laboratory accident "in late 1985 in which a deep cut in his right hand was grossly contaminated with plasma." Early in 1986 he experienced an acute illness characterized by fever and lymphadenopathy lasting several days. In 1987 the worker experienced a seven-month illness characterized by persistent diarrhea, weight loss, persistent oral thrush, intermittent fever, generalized lymphadenopathy, anisocoria and signs of meningitis. He eventually was hospitalized on December 11, 1987 two weeks after dizziness, mental confusion and vomiting enused. Tests revealed the presence of the opportunistic infection cryptococcosis. The worker tested HIV-antibody-positive and was diagnosed as having AIDS. The patient died on December 18, 1987. He had denied other risk factors for HIV and his wife was seronegative for HIV-antibody.

Epidemiologic Studies

A number of prospective studies and surveys have been conducted to determine occupational risks for HIV infection.

Marcus and co-workers (Ex. 6–372) reported that the Centers for Disease Control has been conducting a national prospective study beginning in 1983, to assess initially the risk of Acquired Immunodeficiency Syndrome and later, with the advent of HIV-antibody testing, the risk of Human Immunodeficiency Virus among healthcare workers exposed to the blood or body fluids of persons with HIV infection. In 1986, data were reported on the first 451 healthcare workers who had entered the study and had been tested for HIV antibody. Initially the eligibility criteria for entering the study included having been exposed to the blood or body fluids of a patient with AIDS or AIDS-related illness by a needlestick, a cut with a sharp object or contamination of an open wound or mucous membrane. However, as of October, 1987, the available information implicated exposure to HIV-contaminated blood as the most likely mode of transmission and therefore, subjects were enrolled only if they had had parenteral, mucous membrane or non-intact skin exposure to the *blood* of an *HIV-infected* individual.

As of July 31, 1988, a cohort of 1201 healthcare workers with exposure to HIV-contaminated blood was being followed. Of these, 751 (63%) were nurses, 164 (14%) were physicians or medical students, 134 (11%) were technicians or laboratory workers, 90 (7%) were phlebotomists, 36 (3%) were respiratory workers and 26 (2%) were housekeeping or maintenance staff. Upon enrollment the subjects provided investigators with epidemiologic data including demographic information, medical history, details of the exposure circumstances, infection control precautions used and post-exposure treatment. Nine hundred sixty-two (80%) of the subjects had sustained needlestick injuries, 103 (8%) had been cut with a sharp object, 79 (7%) had contaminated an open wound and 57 (5%) had had a mucous membrane exposure. Seven hundred seventy-nine (65%) of the exposed healthcare workers were exposed in a patient room, on a ward or in an outpatient clinic; 161 (14%) in an intensive care unit; 87 (7%) in an operating room; 84 (7%) in a laboratory; 62 (5%) in an emergency room; and 28 (2%) in a morgue.

Each subject was asked to complete a confidential questionnaire to identify nonoccupational risk factors for HIV infection. One thousand eighty-seven healthcare workers (91% of the cohort) completed the questionnaires. Of these, 6 men stated they were homosexual or bisexual, four reported using intravenous drugs since 1978 and 6 stated they had had sexual contact with a person known to be at risk for HIV infection. Their test results and evaluations were retained in the study, but none of them seroconverted.

The 1,201 subjects underwent physical examinations and blood samples were drawn and tested for the presence of HIV-antibodies. An EIA technique was employed and, if reactive, a Western blot technique was performed. Acute blood specimens collected within 30 days after exposure were obtained and tested from 622 subjects. Originally the subjects were followed up at 6-month intervals for a period of 3 years to detect signs of clinical AIDS. When HIV-antibody testing became available during 1985 and 1986, exposed healthcare workers were followed up at 6 weeks, 3 months, 6 months, and 12 months after the exposure incident to determine if seroconversion had occurred. Seroconversions were defined as healthcare workers who were seronegative for HIV antibody within 30 days after occupational exposure and seropositive 90 days or more after the exposure incident.

Nine hundred sixty-three subjects had been followed for at least 6 months, 860 (89%) of whom had sustained either a needlestick injury or a cut with a sharp instrument. Of these, four were seropositive yielding a seroprevalence rate of 4/860=0.47%. One of the four was first tested for HIV-antibody 10 months after sustaining a needlestick exposure to blood of an HIV-infected patient (see CASE 14). As there was no available acute blood specimen collected within 30 days after exposure this case cannot by definition be considered a seroconversion. The remaining 3 HIV-seropositive subjects (see CASES 11, 12, and 13) had HIV-seronegative acute blood specimens and were thus considered seroconversions, yielding a seroconversion rate of 3/860=0.35%.

Weiss and co-workers (Ex. 6–187), conducted a prospective study to assess the risk of Human Immunodeficiency Virus (HIV–1) in laboratory workers. Invitations to participate in the study were issued to workers with possible exposure risk in 15 laboratory facilities from 6 states.

Of the 265 subjects studied, 225 had laboratory exposure (including 99 who worked with concentrated HIV and 126 who worked with blood containing HIV, non-infectious viral proteins, or cloned viral DNA), 30 worked with AIDS patients in support of the laboratory and 10 were clerical staff working in the laboratory environment. Of the 225 laboratory workers, 10 reported one or more episodes of parenteral exposure to HIV, including needlesticks or cuts, and 35 reported one or more episodes of skin contact with HIV.

Participants completed a questionnaire focusing on workplace exposure to human retroviruses, biosafety precautions used at the facility and by the subject, accidents occurring in the laboratory or other areas and the risk factors of drug use, sexual activity, transfusion and country of origin. Eight (3%) of the 265 reported high risk factors for the virus. Of the 225 workers, ten

reported parenteral virus exposure, and 35 reported 1 or more skin contacts. Thirteen workers reported that they did not wear gloves at all times when working with HIV-infective material. Blood samples from all subjects were analyzed for HIV antibodies by enzyme-linked immunosorbent assay and confirmed by tests such as immunoblots and radioimmune assays.

One individual who worked with concentrated HIV–1 was seropositive for the virus upon entering the study (See CASE REPORTS, CASE 3). However, HIV isolated from the subject's blood was shown to be genetically identical to a strain of HIV used in the laboratory, thus strongly implicating occupational exposure as the source of infection. The authors concluded that the most plausible source of exposure was contact of the worker's gloved hand with culture supernatant fluid containing concentrated virus, followed by inapparent exposure to skin. No HIV seroconversions were identified in the other study participants during the period of prospective follow-up. The authors calculated that the rate of HIV infection was 0.48 per 100 person-years for laboratory personnel working with concentrated virus.

Gerberding and co-workers conducted a prospective cohort study to assess the risk of transmitting the human immunodeficiency virus to healthcare workers intensively and frequently exposed to the more than 1600 patients with AIDS and AIDS-related conditions at San Francisco General Hospital (Ex. 6–375, Ex. 6–353).

After inviting the hospital healthcare workers to participate in the study, investigators recruited a cohort of 623 subjects between 1984 and 1988. At the time of enrollment blood samples were drawn from each subject and tested within six months for HIV antibody. Upon entering the study, each subject was asked to complete a confidential, self-administered questionnaire designed to elicit information regarding demographic characteristics; employment history; medical history; type, frequency, duration and intensity of exposures to HIV-infected patients or laboratory specimens from such patients; a description of infection-control procedures; and non-occupational risk factors for AIDS. Subjects who described non-occupational risk factors for AIDS on the questionnaire were excluded from this study, leaving 468 for prospective follow up. Forty-four percent were physicians (57 of whom were surgeons), 30% were nurses and 11% were laboratory techs. Of these, 11% worked solely in AIDS units or research labs and 26% worked in the operating room, emergency room or intensive care unit. Two hundred twelve of the subjects reported having had accidental exposure (with some having had multiple exposures) to HIV-infected blood by needlestick or by splashes to mucous membranes or nonintact skin. Of the one hundred eighty subjects who received follow-up HIV antibody testing at least 6 months after exposure, Gerberding and co-workers reported that only one, a healthcare worker who had sustained a deep needlestick injury with an HIV-contaminated needle, seroconverted to the virus (See CASE REPORTS, CASE 15) yielding a seroconversion rate of 1/180=0.47%.

Klein and co-workers (Ex. 6–366), conducted a study to assess the occupational risk of HIV among individuals working in the dental profession. Dental professionals in the boroughs of Manhattan and the Bronx in New York City received a mailing requesting their participation in the study. Others were also recruited during dental meetings in the New York City metropolitan area (between October 1985 and May 1987), and during the annual meeting of the American Dental Association in Miami Beach (October 1986).

Written consent was given and questionnaires were completed by a cohort of 1,360 dental professionals. The questionnaires addressed the issues of demographics (including type, duration and location of practice), behavior or other risk factors related to AIDS, "precautions used when treating patients, type and estimated numbers of patients treated, estimated number of accidental parenteral inoculations," and HBV vaccination status. Blood samples were then obtained and analyzed for HIV antibodies by EIA and, if reactive, confirmed by Western blot assay. The blood samples of those subjects who had not received the HBV vaccine were analyzed for HBV antibodies as well.

Twenty-five participants who reported no or "uncertain" contact with patients and 13 subjects for whom blood samples were not obtained were excluded from the study. For 13 participants who reported other risk factors for HIV, including 10 homosexual or bisexual men, 2 heterosexual intravenous drug users and 1 homosexual or bisexual IV drug user, blood samples were analyzed separately.

The remaining cohort of 1,309 subjects consisted of 1,132 dentists, 131 dental hygienists and 46 dental assistants. Most of the dentists were male and 5% were oral surgeons. Nearly all of the dental hygienists and assistants were female. About half of the participants practiced in cities where large numbers of AIDS cases have been reported.

Although the vast majority of subjects reportedly worked either with AIDS patients (15%) or with patients at high risk for AIDS (72%), only 31% of the dentists and 8% of dental assistants reported always wearing gloves when performing dental treatment. Most of them did use gloves intermittently. Seventy three percent of the hygienists reported always wearing gloves while working with patients. Most of the dentists and dental hygienists used masks, eye protection and disposable gowns intermittently, although the majority of dental assistants never used these infection control procedures. Nearly all subjects who used precautions reported they had increased their use of precautions since 1983 due to concern about AIDS.

Approximately 94% of the subjects reported sustaining accidental "parenteral inoculations with sharp instruments," ranging from one to as many as 7,500 within a 5-year period. Serologic test results revealed that at least 21% of the subjects who had not receive the HBV vaccine had been infected with HBV; however, only 1 subject, a male dentist, was seropositive for HIV (See CASE REPORTS, CASE 20.)

Klein and co-workers concluded that there is a risk of dental professionals acquiring HIV occupationally. Because the study represents a point prevalence survey, the HIV seroconversion rate among dental personnel cannot be estimated from it.

Henderson and co-workers are conducting a prospective study that began September, 1983, to assess the risk of nosocomial transmission of HIV to healthcare workers (Ex. 6–377, Ex. 6–352). Investigators invited healthcare workers with varying degrees of occupational exposure to more than 1,000 HIV-infected patients seen at the Clinical Center at the National Institutes of Health (NIH) to participate in the study. As of October 1988, the cohort being followed consists of healthcare workers, including clinical and research laboratory personnel as well as healthcare workers providing direct patient care. Blood was obtained from each subject at the time of enrollment and every 6 months thereafter. The samples were tested for the presence of HIV antibody by ELISA and if reactive, were then confirmed by Western blot. Questionnaires designed to obtain

demographic information, job description, type and frequency of procedures performed on HIV-infected patients, type and frequency of patient blood or body fluid exposure, and type and frequency of exposure to patient specimens were given to each subject at the time of enrollment and every 6 months thereafter. Questions regarding non-occupational risk factors were not included. Two categories of exposure were defined: "physical contact with either a patient or specimen container in routine work"; and "adverse" exposure, either parenterally (by a needle, scalpel or other sharp object contaminated with blood or body fluids from HIV-infected patients) or by splash to the mouth, nasal or conjunctival membranes (by blood, urine, saliva, sputum or feces from an HIV-infected patient). Three hundred fifty-nine of the subjects in the cohort reported percutaneous or mucous membrane exposure to blood or body fluids from HIV-infected patients and were evaluated separately, given more comprehensive initial and follow-up questionnaires, and were requested to provide serologic baseline samples as close as possible to the time of exposure as well as yearly samples thereafter. All adverse exposures were followed for at least 6 months (ranging from 6 to 63 months.)

For 6 subjects, blood samples were positive for HIV antibody at the time of entry into the study. None of the 6 had reported an adverse exposure to blood or body fluids. However, upon reevaluation, all 6 described having at least one other risk factor for AIDS. As there were no baseline serologic data for these subjects, it could not be determined when seroconversion occurred. Henderson and co-workers have not published reports of any seroconversions.

Kuhl and co-workers at UCLA School of Medicine conducted a prospective study to assess the occupational risk of HIV to healthcare personnel caring for AIDS patients (Ex. 6–355). Investigators enrolled a cohort of 292 female healthcare workers consisting of physicians, nurses, nursing aids, and laboratory technicians. Upon entering the study, each subject was asked to complete a self-administered, confidential questionnaire designed to elicit information regarding the individual's demographic characteristics, sexual history, job description, medical history concerning immune system function, and frequency and intensity of exposure to biological specimens of AIDS patients. Blood was obtained from each subject and tested for the presence of HIV antibody by EIA. If the original and at least one of two repeat EIA tests were reactive, the subject was considered HIV-seropositive. "Reactive or nonreactive samples that were near the cutoff value were confirmed by Western blot analysis." All members of the cohort tested HIV-seronegative.

Two hundred forty-six (84%) of the subjects were followed up 9–12 months after enrollment. Of these, 102 reported at least 50 AIDS "specimen contacts" during the previous 3 years and were classified as the "high exposure group"; 111 subjects reported no exposure to AIDS patients or specimens from such patients during the previous 3 years and were classified as the "no exposure group." The 43 remaining subjects reported 1–49 AIDS specimens contacts and were classified as the "low exposure group." The subjects reported exposure to various body fluids including blood and blood products, urine, respiratory secretions, upper gastrointestinal secretions, pleural fluid, cerebrospinal fluid and semen. Ten of the high exposure subjects reported needlestick exposures and 15 reported mucous membrane exposures. Each completed an updated questionnaire and had serologic testing for HIV antibody. None of these subjects have seroconverted to an HIV-antibody-positive status.

Healthcare Workers With AIDS

Further evidence of occupational transmission is provided by reports of healthcare workers who have AIDS, but have no identifiable risk for infection (Ex. 6–378). As of September 19, 1988, there were 169 workers in this group. Information is not complete for 28 of these due to death or refusal to be interviewed. Investigations are in progress for 97 and case investigations have been completed for the remaining 44 persons. Among the latter there are 8 physicians, including 4 surgeons; 1 dentist; 6 nurses; 9 nursing assistants; 8 housekeeping or maintenance workers; 4 clinical laboratory technicians; 2 therapists; 1 mortician; 1 paramedic and 4 others who did not have contact with patients. Eighteen of these healthcare workers recalled having needlestick or other parenteral exposure to blood or "body fluids" from patients in the 10 years preceding their diagnosis of AIDS. However, none of the patients were known to be infected with HIV at the time of exposure. While data on these cases are less complete compared to the 25 case reports discussed above, it is reasonable to assume that at least some of them resulted from occupational exposure.

D. Other Bloodborne Pathogens

Several additional infectious diseases are characterized by a phase in which the causative agent may circulate in blood for a prolonged period of time. With the exception of syphilis and malaria, which are both treatable with chemotherapeutic agents, these diseases are rare in the United States and would therefore be unlikely to pose a measurable risk to healthcare workers.

Syphilis

Syphilis, a sexually transmitted infectious disease, is increasingly prevalent in the United States; 35,147 cases were reported in civilians in 1987 (Ex. 6–465). Marked increases occurred in 1987. The 25% increase over the 1986 rate was the largest single-year increase since 1960 (Ex. 6–453). Moreover the incidence of 14.6 cases per 100,000 persons in 1987, equal to that of 1982, is the highest rate since 1950 (Ex. 6–453). Syphilis is caused by infection with *Treponema pallidum*, a spirochete.

The natural history of syphilis is characterized by an incubation period of 10 to 90 days during which the patient is seronegative and asymptomatic (Ex. 6–495). Subsequent to this incubation period, a primary stage occurs, usually characterized by the appearance of a single lesion, or chancre, and normally accompanied by reactivity in serologic tests. Untreated, the primary lesion heals in weeks. Within weeks to months, a variable systemic illness, the secondary stage, characterized by rash, fever and widespread hematogenous and lymphatic dissemination of spirochetes occurs. All infected persons have reactive serologic tests in this stage (Ex. 6–495). Furthermore, the highest levels of spirochetemia (spirochetes present in blood) are reached during this period. Over two-thirds of patients probably have a prolonged period of latency when they are asymptomatic: the rest, after a variable period of latency, progress to a tertiary stage with high morbidity and mortality including involvement of skin, bones, central nervous and cardiovascular system (Ex. 6–495).

During latency and tertiary syphilis, spirochetemia is markedly reduced, as is infectivity. However during the course of untreated syphilis, spirochetes may be intermittently found in the bloodstream, and syphilis can probably be transmitted through the course of the illness, though not as readily as during the primary and secondary stages (Ex. 6–495). Although syphilis is primarily transmitted sexually and *in utero*, a few cases of transmission by needlestick, by

tattooing instruments, and by blood transfusion have been documented (Ex. 6–453, Ex. 6–496). A reported transmission has occurred by needlestick exposure to the blood of a patient with secondary syphilis, resulting in a chancre on the hand (Ex. 6–453). Preventive treatment of an exposed healthcare worker with an antibiotic during the incubation period would be expected to prevent seroconversion and the potential for permanent reactivity on treponemal testing, as well as preventing the manifestations of infection.

Malaria

Malaria is a potentially fatal mosquito-borne parasitic infection of the blood cells characterized by paroxysms of fever, chills, and anemia; 944 cases were reported in the United States in 1987 (Ex. 6–465). Malaria is an important health risk to immigrants from numerous malaria-endemic areas of the world and to Americans who travel to such areas. Moreover, transmission by mosquito vector has been documented in some areas of the United States. Malaria is characterized by a prolonged erythrocytic phase during which the causative agent, one of several species of the *Plasmodium* genus, will be present in the blood. In many nations, malaria is among the most common transfusion-related infectious diseases. In temperate countries, it is only occasionally reported (Ex. 498). Malaria has also been transmitted by needlestick injury; in one incident, malaria was transmitted to a child who received a unit of blood and to the recipient's physician, who stuck himself with a needle (Ex. 467).

Babesiosis

Babesiosis is a tick-borne, parasitic disease similar to malaria which is caused by the intraerythrocytic parasite *Babesia microti*. It is endemic in certain islands off the northeastern coast of the United States. Transmission by transfusion of fresh blood from asymptomatic donors has been reported (Ex. 454).

Brucellosis

Brucellosis is a febrile illness caused by members of the genus *Brucella*. It is typically associated with occupational exposure to livestock or with ingestion of unpasteurized dairy products; 129 cases were reported in 1987 (Ex. 6–465). It is characterized by fever and weakness, sweats and arthralgias. Transmission by blood transfusion has been reported; in one incident, brucellosis and syphilis were transmitted in the same unit of blood to one recipient (Ex. 6–496).

Leptospirosis

Leptospirosis, a prolonged illness characterized by fever, rash, and occasionally jaundice, is caused by strains of *Leptospira interrogans*, a spirochete. The septicemic phase, during which leptospira are present in the bloodstream of patients, usually resolves within 1–2 weeks. It is typically acquired by contact with urine of infected animals, including cattle, swine, dogs, and rats; 43 cases were reported in 1987 (Ex. 6–465). No cases of nosocomial transmission by blood have been reported.

Arboviral Infections

Arboviral infections generally do not lead to high or sustained levels of viremia in humans, therefore, there is little potential for person-to-person transmission of these infections through blood products or needlestick exposure. The exception is Colorado tick fever (CTF) caused by a tick-borne virus which infects red blood cells. Within 3–14 days following tick exposures, the patient experiences fever, chills, headache, muscle and back aches. Several hundred cases are reported annually and transmission by blood transfusion has been documented (Ex. 6–416).

Relapsing Fever

Relapsing fever is a rare disease, caused by pathogenic *Borreliae*, transmitted by lice or ticks and characterized by recurring febrile episodes separated by periods of relative well-being. In the United States, a few cases of tick-borne relapsing fever are reported in localized geographic areas (Western United States). Though very rare, occupational transmission as a result of patient care practices has been reported. Infections have been attributed to blood from the vein of a patient squirting into the nose of a technician and, in another incident, splashing into another HCW's eye from a placental specimen (Ex. 6–488).

Creutzfeldt-Jakob Disease

Creutzfeldt-Jakob disease, a rare disease with worldwide distribution, is a degenerative disease of the brain caused by a virus. It is believed to be transmitted by ingestion of or inoculation with infectious material, primarily neural tissue. No cases of nosocomial transmission by blood have been reported, although rare instances of transmission have occurred secondary to homologous dura mater implants, receipt of human growth hormone, and insertion of unsterilized stereotactic electrodes which had been inserted into the brains of Creutzfeldt-Jakob disease patients and then used on others (Ex. 6–492).

Human T-lymphotropic Virus Type I

Human T-lymphotropic virus type I (HTLV–I), the first human retrovirus to be identified, is endemic in southern Japan, the Caribbean, and in some parts of Africa, but it is also found in the United States, mainly in intravenous drug users (Ex. 6–493). The virus can be transmitted by transfusion of cellular components of blood (whole blood, red blood cells, platelets) (Ex. 6–499). HTLV–I has been associated with a hematologic malignancy known a adult T-cell leukemia/lymphoma and with a degenerative neurologic disease known as tropical spastic paraparesis or HTLV–I-associated myeopathy. There is some evidence that the neurologic disease may be associated in some cases with blood transfusion (Ex. 6–494). No cases of occupational acquisition of HTLV–I infection have been reported.

Viral Hemorrhagic Fever

The term viral hemorrhagic fever refers to a severe, often fatal illness caused by several viruses not indigenous to the United States, but very rarely introduced by travelers coming from abroad. These illnesses are characterized by fever, sore throat, cough, chest pain, vomiting, and in severe cases, hemorrhage, encephalopathy and death. Although a number of febrile viral infections may produce hemorrhage, only the agents of Lassa, Marburg, Ebola, and Crimean-Congo hemorrhagic fevers are known to have caused significant outbreaks of disease with person-to-person transmission, including nosocomial transmission (Ex. 6–417). Blood and other body fluids of patients with these illnesses are considered infectious. Any patient suspected of illness due to one of these agents should be reported immediately to the local and state health departments and to the Centers for Disease Control.

The bacterial and parasitic diseases listed above are treatable with antibacterial or antimalarial drugs. No specific therapy is available for the viral diseases, with the exception of Lassa fever. Precautions designed to minimize the more important bloodborne viral diseases, namely HIV, hepatitis B, and non A non B hepatitis, would be effective in minimizing occupational transmission of all the above agents in the clinical setting.

E. Cytomegalovirus Infection and Disease

Risk From Exposure to Blood

In contrast to some other viral agents, there have been no documented reports of cytomegalovirus (CMV) transmission by needlestick or other occupational exposure to blood. While infection can be transmitted via blood transfusion, the risk per unit of blood is low and infection is more likely to occur after multiple transfusions. Even in patients with active CMV infection, the titer of virus found in blood samples is extremely low.

Risk From Exposure to Patients Excreting CMV in Their Secretions

The medical community has become increasingly aware of cytomegalovirus and cytomegalic inclusion disease of newborns. This awareness has prompted the publication of guidelines for the prevention and control of CMV infection and disease, particularly in settings where women of childbearing age may be affected (Ex. 6–396, Ex. 6–483).

CMV is an ubiquitous, non-seasonal virus that infects most persons at some time during their lives (Ex. 6–397, Ex. 6–450). The virus persists in latent form after a primary infection and reactivation may occur years later, particularly under conditions of immunosuppression. Transmission of CMV from person to person probably occurs most commonly as a result of contact with salivary secretions, but urine may also play a role. Although the virus is not highly contagious, spread of CMV in households and day care centers is well documented. Acquisition appears to require close or intimate contact with persons who are excreting CMV in their urine, saliva, seminal fluid or cervical secretions. Sexual spread also occurs as could be expected with seminal and cervical excretion of virus. The frequency with which sexual contact may cause transmission of CMV is not clear, but sexual transmission appears to be a major source of infection among some adult populations (i.e., homosexual men and patients attending a sexually transmitted disease clinic) (Ex. 6–398). Infants and children acquire CMV infection either from other infected children or from their mother *in utero*, at birth, or during the perinatal period (Ex. 6–396, Ex. 6–397). CMV can also be transmitted via blood transfusions, breast milk, and transplanted organs (Ex. 6–399, Ex. 6–400). Infection in normal children and adults is usually asymptomatic, although, in immunocompromised hosts, CMV may be an opportunistic pathogen, causing serious illness with high morbidity and mortality. CMV infection is the most common of all the intrauterine infections, occurring in an estimated 0.4% to 2.3% of all live births (Ex. 6–397). It can have a variable outcome and may result from either primary infection acquired during gestation or from a recurrent (reactivation or reinfection) maternal infection in a seropositive woman (Ex. 6–401). It is currently believed that most but not all symptomatic congenital CMV infections result from primary infection (Ex. 6–402).

In the United States, 10%–65% of women (the percentage is higher in the white race and those of upper socioeconomic status) entering their childbearing years are seronegative and susceptible to primary CMV infection (Ex. 6–401). The rate of primary infection as measured by seroconversion during pregnancy is estimated to be between 1% and 2% (Ex. 6–402, 6–482); however, only 40%–50% of pregnant women who develop primary CMV infection will transmit that infection to their fetuses. Of these infected infants, one study has shown that 5%–10% will be symptomatic at birth (Ex. 6–402). The most severely affected are those with cytomegalic inclusion disease (CID) manifested by hepatosplenomegaly, jaundice, petechial rash, chorioretinitis, cerebral calcifications, and microcephaly. These children with CID are one of the major long-term public health problems associated with CMV. Of congenitally infected infants, 90% to 95% are asymptomatic at birth: 10% of these will develop manifestations of infection later in childhood, usually as hearing loss which is sometimes progressive, or poor intellectual performances (Ex. 6–403, Ex. 6–404). Congenital or perinatal acquired infections are chronic in nature with viral excretion persisting for months or years (Ex. 6–450). It is unknown why some offspring are severely affected, while others remain asymptomatic.

Since CMV infection is endemic in the community and infection in childhood is common and usually asymptomatic, day-care centers, nurseries, hospitals, developmental centers, schools, and other group settings usually contain a number of children who are excreting CMV in urine or saliva. The prevalence of excretion of CMV in urine or saliva in day-care centers in one study has been reported as 59% of healthy children between 1 and 5 years of age and was highest, 83%, in the second year of life (Ex. 6–450). In another study, the prevalence was 22% (Ex. 6–481). Adults who have young children in the home, particularly children who attend day-care centers, are unknowingly exposed and frequently become infected with CMV (Ex. 6–406, Ex. 6–407).

The risk of spread of CMV infection to patient-care personnel who practice good personal hygiene appears to be no higher than that of their peers who are not engaged in patient care. In the largest study to date, Balfour and Balfour (Ex. 6–117) enrolled 943 subjects including renal transplant nurses, neonatal intensive care nurses, student nurses, and blood donor controls. The rate of seroconversion during the study, based on observing 519 seronegative subjects for a median period of two years, was 1.84% and did not differ significantly among the study groups. Another study by Demmler et al. (Ex. 6–159) investigated possible nosocomial transmission of CMV by detailed serologic and virus isolation procedures in two different hospital areas for a two year period. One was a busy, crowded pediatric chronic care unit with high (16%) prevalence of CMV among its patients and another was a neonatal unit with low (0.7%) prevalence of CMV. None of the 58 seronegative personnel in the chronic care unit became infected and only 2 of 37 nurses in the neonatal unit seroconverted. The source of one infection was proved to be familial, and an occupational source in the second was unlikely because this nurse did not care for either of the two congenitally infected infants in the unit. Similar to the Balfour study (Ex. 6–117) the annual seroconversion rates among nurses from various areas of the hospital did not correlate with the average CMV prevalence of the patients housed within those areas. Three smaller epidemiologic studies suggested that pediatric nurses or nursing students may have acquired CMV in the workplace (Ex. 6–409, Ex. 6–410, Ex. 6–411) while five additional studies concluded that patient-to-staff transmission was not a risk (Ex. 6–412, Ex. 6–413, Ex. 6–451, Ex. 6–452, Ex. 6–414).

Yearly seroconversion rates in hospital personnel have varied from 0% to 12%. However, when controls are included, these rates have not been significantly different from those of age-matched adults of similar socioeconomic background in the same community who did not care for CMV-infected patients. The study of Friedman et al (Ex. 6–411) appears to be the only exception. A significant difference was found only when a subset of pediatric personnel was compared with the rest of the study population. The overall seroconversion

rate for all patient-contact employees was not significantly different from noncontact personnel. Differences in patient care practices or infection control policies could also explain some of the conflicting results between hospitals. Intimate exposure to infected infants could be responsible for transmission to staff in some instances. Heneberg et al (Ex. 6–410) in Norway found a high rate of seroconversion among student nurses on their first two-month pediatric rotation. They noted that "it is common to see personnel kiss drooling infants while feeding them." Rates of infection fell when more attention was given to hygiene. Therefore, the risk of infection in hospital workers who care for pediatric patients and who practice good personal hygiene is probably no greater than that of women in the general community. Screening programs to identify children or adults such as renal transplant recipients who are asymptomatic excretors of CMV are currently impractical and costly. The intermittent nature of CMV shedding, the days required for testing and the high cost of the tests create problems for such screening programs. Since a significant percentage of such patients may be present in any institutional setting, care for any infants and children should include routine hygienic measures such as thoroughly washing hands after each contact with urine, respiratory tract, or other potentially infectious secretions and careful handling and disposal of diapers and other articles known to be contaminated with urine or other secretions (Ex. 6–396), (Ex. 6–483), (Ex. 6–442), (Ex. 6–74). The most practical means by which pregnant women or women planning pregnancy can prevent acquiring CMV is rigorous, good personal hygiene while working in these settings and at home throughout their pregnancy (Ex. 6–394).

The petitioners specifically requested that the Agency address the risk of occupational exposure to cytomegalovirus from patients with AIDS. In order to respond to the request of the petitioners, we have included the above discussion in the proposed standard. As discussed above, CMV is most often transmitted by saliva and urine and not by blood. The infection control procedures that would be employed to control the spread of pathogens transmitted by urine and saliva (except dental operations) are not required by this proposed standard and are not the focus of this rulemaking. The Agency seeks comments on this matter.

V. Preliminary Quantitative Risk Assessment

(A) Introduction

The United States Supreme Court, in the "benzene" decision, (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)) has ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment under existing exposure conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (448 U.S. 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (448 U.S. 644).

The Court in the Cotton Dust case, (*American Textile Manufacturers Institute* v. *Donovan,* 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

Quantifying the risk associated with exposure to bloodborne diseases such as HBV or HIV is different than quantifying the risk associated with exposure to toxic chemicals, the risks that OSHA has typically quantified. For most of these chemicals, response is associated with cumulative dose, and workers risk chronic health effects from long term exposure to airborne concentrations of the chemical. The response associated with exposure to bloodborne pathogens does not depend on cumulative dose acquired through years of exposure. With each exposure, either infection occurs or it does not occur. While repeated exposure increases the risk of infection, each exposure is associated with a unique risk which depends upon the virulence of the pathogen, the size of the delivered dose, the route of exposure, etc., and not upon any prior exposure. Thus, in the case of bloodborne diseases, it is necessary to reduce the risk of exposure. The use of a vaccine or other prophylactic treatment against a particular viral agent will further reduce the risk.

HBV is the only bloodborne pathogen for which there are sufficient data to quantify the risk of infection from occupational exposure to blood and other potentially infectious materials for an entire population of workers. A number of epidemiological studies demonstrate an increased prevalence of HB markers in the blood of health care workers with frequent blood exposure, and a brief review of some of these studies is presented below, followed by OSHA's estimates of risk. Finally, OSHA presents a qualitative risk assessment for infection from occupational exposure to HIV.

(B) Review of the Epidemiology of HBV Infection in Health Care Workers

Numerous epidemiological studies have measured the prevalence of HBV infection among health care workers. These studies determined what proportion of health care workers had ever been infected with HBV and measured prevalence as the proportion of workers with any serological marker of past or present HBV infection. Most of the studies relied upon the voluntary cooperation of the study population, so there is some chance for bias to be introduced into any estimate of HBV prevalence. Health care workers who know they are infected with HBV at the time of study or who know they are HBV carriers may decline to participate in a study which they may feel could jeopardize their careers. This would lead to an underestimate of the prevalence of HBV infection among health care workers.

Jovanovich et al did not rely upon voluntary participation in their study of HBV prevalence among workers at a 1000-bed community hospital in Detroit (Ex. 4–14). The authors reported a high prevalence of HBV among employees in worksites where blood and other potentially infectious materials are frequently present. All new employees were screened for HBV markers at the time of hire, and the blood tests were repeated every six months thereafter for all employees designated as being at high risk for HBV infection. In the hemodialysis unit, these tests were repeated monthly. This design allowed investigators to determine not only the HBV prevalence but also the conversion

rate to HBV seropositivity per 100 employee-years.

Jovanovich et al reported the highest prevalence of HBV among the emergency room staff (27.9%), followed by the operating room staff (25.2%), the hemodialysis unit staff (17.2%), the dental staff (15.4%), and the staff of the intensive care unit (12.7%). The authors did not state what proportions of the study subjects were in specific occupations (e.g. physicians, nurses, etc.). The emergency room staff experienced the highest rate of conversion to HBV seropositivity with a conversion rate of 11.7 per 100 employee-years.

Like Jovanovich et al, Dienstag and Ryan found the highest prevalence of serological markers for HBV among the emergency room staff, (specifically nurses), in a study of workers at an 1100 bed urban teaching hospital in Boston (Ex. 4–13). This study relied upon voluntary participation, and of 830 staff at the hospital, 624 or 75% agreed to participate. Among workers with frequent blood contact, the prevalence of HBV serological markers was 21.2% versus 8.6% for workers with occasional, rare, or no blood contact ($p<.001$). The highest rates of seropositivity were found among emergency room nurses, pathology staff, blood bank staff, laboratory technicians, intravenous teams, and surgical house officers. The prevalence of HBV serological markers was 30% among emergency room nurses and was in excess of 15% in each of the other groups. Workers with less frequent blood contact had HBV serological markers at rates between 5% and 10%. Four of thirty-two administrators, (16%), were found to have serological markers of HBV infection, but the authors stated that the high observed prevalence among this group may have been related to the inclusion of two persons known to be members of a high risk group. All of these groups were compared to a population of 462 volunteer blood donors, which had a 5% prevalence of HBV.

Neither frequency of patient contact nor socioeconomic status (SES) as measured by years of education were found to be associated with the prevalence of HBV serological markers. SES is often associated with prevalence of HBV infection but not among this cohort. Indeed, as demonstrated in Table A, among workers with a comparable level of education, frequency of blood contact was statistically significantly associated with HBV prevalence. Prevalence increased with age for all employees regardless of degree of blood contact, but prevalence was observed to increase with years in occupation only for workers with frequent blood contact.

TABLE A.—CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH UNIFORM SOCIOECONOMIC STATUS MEASURED BY YEARS OF EDUCATION [a]

Personnel	Exposure to blood	N	Number with HBV markers (percent)	Odds ratio	Chi-square (p-value)
Physicians [b]	Frequent	81	17 (21)	3.11	6.02
	Infrequent	89	7 (8)		(p<.02)
Nurses [c]	Frequent	104	22 (21)	2.80	7.16
	Infrequent	126	11 (9)		(p<.01)

[a] Data from Table 2 of Dienstag and Ryan (Ex. 4–13).
[b] Median level of education for the physicians was 20 years.
[c] Median level of education for the nurses was 17 years.

Pattison et al. reported similar findings of the relationship between frequency of blood contact and the prevalence of HBV in an earlier study conducted between 1972 and 1974 at a 495 bed urban hospital in Arizona (Ex. 6–65). The study population was selected from consecutive employees undergoing yearly physical examination on the anniversary of their initial employment examination. Except for physicians, study participants had been affiliated with the hospital for at least two years. Over 99% of the eligible employees who represented 40% of all hospital personnel participated in the study.

The overall prevalence of HBV serological markers was 14.4%. No association was observed between frequency of patient contact and prevalence of HBV, but the association between frequency of blood contact and prevalence of HBV was statistically significant ($p<.05$). Among workers with frequent blood contact, the seroprevalence of HBV markers was 18.9%; for workers with occasional blood contact, it was 13.4%; and for workers with no blood contact, it was 11.4%. Socioeconomic status, as measured by the Hollingshead Index derived from educational level attained and category of employment (highest socioeconomic level corresponding to Hollingshead Index 1; lowest socioeconomic level corresponding to Hollingshead Index 5), was statistically significantly associated with HBV prevalence but only when categories 1 through 4 were combined and compared to category 5. Among workers with similar Hollingshead indicies (i.e. controlling for socioeconomic status), workers with frequent or occasional blood contact were twice as likely to have serological markers for HBV as were workers with no blood contact. This is demonstrated in Table B.

TABLE B.— CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH SIMILAR SOCIOECONOMIC STATUS MEASURED BY THE HOLLINGSHEAD INDEX [a]

Hollingshead Index [b]	Exposure to Blood [c]	N	Number with HBV markers (percent)	Odds ratio	Chi-square (p-value)
1 and 2	Freq/Occ	136	18 (13.2)	2.21	1.09
	Never	31	2 (6.5)		(p<.25)
3 and 4	Freq/Occ	125	20 (16.0)	1.97	2.56

TABLE B.— CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH SIMILAR SOCIOECONOMIC STATUS MEASURED BY THE HOLLINGSHEAD INDEX [a]—Continued

Hollingshead Index [b]	Exposure to Blood [c]	N	Number with HBV markers (percent)	Odds ratio	Chi-square (p-value)
5	Never	102	9 (8.8)		(p<.10)
	Freq/Occ	41	13 (31.7)	2.55	4.34
	Never	78	12 (15.4)		(p<.05)
Total	Freq/Occ	302	51 (16.9)	1.66	3.57
	Never	211	23 (10.9)		(p<.10)

[a] Data from Table 3 of Pattison et al. (Ex. 6–65).
[b] The Hollingshead Index is a measure of socioeconomic status derived from educational level attained and category of employment. The highest socioeconomic level corresponds to Hollingshead Index 1; the lowest socioeconomic level corresponds to Hollingshead Index 5.
[c] Pattison categorized blood exposure as frequent or occasional (Freq/Occ) versus never.

In a more recent study by Hadler et al. frequency of blood contact but not frequency of patient contact was again shown to be strongly related to HBV prevalence (Ex. 4–16). Of all employees at three urban teaching hospitals and two midwest community hospitals, 5,697 (36%) participated in this study. Serological markers of past or present HBV infection were found in 14.2% of the study population. For workers with frequent blood contact, the prevalence of HBV markers increased with duration in occupation at a rate of 1.05 infection per 100 person-years ($R=.95$; $p<.01$), and for workers with occasional blood contact, the prevalence increased at a rate of .71 infections per 100 person-years ($R=.85$; $p<.05$). Among workers with no blood contact, HBV prevalence was constant over duration of employment.

Hadler et al. also found that frequency of needle accidents was related to HBV prevalence. Among workers with frequent or occasional needle accidents, HBV prevalence increased with duration in occupation at a rate of .80 infections per 100 person-years, and among workers with rare needle accidents, prevalence increased at a rate of .72 infections per 100 person-years. Among workers who reported no needle accidents, the increase in HBV prevalence with duration in occupation was much lower (.24 infections per 100 person-years). When subjects were stratified into groups by degree of blood contact, frequency of needle contact was positively associated with HBV infection rates only in persons with frequent blood contact and not in persons having occasional or no blood contact.

Needlesticks and cuts with sharp objects are by no means the only way workers with exposure to blood or other potentially infectious materials can be exposed to the HB virus. In a study of the transmission of HBV in clinical laboratory areas, Lauer et al. found that 26 of 76 (34%) environmental surfaces sampled were positive for HBsAg (Ex. 6–56). Samples were taken in a dialysis room specifically used for patients who had HBV infections at the time of dialysis. In addition, samples were collected in the clinical laboratory where tests were done on blood samples drawn from HBV-infected dialysis patients.

The HB surface antigen was found on the outside of 6 of 11 (55%) of the sampled blood-specimen containers and 4 of 9 (44%) of the sampled serum-specimen containers. The gloves and bare hands of personnel who had contact with the blood- and serum-specimen containers were also sampled, and two of the three samples taken, including one from a bare hand, were positive for HBsAg. Other contaminated surfaces included the handle portion of pipetting aids, marking devices, and an assay instrument for complete determination of blood cell counts. The authors stated that their data "indicate that transmission of HBV in the clinical laboratory is subtle and mainly via hand contact with contaminated items during the various steps of blood processing. These data support the concept that the portal of entry of HBV is through inapparent breaks in skin and mucous membranes."

(C) Quantitative Assessment of HBV Risk

OSHA's quantitative risk assessment focuses on HBV infection in healthcare workers because healthcare workers with frequent exposure to blood or other potentially infectious materials constitute the only occupational group with such exposure for which OSHA has sufficient data to estimate the occupational risk of HBV infection. OSHA believes, however, that it is the exposure to blood and other potentially infectious materials that places these workers at risk for HBV and not some other factor unique to health care workers. This conclusion is borne out by the epidemiological studies reviewed in the previous section. Therefore, for this risk assessment, OSHA will use the data available for health care workers with frequent exposure to blood or other potentially infectious materials to predict the HBV infection risk to any worker with frequent occupational exposure to blood or other potentially infectious materials.

Estimates of the incidence of HBV infection in the U.S. population in general and among health care workers in particular come from the Hepatitis Branch of the Center for Infectious Disease of the U.S. Public Health Service's Centers for Disease Control (CDC). There are two systems for collecting information on hepatitis: the CDC National Morbidity Reporting System and the Viral Hepatitis Surveillance Program (VHSP). The National Morbidity Reporting System collects data on the number and type of hepatitis infections as well as the patients' ages in reported cases. The VHSP collects serological and epidemiological data pertaining to risk factors for the disease (Ex. 6–217). Based on data from these systems, the CDC estimates that there are over 300,000 HBV infections each year in the U.S. (Ex. 6–176). Only a fraction of all infections are actually reported to the CDC because most infections produce no symptoms and people are unaware that they are sick. Furthermore, even when people become ill enough to seek medical help, the disease is not always correctly diagnosed or faithfully reported. For its risk assessment, OSHA will assume that exactly 300,000 HBV infections occur each year, but the reader should bear in mind that CDC estimates the number to be higher (Ex. 6–176).

It is estimated that there are approximately 5.3 million health care workers who have frequent contact with blood or other potentially infectious materials putting them at high risk for bloodborne diseases including HBV (Ex.

6–13). This estimate includes staff at institutions for the developmentally disabled.

A portion of the 5.3 million workers with frequent blood contact or exposure to other potentially infectious materials are not at risk for HBV infection. CDC estimates that between 15% and 30% of these workers (795,000 to 1,590,000) have already been infected with HBV and are now immune to further infection (Ex. 6–199). In addition, it is estimated that approximately 1.2 million health care workers have received the plasma-derived HB vaccine since its introduction in 1982. CDC reports that 1.4 million persons have completed the three-dose series of vaccine injections. Although no precise figures are available, it is estimated that over 85% of the distributed vaccine has gone to health care workers with frequent blood contact, staff and clients of institutions for the developmentally disabled, and staff and patients in hemodialysis units (Ex. 6–176). The vaccine has been demonstrated to provide protective antibody levels in over 90% of healthy adults who have received the series (Ex. 6–385), so OSHA estimated that 1,080,000 workers, (1,200,000×.9) are immune to HBV from vaccination. These factors, prior infection and vaccination, remove between 1,875,000 and 2,670,000 from the pool of 5.3 million health care workers with frequent exposure to blood or other potentially infectious materials, leaving between 2,630,000 and 3,425,000 workers at risk for HBV infection.

Of the 300,000 HBV infections each year, CDC estimates that 6% or 18,000 occur in all health care workers. Two-thirds of these 18,000 cases, or 12,000 cases, are believed to occur in health care workers who have frequent exposure to blood or other potentially infectious materials (Ex. 6–392). If between 2,630,000 and 3,425,000 workers are exposed, then the annual HBV infection rate for these workers is between 4.89 and 6.63 per 1000 exposed workers.

Clearly it is possible for workers with frequent blood exposure to become infected with HBV by means other than occupational exposure. Over 50% of all cases reported in 1985 had no known risk factors (Ex. 6–217). The risk attributable to occupational exposure is the difference between the risk faced by exposed workers and the background risk faced by the general population. Thus, to determine whether workers exposed to blood and other potentially infectious materials face a significant risk of infection due to their occupational exposure, OSHA has estimated the background risk of HBV infection.

The vast majority of the 300,000 infections that occur each year in the U.S. are in young adults. In 1985, for example, 70% of all reported cases of acute infection occurred in the 20 to 39 year old age group. In contrast, only 1.4% of the reported cases of acute infection occurred in children under 15 years of age (Ex. 6–217). Because of the low incidence of HBV infection in children, OSHA has assumed for this risk assessment that infections occur only in adults in order to arrive at an estimate of the HBV infection rate in the adult population. While this assumption may lead to an overestimate of the infection rate, any bias will be offset to some degree by the assumption that exactly 300,000 HBV infections occur each year, which is probably an underestimate.

There are approximately 180 million adults in the U.S. (Ex. 6–389; in 1985, there were 186,778,000 residents in the U.S. 15 years of age or older). Of these, it is estimated that 4.8% (approximately 8.6 million) are immune because they have already had the disease (Ex. 6–390). In addition, we will assume that all of the 1.4 million persons who have received the HB vaccine are adults and that 90% of them (1,300,000) are immune. Therefore, of the 180 million adults in the U.S., approximately 170 million are at risk of HBV infection. Given that there are 300,000 cases of infection each year, the annual infection rate is 1.76 infections per 1000 adults. This estimated infection rate for the entire adult population constitutes the background risk for HBV. In other words, OSHA estimates that the probability that an adult in the U.S. will be infected with HBV this year is .00176. Estimates of the populations at risk and their HBV infection rates are given in Table C.

TABLE C.—ESTIMATE OF POPULATIONS AT RISK FOR HBV INFECTION

	U.S. adults	High risk health care workers
Number in population	180,000,000	5,300,000
Percent immune [a]	4.8	15–30
Number immune	[b] 8,600,000	795,000–1,590,000
Number vaccinated	1,400,000	1,200,000
Percent vaccinated	0.1	22.6
Number immune from vaccination [c]	[b] 1,300,000	1,080,000
Number at risk	170,100,000	2,630,000–3,425,000
Annual HBV infection rate per 1000	1.76	3.50–4.56

[a] Percent immune is the proportion of the population which has already been infected with the HB virus. Previous infection confers life-long immunity.
[b] This number has be rounded to the nearest hundred-thousand.
[c] This assumes that vaccination confers immunity on 90% of those that receive it.

OSHA's estimate of the background risk of HBV infection is probably much higher than the actual risk faced by most adults. Certain behaviors are known to substantially increase the risk of HBV infection, but not all adults engage in these behaviors with equal probability. For example, a recent General Social Survey conducted in early 1988 recorded homosexual activity among 3.2% of 504 sexually active men in the previous 12 months (Ex. 6–342), yet the proportion of HBV cases associated with homosexual activity in 1987 in the CDC's sentinal county study was 9%, nearly three times as large (Ex. 6–321). Intravenous drug users, who accounted for 28% of the HBV cases in 1987 in the same CDC study, are another group which are disproportionately represented in the number of HBV cases as compared to their number in the adult population. Removing the HBV cases associated with male homosexual activity and IV drug use from the annual number of cases and removing adult men who engage in homosexual activity and IV drug users from the population at risk would substantially reduce OSHA's estimate of the background risk of infection because a greater proportion of cases would be removed from the number of HBV cases (i.e. the numerator) than the proportion of people removed from the population at risk (i.e. the denominator). This

approach would be reasonable because males represent only 25% of all healthcare workers, as opposed to 48% of the general population, and IV drug users most likely are underrepresented among the healthcare worker population.

Unfortunately, there are no reliable estimates of the number of people engaging in high risk behaviors such as homosexual activity or IV drug use. Therefore, OSHA must rely on its estimate of 1.76 HBV infections per 1000 adults as its estimate of the background risk aware that the true risk for most adults in the U.S., and therefore the background risk for healthcare workers, is probably much lower.

As outlined in the discussion of the health effects of HBV, there are a number of possible outcomes following infection. Between two thirds and three fourths of all infections result in either no symptoms of infection or a relatively mild flu-like illness. Between one quarter and one third of the infections, however, take a much more severe clinical course. As noted above, the symptoms include jaundice, dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. Hospitalization is required in about 20% of these cases. For its risk assessment, OSHA will use the lower estimate of 25% as the proportion of HBV infections which take a more severe clinical course.

CDC estimates that 2.2% of HBV infections lead to death. Death from fulminant hepatitis occurs in 0.125% of cases. Death from cirrhosis of the liver is estimated to occur in 1.7% of cases, and death from primary hepatocellular carcinoma is estimated to occur in 0.4% of cases (Ex 6–392).

Between 5% and 10% of individuals infected with HBV become chronic carriers of the virus. These individuals represent a pool from which the disease may spread. About 25% of the chronic carriers suffer from chronic active hepatitis (Ex 6–392).

The estimated numbers of infections that result in any of these outcomes each year in both the adult population and in the population of high risk health care workers is presented in Table D. Recall that among the adult population, approximately 170 million persons are estimated to be at risk for HBV and among health care workers with frequent exposure to blood or other potentially infectious materials, there are between 2,630,000 and 3,425,000 workers estimated to be at risk for HBV infection. Using the numbers in Table D and these population estimates, the annual risk of HBV infection for the adult population and for any worker with frequent occupational exposure to blood or other potentially infectious materials have been calculated and are presented as rates per 1000 in Table E.

TABLE D.—ESTIMATES OF THE NUMBER OF HBV INFECTIONS AND OUTCOMES IN THE U.S. ADULT POPULATION AND AMONG HEALTH CARE WORKERS EXPOSED TO BLOOD AND OTHER POTENTIALLY INFECTIOUS MATERIAL [a]

	U.S. adults	Health care workers
HBV Infections	300,000	12,000
Clinical Illness (25%)	75,000	3000
Hospitalized (5%)	15,000	600
HBV Carrier (5% to 10%)	15,000–30,000	600–1200
Chronic HB (25% Carriers)	3750–7500	150–300
Fulminant Death (.125%)	375	15
Death—Cirrhosis (1.7%)	5100	204
Death—PHC [b] (0.4%)	1200	48
All Deaths (2.225%)	6675	267

[a] Data from Ex. 6-392.
[b] Primary hepatocellular carcinoma.

TABLE E.—ESTIMATES OF THE ANNUAL RISK HBV INFECTION AND ITS OUTCOMES IN THE U.S. ADULT POPULATION AND AMONG WORKERS EXPOSED TO BLOOD AND OTHER POTENTIALLY INFECTIOUS MATERIAL [a]

	U.S. adults	Exposed workers [b, c]
HBV Infections	1.76	3.50–4.56
Clinical Illness (25%)	0.44	0.88–1.14
Hospitalized (5%)	0.09	0.18–0.23
HBV Carrier (5% to 10%)	0.09–0.18	0.18–0.46
Chronic HB (25% Carriers)	0.02–0.04	0.04–0.11
Fulminant Death (.125%)	0.002	0.004–0.006
Death—Cirrhosis (1.7%)	0.03	0.06–0.08
Death—PHC [d] (0.4%)	0.007	0.014–0.018
All Deaths (2.225%)	0.04	0.08–0.10

[a] Risks are expressed as the number of events per 1000 at risk.
[b] Exposed workers are workers with occupational exposure to blood and other potentially infectious materials.
[c] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
[d] Primary hepatocellular carcinoma.

Table F presents the risk attributable to occupational exposure for HBV infection and its outcomes per 1000 exposed workers. The annual risk attributable to occupational exposure is simply the difference between the annual risk faced by exposed workers and the annual risk faced by the adult population, both given in Table E. Because section (6)(b)(5) of the OSH Act states that no employee shall suffer "material impairment of health or functional capacity even if such an employee has regular exposure to the hazard dealt with * * * for the period of his working life," OSHA has converted the attributable annual risk into an attributable lifetime risk on the assumption that the a worker is employed in his or her occupation for 45 years.

TABLE F.—HBV RISK ATTRIBUTABLE TO OCCUPATIONAL EXPOSURE FOR WORKERS [a] EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS

	Annual risk [b]	Lifetime occupational risk [b, c]
HBV Infections	1.74–2.80	75.38–118.54
Clinical Illness	0.44–0.70	19.61–31.02
Hospitalized	0.09–0.14	4.04–6.28
HBV Carrier	0.09–0.28	4.04–12.52
Chronic HB	0.02–0.07	0.90–3.15
Fulminant Death	0.002–0.004	0.09–0.18
Death—Cirrhosis	0.03–0.05	1.35–2.25
Death—PHC [d]	0.007–0.011	0.31–0.49
All Deaths	0.04–0.06	1.80–2.70

[a] Risks are expressed as the number of events per 1000 at risk.
[b] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
[c] Assumes 45 years of occupational exposure and is calculated as $1-[(1-p)^{45}]$, where p is the annual risk.
[d] Primary hepatocellular carcinoma.

Table F shows that for every 1000 workers with frequent exposure to blood or other potentially infectious materials, between 75 and 119 will become infected with HBV over the course of their working lifetime because of occupational exposure to the virus. Of these, 20 to 31 will suffer clinical illness and 4 to 6 will need hospitalization. Between 4 and 13 of these workers will become chronic carriers, and 1 to 3 of them will suffer from chronic hepatitis. HBV infection from occupational exposure will lead to the death of 2 to 3 of these 1000 exposed workers.

OSHA's estimate of the risk of HBV infection attributable to occupational exposure for workers with frequent exposure to blood or other potentially infectious materials is most likely an underestimate of the true risk. As noted above, the true risk of HBV infection among the majority of U.S. adults is probably much lower than OSHA's estimate of the background risk since

the majority of adults do not engage in the high risk behaviors associated with a large proportion of HBV infections. By overestimating the background risk, OSHA has probably underestimated the risk attributable to occupational exposure. Nonetheless, OSHA's calculations show that exposed workers are at an increased risk of infection, clinical illnesses, hospitalization, chronic hepatitis, and death over the course of their working lifetime. In addition, these workers are at an increased risk of becoming HBV carriers and of transmitting the infection sexually and perinatally.

Since 1982, a plasma-derived HB vaccine has been available. In July of 1986, a new genetically engineered HB vaccine was licensed by the U.S. Food and Drug Administration. When given in the recommended three dose series, the new vaccine has been found to induce protective antibodies in over 95% of healthy adults 20–39 years of age, but like the plasma-derived vaccine, the new vaccine induced a somewhat lower antibody response in older adults (Ex. 6–176). Assuming that both vaccines are 90% effective in preventing HBV infection, OSHA believes that administration of either vaccine will lead to a significant reduction in the HBV infection risk faced by workers with frequent exposure to blood or other potentially infectious materials.

OSHA's Office of Regulatory Analysis estimates that there are 5.3 million workers with frequent exposure to blood or other potentially infectious materials who would be covered by this standard (see Section VII of this preamble). Approximately 4.7 million of these exposed workers are employed in the health care field, (OSHA estimates that there are approximately 600,000 health care workers who would not be covered by this standard). Approximately 600,000 of these 5.3 million exposed workers are employed in fields other than healthcare. If it is assumed that 23% of the 4.7 million health care workers have been vaccinated (1,081,000) and that between 15% and 30% healthcare workers are immune to HBV because of previous HBV infection (705,000 to 1,410,000), then there are between 2,209,000 and 2,914,000 health care workers who are both at risk for HBV and would be covered by this standard. The 10% of vaccinated workers on whom immunity was not conferred would most likely not participate in a vaccination program because they would not know they were not immune.

There are no estimates of the number of other exposed workers (i.e. those not employed in the health care field) who have been vaccinated or are immune to HBV from prior infection. Because 85% of all people vaccinated have been in the health care field, it is reasonable to assume that this group of nonhealthcare workers has been vaccinated at a rate more like the entire adult population (.1%) than like the population of exposed health care workers. Because these workers have frequent exposure to blood or other potentially infectious materials, however, it is reasonable to assume that like the health care workers, between 15% and 30% are immune to HBV because of previous HBV infection. If it is assumed that 0.1% of the 600,000 other workers have been vaccinated (660) and that between 15% and 30% are immune to HBV because of previous HBV infection (90,000 to 180,000), then there are between 419,340 and 509,340 other workers who are both at risk for HBV and would be covered by this standard.

In total, OSHA estimates that between 2,628,340 and 3,423,340 workers with frequent exposure to blood or other potentially infectious materials are at risk for HBV. If all of these workers were vaccinated with a 90% effective HBV vaccine, then over a 45 year working lifetime, OSHA estimates that between 232,000 and 280,000 HBV infections would be prevented, between 60,000 and 73,000 cases of clinical illness would be prevented, and between 5500 and 6400 deaths would be prevented. The numbers of HBV infections and their outcomes which would be prevented by this provision are presented in Table G.

TABLE G.—HBV INFECTIONS AND OUTCOMES PREVENTED IN WORKERS WITH LIFETIME OCCUPATIONAL EXPOSURE TO BLOOD AND OTHER POTENTIALLY INFECTIOUS MATERIAL AFTER ADMINISTRATION OF HB VACCINE WITH 90% EFFICACY [1]

	Number prevented [2]
HBV infections	232,246–280,407
Clinical illness	60,419–73,378
Hospitalized	12,447–14,855
HBV carrier	[3] 12,447–29,616
Chronic HB	[3] 2,773–7,451
Fulminant death	277–426
Death—cirrhosis	4,159–5,322
Death—PHC [4]	955–1,159
All deaths	5,546–6,387

[1] Numbers calculated assuming that vaccine is given to all workers with frequent exposure to blood and other potentially infectious materials who are covered by this standard and who have not been vaccinated or had a prior HBV infection. The population at risk is estimated to be between 2,628,340 and 3,423,340. Numbers are calculated by applying 90% of the lifetime HBV risk attributable to occupational exposure given in Table F to the estimates of the population at risk. See text for details.

[2] Risks for all exposed workers are estimated assuming 15% and 30% had a previous infection and are thus immune.

[3] Smaller number assumes that 30% of the workers are immune due to prior infection and 5% of the workers infected will become HBV carriers. Larger number assumes that 15% of the workers are immune due to prior infection and 10% of the workers infected will become HBV carriers.

[4] Primary hepatocellular carcinoma.

Table H presents the lifetime risk of HBV infection and its outcomes attributable to occupational exposure after administration of a 90% efficacious HB vaccine. The numbers show that even with a vaccine which is 90% effective, there remains an increased risk of HBV infection to workers with occupational exposure to blood and other potentially infectious materials. Table H shows that after vaccination, the lifetime risk of infection is between 8 and 12 per 1000, the risk of clinical illness is between 2 and 3 per 1000, and the risk of death from fulminant hepatitis, cirrhosis, or primary hepatocellular carcinoma is between 2 and 3 per 10,000. By employing engineering controls, work practices and personal protective equipment, the remaining risk to health care workers can be further reduced.

TABLE H.—ESTIMATE OF HBV INFECTION AND ITS OUTCOMES AMONG WORKERS WITH EXPOSURE TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS AFTER ADMINISTRATION OF HB VACCINE WITH 90% EFFICACY [1]

	Lifetime occupational risk [2, 3]
HBV infections	7.54–11.85
Clinical illness	1.96–3.10
Hospitalized	0.40–0.63
HBV carrier	0.40 –1.25
Chronic HB	0.09–0.32
Fulminant death	0.009–0.018
Death—cirrhosis	0.14–0.23
Death—PHC [4]	0.03–0.05
All deaths	0.18–0.27

[1] Risks are expressed as the number of events per 1000 at risk.

[2] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.

[3] Assumes 45 years of occupational exposure.

[4] Primary hepatocellular carcinoma.

(D) Qualitative Assessment of HIV Risk

The CDC estimates that there are between 1 million and 1.5 million HIV-infected persons in the U.S. (Ex. 6–356). While the exact number of infections is unknown, CDC reported the number of adults with AIDS to be 78,312 as of November, 1988 (Ex. 6–379). Occupational information is available for 61,929 of the cases, and of these,

3,182 or 5.1% are health care workers (Ex. 6–378). This proportion is similar to the proportion of the labor force employed in the health care field.

Most health care workers with AIDS also belong to some other group which places them at high risk for HIV infection (e.g. homosexual men, intravenous drug users, etc.). There is, however, a statistically significantly larger proportion of health care workers with no known risk factors (5.3%), than the proportion of other AIDS cases (i.e. individuals with AIDS not in the health care field) with no known risk factors (2.8%). These.169 health care workers with no known risk factors are being studied further. CDC reports that 44 could not be assigned to a risk group after follow-up, 28 had either died or refused to be interviewed, and 91 were still under investigation (Ex. 6–378).

Adequate data do not exist for quantifying the risk of infection to health care or other workers with frequent occupational exposure to blood or other potentially infectious material. Because the extent of HIV infection in the general population is unclear, it is not possible to estimate an "expected" infection rate, and because the prevalence of HIV infection among health care and other workers with frequent exposure to blood or other potentially infectious material is unknown, it is not possible to estimate an "observed" infection rate. Therefore, it is not possible to quantify the risk as was done for occupational exposure to HBV. Certain deductions, however, can be made. It is known that the virus js present only in blood or certain body fluids and that exposure to these fluids from an HIV-infected person puts one at risk for HIV-infection. Therefore, workers who have frequent contact with blood or certain body fluids are at risk.

No case of infection due to casual contact with these fluids has been documented. Rather, infection can occur only if infectious fluids enter the body either through a percutaneous or mucosal route, although exposure by either of these routes does not mean that infection will occur. In several prospective studies of health care workers with HIV exposures, seroconversions have been observed. Although the rate of infection is low, it is not insignificant.

The most recent report from the CDC Cooperative Needlestick Surveillance Group (Marcus et al) shows that of 860 health care workers with an exposure to HIV-infected blood through needlestick or cut from sharp instruments, 3 workers became infected with the virus (Ex. 6–372). This leads to a seroconversion rate of 3.5 per 1000 exposures to infected blood through needlestick or cut, with a 95% upper confidence limit of 9 per 1000 exposures. Gerberding et al recently reported that of 180 workers with 215 exposures to HIV-infected blood through needlesticks, 1 worker became infected with the virus (Ex. 6–375). This leads to a seroconversion rate of 4.7 per 1000 exposures to infected blood through needlestick with a 95% upper confidence limit of 14 per 1000 exposures. The HIV infection rates reported by both of these studies are very close, and the upper confidence limit from each includes the estimated infection rate from the other. The upper confidence limit constructed from the Gerberding et al data is much larger than the upper confidence limit constructed from the CDC data because of the smaller sample size.

Both the CDC and the Gerberding et al studies provide estimates of the risk of infection given parenteral exposure to HIV-infected blood. Neither study, however, provides estimates of the risk of all occupational exposure. One approach to this problem has been suggested by Wormser et al who estimated the probability of HIV infection in terms of HIV-infected patient-days for hospital staff caring for HIV-infected patients (Ex. 6–388). For the 18 month period from January of 1986 to June of 1987, the authors observed a needlestick rate of 1.9 per 1000 HIV-infected patient-days among staff caring for HIV-infected patients. This rate was substantially lower than the needlestick rates of 4.3 and 4.6 per 1000 HIV-infected patient-days reported at the hospital for 1985 and 1984, respectively.

Using the observed rate of 1.9 needlesticks per 1000 HIV-infected patient-days, Wormser et al estimated the expected number of needlesticks for different numbers of HIV-infected patient-days. For example, for 45,000 HIV-infected patient-days, (750 HIV-infected patients hospitalized for 60 days, 1500 HIV-infected patients hospitalized for 30 days, etc.), the expected number of needlesticks is 86 (1.9/1000 x 45,000). Wormser et al then estimated the probability of at least one exposed worker becoming infected with HIV as $1-[(1-p)^n]$, where n is the number of needlesticks and p is the probability of becoming infected with HIV given needlestick exposure to HIV-infected blood, which the authors assumed to be 0.0035. The estimated probabilities, which are expressed per expected number of needlesticks or per HIV-infected patient-days, are presented in Table I. In addition, OSHA has calculated these probabilities using Gerberding et al's estimate of 4.7 infections per 1000 needlestick exposures to HIV-infected blood and has included them in Table I.

In reviewing Table I, it is important to remember that the probabilities presented there do not represent an estimate of the number of exposed workers who will become infected with HIV. "Number of workers exposed" is not used in any of the calculations, and therefore an expected number of infections per some number of workers caring for HIV-infected patients can not be calculated. One worker may experience more than one needlestick. The probabilities in Table I depend only upon the number of needlesticks which, in turn, depends only upon the number of HIV-infected patient-days and the assumption that needlesticks occur at a rate of 1.9 per 1000 HIV-infected patient-days.

Table I shows that the probability of HIV infection for at least one health care worker caring for HIV-infected patients does not increase linearly as the number of HIV-infected patient-days increases. A ten-fold increase in HIV-infected patient-days from 20,000 to 200,000 leads only to a six-fold increase in the probability of at least one infection. If one were to assume that the needlestick rate were two times higher than the rate used in Table I (i.e. 3.8 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection doubles at 5000 HIV-infected patient-days but increases only 6% at 440,000 HIV-infected patient-days. If one were to assume that the needlestick rate were half as high as the rate used in Table I, (i.e. .95 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection is one-third smaller at 5000 HIV-infected patient-days but only one-fifth smaller at 440,000 HIV-infected patient-days.

TABLE I.—PROBABILITY OF AT LEAST ONE INFECTION DUE TO NEEDLESTICK EXPOSURE TO HIV-INFECTED BLOOD [a]

Estimated		Probability of at least 1 infection	
HIV-infected patient-days	Number of needlesticks [b]	Wormser [c]	Gerberding [d]
5,000	10	.03	05
20,000	38	.12	16
45,000	86	.26	.33
105,000	200	.50	.61
200,000	380	.74	.83
440,000	836	.95	.98

[a] Probabilities are binomial (n,p) and calculated as one minus the probability of no infections.
[b] Number of needlesticks is calculated based on the estimated rate of 1.9 needlesticks per 1000 HIV-infected patient-days.
[c] From Wormser et al. (Ex. 6-388). Assumes that the probability of infection give needlestick exposure to HIV-infected blood is 3.5 per 1000 exposures.
[d] Probabilities calculated by OSHA using Gerberding et al's estimate of 4.7 infections per 1000 needlestick exposures to HIV-infected blood (Ex. 6-375).

This approach to estimating the risk of HIV infection would apply only to staff caring for HIV-infected patients because Wormser et al used a needlestick rate per HIV-infected patient-days which was estimated from this population. Instead of expressing the risk for a limited population in terms of HIV-infected patient-days, it has been suggested that the risk of HIV infection be expressed for all workers performing a certain procedure in terms of the number of procedures performed. The cumulative probability of HIV-infection would be estimated by

$$1-[(1-p)^N],$$

where N is the number of procedures performed and p is the probability of HIV infection for a single procedure. This probability is estimated by the product of the probability that blood or other potentially infectious material is infected with HIV, the probability that the worker is exposed while performing the procedure, and the probability the workers becomes infected if the blood or other potentially infectious material is HIV-infected and the worker is exposed. OSHA seeks comments on this approach for estimating the HIV infection risk to workers with frequent exposure to blood or other potentially infectious material.

Clearly, reducing the risk of needlestick will reduce the probability of HIV infection. CDC reported that of 1,201 exposures to HIV-infected blood through needlesticks, cuts with sharp objects, contamination of open wounds, or contamination of mucous membrane, 37% of the exposures could have been prevented if recommended infection control precautions had been followed. Recapping of needles accounted for 17% of the 1,201 exposures, improper disposal of needles or sharp objects accounted for 14%, and contamination of open wounds accounted for 6% (Ex. 6-372).

A study of needlestick injuries among hospital personnel by Jagger et al found that the risk of injury depended upon the type of device used and that devices requiring disassembly had the highest risks (Ex.6-350). Jagger investigated 326 needlestick injuries over a 10 month period and found that 17% occurred before or during use of the device, and 13% occurred during or after disposal of the devices. The majority (70%), however, occurred after use but before disposal of the devices. The single largest cause of injury was due to recapping. Workers missed the cap and stabbed themselves when attempting to cover a used needle in 17.8% of the injuries. Other major causes of injury were needles piercing caps when recapped after use (12.3%), contacting needles on exposed surfaces after use (10.7%), and needles protruding from trash (8.9%). The largest number of injuries was associated with disposable syringes, but when the injury rate for various devices was adjusted for the number of each type of device purchased, disposable syringes had the lowest accident rate at 6.9 per 100,000 purchased. All of the devices requiring disassembly had higher accident rates ranging from 8.3 per 100,000 purchased for prefilled cartridge injection syringes to 36.7 per 100,000 purchased for intravenous tubing and needle assemblies.

While most of the epidemiological investigations have concentrated on assessing the risk of HIV infection to health care workers exposed to HIV-infected blood through needlesticks or cuts with sharp objects, there is evidence that workers in research and production laboratories routinely exposed to high concentrations of the virus are also at risk of infection. Weiss et al prospectively studied 265 laboratory and affiliated workers and found one worker infected with the same strain of HIV as was used in the laboratory (Ex. 6-187). The infected worker reported occurrences of HIV contamination in the work area but could not recall any episode of direct skin exposure with the virus and denied any parenteral exposures. The worker reported that double gloves were worn whenever there were bandaged cuts on fingers or hands. An episode of nonspecific dermatitis on the arm was recalled, but the affected area was always covered by a cloth laboratory gown. There was no contact of potentially infectious material with these areas as has been reported for health care workers infected after clinical exposure to HIV-infected fluids (see Case Reports in the discussion of HIV health effects). For 99 workers who shared a work environment involving exposure to concentrated virus, the authors estimated the HIV infection rate to be .48 per 100 person-years with a 95% upper confidence limit of 2.39 infections per 100 person-years. Over a 45 year working lifetime, this would lead to a risk of 195 per 1000 exposed workers in research and production laboratories with a 95% upper confidence limit of 663 per 1000.

Weiss et al also reported a second incident of HIV infection in a research laboratory worker who was employed in the production of concentrated virus and who was cut on the hand with a potentially contaminated stainless steel needle used for cleaning an apparatus. The worker was not part of the Weiss et al cohort, and it is not yet known whether the virus which infected this worker is the same (i.e. genetically identical) as was found in the laboratory. Weiss et al noted that although the infected workers were careful, neither was fully conversant with or strictly adhered to biosafety guidelines in day to day procedures at all times. Weiss et al concluded that the infection of laboratory workers under prescribed Biosafety Level 3 containment "suggests the need to review carefully all operations involving highly concentrated infectious material and to ensure proficiency in the conduct of recommended safeguards" (Ex. 6-187).

Although it is not possible to quantify the risk of HIV infection in health care or other workers with frequent exposure to blood or other potentially infectious material or with direct exposure to the virus itself, the data show that a risk does exist. As the number of people with HIV-associated illnesses increases, the probability that workers exposed to blood or infectious material will also be exposed to HIV increases. Given needlestick exposure to HIV-infected blood, the risk of seroconversion is estimated to be between 3.5 and 4.7 per 1000 exposures, with 95% upper confidence limits of 9 and 14 per 1000 exposures respectively. For research and production laboratory workers with occupational exposure to high concentrations of the virus, the risk of seroconversion is estimated to be 4.8 per 1000 person-years, with a 95% upper confidence limit of 24 per 1000 person-years. Over a 45 year working lifetime, the risk would be 195 per 1000 exposed workers. By reducing the risk of exposure to blood and other potentially infectious material and by strictly adhering to biosafety procedures in handling the virus in laboratories, the risk of HIV infection can be reduced.

(E) Risk from Other Bloodborne Pathogens

As described in the health effects discussions, there are other bloodborne pathogens, such as syphilis and malaria which are present in blood during certain phases of infection. During these phases, the blood of infected individuals

poses a risk to exposed workers. Although this risk has not been quantified, it does exist and will be minimized or eliminated by preventing occupational exposure to blood.

VI. Significance of Risk

Section 6(b)(5) of the OSH Act vests authority in the Secretary of Labor to issue health standards. This section provides, in part, that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

OSHA's overall analytic approach for setting worker health standards is a four-step process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, a quantitative risk assessment is performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the regulatory alternatives being considered will substantially reduce the risk. In the third step, OSHA looks at the best available data to set the most protective requirements that are both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might well consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D. v. A.P.I.*) 448 U.S. at 655).

The Supreme Court's language indicates that the examples given were of excess risk over a lifetime. It speaks of "regular inhalation" which implies that it takes place over a substantial period of time and refers to the "odds * * * that a person will die," obviously a once in a lifetime occurrence.

The Court indicated, however, that the significant risk determination required by the OSH act is "not a mathematical straitjacket" and that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge (and that) * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

As part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, and the statistical significance of the findings.

The risks presented by the transmission of bloodborne pathogens are serious, as detailed above in the section on health effects. Hepatitis B is a viral infection that can cause acute and chronic disease. Symptoms of the disease can range from a flu-like illness to a more severe clinical illness characterized by jaundice, dark urine, nausea, vomiting, loss of appetite, abdominal pain and diarrhea. Chronic infection may also occur resulting in frequent periods of illness, and continual, usually life-long, infectious status. When an individual is infectious, either because of acute infection or because the individual has become a carrier, his or her blood and certain body fluids can transmit the virus to others. The hepatitis B infection may place other members of the infected individual's family at risk. There is a 30% chance that a sexual partner will become infected if the patient has an acute infection. If the patient is a carrier the probability is much higher. Perinatal transmission from an infected employee to her infant is an efficient mode of transmission with a particularly serious outcome. In the most extreme cases of infection death can result from fulminent hapatitis, viral cirrhosis of the liver or liver cancer. (See Section IV Health Effects).

HIV, the other major bloodborne pathogen, attacks the immune system, causing disease and death. Within a month following infection, the individual may experience an acute retroviral syndrome characterized by a mononucleosis-like syndrome. Later signs and symptoms can include persistent, generalized lymphadenopathy, fever, and constitutional illness characterized by wasting syndrome which may lead to death. HIV infected individuals who have developed AIDS may develop neurologic problems or cancer as well as opportunistic infections. Common conditions include encephalopathy, dementia, *Pneumocystis carinii* pneumonia; Kaposi's sarcoma; candidiasis of the esophagus, trachea bronchi or lungs; as well as bacterial infections. The blood and certain other body fluids from an infected individual are capable of transmitting the infection to others.

In this proposed standard, OSHA has presented quantitative estimates of the risk of death and clinical illness from occupational exposure to HBV infected blood and other potentially infectious materials. Qualitative evidence of occupational transmission of HIV is also included in OSHA's risk assessment.

OSHA estimates the lifetime risk of infection from HBV to be from 75 to 119 cases per thousand, the risks of material impairment of health or functional capacity, that is, clinical hepatitis, to be from 20 to 31 per thousand. The risk of death from HBV is 2 to 3 per one thousand. These estimates are based on the assumption of exposure to HBV for the period of a working lifetime of 45 years. Moreover, OSHA's risk assessment shows that even if every employee were to receive the HBV vaccine there would still be a remaining risk of material impairment of health of 2 to 3 per one thousand workers based on the 90% efficacy of the vaccine. OSHA believes these preliminary estimates may understate the risk; the actual risks attributable to occupational exposure to bloodborne diseases may be much higher as suggested in the previous section.

In the benzene decision the Court wrote of deaths from carcinogens, but the Act requires the Agency to assure that no employee will suffer" * * * material impairment of health or functional capacity * * *" Obviously, material impairment includes not only death, the risk of which is more than twice the risk the Supreme Court suggested might be significant, but also serious illnesses or the development of permanent infectious status (HBV carrier). For HBV infection, material impairment occurs when the patient presents acute symptoms, suffers chronic hepatitis, or becomes a carrier.

As detailed above in Section IV—Health Effects, HBV infection can result in very serious and debilitating illnesses. Any one of the symptoms characterizing an acute or chronic infection such as fatigue, fever,

vomiting, abdominal pain, diarrhea and jaundice, by itself, is enough to prevent an employee from doing his or her job effectively, efficiently or at all. An infection that requires hospitalization, such as occurs in 20% of the cases of clinical hepatitis, will prevent an employee from working. The shortest period that an employee would be unable to work would be the time he or she is hospitalized, but undoubtedly the out-of-work time would be longer as additional recovery time is invariably required following hospital discharge. Since symptoms typically last from several weeks to several months and, in the case of chronic hepatitis, several years, there can be considerable lost work time. Becoming a carrier is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier's blood or certain other body fluids will be at risk of becoming infected.

OSHA's preliminary risk estimates from HBV are comparable to other risks which OSHA has concluded are significant, and are substantially higher than the example presented by the Supreme Court.

Public response to the ANPR indicated general agreement that the risk to employers of contracting HBV are unacceptably high. Indeed, many employers have already instituted or upgraded their infection control programs and are vaccinating their employees. Industry response to the various pertinent CDC guidelines, the Joint Advisory Notice published by DOL and HHS, and the OSHA compliance initiative has been generally positive, indicating an acceptance by employers that employees who are not provided the protections that would be mandated by this proposed standard are at risk of contracting HBV.

After thoroughly considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA preliminarily concludes that the risk of death and material impairment of health resulting from acute and chronic HBV infection is significant, that HBV presents a significant risk to both unvaccinated employees and employees who have been vaccinated but have not developed immunity. Moreover, because HBV is not the only bloodborne pathogen capable of causing disease, all employees who are exposed to blood and other potentially infectious materials, whether they are HB-vaccinated or not, are at risk of infection.

At this time, OSHA believes that there are not sufficient data on HIV to quantify the occupational risk of infection. Nevertheless, the epidemiological data on HIV provide additional qualitative evidence that another bloodborne pathogen can be transmitted in the workplace and serve to further illustrate risk remaining after the major protection measure of HBV vaccination is implemented. OSHA's preliminary determination that employees who work in virus research and production facilities are at risk is supported by the report of one employee out of a population of less than 100 who were working with concentrated HIV who seroconverted. These employees are at risk because the virus is concentrated and is present in much higher titers than in blood, thus increasing the likelihood of the employee becoming infected following an exposure incident.

OSHA also preliminarly concludes that the new bloodborne pathogen standard will result in a substantial reduction of significant risk. The risk of HBV infection is most efficiently and dramatically reduced by vaccinating all workers exposed to blood and other potentially infectious materials. Based on OSHA's estimate of risk, vaccination of all workers would result in 2 fewer deaths and 18 to 28 fewer cases of material impairment of health per 1000 workers exposed over a working lifetime. If 30% of the population at risk is immune to HBV because of prior infection, then vaccinating the remaining 70% at risk will prevent approximately 280,407 infections, over 73,378 of which will be clinical infections including, in addition to cases of acute and chronic symptomatic illness, 29,616 carriers and 6,387 deaths over 45 years. If only 15% of the population at risk is immune, the number of infections prevented by vaccinating the remaining 85% at risk is estimated to be approximately 232,246 including 60,419 cases of clinical disease, over 12,447 carriers and more than 5,546 deaths over 45 years.

Despite these dramatic decreases in infections, OSHA's risk assessment estimates 8 to 12 HBV infections with 2 to 3 cases of clinical hepatitis per 1000 workers would occur even if all exposed employees were to receive the HBV vaccine. This is because the vaccine is effective for only 90% of the people to whom it is given. Even this remaining risk is probably an underestimate of the number of HBV infections that are likely to occur because it is unlikely that all workers will agree to be vaccinated. Moreover, the HBV vaccine will not protect employees from other bloodborne pathogens such as HIV. Based on these data, OSHA has preliminarily concluded that widespread administration of the vaccine will not completely eliminate significant risks.

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this, it is clear that Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. Typical occupational risk of death (from all causes including accidents and illness) in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all service employment derived from 1979 and 1980 Bureau of Labor Statistics data from employers with 11 or more employees adjusted to 45 years of employment for 46 weeks per year. As OSHA believes the proposed standard for bloodborne pathogens will reduce HBV associated risk of death and material impairment of health from 20 to 31 per thousand to 3 to 4 per 1000, the Agency is carrying out the Congressional intent and is not attempting to reduce insignificant risks.

Under both the Congressional intent and the Supreme Court rationale, OSHA must, if feasible, reduce all significant risks including those remaining after administration of the HBV vaccine. OSHA expects that the proposed rule as drafted will reduce the risks of exposure to levels well below those estimated. This is because the estimates of risk reduction only quantify the reduction achieved with universal vaccination, and do not fully take into account the other protective provisions of the proposed standard such as the infection control program, and methods of compliance including universal precautions, engineering controls, work practices and personal protective equipment, as well as medical surveillance and training. For the purpose of this discussion, the decrease in risk to be achieved by the additional provisions is not quantified beyond a determination that they will add to the protection provided by the requirement to vaccinate alone.

OSHA has considered various regulatory alternatives in addressing the risks of occupational exposure to bloodborne pathogens. These include informing employers and employees of the risk through the Joint Advisory Notice published in the **Federal Register** by the Department of Labor and the Department of Health and Human Services and the institution of an

enforcement program. Although these efforts have been fruitful, they have not eliminated the risks and therefore OSHA has preliminarily concluded that a standard specifically addressing the risks of bloodborne pathogens is necessary. OSHA's current data indicate the alternative selected is both technologically and economically feasible. OSHA's preliminary analysis of technological and economic feasibility of the proposed standard is discussed in the following section of the preamble.

VII. Preliminary Regulatory Impact and Regulatory Flexibility Analysis

Executive Summary

The Occupational Safety and Health Administration (OSHA) has prepared a Preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed Bloodborne Pathogens standard. The analysis is presented in six sections: Introduction; Industry Profile; Benefits; Technological Feasibility; Costs of Compliance; and Economic Impacts.

Industry Profile

Industries where workers are in contact with or handle blood and other potentially infectious materials will be affected by the proposed standard. Sixteen such industry sectors were identified for this analysis: hospitals (SIC 806); dental offices (SIC 802); offices of physicians (SIC 802. 803); medical and dental laboratories (SIC 807); nursing homes (SIC 805); residential care facilities (SIC 836); outpatient care facilities (SIC 808); blood collections and processing (SIC 809); health clinics in industrial facilities (various SIC codes); research laboratories (SIC 7391); law enforcement (SIC 9221); fire protection (SIC 9224); correctional institutions (SIC 9223); funeral homes (SIC 726); personnel services (SIC 7362); and medical and dental equipment repair (SIC 384,7699).

Table E.S.-1 provides a summary of the number of affected establishments and employees by SIC classification. Over 616,000 establishments are estimated to be affected by the proposed rule. Most of these establishments, about 585,000, are in the health care sector.

Any employee who is routinely exposed to human blood or other potentially infectious material as part of their assigned duties and who comes under OSHA's purview is affected by the proposed standard. On this basis, it is estimated that approximately 5.3 million workers will be affected by the standard. Approximately 87 percent of these workers, over 4.6 million people, are employed in health care occupations.

TABLE E.S.-1.—SUMMARY OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK

SIC code	Type of establishment	Number of establishments	Population at risk
801, 803	Offices of physicians	179,405	536,122
802	Offices of dentists	94,994	322,676
805	Nursing homes	16,247	778,375
806	Hospitals	5,983	2,145,140
807	Medical and dental labs	12,195	40,822
	Medical	4,916	
	Dental	7,279	
808	Outpatient care	29,706	370,514
809	Blood/plasma/tissue centers	672	22,198
836	Residential care	20,537	80,569
7362	Personnel services	1,615	155,844
726	Funeral services	15,051	26,407
(*)	Health units in industry	221,650	223,903
7391	Research labs	2,146	98,715
9221	Law enforcement **	6,205	208,693
9224	Fire and rescue***	3,174	201,749
9223	Correctional facilities	2,333	97,945
384	Medical equipment repair	2,967	1,882
	Totals	616,880	5,311,554

* Includes various SIC codes.
** Includes state and local departments only.
*** Includes fire departments and private ambulance services.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Benefits

After adjusting for background risk, OSHA has estimated that occupational exposures are responsible for between 5,953 and 7,416 cases of hepatitis B virus (HBV) infections per year. In total, considering the full combination of proposed provisions, including vaccination, engineering controls, work practices, protective equipment, housekeeping, and training, OSHA believes that the great majority of these HBV cases can be avoided. Compliance with the standard is estimated to prevent between 5,089 and 6,324 cases of occupationally induced HBV infection per year, of which 1,272 to 1,581 would have resulted in acute symptoms, and 113 to 141 in death.

In addition, OSHA estimates that between 3,653 and 4,132 non-occupationally induced cases of hepatitis B infection will be prevented annually, of which 81 to 92 would be fatal. These cases will be prevented due to the substantial elimination of background risk (non-occupational risk) for vaccinated workers and due to the reduced transmission of infections to sex partners of employees. In total, OSHA expects the proposed standard to prevent between 9,221 and 9,977 infections and between 205 and 222 deaths annually.

In addition to hepatitis B, the provisions of the standard will greatly reduce workers' risk of contracting acquired immune deficiency syndrome (AIDS) and other bloodborne diseases. Since at least 25 cases of human immunodeficiency virus (HIV) infection were reported to be associated with occupational exposure, OSHA believes that at least some cases of AIDS will be avoided.

Technological Feasibility

Limiting worker exposure to bloodborne diseases is achieved through the implementation of the following categories of controls:

- Training and education programs
- Use of personal protective equipment, especially gloves, gowns masks, and eye protection
- Use of mouth pieces, resuscitation bags or other ventilation devices
- Work practices, such as careful hand-washing after each patient contact and procedures for handling sharps
- Engineering controls, such as the use of puncture resistant containers
- Immunization programs
- Disposal and handling of contaminated waste
- Use of disinfectants
- Post exposure follow-up
- Labeling and signs

The requirements of the standard follow closely the guidelines issued by the Centers for Disease Control (CDC) on universal precautions (UP). As a consequence, the efforts by many organizations to adopt UP have created a solid base of practices and technology for the implementation of the standard. Table E.S.-2 provides a tabular summary of estimated current rates of compliance with the various provisions of the proposed standard.

OSHA findings with respect to the technological feasibility of the proposed Bloodborne Pathogens Standard are that the provisions of the standard permit practical means to reduce the risk now faced by those employees working with blood and other infectious materials and that there do not appear to be any major obstacles to implementing the proposed rule.

Costs of Compliance

Net compliance costs were estimated for each provision of the proposed standard by each facility type affected. These costs represent the additional costs of fully complying with the requirements of the standard, after deducting from total cost the current baseline activities that already voluntarily occur at affected facilities. One-time costs were annualized using a capital recovery factor. Exhibit E.S.-3 summarizes annual net compliance costs by facility type and by provision, while Table E.S.-4 provides cost by provision components. The total annual costs amount to about $852 million.

TABLE E.S.-2—SUMMARY OF CURRENT COMPLIANCE

Industry	PPE		Housekeeping		Post exposure follow-up (percent)	Records (percent)	Training (percent)
	Gloves (percent)	Other (percent)	Containers (percent)	Waste disposal (percent)			
Offices of physicians	60	60	40	39	0	0	0
Offices of dentists	75	40	50	39	75	0	60
Nursing homes	50	25	50	81	20	0	60
Hospitals	90	60	80	81	75	0	60
Medical/dental labs	90	90	92	86	0	0	60
Outpatient care	90	90	50	39	85	0	75
Blood/plasma/tissue centers	50	25	35	86	80	0	20
Residential care	50	25	50	81	20	0	60
Personnel services	N/A	N/A	N/A	N/A	0	0	0
Funeral services	100	100	100	39	100	0	60
Research labs	90	90	85	86	0	0	60
Fire and Rescue	50	50	50	39	50	0	50
Corrections	100	50	100	39	50	0	50
Police	50	50	50	39	50	0	50
Health units in industry	50	50	50	39	0	0	0
Medical equipment repair	50	50	50	86	0	0	50

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis. (Adapted from Ex. 13, Table II-31).

TABLE E.S.-3.—SUMMARY OF COMPLIANCE COSTS

[Grand Totals]

Industry	Infection control plan	Vaccination/ post exposure follow-up	PPE	Training	Housekeeping	Recordkeeping	Totals
Offices of physicians	$4,403,308	$9,786,439	$36,594,622	$53,761,970	$44,558,542	$481,395	$149,586,276
Offices of dentists	2,331,528	4,876,909	161,765,977	11,066,362	43,218,848	314,054	223,573,678
Nursing homes	895,707	14,765,531	69,627,753	9,311,852	27,438,924	842,452	122,882,219
Hospitals	528,647	28,787,707	90,338,514	31,345,685	41,864,493	2,041,164	194,906,210
Medical/dental labs	299,313	681,200	1,250,981	1,347,072	1,556,349	49,113	5,184,028
Outpatient care	745,154	4,459,264	17,961,080	5,622,316	9,268,560	338,261	38,394,636
Blood/plasma/tissue centers	16,494	252,304	6,044,858	850,181	1,880,171	19,089	9,063,097
Residential care	1,008,118	1,464,328	7,347,507	1,883,237	9,787,658	147,643	21,638,492
Personnel services	39,638	2,393,285	0	8,662,944	0	404,305	11,500,173
Funeral services	369,411	425,625	0	821,269	472,850	32,505	2,121,660
Research labs	52,671	2,285,227	4,663,091	1,872,736	4,564,571	217,188	[1] 13,659,113
Fire and rescue	90,174	1,850,542	1,388,457	715,333	770,839	133,149	4,948,495
Corrections	57,261	1,407,964	98,861	1,209,767	1,637,316	112,482	4,523,651
Police	152,295	552,494	814,121	2,219,885	254,751	128,157	4,121,702
Health units in industry	5,440,167	4,331,546	2,550,640	31,438,546	1,603,392	291,164	45,655,456
Medical equipment repair	72,822	53,714	271,255	22,099	0	2,088	421,977
Total	16,502,710	78,374,079	400,717,716	162,151,255	188,877,264	5,554,209	852,180,862

[1] Includes $3,628 for signs.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE E.S.-4.—SUMMARY OF COMPLIANCE COSTS BY PROVISION

Infection Control Plan		16,502,710
Vaccination/Follow-up		78,374,079
Vaccination Program	60,386,424	
Post-Exposure Follow-up	17,987,655	
PPE		400,717,716
Gloves	161,144,593	
Masks	159,330,782	
Gowns	62,914,128	
Goggles	8,895,488	
Resuscitation Devices	8,432,726	
Training		162,151,255
Housekeeping		188,877,264
Sharps Disposal	28,448,263	
Biohazard Bags	28,348,256	
Infectious Waste Disposal	117,217,433	
Foil Covering (Dental Offices)	14,863,312	
Labeling/Signs		3,628
Recordkeeping		5,554,209
Total		852,180,862

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Personal protective equipment accounts for the largest amount of net compliance costs ($400 million per year). Housekeeping ($189 million), training ($162 million), and vaccination and post exposure follow-up ($78 million) were also found to be significant cost components.

Economic Feasibility and Regulatory Flexibility Analysis

Table E.S.-5 provides a summary of economic impacts for the facility types affected by the proposed standard. The cost of the standard is largest relative to profits for temporary help services, where costs may represent over 12% of profits. Profit impacts also exceed 10% for dental offices (11%), though this impact estimate uses a profit figure which is exclusive of dentists' salaries. Dental offices have the highest costs relative to revenue. Two other high impact sectors are nursing homes (over 9 percent) and residential care facilities (over 5 percent).

It is probable that a large part of the compliance costs for establishments in SIC 80 (health care) will be passed on to consumers and third party payers. Also, the structure of health care financing in the United States dictates that a large proportion of the cost impact will be borne by federal, state and local government.

OSHA finds that a large number of small businesses, defined as firms with annual revenues of less than $3.5 million, will be affected by the proposed rule. With the exception of hospitals, over 87 percent of all health care facility types are small businesses. Thus, the impact on small business should not differ significantly from the impact on the affected universe as a whole. In the hospital sector, one consequence may be some increased industry consolidation, as smaller hospitals report lower operating margins than larger hospitals (Ex. 13, p. IV-18).

TABLE E.S.-5—SUMMARY OF ECONOMIC IMPACTS

Industry	Revenue/budget ($ million)	Profits [a] ($ million)	Annual costs ($ million)	Costs/revenue (percent)	Costs/profits [a] (percent)
Offices of physicians	92,900	[b] 6,900	149.59	0.161	2.168
		[c] 57,500			0.260
Offices of dentists	25,700	[b] 2,030	223.57	0.870	11.013
		[c] 19,000			1.177
Nursing homes	30,600	961	122.88	0.402	9.339
Hospitals	161,000	1,589	194.91	0.121	2.576
Medical/dental labs	7,100	475	5.18	0.073	1.091
Outpatient care	33,750	[d] 1,033	38.39	0.114	2.231
Blood/Plasma/Tissue centers	1,420	N/A	9.06	0.638	N/A
Residential care	8,700	[e] 254	21.64	0.249	5.784
Personnel services	3,200	96	11.50	0.359	11.979
Funeral services	5,500	390	2.12	0.039	0.543
Research labs	10,300	433	13.66	0.133	2.017
Fire and rescue	4,000	N/A	4.95	0.124	N/A
Corrections	9,900	N/A	4.52	0.046	N/A
Police	16,900	N/A	4.12	0.024	N/A
Health units in industry	([h])	([h])	45.66	N/A	N/A
Medical equipment repair	18,700	[f] 1,000	0.42	0.002	0.042

[a] Profit totals reflect proprietary firms only.
[b] Profits exclusive of salary.
[c] Profits including salaries.
[d] Based on profit margin of ambulatory facilities.
[e] Based on profit margin of nursing home sector.
[f] Medical equipment supply firms only.
[g] Ratio reflects private firms only.
[h] Health care budgets not estimated.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

a. *Introduction.* Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory impact analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. Similarly, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the Occupational Safety and Health Administration (OSHA) to consider the impact of the regulation on small entities.

Consistent with these requirements, OSHA has prepared a preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed Bloodborne Pathogens standard. This analysis describes the industries affected by the standard, the potential benefits that will be realized by health care workers and others who are currently at risk, the current infection control practices in the workplace, the costs of compliance, and OSHA's assessment of the technological and economic feasibility of the standard.

b. *Industry Profile.* Of interest in this proposed rulemaking are those workplaces in which employees are exposed to blood or other potentially infectious materials (as defined earlier in this preamble) during the performance of their duties. OSHA has

included sixteen industry sectors in this analysis: hospitals (SIC 806); dental offices (SIC 802); offices of physicians (SIC 802, 803); medical and dental laboratories (SIC 807); nursing homes (SIC 805); residential care facilities (SIC 836); outpatient care facilities (SIC 808); blood collections and processing (SIC 809); health clinics in industrial facilities (various SIC codes); research laboratories (SIC 7391); law enforcement (SIC 9221); fire protection (SIC 9224); correctional institutions (SIC 9223); funeral homes (SIC 726); personnel services (SIC 7362); and medical and dental equipment repair (SIC 384,7699).

Estimates of the number of affected establishments were based largely on government statistical publications as presented in a report to OSHA by Jack Faucett Associates (JFA) [Ex. 13]. Table VII–1 enumerates affected establishments by SIC code. As shown in the table, an estimated 616,880 establishments will be affected by the proposed rule.

JFA also provided estimates of the affected worker population. The major occupational groups exposed to blood and other infectious materials include nurses, physicians, dental professionals, laboratory workers, phlebotomists, and emergency responders. Table VII–2 provides a tabular summary of the population at risk. (Except where otherwise noted, population at risk data are based on the Bureau of Labor Statistics' (BLS) Industry Occupation Matrix for 1986). The 5.3 million workers identified do not include state and local government workers in states without state occupational safety and health plans, because these workers are not covered by OSHA. Thus, unless noted otherwise, estimates of the population at risk and the number of affected establishments used below reflect state and local governments only to the extent that state occupational safety and health plans are in place. Moreover, the estimate does not include the reported 190,000 self-employed physicians and dentists who would not fall under OSHA's purview.

The most common routes of exposure are by needlestick or entry through mucousal membranes or non-intact skin. These types of exposure occur across all of the affected industry sectors and throughout the various occupational categories. Exposure also takes place via cuts with sharp instruments or broken glass. Other routes of exposure are more or less confined to certain types of procedures. For example, laboratory employees may be exposed to contaminated equipment such as centrifuges or pipetting devices.

The remainder of this section briefly examines each industry, developing estimates of the number of affected establishments and employees, and describing the industry structure. Sources of exposure are also discussed.

TABLE VII–1.—ESTABLISHMENT SUMMARY

SIC code	Type of establishment	Number of establishments
801,803	Offices of physicians.	179,405
802	Offices of Dentists	94,994
805	Nursing homes	18,247
806	Hospitals	5,983
807	Medical and dental labs.	12,195
	Medical	4,916
	Dental	7,279
808	Outpatient care	29,706
809	Blood/plasma/ tissue centers.	672
836	Residential care	20,537
7362	Personnel services	1,615
726	Funeral services	15,051
[1]	Health units in industry.	221,650
7391	Research labs	2,146
9221	Law enforcement	[2] 6,205
9224	Fire and rescue	[3] 3,174
9223	Correctional facilities.	2,333
384	Medical equipment repair.	2,967
Total		616,880

[1] Includes various SIC codes.
[2] Includes state and local departments only.
[3] Includes fire departments and private ambulance services.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE VII–2.—SUMMARY OF POPULATION AT RISK

[Number of affected workers]

	Hospitals	Dental offices	Physicians offices	Med./dent. labs	Research labs	Police depts.	Fire & rescue	Nursing homes	Residential care	Outpatient care	Funeral homes	Personnel services	Correctional institutions	Blood/tissue collection	Industrial clinics	Equipment repair	Total
Physicians	100,460	1,194	208,929	2,223				2,294	579	50,586					2,251		368,516
Dentists	1,938	74,679	451	233				295		2,371							79,967
Registered nurses	756,836	1,505	97,515	534				10,366	1,074	119,877		43,455					1,031,162
Lic. pract. nurses	301,951	486	52,759	248				116,565	8,125	33,530		28,556					542,220
Occupational nurse															8,492		8,492
Therapists	83,730	136	5,815	226				23,297	1,460	14,124		2,235					131,025
Therapy assistants	16,998		1,191							3,760							21,949
Dental hygienists	620	84,332	495	164				50		890							86,551
Laboratory tech.	132,619	566	30,075	28,065		7,820		233		14,281							213,659
Emerg. med. tech.	12,921		239				25,550			11,621							50,331
Surgical tech.	31,497	77	864							317							32,775
Other health prof.	54,327	886	6,026	2,399			302	2,809	4,387	27,359	357	38,486					137,338
Dental asst.	1,390	148,556	564	211				185		3,983							154,889
Nursing aids/orderlies	325,743		1,641					509,573	40,282	60,814		43,112					981,165
Psychiatric aids	52,042							2,636	850	(in above)							55,528
Other health service	41,792	465	929	1,932				4,876	2,885	7,747					27,564		88,190
Physician asst.	4,792		11,207					705		5,004							21,708
Medical asst.	16,204	1,104	88,621	423				1,190		7,930							115,472
Ambulance drivers	2,830						5,382	119		1,322	754						10,407
Janitors & cleaners	206,450	8,690	28,801	1,313				103,182	20,927	4,998	4,375			692			379,428
Life scientists				2,849													2,849
Lab researchers					98,715												98,715
Police officers						200,873											200,873
Fire fighters							170,515										170,515
Embalmers											20,921						20,921
Corrections staff													97,945				97,945
Nurses/phlebotomists														9,300			9,300
Blood bank lab workers														6,510			6,510
Plasma center workers														5,600			5,600
Tissue bank workers														96			96
Emergency personnel															234,536		234,536
Unpackers/cleaners																1,882	1,882
Total affected	2,145,140	322,676	536,122	40,822	98,715	208,693	201,749	778,375	80,569	370,514	26,407	155,844	97,945	22,198	223,903	1,882	5,311,554

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis; Bureau of Labor Statistics; and Jack Faucett Associates.

Hospitals. It is expected that approximately 5,983 hospitals will be affected by the proposed standard. There are 343 federal hospitals. Of the remaining 5,640, it is estimated that approximately 979 are administered by state and local governments in state plan states.

Virtually all hospitals fall into one of three major categories: long-term, short term, or psychiatric. The American Hospital Association (AHA) reports that 90 percent of all nonfederal hospitals are classified as short-term, or community hospitals. Roughly 60 percent of all community hospitals are non-profit.

OSHA believes that over 2,000,000 workers are at risk in hospitals. Nurses and nursing aids comprise over 60 percent of the population at risk. Physicians (including surgeons), laboratory technicians, and janitors collectively make up an additional 20 percent (Ex. 13, p. I–16).

As most hospitals perform a great variety of services, there are many different exposure scenarios. The most frequently reported route of exposure for hospital personnel is by needlestick, with the greatest potential for exposure occurring during needle recapping (Ex. 13, pp. II–16, –19). Other hospital procedures that are associated with frequent exposure include phlebotomy, IV line placement, bronchoscopy, intubation, airway suction, endoscopy, colonoscopy, and proctosigmoidoscopy (Ex. 13, p. II–19). The highest risk areas in hospitals include the emergency room, surgical suite, hemodialysis center, and intensive care unit. Laundry workers and janitors may be exposed when handling contaminated linen or refuse.

Total revenue in 1986 for all hospitals is estimated at $174 billion (Ex. 13, p. I–10), about 84% of which was received by community hospitals. The total margin for hospitals, that is, the difference between revenue from all sources and total expenses expressed as a percentage of total revenue, is estimated to be about 4.5 to 5% (Ex. 13, p. I–10). U.S. Commerce Department estimates indicate that the 1988 total revenue for hospitals affected by the standard will be $169.1 billion with profits for proprietary hospitals totalling $1.6 billion.

Offices of Physicians. As shown in Table VII–1, an estimated 179,405 physicians' offices will be covered by the proposed rule. (This estimate is based on 1982 Census of Service Industries for offices with salaried employees).

While exposure to blood and body fluids would be expected in a physician's office, the increase in the number of physician office laboratories (POLs) now provides an even greater potential for exposure. These office-based laboratory facilities have recently grown in number by about 15 percent annually, though the total number of such facilities is unknown (Ex. 13, p. I–38).

The number of potentially exposed workers in physicians' offices is estimated to be 536,122 (Ex. 13, p. I–37). Physicians are the predominant occupational group, making up just under 40 percent of the total. (As noted above, 119,000 self-employed physicians are excluded). Nurses comprise approximately 28 percent of the total and medical assistants about 17 percent.

Frequency and type of exposure in a physician's office depends on the type of practice and the distribution of tasks. It is likely that phlebotomy is performed in a large number of offices, especially those with laboratory facilities. This task is typically performed by nurses. Nurses also change wound dressings. Physicians performing gynecological examinations or examining patients for sexually transmitted diseases are most certainly at risk. Invasive procedures and examination of mucous membranes can also put the examining physician at risk. Other types of procedures commonly encountered which place physicians and physicians' assistants at risk are treatment of lacerations, abrasions, and compound fractures.

Revenue for SIC codes 801 and 803 (offices of medical doctors and of doctors of osteopathy, respectively) totalled $76.7 billion in 1986 and are expected to climb to about $92 billion in 1988. Pre-tax profits are expected to reach $6.9 billion, non-inclusive of physicians' salaries. Profits including physicians' salaries are expected to total $57.5 billion (Ex. 13, p. I–33, –36).

Offices of Dentists. Based on 1982 Census data, OSHA estimates that 94,994 dental facilities will be affected by the proposed rule. (As noted above for Offices of Physicians, this includes offices with salaried employees). Dentist office laboratories numbered 9,737 in 1982, which is consistent with the American Dental Association (ADA) report that 11% of all dentists practice in an office with a laboratory. However, only 8.4% of these offices employ a lab technician (Ex. 13, p. I–26).

The potentially exposed workforce numbers 322,676 (Ex. 13, p. I–29). Dental Assistants are the predominant occupational category, with over 148,000 listed by BLS. The number of dental hygienists is estimated to be 84,332 and the number of dentists is approximately 74,679. (The 71,000 dentists who are reported as self-employed were not included in this figure). Data from the ADA indicate that 51% of all dental practices employ hygienists, with a mean work week of 23 hours for this occupation. About 88% of dental practices employ a dental assistant (Ex. 13, p. I–27, –28).

Evidence suggests that a common route of exposure in the dental office is allowing chapped or abraded skin to come into contact with saliva and/or blood. Also, dental staff receive on average in excess of one needlestick injury per month, a result consistent with the high percentage of dental staff who engage in recapping (Ex. 13, p. 11–52). Instances where the face or eyes are splashed or spattered with saliva, blood, or tissue fluids also increases risk. Dental workers are also exposed if improper procedures are employed when disinfecting dental instruments.

Revenues for dental offices for 1986 were reported by the U.S. Commerce Department to be $21.4 billion. Operating profits were 7.7% of revenues, according to data from Robert Morris Associates. Commerce Department estimates indicate that 1988 total revenues for dentists will be $25.7 billion. Applying the 1987 profit margin of 7.9% yields total profits for 1988 of $2 billion (Ex. 13, p. I–27).

Total income, including dentists' salaries, was also estimated. ADA data from 1983 indicate that general practitioners had average annual gross income of $154,830 and average net income of $55,570. For specialists, average gross income was $213,700, and net income was $84,250 (Ex. 13, p. I–28). Assuming an average net income of $60,000, an average number of dentists per practice of 3.4, and a number of affected practices of 94,994, yields a total income estimate of approximately $19 billion.

Medical and Dental Laboratories. Census data from 1982 indicate that approximately 12,000 medical and dental labs will be affected by the proposed rule. An estimated 7,279 dental laboratories and 4,916 medical laboratories were identified (Ex. 13, p. I–39).

The population at risk in medical and dental labs totals 40,822 workers (Ex. 13, p. I–41). Laboratory technicians comprise 68 percent of this total. Other occupational categories represented include physicians (2,223), phlebotomists and medical technologists (4,754), janitors (2,849) and nurses (782). According to census data, medical labs averaged 13 employees each and dental labs averaged 5 employees each in 1984.

Procedures that most often result in exposure in the laboratory are specimen collection and specimen processing. Workers are exposed through needlesticks (phlebotomists), spills, or the improper use of laboratory equipment, such as the centrifuge. Phlebotomists appear to have the highest rate of exposure incidents (Ex. 13, p. II–68).

Revenues for medical labs were $4.4 billion in 1986, and dental lab receipts totaled $1.6 billion for that year. Based on Robert Morris data, medical labs realized pre-tax profits of 7.5% of total receipts in 1986, and thus earned net profits of $300 million. Assuming the same margin is applicable for dental labs yields a net profit figure of $120 million for 1986. Revenue for medical and dental labs is estimated to be $7.1 billion in 1988, with profits totalling $475 million (Ex. 13, p. I–39).

Nursing Homes. This sector includes three types of facilities: nursing homes, of which there are estimated to be about 17,000; homes for emotionally disturbed children, of which there are 322; and homes for the mentally ill, of which there are 1,341. (Preliminary data on number of establishments were obtained from the 1986 National Center for Health Statistics survey of nursing and related care homes and from the public Health Service.) It was reported that in 1988 roughly 72% of nursing homes were proprietary (Ex. 13, pp. I–55, –56).

The potentially exposed workforce for this sector is estimated at 778,375. Nursing aids and orderlies are by far the most numerous workers, comprising over 65% of the total. Over 125,000 nurses are potentially exposed, as well as over 100,000 janitors and cleaners (Ex. 13. p. I–59).

It is the nursing staff who most often come into contact with body fluids of patients. Although the types of care rendered do not put staff into direct contact with blood very often, some contact with blood occurs. Needlesticks and sharps do not appear to present a great hazard, as the number of invasive procedures performed by staff is generally low (Ex. 13. p. II–97). Nonetheless, the number of these exposures is increasing as cost-containment measures by hospitals encourage early patient release. As OSHA lacks full information on these job tasks, the Agency requests additional public comment on the nature of employee exposures to blood and other infectious materials in nursing homes.

The 1986 revenue for nursing homes was $26.4 billion, representing 9.4% of the national health care budget. Based on Commerce Department information, gross revenues for those homes affected by the proposed rule will be $30.6 billion in 1988 (Ex. 13, p. I–58). Using the 1987 Robert Morris pre-tax profit estimate of 4.3% of receipts, 1988 profits for proprietary homes are estimated to be $960 million.

Residential Care. Residential care establishments affected by the proposed rule number about 20,537, based on information obtained from the National Center for Health Statistics for 1986. These include homes for the elderly and homes for the developmentally disabled. About 83% of homes for the elderly and 43% of homes for the developmentally disabled are proprietary. Homes for the elderly are generally quite small, with about 60% consisting of only 3 to 9 beds (Ex. 13, p. I–64, –65).

BLS employment data suggest that 80,569 workers are at risk in residential care facilities. As in nursing homes, nursing aids and orderlies make up the largest percentage of workers. About 50% of all potentially exposed workers fall into this category. Janitors and cleaners make up another 25% and over 9,000 nurses are at risk (Ex. 13, p. I–69).

As in nursing homes, blood exposures in residential care facilities do not occur often, but contact with blood does occur. The risk of exposure is greatest where unprotected chapped or non-intact skin comes into contact with blood or other potentially infectious materials. As noted above for nursing homes, OSHA requests additional public comment on the nature of potential exposures in this sector.

Estimated 1986 revenues for residential facilities affected by the standard were $7.4 billion. Estimated revenues for 1988 are $8.7 billion (Ex. 13, p. I–66) and estimated profits for proprietary facilities are estimated to be approximately $254 million.

Outpatient Care Facilities. Most outpatient care facilities fall into one of the following six categories: Health Maintenance Organizations (HMOs), freestanding ambulatory, hospices, home health care, drug treatment, or hemodialysis.

An estimate of the number of HMOs is based on the 1987 Census of Health Maintenance Organizations conducted by Interstudy and includes 654 establishments (Ex. 13, p. I–72). Most HMOs are independent, but some are administered by insurance companies (31 plans), hospital chains (10 plans), and corporations or consulting firms (16 plans) (Ex. 13, p. I–72).

The number of ambulatory care facilities is estimated to be 4,300, based on information for 1987 from the National Association of Ambulatory Care (NAAC). A reported 41.4% of these facilities are owned by corporations (Ex. 13, p. I–74).

Information published in 1987 puts the number of hospice care facilities at about 812, excluding hospices based in hospitals or home health establishments. The vast majority of hospices are non-profit, with 42% being independent, community based organizations (Ex. 13, p. I–74).

The number of home health care facilities that would be affected is estimated to be 7,000, based on 1987 data on Medicare-certified establishments and on 1987 data from the National Association of Home Health Care (Ex. 13, p. I–72).

The most recent data regarding drug treatment centers, a 1982 survey by the National Institute on Alcohol Abuse and Alcoholism, placed the number of such facilities at 4,818. Excluding those facilities based in hospitals and correctional facilities leaves an estimated 3,887 centers that classify as outpatient facilities (Ex. 13, p. I–75).

Medicare-certified hemodialysis centers numbered 1,578 in 1986, but only 861 were freestanding. About 80% of these facilities are for-profit (Ex. 13, p. I–75).

Also, 10,483 government outpatient care facilities are estimated to be in operation (Ex. 13, p. I–75A). It is likely that this total includes a number of facilities which provide care for the mentally retarded.

Thus, the total number of outpatient facilities believed to be covered by the proposed rule is 29,706.

The affected worker population totals 370,514 (Ex. 13, p. I–79). Over 150,000 nurses are at risk in this sector, as well as approximately 61,000 nursing aids and orderlies. An estimated 50,586 physicians and surgeons are also at risk.

With so many different kinds of services offered within this SIC, all major routes of exposure are expected. Ambulatory centers and HMOs perform many of the same procedures that are performed in a physician's office, and thus exposure routes are similar to those outlined for that sector. Home health and hospice services perform many of the same procedures performed in a nursing home or residential care facility, and thus the exposure potential is similar. Over 14,000 laboratory technicians were identified in this sector by BLS, so exposure via laboratory procedures and equipment is probable.

Revenues for home health care establishments is estimated at $8 billion, as this was the level of expenditure on such services in 1987. Total revenue for ambulatory centers is estimated at $2 billion, based on 1983 data compiled by

NAAC. Profit levels for ambulatory care centers were reportedly 5.1% of profits (Ex. 13, pp. I–76, –77). In 1988, outpatient facilities are projected to receive about $33.7 billion in revenues and proprietary facilities are projected to receive about $1.0 billion in profits.

Blood Collections and Processing. According to information received from the American Association of Blood Banks (AABB), there are 260 independent blood centers in operation. About 400 plasma centers and 12 tissue banks will also be affected by the proposed rule, based on information supplied by the American Blood Resources Association (ABRA) and the American Association of Tissue Banks (Ex. 13, p. I–95).

The population at risk for this sector is estimated to be 22,198 workers (Ex. 13, p. I–98). Phlebotomists, nurses, and laboratory workers are the predominant occupational categories for blood banks, and it is reasonable to assume that this is also true for plasma centers and tissue banks. Over 40% of all blood center employees are part-time.

Workers in this sector are exposed most often during blood collection and blood processing. As in medical and dental labs (discussed above), workers in this SIC are exposed through needlesticks (phlebotomists), mucous membrane contacts, spills, or the improper use of laboratory equipment, such as the centrifuge [Ex. 13. pp. II–125–127].

Revenue for blood centers was estimated at $1.3 billion in 1987, based on data obtained from 106 members of AABB. Using this figure as an indicator for the sector as a whole yields a total revenue estimate of $1.42 billion for SIC 809.

Health Clinics in Industrial Facilities. Of the 16 sectors included in this analysis, this sector includes the most facilities, as 221,650 industrial health clinics have been identified [Ex. 13. p. I–10]. These services are in operation throughout industry and are not peculiar to any SIC code or industry sector.

The potentially exposed workforce is estimated to be 223,903. The great majority of these workers are full or part-time emergency personnel. In almost 11,000 workplaces, a physician or nurse is in charge [Ex. 13, pp. I–100–101].

Traumatic injuries occur in industrial facilities, giving rise to potential for blood exposure. Invasive procedures or the changing of wound dressings also occur.

Research Laboratories. For the purposes of this analysis, research laboratories include any laboratory performing research activities where workers may be occupationally exposed to blood or other potentially infectious materials. (This definition differs from that used in the standard which defines as research laboratories only those facilities producing research laboratory scale amounts of HIV or HBV.) Research laboratories have been classified into four categories: academic labs; independent labs; captive labs (industry affiliated); and government sponsored labs.

The number of labs covered by the proposed rule is estimated at 2,146 [Ex. 13, p. I–42]. These include 246 academic labs, 719 independent labs, 1081 captive labs, and 100 medical labs sponsored by the federal government. These estimates are based on a 1987 survey of laboratories performed by Booz, Allen, and Hamilton (BAH) and on 1982 Census of Manufactures data.

The potentially exposed workforce is estimated to be 98,715 [Ex. 13, p. I–46]. These workers are scientists, research assistants, and laboratory technicians.

Exposure incidents in this sector, as in all others, tend to be linked to procedures. Workers in these types of establishments, however, have little or no patient contact. Spills, which may cause infectious material to come into contact with non-intact skin, mucous membrane contamination, and cuts with sharp instruments are the most frequent routes of exposure in these facilities. Reduction of risk will be almost totally dependent upon the use of engineering controls and proper laboratory work practices when handling potentially infectious materials. Paragraph (e) of the standard contains special requirements for research laboratories and production facilities handling the concentrated virus. Additional training requirements for employees in these facilities is found in paragraph (9)(2)(v).

Based on a study by the National Science Foundation, approximately 28% of funds expended for private research went for medical research. This translates to an annual budget of $2.5 billion for 1986. Additionally, $3.8 billion was spent in the U.S on pharmaceutical research in 1986. Profit margins for commercial and development labs were 4.3 percent of receipts for that year. Information obtained by BAH indicates that federally sponsored labs have average budgets of $2.2 million. Assuming this figure is applicable to medical research labs, the 100 federally sponsored medical labs would have a total budget of about $220 million [Ex, JFA, pp. I–43–44].

Total revenues for this sector are estimated to be $10.3 billion [Ex. 13, p. I–44]. Profits for proprietary labs are estimated at $433 million.

Law Enforcement. The total number of law enforcement establishments affected is approximately 6,205 [Ex. 13, p. I–47]. This number includes state and local police departments in states with state occupational safety and health plans. These departments employ approximately 170,000 workers who are at risk. Based on Bureau of Justice Statistics (BJS) and Census Bureau data, Federal law enforcement personnel at risk number approximately 31,000. These personnel, at risk because their jobs provide potential for contact with blood and blood contaminated weapons and drug paraphernalia, are estimated to represent 70 percent of all law enforcement officers [Ex. 13, p. I–48]. Additionally, approximately 8,000 laboratory technicians are estimated to be at risk in police labs [Ex. 13, p. I–49].

Law enforcement personnel are at risk because they may come into contact with blood or other potentially infectious materials during the course of duty. In the event that violent crime or life-saving situations are encountered, appropriate precautions need to be taken in the form of proper work practices and personal protective equipment. The frequency of these exposures varies with the locality and the rate of violent crime, but OSHA estimates that about 10% of these employees are exposed on a fairly frequent basis.

According to BJS, expenditures for law enforcement totalled $22 billion for fiscal year 1984–85. State and local governments spent $19.2 billion and federal expenditures were $2.8 billion [Ex. JFA. p. I–47]. It is estimated that 1988 expenditures will be $30.8 billion, with 47.5%, or $16.7 billion, occurring in state-plan states.

Fire Protection. About 3,174 fire departments will be covered by the proposed rule. All-volunteer fire departments do not come under OSHA's purview and thus are not included in this estimate. (The actual number of stations, however, appears to be roughly 5,232, as many departments operate out of more than one station.) Private emergency medical establishments number about 500 [Ex. 13, p. I–51].

The potentially exposed workforce is estimated to be 201,749 workers. These are mostly career fire fighters plus volunteers who are paid part-time wages. Private rescue services employ 25,550 of these potentially exposed workers [Ex. 13, p. I–53].

Emergency responders, who are estimated to comprise about 30% of these employees, are very often in situations where there is a potential for occupational exposure. Emergency

medical technicians perform invasive procedures and administer resuscitation. These workers are frequently exposed to blood.

Expenditures on fire protection in state plan states is estimated to be approximately $4.0 billion [Ex. 13, p. I–52].

Correctional Institutions. An estimated 2,333 correctional institutions are affected by the proposed rule. Of these, 47 facilities are federally administered. A reported 65 of the 2,333 facilities identified medical treatment or hospitalization as a primary function. (These figures are based on BJS census information for the years 1983 and 1984). [Ex. 13, p. I–92]

The number of state and local custody and security employees estimated to be at risk is 74,000. Additionally, 12,000 treatment, and education employees are estimated to be at risk in state and local facilities. Adding the 12,000 federal workers at risk yields a total population at risk of 98,000 [Ex. 13, p. I–92].

Situations putting correctional employees at risk of blood exposure include violence and emergency medical treatment. While exposure to other potentially infectious materials takes place in correctional facilities, such situations do not occur on a daily basis.

Expenditures for corrections in state plan states is estimated to have reached $6.9 billion in fiscal year 1984–85. Federal government expenditures were $779 million in 1985. Total expenditures are expected to be $9.9 billion in 1988 [Ex. 13, p. I–92].

Funeral Homes. The number of funeral homes believed to be affected by the proposed rule is 15,051. This is based on the 1982 Census of Service Industries [Ex. 13, p. I–84].

The total number of workers estimated to be at risk in funeral homes is 26,407 [Ex. 13, p. I–87]. The majority of these workers are embalmers (about 80%) with janitors making up most of those remaining.

Procedures placing funeral home workers at risk of exposure are embalming, cleaning, disinfecting, and transporting cadavers. Embalmers are at risk due to the presence of uncontained blood, and the need to handle various body parts and tissues and to suture incisions.

According to census data, revenues for all funeral services and crematories were $5.5 billion in 1986. Average profit margins were estimated to have been 7.1% in 1987, making profit levels for the industry about $390 million [Ex. 13, p. I–84].

Personnel Services. JFA estimates that between 1,301 and 1,615 personnel firms worked with registered nurses in 1983 [Ex. 13, p. I–88]. For the purposes of this analysis, OSHA assumes that there are 1,615 affected establishments in this sector.

BLS estimates that only about one-tenth of all temporary workers work in the health field. This potentially exposed workforce is approximated at 155,844 [Ex. 13, p. I–89]. These workers are primarily nurses and nursing aides.

The risk of exposure for temporary nurses and nursing aides is the same as for permanent nurses.

Revenues for personnel supply companies were $10.4 billion in 1986, according to the Service Annual Survey. On the assumption that revenues are divided by establishment share, $2.7 billion is estimated to have been earned by those personnel service companies affected by the proposed rule. Similarly, pre-tax profits were estimated at $70 million, based on data reported by Robert Morris Associates. Revenues in 1988 are projected to be $3.2 billion while profits are projected to be $96 million [Ex. 13, p. I–88].

Medical Equipment Repair. OSHA estimates that 2,967 facilities that repair medical or dental equipment will be affected by the proposed rule. The 1982 Census of Manufactures includes 2,711 of these establishments in the medical instrument industry. Industry sectors included: Surgical and Medical Instruments (SIC 3841); Surgical Appliances and Supplies (SIC 3842); and Dental Equipment and Supplies (SIC 3843). In addition, 256 firms were identified which exclusively repair and service medical equipment [Ex. 13, p. I–104].

The affected workforce, which is estimated to be 1,882 workers [Ex. 13, p. I–107], includes only those workers who unpackage and clean and disinfect the equipment prior to servicing.

The total value of shipments for this sector is estimated to be $18.7 billion, based on Commerce Department data. Assuming profit margins are approximately equal to those of 1987, profits for this industry will be $1 billion [Ex. 13, p. I–105].

c. *Benefits—Introduction.* OSHA's standard to reduce occupational exposure to bloodborne pathogens, including hepatitis B virus (HBV), non-A, non-B hepatitis virus, and human immunodeficiency virus (HIV), includes provisions applicable to the wide range of occupational settings where potential exposure to such bloodborne pathogens exist. This section describes how the standard will reduce the risk and estimates the expected reduction in HBV cases among the employees affected by the standard. These estimates are based on data and information provided to OSHA by Jack Faucett Associates, the Centers for Disease Control (CDC), and commenters to the rulemaking record.

Hazard Abatement. OSHA's standard for reducing worker exposure to bloodborne pathogens includes eight primary categories of control. The standard is based on the adoption of universal precautions as a method of infection control. Fundamentally different from traditional procedures that isolate known infectious individuals and materials in the health care setting, this approach assumes that all human blood and certain body fluids and tissues are potentially infectious for HIV, HBV, and other bloodborne pathogens. The rationale for this approach is that carriers of these diseases are not always identifiable in the health care giving setting, and that contaminated materials are not always properly labelled. Thus, the exposed worker can be at great risk without warning.

The standard will apply to widely varying workplace settings, including research laboratories, funeral homes, hospitals, prisons and police and fire departments. Hazard abatement measures will be developed by the employer to best suit the workplace setting and accomplish the common objective of protecting the worker from contact with blood and other potentially infectious materials.

In implementing the standard, employers will first develop an infection control program that identifies (1) the tasks and work areas that are likely to present exposures to blood, or other potentially infectious products, (2) the employee positions that are involved, and (3) the controls that will be used to reduce the potential risk.

All exposed employees must participate in employer provided training, which is to be accomplished within 90 days of the effective date of the standard or at the time of employment, and at least annually thereafter. The training must include clinical and epidemiologic information about infectious diseases, modes of transmission, and means to reduce risks of exposure. It must designate specific procedures to be used in the work setting and specific policies to deal with exposures.

In a series of case studies conducted by Jack Faucett Associates, hospitals reported that one of the most important aspects of employee compliance with infection control programs was an understanding of the risk. The employee training that conveys this risk becomes

an indispensable link in hazard abatement.

Another requirement of the standard is that employers offer prescreening and HBV vaccine to those employees who are exposed to blood or other potentially infectious materials on average once or more times per month. HBV vaccination is a means of achieving substantial reduction in the risk of infection for non-immune employees, achieving up to a 98 percent rate of efficacy (Exs. 4–20; 6–45).

The standard also requires post exposure evaluation and treatment. This includes testing to determine whether there has been transmission of infection, and follow-up treatment and counseling. In the case of exposure to HBV, follow-up treatment can prevent illness. Thus, procedures for reporting exposures are an important part of the infection control program.

Additional controls that employers will use include engineering controls, work practices, personal protective equipment and housekeeping measures. There is a clear understanding that effective hazard abatement in health care settings will require a full range of protective measures, with personal protective clothing being integral to the program. Engineering controls such as splash guards and biosafety cabinets will complement work practices involving safe use of centrifuges and housekeeping provisions for disposal of needles and sharps. In one study, approximately 41% of the laboratory accidents preceding infection were related to needles and sharps and an additional 27% were related to spillage and splashes, especially from centrifuge use (Ex. 13, p. II–79). Collins also reports that 37% of the infected laboratory staff were not trained.

Work practices can also have a substantial impact on hazard abatement by altering the manner in which a task is performed. Needlesticks, which occur frequently when recapping contaminated needles, have been identified as a major route of exposure. Indeed, the most commonly reported route of exposure to blood and other potentially infectious materials is the needlestick or cut with other types of sharps. Health care facilities report an average of 4 to 16 needlesticks per 100 employees per year (Ex. 6–82; Ex. 4–13), and these figures may underestimate the actual exposure rate by 40 to 50 percent (Ex. 13, p. II–16; Ex. 6–100). Maynard and Hollinger have estimated that at least 1 percent of hospitalized patients are HBV carriers, and Gerberding has estimated a seroconversion rate of 19 to 27 percent for HBV after accidental percutaneous injection of blood serum from patients who are positive for HBe antigen (highly contagious)(Ex. 6–114).

In conjunction with a firmly enforced policy of not recapping needles by hand, adequate and accessible puncture resistant disposal containers must be provided in order to substantially reduce these exposures (Ex. 13, p. II–29). Studies suggest that adopting a point-of-use, puncture resistant container system may reduce injuries for housekeeping, medical and nursing staff (Ex. 13, p. II–30).

Under this standard the employer shall make appropriate personal protective equipment readily accessible if there is a potential for exposure to blood or other potentially infectious materials. The equipment shall include gloves, masks, face shields, gowns, and aprons of appropriate material. In addition, emergency ventilation devices shall be used to minimize the need for mouth-to-mouth resuscitation.

The use of personal protective equipment is a direct line of defense for health care workers whose exposures occur through contact with infected patients. Gowns and gloves, used for many years in surgery and nurseries, are now routinely used by many emergency room and hemodialysis personnel to reduce the risk of infection and disease transmission. The effectiveness of these controls in reducing the incidence of HBV infections is exemplified by the experience of a large mid-western hospital, which in the 1970's had a growing number of infections among its staff. After instituting a full range of infection control practices the hospital reported no known HBV infection in 1986 and 1987 (Ex. 13, p. 88). In order to evaluate such programs, OSHA requests additional public comment on infection control experiences of other affected institutions.

Since linens or waste products contaminated with blood or other potentially infectious products may present a risk of disease transmission, the proposed standard establishes procedures for the handling of contaminated linen and waste by housekeeping or laundry staff. The standard provides measures that will reduce contact with contaminated linens and waste by requiring clearly labelled, leakproof containers or bags.

Under the standard, laboratories producing HIV and HBV for research or laboratories concentrating these viruses shall conduct procedures according to paragraph (e) of the proposed standard. These procedures were derived from the NIH/CDC guidelines for Biosafety Level (BSL) 2 and BSL 3.

As documented earlier in this preamble, concentrated HBV and HIV present a high risk for infection in the laboratory environment, thus emphasizing the importance of implementing stringent infection control practices in this facility type.

Population-at-Risk. Table VII–3 identifies by SIC code and facility type OSHA's estimates of the total number of workers at risk of exposure to HBV and HIV. The population-at-risk of HBV infection is a subset of the total population at risk of HIV infection because prior exposure or vaccination may result in immunity to HBV infection.

Quantification of Benefits. Bloodborne pathogens are associated with a variety of diseases among employees exposed to infectious materials, and OSHA has not been able to quantify all of the potential benefits expected from the proposed standard. Most importantly, the relatively short history of the HIV epidemic has made it difficult to develop a precise projection of the number of job-related AIDS cases that will be averted. It is known that the probability of HIV transmission in most workplace settings is low; only 25 cases of HIV infection associated with occupational exposure have been documented (see Health Effects). Nonetheless, the prevalence of AIDS continues to climb rapidly among the general population, and in the absence of strict infection control, the rate of occupational risk will grow accordingly. A recent study conducted by CDC found that 37% of the reported exposures to the HIV virus could have been prevented if routine precautions had been followed [Ex. 6–372].

TABLE VII–3—POPULATION AT RISK: HEALTH CARE AND OTHER EMPLOYEES AT RISK BY SIC AND FACILITY

SIC	Facility name	Total employees
High risk health care workers:		
8060	Hospitals	2,145,140
8020	Dental Offices	322,676

TABLE VII-3—POPULATION AT RISK: HEALTH CARE AND OTHER EMPLOYEES AT RISK BY SIC AND FACILITY—Continued

SIC	Facility name	Total employees
8010, 1830	Physician's Offices	536,122
8070	Medical and Dental Labs	40,822
8050	Nursing Homes	778,375
8360	Residential Facilities	80,569
8080	Outpatient Care Facilities	370,514
8090	Blood Banks and Others	22,198
	Industrial Clinics	223,903
7362	Temporary Workers	155,844
Total at Risk of HIV		4,676,163
Total at Risk of HBV, Assuming 23% Of Employees Are Now Vaccinated And A 15% To 30% Natural Immunity Rate.		2,320,436-3,021,860
Other employees at risk:		
7260	Funeral Homes	26,407
9221	Police	208,693
9224	Fire Department	201,749
9223	Correction Workers	97,945
7391	Research Laboratories	98,715
	Medical Equipment	1,882
Total at Risk of HIV		635,391
Total at Risk of HBV, Assuming 0.1% of Employees Are Now Vaccinated, And A 15% To 30% Natural Immunity Rate.		444,202-539,510
Total Population At Risk Of HIV		5,311,554
Total Population At Risk Of HBV, Given Vaccinations and Immunity.		2,764,638-3,561,370

Source: Office of Regulatory Analysis, 1989.

In contrast to the limited knowledge concerning the risk of AIDS, the risk of contracting hepatitis B at the workplace has been studied extensively for many years. OSHA therefore has developed quantitative estimates of the effect of the proposed standard on the future number of hepatitis B infection cases among the employees at risk. First, OSHA addressed the vaccine provision by estimating the annual number of cases of each type of hepatitis B that would be avoided by offering all eligible employees the opportunity for vaccination. The basic assumptions for this benefits analysis are that 15% to 30% of the workers have acquired lifetime immunity from past exposure to HBV, and that 23% of the health care workers and 0.1% of the non-health care workers at risk have already received the vaccine (see Preliminary Quantitative Risk Assessment). Of the remaining exposed workers, OSHA assumes that all of the identified employees, except for 70% of the firemen and 90% of the police, are potentially exposed more than once a month and therefore will be eligible for the vaccination program. OSHA assumes that 50% of these employees will choose to participate and, if found not to be immune, to receive the HBV vaccine. The efficacy rate for the vaccine is assumed to be 90% (Ex. 4–20; 6–45; Ex. 13, p. II–32).

Next, OSHA multiplied estimates of the number of employees at risk by the extent of the excess risk. As developed earlier in this preamble, the annual occupational risk of contracting HBV infection for these employees is estimated at from 1.74 to 2.80 per thousand employees. For the employees exposed less often than once a month, OSHA assumed that the excess risk would be one-half as large. The first four columns of Table VII–4 present estimates of the baseline annual incidence of work-related cases of HBV infection and the number of these cases that would be avoided annually following the implementation of the new vaccination programs. As shown, OSHA estimates that the current number of occupationally-related cases is between 5,953 and 7,416 per year, of which over 40% would be prevented by offering vaccination. (More cases are predicted for the higher natural immunity rate (30%) because, given the reported number of cases and the fixed background incidence, it implies a proportionately greater risk of occupationally-related disease among employees who are not immune.)

The 1.7 to 2.1 million workers at risk who will not be protected by vaccination must rely on the other provisions of the standard, including engineering controls, work practices, personal protective equipment, post-exposure medical evaluation, housekeeping and training. In the midwestern hospital mentioned earlier, less than 20% of the eligible employees chose to receive the vaccine, yet this facility was able to reduce its incidence of reported HBV infection from 160 cases during a 2-year period in the early 1970s to one case in 1985 and none in 1986 and 1987. This was accomplished through the establishment of a comprehensive program of infection control practices, including aggressive post-exposure protocol, and supports OSHA's belief that although HBV vaccination is a key protective measure, a very high degree of disease avoidance can be maintained through ancillary infection control practices. Thus, OSHA has assumed that 75% of the remaining risk would be prevented by implementing the non-vaccine related provisions of the standard.

TABLE VIII–4.—ANNUAL BASELINE CASES AND CASES AVOIDED OF OCCUPATIONALLY INDUCED HEPATITIS B

	Baseline cases		Cases avoided due to vaccine		Total cases avoided	
	15 immune	30 immune	15 immune	30 immune	15 immune	30 immune
HBV Infections	5,953	7,416	2,498	3,049	5,089	6,324
Acute Symptoms	1,488	1,854	624	762	1,272	1,581
Hospitalized	298	371	125	152	254	316
Fulminant Death	7	9	3	4	6	8
HBV Carrier	298	742	125	305	254	632
Chronic HB	74	185	31	76	64	158
Death Cirrhosis	101	126	42	52	87	108
Death PHC	24	30	10	12	20	25
All Deaths	132	165	56	68	113	141

Source: Office of Regulatory Analysis, 1989.

In total, considering the full combination of provisions, including vaccination, engineering controls, work practices, protective clothing, housekeeping, and training, OSHA believes that the great majority of HBV cases caused by workplace exposure can be avoided. The final columns of Table VII–4 display OSHA's estimate that compliance with the standard will prevent from between 5,089 and 6,324 cases of occupationally-contracted HBV infection per year, of which from 1,272 to 1,581 would have resulted in acute symptoms, and from 113 to 141 in death.

In addition, a considerable number of non-occupationally induced illnesses will be prevented. OSHA estimates the background risk of HBV to be 1.74 cases per 1000 employees. On this basis, immunizing the 1,210,407 to 1,595,097 employees who are estimated to be vaccinated as a result of this standard will prevent about 1,921 to 2,532 background cases per year. Furthermore, sex partners of those with HBV infections will become infected about 30% of the time (Ex. 6–425; 6–430). As over 60% of the U.S. workforce is married, OSHA assumes that about 70% of the HBV victims could potentially spread this disease. Thus, halting its dissemination to the non-occupationally exposed population will boost the full benefits of the standard by about 21% (30% x 70%) per year. These results, which are displayed in Table VII–5, indicate that this standard will prevent from 3,653 to 4,132 cases of non-occupationally induced cases of hepatitis B, of which from 81 to 92 would be fatal. Table VII–6 combines the estimates presented in the two previous tables and shows that OSHA expects the standard, in total, to prevent from 9,221 to 9,977 infections and from 205 to 222 deaths per year from both occupational and non-occupationally-induced cases of hepatitis B.

TABLE VII–5.—ANNUAL CASES AVOIDED OF NONOCCUPATIONALLY INDUCED HEPATITIS B

	Cases avoided due to vaccine		Cases avoided by sex partners		Total cases avoided	
	15 percent immune	30 percent immune	15 percent immune	30 percent immune	15 percent immune	30 percent immune
HBV infections	2,532	1,921	1,600	1,732	4,132	3,653
Acute Symptoms	633	480	400	433	1,033	913
Hospitalized	127	96	80	87	207	183
Fulminant Death	3	2	2	2	5	5
HBV Carrier	253	192	160	173	413	365
Chronic HB	63	48	40	43	103	91
Death Cirrhosis	43	33	27	29	70	62
Death PHC	10	8	6	7	17	15
All Deaths	56	43	36	39	92	81

Source: Office of Regulatory Analysis, 1989.

TABLE VII–6.—ANNUAL NUMBER OF OCCUPATIONAL AND NONOCCUPATIONAL HEPATITIS B CASES AVOIDED

	Occupational cases avoided		Nonoccupational cases avoided		Total cases avoided	
	15 percent immune	30 percent immune	15 percent immune	30 percent immune	15 percent immune	30 percent immune
HBV Infections	5,089	6,324	4,132	3,653	9,221	9,977
Acute Symptoms	1,272	1,581	1,033	913	2,305	2,494
Hospitalized	254	316	207	183	461	499
Fulminant Death	6	8	5	5	12	12
HBV Carrier	254	632	413	365	668	998
Chronic HB	64	158	103	91	167	249
Death Cirrhosis	87	108	70	62	157	170
Death PHC	20	25	17	15	37	40
All Deaths	113	141	92	81	205	222

Source: Office of Regulatory Analysis, 1989.

D. *Technological Feasibility.* In this section, the provisions of the proposed standard are examined with respect to their role in reducing the occupational risk faced by workers within the 16 industry sectors identified. Baseline conditions, or the level of current compliance with the provisions of the proposed rule, will also be discussed and compliance rates, expressed as a percentage of full compliance, are presented. Finally, issues of feasibility regarding the implementation of the provisions of the proposed standard are addressed.

Compliance rates were based on information in the public record, OSHA inspection files, and site visits conducted by Jack Faucett Associates (JFA). These sources generally provided one of two different measures of current compliance. The first measure is the extent of partial compliance with a particular provision, assuming that all affected facilities have instituted a program of infection control. For example, a partial compliance rate of 50% estimated for a sector with respect to the post exposure follow-up provision indicates that facilities have follow-up programs in place, but that only 50% of the workers at risk are in fact offered treatment and counseling. The alternative measure provides an estimate of the proportion of facilities in a sector that are in full compliance with a particular provision of the proposed rule. For example, a compliance rate of 50% for the post exposure follow-up provision using this measure of compliance indicates that within a particular sector one-half of the facilities have instituted a program but that all affected workers within those facilities are offered treatment and counseling. The interpretation given to these respective measures of baseline data is dependent upon the way in which the data are presented. The most appropriate interpretation is used in each case.

The provisions of the proposed rule are expected to make a substantial reduction in the occupational risk of those workers potentially exposed to blood or other infectious materials. The provisions having the greatest impact on occupational risk are those requiring, at no cost to the employee, the vaccine and post-exposure prophylaxis against the hepatitis B virus (HBV), the use of personal protective equipment, the training and information programs, the implementation of engineering controls, and the practicing of safe work procedures. Additional provisions address the use of proper procedures for the handling and disposing of contaminated waste, labeling, and recordkeeping.

HBV Vaccination and Post Exposure Follow-up. The most effective method of infection control against HBV is the hepatitis B vaccine. While there are two types of vaccine, serum derived and genetically engineered, immunogenicity is reported to be similar for both [Ex. 13, p. II–32]. Evidence indicates that HBV vaccine will induce antibody in 85 to 98 percent of healthy young adults [Exs. 4–20; 6–45]. There do not appear to be any technical obstacles to this provision.

The proposed standard requires that all employees who incur occupational exposures to blood on average one or more times per month be offered the vaccine. The current rate of employee acceptance in many sectors is only about 30%. However, refusal seems to be in large part linked to concerns regarding the safety of the vaccine [Ex. 4–31]. Thus, following the provision of new educational programs [Ex. 11–86, p. 15], OSHA expects that at least 50% of the unvaccinated employees at risk will participate in the vaccination program.

The proposed standard also includes a provision for post-exposure prophylaxis against HBV. This prophylaxis consists of the hepatitis B immune globulin (HBIG) injection. This post-exposure treatment appears to be highly effective in preventing HBV infection when administered shortly aftar the exposure incident [Ex. 6–45]. JFA estimated the levels of baseline compliance with this provision [Ex. 13, Table III–18]. (Table VII–7 provides a summary of compliance rates for all provisions, by SIC code). A serious obstacle to the implementation of this requirement, however, is that not all exposures are reported [Ex. 6–100].

Thus, HBV vaccination and post exposure follow-up can provide effective protection for those exposed employees who are at risk of contracting HBV. The limitations of this provision are that not all workers will participate in the vaccine program, not all exposures will be reported, and, finally, workers will still be at risk for other bloodborne diseases, such as AIDS and non-A, non-B hepatitis.

TABLE VIII–7.—SUMMARY OF CURRENT COMPLIANCE

[Percent]

Industry	PPE		Housekeeping		Post exposure follow-up	Records	Training
	Gloves	Other	Containers	Waste disposal			
Offices of physicians	60	60	40	39	0	0	0
Offices of dentists	75	40	50	39	75	0	60
Nursing homes	50	25	50	81	20	0	60
Hospitals	90	60	80	81	75	0	60
Medical/dental labs	90	90	92	86	0	0	60
Outpatient care	90	90	50	39	85	0	75
Blood/plasma/tissue centers	50	25	35	86	80	0	20
Residential care	50	25	50	81	20	0	60
Personnel services	N/A	N/A	N/A	N/A	0	0	0
Funeral services	100	100	100	39	100	0	60
Research labs	90	90	85	86	0	0	60
Fire & rescue	50	50	50	39	50	0	50
Corrections	100	50	100	39	50	0	50
Police	50	50	50	39	50	0	50
Health units in industry	50	50	50	39	0	0	0
Medical equipment repair	50	50	50	86	0	0	50

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis. (Adapted from Ex. 13, Table II–31).

Personal Protective Equipment. The proposed standard also requires employers to provide personal protective equipment (PPE) to all potentially exposed workers and to ensure its proper use. This type of equipment will reduce risk from all bloodborne pathogens. Gloves will provide an effective barrier against entry of pathogens through non-intact skin and can be worn by virtually all workers in all sectors. For example, health care workers performing phlebotomy will be protected in the event that this task results in blood contamination of the hands. Laundry workers and janitors who are at risk of exposure from contaminated laundry or waste can substantially reduce their risk by wearing utility gloves.

Other types of PPE include coats or gowns, masks and eye protection (such as safety glasses or goggles), and face shields. Like gloves, these items serve as a barrier between the infectious material and the worker. Not all workers would be expected to require these items, however. Dentists will need eye and face protection when performing oral surgery or any other procedure which may result in the splattering or spraying of blood or saliva contaminated with blood, but this level of protection would seldom be necessary for a physician in an outpatient facility. Likewise, protective foot coverings may be required to reduce risk in a surgical or autopsy suite but would rarely be necessary for a nurse in a residential care facility.

Respiratory equipment such as ambubags or pocket respirators are another type of PPE. These devices are most useful for emergency responders in reducing risk where the emergency situation requires resuscitation.

Estimates of current compliance rates for PPE appear in table VII–7. No sector is believed to be currently complying at a rate of less than 25%.

Limitations in implementing a PPE program include availability, interference with the performance of certain tasks, and physical variability of the workforce. For example, commenters have reported that certain types of gloves are in short supply [Exs. 11–73; 11–124]. OSHA is aware of this problem, but finds that many new sources of supply are being developed and that current producers of the types of gloves that are required by this proposed rule should have ample time to adjust their production schedules to meet the required demand. As a great many establishments are already providing gloves for their employees who are at risk, incremental glove usage is not expected to be a serious obstacle to implementation by the time that a final rule is promulgated.

Commenters have also asserted that during certain procedures requiring manual dexterity, such as phlebotomy, glove use will not allow the proper performance of the task [Ex. 11–124]. OSHA recognizes that many workers who are at risk are performing their duties in the manner that is most comfortable for them, and may have been doing so for some time. However, the proposed rule also provides for training in and monitoring of proper work practices (this provision will be discussed more fully below) and employers shall be expected to instruct workers in a manner that will increase their proficiency in performing all tasks while using the appropriate precautions.

Finally, some workers may be susceptible to dermititis from frequent handwashing (handwashing is required by the proposed standard whenever gloves are changed). Others may be allergic to certain types of gloves or the powder they contain. OSHA does not believe that the impact of the proposed rule will be such that an excessive amount of additional handwashing will be required. Additionally, it is OSHA's understanding that hypoallergenic gloves are available [Ex. 13, p. II–27]. Administrative controls, such as rotating employees, would also be useful, when possible, to avoid these instances.

Training and Information Programs. This provision of the proposed rule is applicable to all workers at risk throughout all industry sectors. A comprehensive training program is paramount in the implementation of a standard such as this, since protective measures such as PPE and proper work practices will not be effective unless employees are instructed in their correct use. Training is also an important factor in risk reduction because not all employees are aware of the risks that they routinely face in the workplace. As noted above, information programs can increase employee acceptance of HBV vaccine [Ex. II–86, p. 15]. The provision also requires employers to ensure that employees understand the employer's infection control program. In one hospital, PPE usage increased from 50–75% to 95–98% when proper work practices were explained and enforced [Ex. II–119]. Also, evidence indicates that adherence to established work practice procedures could reduce needlestick exposures by as much as 40% [Ex. 6–160].

While employers will be required to train all employees at risk, the content of the training program will not be the same for all occupational categories. For example, registered nurses employed at a hospital will require a more detailed program than will housekeepers employed at such an establishment.

Estimates of the current level of compliance with this provision indicate that a substantial number of establishments are currently providing some level of training to their at-risk employees. Most facilities, then, will only need to adjust their programs incrementally rather than to construct a training program from the ground up.

Limitations of the training requirement are minor. As little information is available regarding the relative effectiveness of different training methods [Ex. 13, p. II–24], employers may need to "experiment" a bit until they find the method that is best suited for their particular establishment or worker population. This should not delay, however, the implementation of an initial program of education end information necessary for at-risk employees, as such a program may subsequently be modified as appropriate.

OSHA finds, therefore, that a program of training offered to all at-risk employees is central to the implementation of the proposed standard and will significantly contribute to the overall reduction of risk to workers potentially exposed to infectious materials. No major problems are foreseen for compliance with this provision.

Engineering Controls. The most ubiquitous engineering control required by the proposed rule is the puncture-resistant sharps container. The purpose of the container is to eliminate the need for employees to transport needles and other sharps while looking for a place to dispose of them, and to support the prohibition against recapping, bending, breaking, or otherwise manipulating sharps by hand. Injuries also occur to housekeeping personnel when contaminated sharps are left on a bed, concealed in linen. It is expected that a number of unnecessary disposal-related exposures will be prevented by this control [Ex. 13, p. II–30].

Other engineering controls that will be required are mechanical pipetting devices, biosafety cabinets, and safety equipment for centrifuges. (Pipetting is a procedure by which fluid is drawn into a narrow tube by suction. The fluid may then be dispensed as needed.) Risk will be reduced as these controls, like the sharps containers, tend to confine or isolate the infectious material from the worker. While these controls will be necessary only in a laboratory environment, many types of establishments operate laboratories. For

example, such controls might be necessary in a police lab or in a physician's office, as well as in a hospital.

Baseline information, where available, indicates that most facilities are already in compliance with the container requirement. (Baseline information on sharps containers appears under "Housekeeping" in Table VII–7). Further, it is assumed that research laboratories involved in biosafety level 2 or biosafety level 3 work are equipped with the necessary cabinets and centrifuge safety equipment. Since mouth pipetting has been discouraged for some time, it is probable that mechanical pipettes are standard equipment in most medical and research labs.

Affected establishments should not experience difficulty introducing sharps containers. One concern noted by industry is the potential for unauthorized tampering with the sharps containers [Ex. 13, p. II–30]. There are, however, safety features such as locking mechanisms to prevent removal of the containers until they are ready to be replaced. Also, containers are now made with a "mail box" drop system so that discarded sharps cannot be retrieved.

It is clear that engineering controls can reduce risk by confining or isolating infectious material. The equipment is readily available and should present few difficulties in its implementation. Moreover, a number of new technologies are being developed, which would effectively eliminate many types of needlestick incidents. OSHA solicits public comment on the progress of these new technologies.

Work Practice Controls. Work practice controls are extremely important in preventing the spread of infection. This provision will reduce risk by requiring employers to ensure that at-risk employees are performing their tasks in the safest manner possible, consistent with universal precautions. The forbidding of needle recapping by hand when disposable needles are used is one work practice which should provide significant reductions in needlestick exposures, as this procedure has been shown to be associated with needlestick injury [Ex. 6–350]. In certain circumstances, however, such as where injections are administered in series, some effort may be required to find the best technology or to develop new procedures. Simply ensuring that disposable needles are used wherever possible will also reduce risk.

In any environment where engineering controls are available, workers must use such equipment properly. For example, safety cups for use during centifuging will not be effective if not used correctly. Thus, all training programs should provide at-risk workers with comprehensive instructions regarding the safest procedures for performing each employee's respective tasks. OSHA finds that implementing safe work practices will not present significant difficulty for the great majority of affected workers.

In conclusion, the provisions of the proposed rule are expected to reduce substantially the risk now faced by workers who must come into contact with blood and other potentially infectious material. The provisions of the standard operate in concert, maximizing the rule's effectiveness. The provision of PPE will not be effective without comprehensive training and monitoring of proper work practices. Offering the HBV vaccine will likewise not be effective unless workers are provided with information on the risks of contracting hepatitis and the safety and efficacy of the vaccine. Many establishments are currently complying with much of OSHA's proposed rule, but additional effort must be made to ensure that all workers are protected. Finally, there do not appear to be any major obstacles to implementing the proposed rule, though certain situations may require sophisticated approaches.

E. *Costs of Compliance.* This section presents OSHA's estimates of total net compliance costs, which are total costs less the amount associated with current compliance, for each provision of the proposed standard. The costs are based on data collected by Jack Faucett Associates [Ex. 13] and other information in the public record, and are developed in the following sequence: development of the infection control plan, HBV vaccination and post exposure follow-up, personal protective equipment (PPE), engineering controls, training, housekeeping (including costs incurred for the disposal of infectious waste), labeling and signs, and recordkeeping.

Development of the Infection Control Plan. Costs incurred for this task are due to the time expended to prepare the written determination of risk, the schedule of implementation for each applicable provision of the proposed rule, and the training program. OSHA believes that much of the required information is currently compiled and will only need to be restructured to reflect compliance with the proposed standard. In calculating the incremental costs for performing this task, OSHA estimates that the time required will be 16 hours for large establishments, such as hospitals and nursing homes, 8 hours for health maintenance organizations, and 4 hours for all other facilities. Assuming a wage rate of $23.26 per hour for the infection control official (this is equivalent to the compensation rate for head nurses) the costs for this provision are computed as:

$23.26 × (time required)

It is not likely that this type of documentation has been developed by many facilities; consequently, incremental costs are estimated to be 100% of total compliance costs except for hospitals, where a 10% baseline was used for current compliance.

Costs were annualized using a five year payback period and a 10% interest rate. (This five year period reflects the need to periodically revise the plan.) Table VII–8 summarizes costs for this provision.

Total annual costs for the infection control plan are estimated to be $16.5 million. Cost per facility will average about $26.60.

TABLE VII–8.—SUMMARY OF COMPLIANCE COSTS—INFECTION CONTROL PLAN

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	4,403,308	24.54
Offices of dentists	2,331,528	24.54
Nursing homes	895,707	47.83
Hospitals	528,647	89.60
Medical/dental labs	299,313	24.54
Outpatient care	745,154	25.08
Blood/plasma/tissue centers	16,494	25.69
Residential care	1,008,118	49.09
Personnel services	39,638	24.54
Funeral services	369,411	24.54
Research labs	52,671	24.54
Fire and rescue	90,174	23.98
Corrections	57,261	24.54
Police	152,295	24.54
Health units in industry	5,440,167	24.54
Medical equipment repair	72,822	24.54
Total	$16,502,710	$26.59

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hepatitis B Vaccination and Post Exposure Follow-Up. Since a portion of the cost of both the HBV vaccination and post exposure follow-up provisions will be incurred as compensation for the time spent by employees in receiving medical care, data on wage rates were necessary to calculate total annual costs. Turnover rates were also estimated, since new employees not previously vaccinated will be offered the HBV vaccine.

Wage data were obtained from BLS national (March, 1987) and hospital (1985) survey data, and wages were

updated to 1988 dollars using the BLS Employment Cost Index.

Turnover rates were calculated by JFA using unpublished job tenure data from the January, 1987 Current Population Survey of BLS [Ex. 13, p. I–17—21]. Annual *job* turnover was estimated as the percentage of workers with one year or less tenure with their current employer minus ths rate of industry wide employment growth. Alternatively, annual *occupational* turnover is used as an indicator of how often workers will be entering health care and other occupations of interest for the first time.

In assigning turnover and wage rates to occupational categories, workers were judged to fall into one of seven employment classifications. Table VII–9 provides a summary of occupational classifications and worker populations within each of the affected industry sectors. Wage and turnover rates for the seven classifications are as follows:

	Wage rate	Turnover rate (percent)	
		Job	Occ.
Diagnosing employees	$49.06	13.5	7.75
Treatment employees	$16.44	21.8	12.9
Service employees	$11.12	36.3	22.5
Janitor/cleaner	$9.09	31.6	19.75
Firefighter	$14.80	8.5	N/A
Security/custody	$11.48	41.0	7.75
Police officer	$14.30	10.1	N/A

Cost formulas for the HBV vaccination and post exposure follow-up provisions were developed separately, as shown below.

TABLE VII–9— EMPLOYMENT CLASSIFICATION SCHEME

	Offices of physicians	Offices of dentists	Nursing homes
Diagnosing	Physicians and Surgeons; Dentists.—Affected Population: 209,380.	Physicians and Surgeons; Dentists.—Affected Population: 75,873.	Physicians and Surgeons; Dentists.—Affected Population: 2,589.
Treatment [a]	Registered Nurse; Therapists; Dental Hygienists; Lab Technicians; Emergency Medical Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 141,029.	Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 87,502.	Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Other Health Professionals.—Affected Population: 36,755.
Service [b]	Licensed Practical Nurse; Therapy Assistants; Dental Assistants; Other Health Service; Physician Assistants, Medical Assistants; Nursing Aids.—Affected Population: 156,912.	Licensed Practical Nurse; Dental Assistants; Other Health Service; Medical Assistants.—Affected Population: 150,611.	Licensed Practical Nurse, Dental Assistants; Nursing Aides and Orderlies; Pyschiatric Aides; Other Health Service; Physician Assistants; Mecdical Assistants; Ambulance Drivers.—Affected Population: 635,848.
Janitor/ Housekeeper.	Affected Population: 28,801	Affected Population: 8,690	Affected Population: 103,182.

	Hospitals	Medical and dental labs	Outpatient Care
Diagnosing	Physicians and Surgeons; Dentists.—Affected Population: 102,398.	Physicians and Surgeons; Dentists; Life Scientists.—Affected Population: 5,305.	Pysicians and Surgeons; Dentists.—Affected Population: 52,957.
Treatment	Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Emergency Medical Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 1,078,651.	Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Other Health Professionals.—Affected Population: 31,390.	Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Emergency Medical Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 188,469.
Service	Licensed Practical Nurse; Therapy Assistants; Dental Assistants; Nursing Aides and Orderlies; Psychiatric Aides; Other Health Service; Physician Assistants; Medical Assistants; Ambulance Drivers.—Affected Population: 772,666.	Licensed Practical Nurse; Dental Assistants; Other Health Service; Medical Assistants.—Affected Population: 2,814.	Therapy Assistants; Licensed Practical Nurse; Dental Assistants; Nursing Aides, Orderlies, and Psychiatric Aides; Other Health Service; Physician Assistants; Medical Assistants; Ambulance Drivers.—Affected Population: 124,090.
Janitor/ Housekeeper.	Affected Population: 210,439	Affected Population: 1,313	Affected Population: 4,998.

	Blood/Plasma/Tissue Center	Residential Care	Funeral Services
Diagnosing		Physicians and Surgeons.—Affected Population: 579.	
Treatment	Nurses and Phlebotomists; Lab workers.—Affected Population: 21,506.	Registered Nurses; Therapists; Other Health Professionals.—Affected Population: 6,922.	Embalmers; Ambulance Drivers and Attendants; Other Health Professionals.—Affected Population: 22,032.
Service		Licensed Practical Nurse; Nursing Aides and Orderlies; Psychiatric Aides; Other Health Service.—Affected Population: 52,142.	
Janitor/ Housekeeper.	Affected Population: 692	Affected Population: 20,927	Affected Population: 4,375.

	Research Laboratories	Fire and Rescue	Corrections
Diagnosing			
Treatment	Academic Scientists; Technicians; Research Assistants; Laboratory Workers—Affected Population: 95,654. [c]	Emergency Medical Technicians; Other Health Professionals; Ambulance Drivers and Attendants.—Affected Population: 31,234.	Treatment and Education Staff.—Affected Population 13,712.
Service			

TABLE VII-9— EMPLOYMENT CLASSIFICATION SCHEME

	Research Laboratories	Fire and Rescue	Corrections
Janitor/ Housekeeper.	Affected Population: 3,061		
Other		Fire Fighters.—Affected Population: 170,515	Security and Custody.—Affected Population: 84,233.
	Law Enforcement	**Industrial Clinics**	**Medical Equipment Repair**
Diagnosing		Physicians.—Affected Population: 2,251	
Treatment	Crime Laboratory Technicians.—Affected Population: 7,820.	Nurses.—Affected Population: 8,492—Emergency Medical Personnel.—Affected Population: 185,594.	
Service		Other Health Workers.—Affected Population: 27,564.	Unpackagers and Cleaners.—Affected Population: 1,882.
Janitor/ Housekeeper.			
Other	Police Officers.—Affected Population: 200,872		
	Personnel Services		
Diagnosing			
Treatment	Registered Nurses; Therapists; Other Health Professionals.—Affected Population: 84,176.		
Service	Licensed Practical Nurse; Nursing Aides and Orderlies.—Affected Population: 71,668.		
Janitor/ Housekeeper.			

[a] This employment category may include professionals not at risk of exposure to infectious materials, such as radiologic or orthopedic technicians. The affected population may, therefore, be somewhat overstated.

[b] Includes persons who assist and work under the direction of physicians, dentists, nurses, therapists, pharmacists, and other health-related professional, paraprofessional, and technical workers. Workers in these occupations provide auxiliary services, such as assisting in the care of patients, relieving nurses of heavier work, preparing treatment rooms, transporting patients, assisting therapists, and mixing pharmaceutical preparations. To the extent that this employment category may include service personnel not at risk of exposure to infectious materials, the affected population may be somewhat overstated.

[c] Includes 14,380 workers in independent labs, 54,050 workers in captive Labs, and 7,000 workers in federal labs.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Bureau of Labor Statistics.

HBV vaccination program. OSHA estimates that 23% of the health care workers and 0.1% of the non-health care workers at risk are already vaccinated (this is the rate of prior vaccination), that 50% of the unvaccinated employees who are offered the vaccine will enter the program, and that 22% of all the employees at risk have developed natural immunity. (See Risk Assessment section for source of vaccination and immunity rates). Since it is assumed that the health care workers who are already vaccinated (23%) are distinct from the immune employees, OSHA estimates that on average 29% [22%/(100%–23%)] of those health care workers agreeing to participate in the program will have a natural immunity. For participating non-health care workers, the natural immunity rate is still estimated at 22%. As a result, it is assumed that 71% (100%–29%) of those health care workers and 78% of those non-health care workers who are tested under the new program will receive the vaccination. The compliance costs are estimated assuming employer pre-screening of all vaccine candidates. That is, it is assumed that each candidate will receive a hepatitis B test to determine antibody status prior to being vaccinated even though in some circumstances it may be more cost-effective to administer vaccine without testing.

Estimates were computed for each of the seven occupational categories, to reflect the effect of varying employee wage and turnover rates. In most sectors, the time required to take the antibody test is estimated to be about 5 minutes. However, as noted above, physicians are not typically located at research labs, funeral homes, personnel service offices, fire stations, medical equipment repair facilities, or dental offices. In these sectors, the test is assumed to take 20 minutes of employee time. Where the vaccine in indicated, it is assumed that the additional time required will be one quarter hour for the entire three-dose-series in most facilities. For those sectors mentioned above where a physician would not normally be on the premises, the added employee time is assumed to be one hour. Costs were computed as follows:

Initial

[(# of workers) × (1-prior vaccination rate) × (participation rate)] × [(antibody test cost + (employee time × wage)) + (non-immunity rate × (vaccine cost + (employee time × wage)))]

Recurring

(initial costs) × (occupational turnover rate)

Total Annual Costs

[(initial costs) × (capital recovery factor)] + (recurring costs)

Initial costs were annualized using a 20-year payback period and 10% interest rate.[1]

The cost for the antibody test is reported to be $24.50 [Ex. 13, p. III–27] and the cost for the vaccine series is estimated to be $108 [Ex. 13, p. III–27]. (It should be noted that Smith, Kline, & French Laboratories (SKF) have applied for Food and Drug Administration approval of a recombinant hepatitis B vaccine [Ex. 6–477]. In countries where the SKF vaccine has already been approved, competition has reportedly reduced the vaccine cost by approximately 40%.)

For example, the initial costs per facility for the treatment employees in physicians' offices would be:

$$\{141{,}029 \times 0.77 \times 0.5\} \times \{(\$24.50 + \{1/12 \text{ hrs.} \times \$16.44\}) + \{0.71 \times (108.00 + \{0.25 \text{ hrs.} \times \$16.44\})\}\}/179{,}405 = \$31.92$$

The recurring costs would be:

$$\$31.92 \times 0.129 = \$4.12$$

and the total annual costs would be:

$$(\$31.92 \times 0.1175) + \$4.12 = \$7.87$$

For all sectors, the total annual costs of the HBV vaccination program will be about $60.4 million.

One commenter, Baylor University Medical Center, provided estimates of

[1] Though the initial vaccination could be considered a one time cost for which annualization should be carried into perpetuity, a more conservative approach is used in this analysis.

the costs of compliance with the HBV vaccination provision [Ex. 11–210]. It is not clear from the information submitted, however, whether these costs reflect worker participation rates (estimated by OSHA to be about 50%); neither is it clearly stated that their estimates are of incremental costs only.

Post Exposure Follow-up. Cost formulas for the post exposure follow-up provision vary due to different follow-up recommendations for possible exposure to the AIDS virus (HIV) and to HBV. Both costs will depend on the number of exposure incidents that will occur per year. Exposure estimates as developed by Jack Faucett Associates are presented in Table VII–10, tabulated by industry and by occupational classification within each industry. These estimates were based on studies primarily of hospital workers and on limited site visit data and take into account the following potential reductions due to implementation of the proposed standard: needlestick reduction, 50%; mucous membrane exposure reduction, 90%; open wound exposure reduction, 90%; and other sharps injuries reduction, 50%. Costs will also depend on the turnover and wage rates presented above.

Additional input for these costing formulas included an estimate that on average, while an employee will recall the source of the reported exposure, the source patient will agree to be tested only 50% of the time. Seropositivity for HIV is expected 0.5% of the time, and for HBV 0.42% of the time in all sectors but hospitals, where the HBV rate is estimated to be 1.25%. The reported unit costs are $17.50 for the HIV antibody test [Ex. 13, p. III–30], $24.50 for the HBV antibody test, and $211 for administering immune globulin [Ex. 13, p. III–28].

One final input is the wage rate of a counselor, whose services would be required in those instances where a possible exposure to HIV has occurred. This wage rate is taken to be $16.44, that of a registered nurse.

The following cost formulas for post-exposure monitoring and treatment were developed to project costs for providing antibody testing and counseling for potential HIV infection, antibody testing for potential HBV infection, and immune globulin for potential HBV infection.

Antibody Testing and Counseling for HIV Infection

(1) (# of exposures)×0.5×(0.5+(0.5×0.005))×4×[(cost of HIV antibody test)+(employee time × wage)]

The equation above reflects OSHA's estimate that each exposed employee will wish to learn their HIV antibody status only about 50% of the time. In those instances, a sequence of four HIV antibody tests will be offered in the 50% of the cases where the source of exposure does not agree to be tested and for the 0.25% of the cases where the source is tested *and* found to be positive (0.5×0.005). (The time required for the HIV antibody testing by employees is assumed to be the same as that required for the HBV antibody testing used above in the vaccine calculations.) Also, additional costs will be incurred to test all source subjects who agree to be tested:

(2) (# of exposures)×(0.5)×(cost of HIV antibody test)

This equation will tend to overestimate costs to the extent that the HIV status of patients is already known.

Costs will also be incurred for counseling where the possibility of exposure to HIV exists.

(3) (# of exposures)×(0.5)×(0.5+(0.5×0.005))×2×[(employee time×wage)+(counselor time × wage)]

This equation reflects costs for two counseling sessions for each employee who accepts the offer of HIV testing. It is estimated that approximately 15 minutes will be required for each session and that the sessions will take place during the first and last antibody test periods.

TABLE VII–10—ESTIMATES OF FREQUENCY OF EXPOSURE

[Exposures Per Year]

	Needlestick	Mucous membrane	Open wound	Other sharps	Total
Physicians' Offices:					
Diagnosing Personnel	25,368	2,357	1,660	6,784	36,170
Treating Personnel	17,087	1,588	1,118	4,569	24,362
Service Personnel	19,011	1,767	1,244	5,084	27,106
Housekeeping Personnel	3,490	324	228	933	4,975
Total	64,957	6,036	4,251	17,370	92,614
Dentists' Offices:					
Diagnosing Personnel	9,193	854	602	2,458	13,107
Treating Personnel	10,602	985	694	2,835	15,116
Service Personnel	18,248	1,696	1,194	4,880	26,018
Housekeeping Personnel	1,053	98	69	282	1,051
Total	39,096	3,633	2,559	10,455	55,742
Nursing Homes:					
Diagnosing Personnel	314	29	21	84	447
Treating Personnel	4,453	414	291	1,191	6,349
Service Personnel	77,039	7,158	5,042	20,601	109,841
Housekeeping Personnel	12,522	1,164	820	3,349	17,854
Total	94,328	8,765	6,174	25,225	134,492
Hospitals:					
Diagnosing Personnel	12,407	1,153	812	3,318	17,689
Treating Personnel	130,692	12,144	8,554	34,949	186,338
Service Personnel	93,616	8,699	6,127	25,034	133,477
Housekeeping Personnel	25,497	2,369	1,669	6,818	36,353
Total	262,211	24,364	17,162	70,119	373,857
Medical and Dental Labs:					
Diagnosing Personnel	643	60	42	172	916
Treating Personnel	3,803	353	249	1,017	5,423
Service Personnel	341	32	22	91	486

TABLE VII-10—ESTIMATES OF FREQUENCY OF EXPOSURE—Continued

[Exposures Per Year]

	Needlestick	Mucous membrane	Open wound	Other sharps	Total
Housekeeping Personnel	159	15	10	43	227
Total	4,946	460	324	1,323	7,052
Outpatient Care:					
Diagnosing Personnel	6,416	594	418	1,710	9,138
Treating Personnel	22,835	2,122	1,495	6,106	32,558
Service Personnel	15,035	1,397	984	4,021	21,436
Housekeeping Personnel	606	56	40	162	863
Total	44,869	4,169	2,937	11,999	63,974
Blood Banks:					
Treating Personnel	2,606	242	171	697	3,715
Housekeeping Personnel	84	8	5	22	120
Total	2,690	250	176	719	3,835
Residential Care:					
Diagnosing Personnel	70	7	5	19	100
Treating Personnel	839	78	55	224	1,196
Service Personnel	6,318	587	413	1,689	9,007
Housekeeping Personnel	2,536	236	166	678	3,615
Total	9,762	907	639	2,610	13,918
Personnel Services:					
Treating Personnel	10,199	948	668	2,727	14,541
Service Personnel	8,683	807	568	2,322	12,381
Total	18,882	1,754	1,236	5,049	26,922
Funeral Services:					
Treating Personnel	2,669	248	175	714	3,806
Housekeeping Personnel	530	49	35	142	756
Total	3,199	297	209	856	4,562
Research Labs:					
Treating Personnel	11,589	1,077	759	3,099	16,524
Housekeeping Personnel	371	34	24	99	529
Total	11,960	1,111	783	3,198	17,053
Fire and Rescue:					
Treating Personnel	3,784	352	248	1,012	5,396
Fire Fighting Personnel	20,660	1,920	1,352	5,525	29,4565
Total	24,444	2,271	1,600	6,537	34,852
Corrections:					
Treating Personnel	1,661	154	109	444	2,369
Security Personnel	8,263	948	668	2,729	12,609
Total	11,867	1,103	777	3,173	16,920
Police:					
Police Officers	2,9%6	0	0	0	2,956
Treating Personnel	948	88	62	254	1,352
Total	3,904	88	62	2%4	4,308
Industrial Clinics:					
Diagnosing Personnel	273	25	18	73	389
Treating Personnel	1,029	96	67	275	1,467
Service Personnel	3,340	310	219	893	4,762
Emergency Personnel	22,487	2,089	1,472	6,013	32,061
Total	27,128	2,521	1,776	7,254	38,678
Medical Equipment Unpackagers	228	21	15	61	325
Totals	624,471	57,750	40,679	166,202	889,102

Source: Jack Faucett Associates.

Antibody tests for potential HBV infection. Table VII-11 displays OSHA's estimates of the conditional probabilities of the various post-exposure HBV medical evaluation programs. It is assumed that HBV antibody tests will be administered to both source patients and employees at the rates shown on the chart. For those exposed workers who have previously been vaccinated, it is estimated that an employee test will be performed 10% of the time. Source testing, which will reflect both the non-response rate of the vaccine (10%) and the rate of acceptance

of the sources to be tested (50%), will be performed 0.5% (0.1 × 0.1×0.5) of the time. (It is assumed that sources will not be asked to submit to a test unless the exposed, vaccinated employee is found to be a non-responder.)

For those cases where workers have not been vaccinated and source patients will not be tested, it is estimated that exposed employees would agree to be tested only for the 5% of the exposures that are attributable to a member of a high risk group. Thus, employee tests will be performed 2.5% of the time (0.5×0.05) when a source does not agree to testing. When a source agrees to be tested, employee tests were estimated to be performed at a rate of (0.5×rate of source infection), as employees would be tested only if the source is found to be HBV positive. The formulas for calculating total costs for antibody testing are given below. Equation (4) represents employee testing for vaccinated workers and equation (5) represents employee testing for non-vaccinated workers. Equation (6) represents source testing.

(4) (# of exposures)×(% vaccinated)×[antibody test cost + (employee time×wage)]×0.1

(5) (# of exposures)×(1− % vaccinated)×[antibody test cost + (employee time×wage)]×[(0.5×rate of source infection)+((1−0.5)×0.05)]

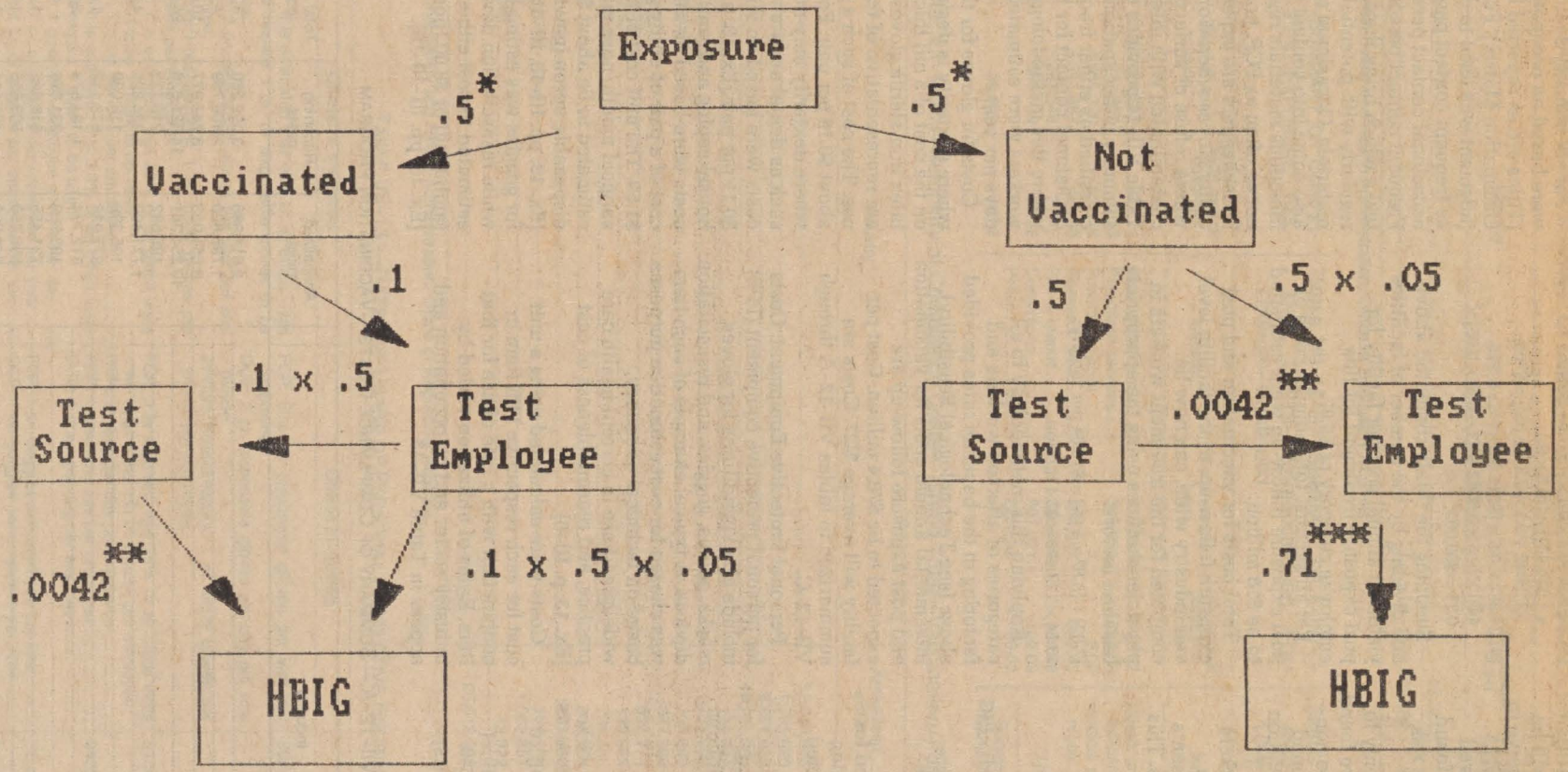
(6) (# of exposures)×[(% vaccinated)×(0.1×0.1×0.5)+(1− % vaccinated)×(0.5)]×(cost of antibody test)

where: (% vaccinated)=prior vaccination rate+0.5×(1− prior vaccination rate)×non-immunity rate.

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Table VII-11

ESTIMATED PROBABILITY OF POST-EXPOSURE HBV MEDICAL ACTIVITIES



Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

* The rates shown are for health workers. The non-health care worker rates are .39 for vaccinated and .61 for not-vaccinated workers.

** For the hospital sector this rate is .0125.

*** The rate shown is for health workers. The non-health care worker rate is .78.

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Immune globulin for potential HBV infection. Immune globulin (IG) will be provided at rates estimated as shown in Table VII–11. For all workers, OSHA estimates that IG will be considered whenever a source is tested and found to be positive or whenever a high risk source refuses to be tested. It is assumed that IG will be offered only to those vaccinated workers who are found to be non-responders and to those non-vaccinated employees who are found not to have natural immunity. Equation (7) represents costs for IG administration to vaccinated workers (IG is administered in a two dose sequence) and equation (8) represents costs for non-vaccinated workers. This cost is calculated as:

(7) (# of exposures)×(% vaccinated)×0.1×[(IG cost+2×(employee time×wage)]×[(0.5×0.1×rate of source infection)+(0.1×0.5×0.05)]

(8) (# of exposures)×(1– % vaccinated)×[(IG cost+2×(employee time×wage)]×[(0.5×rate of source infection)+((1–0.5)× 0.05)]×(non-immunity rate)

Cost per facility can be obtained for equations (4) through (8) by dividing total costs by the number of affected establishments.

Continuing the example of the treatment employees in physicians offices, equations (1) through (8) follow:

(1) 24,362×0.5×(0.5+(0.5×0.005))×4×($17.50+½ hr.×$16.44)=$462,010;

(2) 24,362×0.5×$17.50=$213,168;

(3) 24,362×0.5×(0.5+(0.5×0.005))×2×[(¼ hr.×$16.44) +(¼ hr.×$16.44)]=$100,628;

(4) 24,362×0.5×($24.50+(½×$16.44))×0.1=$31,512;

(5) 24,362×0.5×($24.50+(½×$16.44))×(0.5×0.0042+(1−0.5)×0.05)=$8,540;

(6) 24,362×[0.5×(0.1×0.1×0.5)+(1−0.5)×0.5]×$24.50= $150,700;

(7) 24,362×0.5×0.1×[($211+2×(½×$16.44)]×[(0.5×0.1×0.0042+0.1×0.5×0.05)]=$706;

(8) 24,362×0.5×[$211+2×(½×$16.44)]×[0.5×0.0042+ (1−0.5)×0.05]×0.71=$50,095;

Summing the totals computed above and dividing by the number of facilities yields an annual cost per facility for post exposure treatment for this employee category of $5.67.

For all sectors, total annual costs of post exposure follow-up were estimated to be $18 million.

Total costs for vaccination and post exposure follow-up, at the facility level and industry wide, can now be computed for the treatment workers in physicians' offices using the appropriate baseline factors:

(7.87)+(5.67×1.00)=$13.54 per facility;

13.54×179.405=$2.4 million.

Applyinq this methodology to all categories of affected workers and factoring in the baseline rates provided above (see Technological Feasibility), incremental annual costs for vaccination and post exposure follow-up are expected to be $78.4 million. Cost per facility will average $127. Costs are summarized in tables VII–12–A through VII–12–C.

Personal Protective Equipment. Costs for personal protective equipment (PPE) include all expenditures for gloves, masks, gowns, goggles, and resuscitation devices. A typical example of each item was chosen for cost estimation purposes based on technical adequacy, widespread use in current health care practice, and reasonableness of cost [Ex. 13, p. III–6].

Costs were calculated using a unit cost for each respective PPE item in conjunction with a rate of use for that item. Rates of utilization varied by industry sector and by occupation and appear in Table VII–13.

For six industry sectors, rates of use were based on occupational titles. (Titles are as reported in BLS' Industry-Occupation Matrix). For each title, judgment was used to classify workers as frequent contact personnel (FCP) or occasional contact personnal (OCP). Frequent contact personnel perform tasks which bring them into contact regularly with potentially infectious materials. Occasional contact personnel also come into contact with potentially infectious materials regularly, though not as often as FCP. Janitors and housekeepers are expected to wear utility gloves when working in areas where refuse or surfaces may be contaminated with infectious material. Table VII–14 provides a tabular summary of occupational titles, classified as either frequent contact or occasional contact for the six industries where this methodology was used. All workers were estimated to work 261 days per year.

Costs for gloves for those occupations where dexterity is desirable were based on the cost of 5 mil thickness disposable latex non-sterile gloves, as these gloves are representative of those in current use. The cost of such a pair of gloves is about $0.18 per pair. For occupations where dexterity may not be critical, such as dental assistant or police officer, costs were based on vinyl gloves at $0.11 per pair [Ex. 13. p. III–14]. For housekeeping and janitorial personnel, costs were based on utility gloves. The cost of a pair of utility gloves is about $1.59. The unit cost of a disposable surgical mouth/nose mask was estimated to be about $0.33 and that of a disposable apron (gown) about $0.36 [Ex. 13, pp. III–18, III–16]. The unit cost for goggles was estimated to be $3.25 while resuscitation devices were estimated to cost either $16.95 (ambubag) or $8.00 (pocket resuscitator) [Ex. 13, pp. III–18–19].

TABLE VII–12–A.—SUMMARY OF COMPLIANCE COSTS—VACCINATION PROGRAM

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	2,614,966	3,092,260	5,707,226	31.81
Offices of dentists	1,795,620	2,403,739	4,199,358	44.21
Nursing homes	3,651,033	6,747,877	10,398,911	555.26
Hospitals	10,254,361	14,621,678	24,876,040	4,216.28
Medical/dental labs	195,682	218,173	413,855	33.94
Outpatient care	1,771,400	2,324,825	4,096,225	137.89
Blood/plasma/tissue centers	105,399	118,099	223,497	348.13
Residential care	377,928	673,112	1,051,040	51.18
Personnel services	812,774	1,194,878	2,007,651	1,243.13
Funeral services	193,969	231,656	425,625	28.28
Research labs	731,455	818,925	1,550,380	722.45
Fire and rescue	606,250	503,655	1,109,905	295.19
Corrections	641,830	465,114	1,106,943	474.47
Police	184,152	144,794	328,946	53.01
Health units in industry	1,062,851	1,789,030	2,851,881	12.87

TABLE VII-12-A.—SUMMARY OF COMPLIANCE COSTS—VACCINATION PROGRAM—Continued

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Medical equipment repair	13,322	25,619	38,940	13.12
Total	$25,012,992	$35,373,432	$60,386,424	$99.94

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-12-B.—SUMMARY OF COMPLIANCE COSTS—POST-EXPOSURE FOLLOW-UP

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$4,079,213	$22.74
Offices of dentists	677,551	7.13
Nursing homes	4,366,620	233.16
Hospitals	3,911,667	662.99
Medical/dental labs	267,346	21.92
Outpatient care	363,039	12.22
Blood/plasma/tissue centers	28,806	44.87

TABLE VII-12-B.—SUMMARY OF COMPLIANCE COSTS—POST-EXPOSURE FOLLOW-UP—Continued

Industry	Total annual costs	Total annual costs per facility
Residential care	413,288	20.12
Personnel services	385,633	238.78
Funeral services	0	0.00
Research labs	734,847	342.43
Fire & rescue	740,637	196.98
Corrections	301,021	129.03
Police	223,548	36.03

TABLE VII-12-B.—SUMMARY OF COMPLIANCE COSTS—POST-EXPOSURE FOLLOW-UP—Continued

Industry	Total annual costs	Total annual costs per facility
Health units in industry	1,479,666	6.68
Medical equipment repair	14,773	4.98
Totals	17,987,655	29.11

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-12-C.—Summary of Compliance Costs— Grand Total—Vaccination/Post-Exposure Follow-up

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	$2,614,966	$7,171,473	$9,786,439	$54.55
Offices of dentists	1,795,620	3,081,289	4,876,909	51.34
Nursing homes	3,651,033	11,114,498	14,765,531	788.42
Hospitals	10,254,361	18,533,346	28,787,707	4,879.27
Medical/dental labs	195,682	485,519	681,200	55.86
Outpatient care	1,771,400	2,687,864	4,459,264	150.11
Blood/plasma/tissue centers	105,399	146,905	252,304	393.00
Residential care	377,928	1,086,399	1,464,328	71.30
Personnel services	812,774	1,580,511	2,393,285	1,481.91
Funeral services	193,969	231,656	425,625	28.28
Research labs	731,455	1,553,772	2,285,227	1,064.88
Fire & rescue	606,250	1,244,292	1,850,542	492.17
Corrections	641,830	766,134	1,407,964	603.50
Police	184,152	368,341	552,494	89.04
Health units in industry	1,062,851	3,268,695	4,331,546	19.54
Medical equipment repair	13,322	40,392	53,714	18.10
Total	25,012,992	53,361,087	78,374,079	126.77

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-13.—RATES OF USAGE OF PERSONAL PROTECTIVE EQUIPMENT [1]

	Offices of physicians	Offices of dentists	Nursing homes
Gloves	FCP: It is estimated that 40% of all office visits will require 1 pr. of disposable gloves to be used. OCP: 2 pr. disposable gloves per day per employee. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.	FCP: One pr. disposable gloves per visit per employee. OCP: 2 pr. disposable gloves per day per employee. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.	30,171 pr. disposable gloves per facility per year.
Masks	FCP: It is estimated that 20% of all office visits will require 1 mask to be used. OCP: 1 mask per day per employee	FCP: It is assumed that 75% of all office visits will require the use of 1 mask per employee. OCP: 1 mask per day per employee	81 masks per facility per year.
Gowns	FCP: It is estimated that 3.3% of all office visits will require 1 gown to be used. OCP: 1 gown per employee every other day	FCP: 1 gown per day per employee OCP: 1 gown per day per employee	3433 gowns per facility per year.
Goggles	FCP: 1 pr. of goggles per employee per year OCP: 1 pr. of goggles per employee per year	FCP: 1 pr. goggles per employee per year OCP: 1 pr. goggles per employee per year	36 pr. goggles per facility per year.
Resuscitation devices.	One device per ofc. plus one additional device for every ten employees.	One device per ofc. plus one additional device for every ten employees.	One device per home plus one additional device for every ten employees.

TABLE VII-13.—RATES OF USAGE OF PERSONAL PROTECTIVE EQUIPMENT [1]—Continued

	Hospitals	Medical and dental labs	Outpatient care
Gloves	600 pr. gloves per inpatient year	FCP: 4 pr. disposable gloves per employee per day. OCP: 2 pr. disposable gloves per employee per day. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.	FCP: 4 pr. disposable gloves per employee per day. OCP: 2 pr. disposable gloves per employee per day. Janitors/Housekeepers: 1 pr. utility gloves per month per employees.
Masks	69 masks per inpatient year	FCP: 2 masks per employee per day OCP: 1 mask per employee per day	FCP: 2 masks per employee per day. OCP: 1 mask per employee per day.
Gowns	39 gowns per inpatient year	FCP: 2 gowns per employee per day OCP: 1 gown per employee per day	FCP: 2 gowns per employee per day. OCP: 1 gown per employee per day.
Goggles	17 pr. goggles per inpatient year	FCP: 1 pr. goggles per employee per year OCP: 1 pr. goggles per employee per year	FCP: 1 pr. goggles per employee per year. OCP: 1 pr. goggles per employee per year.
Resuscitation devices.	One device per facility plus one additional device for every ten employees.	One device per facility plus one additional device for every ten employees.	One device per facility plus one additional device for every ten employees.
	Blood banks	Residential care	Funeral services
Gloves	FCP: 4 pr. disposable gloves per employee per day. Janitors/Cleaners: 1 pr. utitlity gloves per month per employee.	3123 pr. disposable gloves per facility per year	FCP: 2 pr. disposable gloves per employee per necropsy. OCP: 1 pr. disposable gloves per employee per necropsy. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.
Masks	FCP: [2] 2 masks per employee per day	8 masks per facility per year	FCP: 1 mask per employee per necropsy.
Gowns	FCP: 2 gowns per employee per day	355 gowns per facility per year	FCP: 1 gown per employee per necropsy.
Goggles	FCP: 1 pr. goggles per employee per year	4 pr. goggles per facility per year	FCP: 1 pr. goggles per employee per year.
Resuscitation devices.	One device per facility plus one additional device for every ten employees.	One device per facility plus one additional device for every ten employees.	Resuscitation devices not required.
	Research Labs	Fire and Rescue	Corrections
Gloves	4 pr. disposable gloves per employee per day	1 pr. disposable gloves per emergency run	1 pr. disposable gloves per employee per year.
Masks	2 masks per employee per day	1 mask per employee for every tenth emergency run.	Masks not required.
Gowns	2 gowns per employee per day	1 gown per employee for every tenth emergency run.	Gowns not required.
Goggles	1 pr. goggles per employee per year	1 pr. goggles per employee per year	Goggles not required.
Resuscitation devices.	One device per facility plus one additional device for every ten employees.	One device per emergency vehicle	One device per facility plus one additional device for every ten employees.
	Law enforcement	Industrial clinics	Medical equipment repair
Gloves	1 pr. disposable gloves per employee per year	It is estimated that 40% of the visits to health clinics in industrial settings will require the use of 1 pr. of disposable gloves.	4 pr. gloves per unpackaging employee per day.
Masks	Masks not required	Masks not required	2 masks per employee per day.
Gowns	Gowns not required	Gowns not required	Gowns not required.
Goggles	Goggles not required	Goggles not required	1 pr. goggles per employee per year.
Resuscitation devices.	One device per patrol officer per year	One device per facility per year	Device not required.

[1] See Table VII-14 for occupational categories included in these classifications.
[2] Excludes Nurses and Phlebotomists.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Jack Faucett Associates.

TABLE VII-14.—OCCUPATIONAL CLASSIFICATION BY FREQUENCY OF CONTACT WITH POTENTIALLY INFECTIOUS MATERIALS

	FCP (frequent contact personnel)	OCP (occasional contact personnel)	Janitors and cleaners
Offices of physicians.	Physicians and Surgeons; Registered Nurses; Licensed Practical Nurse; Laboratory Technicians; Emergency Medical Technician; Surgical Technician; Physician Assistant; Medical Assistant. Affected Population: 491,719	Therapists; Therapy Assistants; Other Health Professionals [1]; Other Health Service [2]; Nursing Aides. Affected Population: 15,602	Affected Population: 28,801.
Offices of dentists.	Dentists; Physicians and Surgeons; Dental Hygienists; Dental Assistants; Laboratory Technicians; Registered Nurses; Medical Assistants; Surgical Technicians. Affected Population: 312,013 (Dentists: 74,679; Hygienists: 84,332; Dental Assistants: 148,556).	Licensed Practical Nurses; Other Health Professionals [1]; Other Health Service [2]; Therapists. Affected Population: 1,973	Affected Population: 8,690
Medical and dental laboratories.	Physicians and Surgeons; Dentists; Registered Nurses; Licensed Practical Nurse; Dental Hygienists, Dental Assistants; Laboratory Technicians; Life Scientists; Medical Assistants; Other Health Professionals/Other Health Service (Phlebotomists, Medical Technologists).. Affected Population: 39,281	Therapists Affected Population: 228	Affected Population: 1,313.

TABLE VII–14.—OCCUPATIONAL CLASSIFICATION BY FREQUENCY OF CONTACT WITH POTENTIALLY INFECTIOUS MATERIALS—Continued

	FCP (frequent contact personnel)	OCP (occasional contact personnel)	Janitors and cleaners
Outpatient care.	Physicians and Surgeons; Dentists; Registered Nurses; Licensed Practical Nurse; Dental Hygienists; Dental Assistants; Laboratory Technicians; Emergency Medical Technicians; Nursing Aides; Orderlies; Psychiatric Aides; Surgical Technicians; Physician Assts.; Medical Assts.; Ambulance Drivers. Affected Population: 312,526	Therapists; Therapy Assistants; Other Health Professionals [1]; Other Health Service [2]. Affected Population: 52,990	Affected Population: 4,998.
Blood/plasma tissue centers.	Nurses; Phlebotomists; Laboratory Workers Affected Population: 21,506		Affected Population: 692.
Funeral homes..	Embalmers..... Affected Population: 20,921	Ambulance Drivers & Attendants; Other Health Professionals. Affected Population: 1,111	Affected Population: 4,375.

[1] This employment category may include professionals not at risk of exposure to infectious materials, such as orthopedic technicians. The affected population may, therefore, be somewhat overstated.

[2] Includes persons who assist and work under the direction of physicians, dentists, nurses, therapists, pharmacists, other health-related professional, paraprofessional, and technical workers. Workers in these occupations provide auxiliary services, such as assisting in the care of patients, relieving nurses of heavier work, preparing treatment rooms, transporting patients, assisting therapists, and mixing pharmaceutical preparations. To the extent that this employment category may include professionals not at risk of exposure to infectious materials, the affected population may be somewhat overstated.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis; Bureau of Labor Statistics; and Jack Faucett Associates.

Cost formulas varied by industry sector, as dictated by available data. These formulas are presented below, and represent annual costs.

Offices of Physicians: There were a reported 520,789,311 patient visits to physicians' offices in 1985 [Ex. 13, p. III–41]. Using the FCP, OCP, and janitor/housekeeper populations given in Table VII–14, PPE costs were estimated as follows:

Gloves, Masks, and Gowns
- FCP: (# of visits)×(usage rate)×(PPE unit cost)
- OCP/Lab. Techs.: (# of OCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- Janitors/Housekeepers (gloves only): (# of workers)×(usage rate)×(PPE unit cost)

Goggles
- FCP: (# of FCP)×(PPE unit cost)×(usage rate)
- OCP: (# of OCP)×(PPE unit cost)×(usage rate)

Resuscitation Devices
- (ambubag unit cost)×(usage rate)×(# of facilities)

Offices of Dentists: PPE use for all FCP except hygienists were determined based on the average number of visits made to dentists' offices in 1985, reported to be 2,993. Hygienists were reported to see 2,049 patients that year. Populations of affected employees are given in Table VII–14. Personnel populations for all categories except dentists were converted to full time equivalent (FTE) personnel using a factor of 0.6 [Ex. 13, p. III–41]. PPE costs were estimated as follows:

Gloves, Masks
- FCP: (# of visits)×(usage rate)×(PPE unit cost)
- OCP: (# of OCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- Janitors/Housekeepers (gloves only): (# of workers)×(usage rate)×(PPE unit cost)

Gowns
- All FCP: (# of FCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- OCP: (# of OCP)×(usage rate)×(days worked per year)×(PPE unit cost)

Goggles
- ALL FCP: (# of FCP)×(PPE unit cost)×(usage rate)
- OCP: (# of FCP)×(PPE unit cost)×(usage rate)

Resuscitation Devices
- (ambubag unit cost)×(usage rate).

Nursing Homes: Costs for PPE in nursing homes were computed using unit costs and usage rates developed from site visit data [Ex. 13. p. III–43].

- Gloves, Masks, Gowns, Goggles
  - (usage rate)×(PPE unit cost)×(# of facilities)
- Resuscitation Devices
  - (ambubag unit cost)×(usage rate)×(# of facilities)

[It is assumed that gloves and gowns are used for protection from blood only 67 percent of the time).

Hospitals: Costs were calculated for this sector based on PPE use per inpatient-year. Using data obtained from site visits conducted at two hospitals believed to be at nearly full compliance, costs were computed at the facility level using the following formula:

(# of inpatient-years per facility)×(PPE usage rate)×(# of facilities)

Average inpatient-years per facility were estimated to be 134.8. PPE use was estimated to be 600 pair of gloves, 39 gowns, 69 masks, and 17 pair of goggles per inpatient year. Costs for resuscitation devices were computed thus:

Resuscitation Devices
- (ambubag unit cost)×(usage rate)×(# of facilities)

Medical and Dental Laboratories: For this industry sector, affected populations were converted to FTE personnel using a factor of 0.856. Costs were calculated as follows:

Gloves, Masks, Gowns
- FCP: (# of FCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- OCP: (# of OCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- Janitors/Housekeepers (gloves only): (# of workers)×(usage rate)×(PPE unit cost)

Goggles
- FCP: (# of FCP)×(PPE unit cost)×(usage rate)
- OCP: (# of OCP)×(PPE unit cost)×(usage rate)

Resuscitation Devices
- (ambubag unit cost)×(usage rate)×(# of facilities)

Outpatient Care Facilities: Costs were calculated as follows:

Gloves, Masks, Gowns
- FCP: (# of FCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- OCP: (# of OCP)×(usage rate)×(days worked per year)×(PPE unit cost)
- Janitors/Housekeepers (gloves only): (# of workers)×(usage rate)×(PPE unit cost)

Goggles
- FCP: (# of FCP)×(PPE unit cost)×(usage rate)
- OCP: (# of OCP)×(PPE unit cost)×(usage rate)

Resuscitation Devices
- (ambubag unit cost)×(usage rate)×(# of facilities)

Blood/Plasma/Tissue Centers: For this industry sector, affected populations were converted to FTE personnel using a factor of 0.856 [Ex. 13, p. 111–47]. Costs were calculated as follows:

Gloves, Masks, Gowns
FCP: (# of FCP)×(usage rate)×(days worked per year)×(PPE unit cost)
Janitors/Housekeepers (gloves only): (# of workers)×(usage rate)×(PPE unit cost)
Goggles
FCP: (# of FCP)×(usage rate)×(PPE unit cost)
Resuscitation Devices
(ambubag cost)×(usage rate)×(# of facilities)

Residential Care: Costs for these establishments were developed from those of nursing homes by using the ratio of the number of affected employees in residential care facilities to the number of affected employees in nursing homes, 0.1035 [Ex. 13, p. III–46].

Funeral Services: Costs for funeral homes were based on the number of necropsies performed yearly by such an establishment, 137.34 [Ex. 13, p. III–46]. The number of FCP per necropsy is 1.05 and the number of OCP per necropsy is 0.074.

Gloves, Masks
FCP: (FCP/necropsy)×(necropsies)×(usage rate)×(PPE unit cost)
OCP: (CCP/necropsy)×(necropsies)×(usage rate)×(PPE unit cost)
Janitors/Housekeepers: (# of workers)×(usage rate)×(PPE unit cost)
Gowns
FCP: (FCP/necropsy)×(necropsies)×(usage rate)×(PPE unit cost)
Goggles
FCP: (# of FCP)×(PPE unit cost)

Research Laboratories: For this industry sector, affected population was converted to FTE personnel using a factor of 0.856 [Ex. 13, p. III–47]. Costs for this sector were computed using an affected worker population (all FCP) of 98,715.

Gloves, Masks, Gowns
(# of workers)×(usage rate)×(days worked per year)×(PPE unit cost)
Goggles
(# of workers)×(usage rate)×(PPE unit cost)
Resuscitation Devices
(ambubag cost)×(usage rate)×(# of facilities)

Fire and Rescue: Costs for this sector were based on the number of medically related emergency runs made in 1986, 6,437,500 [Ex. 13. p. III–48]. Costs for resuscitation devices were estimated assuming one device for every six emergency medical responders (two per shift, three shifts) and one for every twelve firefighters (four per shift). The number of emergency medical responders is 25,550 and the number of firefighters is 170,515.

Gloves, Masks, Gowns
(# of workers)×(# of emerg. runs)×(PPE unit cost)×(usage rate)
Goggles
(# of workers)×(PPE unit cost)
Resuscitation Devices
(# of emergency responders)/6×(device cost)+ (# of firefighters)/12×(device cost)

Corrections: PPE costs for correctional facilities are based on an affected worker population of 97,945.

Gloves
(# of workers)×(PPE unit cost)×(usage rate)
Resuscitation Devices
(ambubag cost)×(usage rate)×(# of facilities)

Law Enforcement: Costs for this sector are based on an affected worker population of 208,693.

Gloves
(# of workers)×(PPE unit cost)×(usage rate)
Resuscitation Devices
(pocket mask cost)×(usage rate)

Industrial Clinics: The costs of PPE usage for this sector are based on the estimated total number of visits made to these clinics, 18,671,000.

Gloves
(# of visits)×(usage rate)×(PPE unit cost)
Resuscitation Devices
(PPE unit cost)×(usage rate)×(# of clinics)

Medical Equipment Repair:

Gloves, Masks
(# of workers)×(usage rate)×(# of days worked)×(PPE unit cost)
Goggles
(# of workers)×(PPE unit cost)×(usage rate)

Personnel Services: It is expected that PPE will be issued to temporary workers upon arrival at the worksite. Consequently, no costs under this provision are expected to be incurred by these establishments.

Costs for PPE are summarized in Tables VII–15–A through VII–15–F. Total incremental annual costs for this provision are expected to be $400.7 million. Cost per facility ranges from $15,311 for hospitals to $11.51 for health units in industry (excluding personnel services and funeral services, for which no costs are expected to be incurred).

Commenters to the record also provided estimates of the costs of PPE. Most of these estimates, unfortunately, are not accompanied by other pertinent information such as baseline compliance levels or estimated rates of usage. For example, St. Francis Hospital and Health Center projected costs for disposable gloves to be $114,000 for 1988 [Ex. 11–119]. While the unit cost is similar to that estimated by OSHA at about $0.19 per pair, incremental costs (those costs attributable to the proposed rule) can not be discerned from the information provided.

TABLE VII–15A.—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT

Gloves

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$17,837,566	$99.43
Offices of dentists	29,613,340	311.74
Nursing homes	49,547,344	2,645.63
Hospitals	48,390,504	8,201.78
Medical/Dental labs	315,432	25.87
Outpatient care	5,618,735	189.14
Blood/Plasma/Tissue centers	1,735,373	2,703.07
Residential care	5,128,150	249.70
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	1,587,925	739.95
Fire and rescue	579,375	154.09
Corrections	0	0.00
Police	10,629	1.71
Health units in industry	672,156	3.03
Medical equipment repair	108,064	36.42
Total	$161,144,593	$260.65

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII–15–B.—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT

[Masks]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$14,113,190	$78.67
Offices of dentists	113,204,411	1,191.70
Nursing homes	361,373	19.30
Hospitals	22,259,632	3,772.82
Medical/dental labs	286,928	23.53
Outpatient care	5,769,188	194.21
Blood/plasma/tissue centers	1,595,640	2,485.42
Residential care	37,402	1.82
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	1,437,954	670.06
Fire and rescue	104,931	27.91
Corrections	0	0.00
Police	0	0.00
Health units in industry	0	0.00
Medical equipment repair	160,132	53.97
Total	159,330,782	257.63

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-15-C— SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT

[Gowns]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$2,767,984	$15.43
Offices of dentists	17,556,524	184.82
Nursing homes	16,913,721	903.12
Hospitals	12,581,531	2,132.46
Medical/Dental labs	632,789	51.89
Outpatient care	6,370,883	214.46
Blood/Plasma/Tissue centers	2,636,327	4,106.43
Residential care	1,750,570	85.24
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	1,587,925	739.95
Fire and rescue	115,875	30.82
Corrections	0	0.00
Police	0	0.00
Health units in industry	0	0.00
Medical equipment repair	0	0.00
Totals	62,914,128	101.83

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-15-D.—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT

[Goggles]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$659,517	$3.68
Offices of dentists	425,613	4.48
Nursing homes	1,645,490	87.86
Hospitals	5,484,257	929.54
Medical/dental labs	5,496	0.45
Outpatient care	101,571	3.42
Blood/plasma/tissue centers	44,872	69.89
Residential care	170,308	8.29
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	27,463	12.80
Fire and rescue	327,842	87.19
Corrections	0	0.00
Police	0	0.00
Health units in industry	0	0.00
Medical equipment repair	3,058	1.03
Totals	8,895,488	14.39

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-15-E.—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT

[Resuscitation Devices]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$1,216,366	$6.78
Offices of dentists	966,089	10.17
Nursing homes	1,159,825	61.93
Hospitals	1,622,590	275.02
Medical/Dental labs	10,335	0.85
Outpatient care	100,703	3.39
Blood/Plasma/Tissue centers	32,646	50.85
Residential care	261,077	12.71
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	21,825	10.17
Fire and rescue	260,434	69.26
Corrections	98,861	42.38
Police	803,492	129.49
Health units in industry	1,878,484	8.48
Medical equipment repair	0	0.00
Total	8,432,726	13.65

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-15-F.—SUMMARY OF COMPLIANCE COSTS PERSONAL PROTECTIVE EQUIPMENT

[Grand Totals]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	$36,594,622	$203.98
Offices of dentists	161,765,977	1,702.91
Nursing homes	69,627,753	3,717.84
Hospitals	90,338,514	15,311.61
Medical/dental labs	1,250,981	102.58
Outpatient care	17,961,080	604.63
Blood/plasma/tissue centers	6,044,858	9,415.67
Residential care	7,347,507	357.77
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	4,663,091	2,172.92
Fire and rescue	1,388,457	369.27
Corrections	98,861	42.38
Police	814,121	131.20
Health units in industry	2,550,640	11.51
Medical equipment repair	271,255	91.42
Total	$400,717,716	$648.15

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Engineering Controls. Available information indicates that those facilities for which engineering controls would be appropriate are currently using such controls [Ex. 13, pp. III-35, 36]. These facilities include research labs, medical and dental labs, and labs located in hospital or outpatient medical establishments. Controls required and believed to be in use include biosafety cabinets (for biosafety level one and two facilities), centrifuge safety equipment, and mechanical pipetting devices. (Puncture resistant sharps containers are included under the housekeeping provision).

Thus, OSHA finds that costs attributable to the proposed provisions for engineering controls will be negligible.

Training. Costs for the training provision were calculated based on the same scheme of occupational classification as was used for medical surveillance, that is, workers were placed into seven different occupational categories with respect to appropriate wage and job turnover rates. (Table VII-9 provides the occupational breakdown into the seven categories along with the affected worker populations.) Additional input data includes the length and frequency of training.

Length of training is expected to vary with occupational classification and is expected to depend on whether training is initial or recurrent. Initial training sessions for diagnosing, treating, and service personnel (except equipment repair) are assumed to be 1 hour in duration while recurrent annual sessions are assumed to be one hour. Initial training for housekeeping personnel, security personnel, police officers, firefighters, and equipment repair personnel are expected to last about 1 hour, with annual sessions at one-half hour.

Initial training costs consist of costs incurred for the time taken by the trainees and compensation for the trainer. (For firefighters, no costs were estimated for time lost to workers, since training can take place during idle hours). Compensation for the trainees and trainer will be paid as follows:

(1) (# of trainees)×(trainee wage rate)×(initial session time)

(2) (trainer wage)×(initial session time)×(# of sessions)

In general, OSHA assumes that one 2-

hour session and one 1-hour session will be offered initially. (For hospitals, it is estimated that 2 of each session will be offered). Compensation for trainers is assumed to be at a rate of $23.26 (head nurse) for sessions with diagnosing and treating employees and $16.44 (floor nurse) for sessions with service and housekeeping personnel. Equations (1) and (2) summed represent total initial costs.

New employees will need to be trained as they are hired. The costs for additional initial training given during the first year can be estimated thus:

(3) (initial trainee compensation)×(job turnover rate)

(4) (trainer wage)×(initial session time)×(# of trainees/group)× (job turnover rate).

Equation (3) reflects the cost of time needed to train each new hire. Equation (4) represents compensation for the trainer. (For hospitals, nursing homes, temporary services, corrections, law enforcement, and fire fighters, it is assumed that new hires will be trained in groups of five. For all other sectors, new hires are assumed to be trained individually). Thus, total first year costs are represented by the summing of equations (1) through (4), which are performed for each of the seven occupational categories across all industries.

Costs for additional training given over all following years will consist of training new hires and tenured employees (in-service). The calculation to estimate the cost of training new hires in these subsequent years is identical to that described by equations (3) and (4) to represent training for new hires during the first year. Equations (5) and (6), given below, represent costs incurred for training tenured (in-service) employees during subsequent years:

(5) (# of trainees)×(1-(job turnover/2))×(trainee wage)× (in-service session time)

(6) (trainer wage)×(in-service session time)×(of sessions)

Equation (5) reflects the cost of the time taken to train tenured employees. The second term of this equation accounts for the employees who will quit before being retrained. (Job turnover has been divided by two to reflect that, on average, only about one-half of the workers leaving over the course of the year will leave before that year's retraining). Equation (6) represents the compensation to the trainer. These calculations have been performed for each occupational catagory within each sector.

Total cost in each subsequent year (recurring cost) is then the sum of equations (3), (4), (5), and (6).

Total annual costs for this provision are the sum of recurring costs plus the annualization of the difference between first year costs and recurring costs. (Annualization was performed using a twenty year payback period). Net costs are summarized in table VII–16. Total annual costs are estimated to be $162.2 million with average costs per facility at $262. The greatest share of incremental costs are expected to be borne by offices of physicians (33%) while the greatest cost per facility will be realized by personnel service establishments, $5,364.

TABLE VII–16.—SUMMARY OF COMPLIANCE COSTS—TRAINING

Industry	Annualized first year costs [1]	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	$300,331	$53,461,639	$53,761,970	$299.67
Offices of dentists	67,231	10,999,131	11,066,362	116.50
Nursing homes	129,499	9,182,353	9,311,852	497.22
Hospitals	408,298	30,937,388	31,345,685	5,312.83
Medical/dental labs	7,529	1,339,543	1,347,072	110.46
Outpatient care	44,842	5,577,474	5,622,316	189.27
Blood/plasma/tissue centers	7,307	842,874	850,181	1,324.27
Residential care	12,597	1,870,640	1,883,237	91.70
Personnel services	284,958	8,377,986	8,662,944	5,364.05
Funeral services	3,989	817,280	821,269	54.57
Research labs	16,250	1,856,487	1,872,736	872.66
Fire and rescue	0	715,333	715,333	190.25
Corrections	71,156	1,138,612	1,209,767	518.55
Police	177,031	2,042,854	2,219,885	357.76
Health units in industry	108,026	31,330,520	31,438,546	141.84
Medical equipment repair	1,930	20,169	22,099	7.45
Total	1,640,973	160,510,282	162,151,255	262.42

[1] Annualized first year costs (AFYC) were computed as follows: AFYC = (total first year cost − recurring cost) × capital recovery factor.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Housekeeping. Costs incurred for housekeeping will arise from five sources: puncture resistant sharps disposal containers; biowaste bags, or "red bags," for the containment of infectious waste; costs of disposal of infectious waste; costs for disinfecting surfaces and equipment; and use of foil coverings (offices of dentists only).

Costs for sharps disposal containers are based on data obtained from hospitals [Ex. 13, p. III–20]. First, the total cost per bed was multiplied by the number of hospital beds nationwide to arrive at a total cost figure for this sector. Costs were then divided by the overall number of diagnosing and treating workers employed by all hospitals to arrive at a cost per diagnosing/treating (D/T) employee. This estimate was in turn used to estimate sharps container costs across all other sectors by multiplying the unit cost per diagnosing/treating employee by the number of such employees in each respective sector. (The affected population of D/T employees for each sector is shown in Table VII–9). Input data for sharps containers included the following:

	Cost per D/T employee
Capital costs	$56.61
Annual labor and materials	$24.12

Thus, for each sector, annualized capital costs required for sharps containers were calculated using the following formula:

(1) (# of D/T workers)×(unit capital cost per worker)×(capital recovery factor),

where annualization occurs over 5 years and the capital recovery factor equals 0.2638.

Recurring annual costs for containers ware calculated as

(2) (# of D/T workers)×(annual cost per worker).

Total annual costs for sharps containers were calculated by summing equations (1) and (2) and amount to $28.4 million. The costs by sector are summarized in Table VII–17–A.

For the purchase of biowaste bags, a similar methodology was used to estimate the added costs for hospitals (though no initial costs will be incurred). Input data included:

	Cost per D/T employee
Annual cost	$35.13

Thus, total annual costs for biowaste bags in the hospital sector were calculated to be:

(3) (# of D/T workers)×(annual cost per worker).

Total annual costs for additional biowaste bags in other sectors were calculated by estimating approximate bag usage with respect to infectious waste disposal. Assuming each bag contains an average of two pounds of waste at disposal, the unit cost is $0.20 per bag, and the infectious waste generation rates are those shown in Table VII–17–C, costs were calculated thus:

(4) [(pounds of infectious waste generation per year)/2]×$0.20

Costs for biowaste bags are shown in Table VII–17–B and total $28.3 million per year.

Costs will also be incurred for the disposal of infectious waste, which is more costly to dispose of than general refuse, to the extent that establishments are not currently practicing proper identification of such waste prior to disposal.

Costs were determined by developing estimates of waste generation for each industry and then multiplying total annual volume by the unit cost of disposal. Rates of infectious waste generation, along with estimates of current compliance and unit costs, which were based largely on a survey of health care establishments in King County of Washington State, are presented in Table VII–17–C. The following formula was used to estimate costs for biowaste disposal:

(5) (total annual volume of waste)×(unit cost).

This total annual cost was then multiplied by the appropriate compliance factor to determine the incremental cost of $117.2 million. Costs for this component of housekeeping are summarized in Table VII–17–D.

The provision requiring the disinfecting of surfaces and equipment is not expected to generate significant cost. First, it is probable that surfaces and equipment are already being disinfected prior to use in almost all instances if visibly contaminated. The OSHA rule may simply alter the schedule of this activity so that disinfection takes place sooner. Second, accepted industry practice is to disinfect any equipment or instrument which comes into contact with patients as a means of preventing the spread of infection from patient to patient. Third, disinfectant solutions are inexpensive and easy to prepare; therefore, any incremental increase in disinfection practices will be of insignificant burden.

The final cost included for this provision of the standard applies only to offices of dentists and is for the use of foil coverings to prevent the contamination of surfaces, switches, etc. Costs are based on the use of fresh foil for every patient at a cost of about $.05 per patient, as shown by the following equation:

(6) [(# of dentists)×(# of visits)+(# of hygienists)× (# of visits to hygienists)]×0.05.

Based on an estimated current compliance level of 25%, total annual costs for coverings amount to $14.9 million.

Costs for leakproof containers to protect workers handling blood in transport have not been estimated, since OSHA assumes that no significant costs would be realized. If public comment indicates otherwise, costs for these containers will be estimated.

Total costs will be the summation of equations (1) through (6) and are presented in Table VII–17–E. Total incremental annual costs for this provision are estimated at $188.9 million. Average cost per facility will be $306.

Labelling/Signs. Costs for signs were estimated based on the requirement that one sign will be posted at each entrance to a research laboratory or virus production facility that handles concentrated virus. Sign costs are estimated to be $13.75 each (the cost of a 10" x 14" aluminum sign, including $1.00 for mounting materials). Total costs for signs were estimated for the research lab sector by assuming that each of the 2,146 facilities identified in the Industry Profile will require two signs, and that one-quarter hour is required for mounting each sign. Signs are expected to be replaced every five years; thus, annualization was calculated based on this time period. The costs of signs were computed as follows:

[(# of signs)×[(unit cost)+(0.25 hrs. ×$9.09)]×(annualization factor),

where $9.09 is the wage rate of maintenance personnel and costs are at the facility level.

Total annual costs for signs in research labs are thus estimated at $3,628. Annual costs per facility will be $1.69.

Labels are also required by the proposed rule. However, since containers and storage apparatus used for transporting and storing blood and other infectious materials would normally have a label affixed to them for the purposes of identification, it is not anticipated that measurable incremental costs will be involved in complying with this requirement. Label style, however, may need to be modified when new labels are ordered.

TABLE VII–17–A—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING

Sharps Disposal

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	$3,139,746	$5,071,119	$8,210,865	$45.77
Offices of dentists	1,219,898	1,970,303	3,190,201	33.58
Nursing homes	293,776	474,489	768,265	41.02
Hospitals	3,527,491	5,697,380	9,224,871	1,563.54
Medical/dental labs	43,839	70,807	114,646	9.40
Outpatient care	1,802,694	2,911,598	4,714,291	158.70
Blood/plasma/tissue centers	208,757	337,171	545,928	850.36
Residential care	56,009	90,462	146,471	7.13
Personnel services	0	0	0	0.00
Funeral services	0	0	0	0.00

TABLE VII-17-A—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING—Continued

Sharps Disposal

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Research labs	214,270	346,076	560,347	261.11
Fire and rescue	233,220	376,682	609,902	162.21
Corrections	0	0	0	0.00
Police	58,391	94,309	152,700	24.61
Health units in industry	80,216	129,561	209,777	0.95
Medical equipment repair	0	0	0	0.00
Total	10,878,307	17,569,956	28,448,263	46.05

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-17-B.—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING

[Biohazard Bags]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	4,214,223	23.49
Offices of dentists	2,479,343	26.10
Nursing homes	9,815,338	524.10
Hospitals	8,298,050	1,406.45
Medical/dental labs	127,684	10.47
Outpatient care	581,495	19.58
Blood/plasma/tissue centers	564,130	878.71
Residential care	1,315,251	64.04
Personnel services	0	0.00
Funeral services	0	0.00
Research labs	578,931	269.77
Fire and rescue	160,938	42.80
Corrections	0	0.00
Police	102,051	16.45
Health units in industry	110,821	0.50
Medical equipment repair	0	0.00
Total	28,348,256	45.88

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-17-C.—INFECTIOUS WASTE—WASTE GENERATION AND CURRENT COMPLIANCE RATES

Industry	Volume of infectious waste generated	Unit disposal costs (dollar)	Baseline rate (percent)
Offices of physicians.	1.5 LB/office/day.	0.75	39
Offices of dentists.	2 LB/office/day.	0.75	39
Nursing homes.	0.5 LB/bed/day.	0.44	81

TABLE VII-17-C.—INFECTIOUS WASTE—WASTE GENERATION AND CURRENT COMPLIANCE RATES—Continued

Industry	Volume of infectious waste generated	Unit disposal costs (dollar)	Baseline rate (percent)
Hospitals	1 LB/bed/day.	0.44	81
Medical/dental labs.	1.75 LB/employee/day.	0.56	86
Outpatient care.	1.5 LB/facility/day.	0.56	39
Blood/plasma/tissue centers.	1.75 LB/employee/day.	0.56	86
Residential care.	0.5 LB/bed/day.	0.75	81
Personnel services.	0	N/A	N/A
Funeral services.	0.5 LB/necropsy.	0.75	39
Research labs.	1.75 LB/employee/day.	0.56	86
Fire and rescue.	0.5 LB/emergency.	0	39
Corrections	1 LB/treating personnel/day.	0.75	39
Police	1 LB/treating personnel/day.	0	39
Health units in industry.	1 LB/treating personnel/day.	0.75	39
Medical equipment repair.	0	N/A	N/A

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Jack Faucett Associates.

TABLE VII-17-D.—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING

[Disposal of Infectious Waste]

Industry	Total annual costs	Total annual costs per facility
Offices of physicians	32,133,454	179.11
Offices of dentists	22,685,992	238.82
Nursing homes	16,855,321	900.01
Hospitals	24,341,572	4,125.69
Medical/dental labs	1,314,019	107.75
Outpatient care	3,972,773	133.74
Blood/plasma/tissue centers	770,113	1,199.55
Residential care	8,325,936	405.41
Personnel services	0	0.00
Funeral services	472,850	31.42
Research labs	3,425,293	1,596.13
Fire and rescue	0	0.00
Corrections	1,637,316	701.81
Police	0	0.00
Health units in industry	1,282,795	5.79
Medical equipment repair	0	0.00
Total	117,217,433	189.72

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-17-E—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING GRAND TOTALS

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	$3,139,746	$41,418,796	$44,558,542	$248.37
Offices of dentists [1]	1,219,898	41,998,950	43,218,848	454.96
Nursing homes	293,776	27,145,148	27,438,924	1,465.13
Hospitals	3,527,491	38,337,002	41,864,493	7,095.68
Medical/dental labs	43,839	1,512,509	1,556,349	127.62

TABLE VII-17-E—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING GRAND TOTALS—Continued

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Outpatient care	1,802,694	7,465,866	9,268,560	312.01
Blood/plasma/tissue centers	208,757	1,671,414	1,880,171	2,928.62
Residential care	56,009	9,731,649	9,787,658	476.59
Personnel services	0	0	0	0.00
Funeral services	0	472,850	472,580	31.42
Research labs	214,270	4,350,300	4,564,571	2,127.01
Fire and rescue	233,220	537,620	770,839	205.01
Corrections	0	1,637,316	1,637,316	701.81
Police	58,391	196,360	254,751	41.06
Health units in industry	80,216	1,523,176	1,603,392	7.23
Medical equipment repair	0	0	0	0.00
Total	10,878,307	177,998,957	188,877,264	305.71

[1] Recurring costs for dental offices include $14,863,312 for coverings.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Recordkeeping. Costs for recordkeeping will be incurred due to the need to keep medical and training records.

Initial costs for medical records will be for the establishment of a file for each employee. It is expected that ten minutes will be required for this task. The wage rate for the employee preparing this file is taken to be that of a service employee at $11.12. Annualized initial costs, computed based on a 20 year payback period, are then:

(# of affected workers) × ⅙ hr. × 11.12 × (capital recovery factor).

Recurring costs for medical records will be:

(initial costs) × (job turnover rate) + (# of exposure incidents × 1/20 × 11.12),

as each new employee will require a file and the records of those workers reporting exposure incidents will require updating, which is assumed to require about 3 minutes per file.

Total annual costs for medical records are the sum of annualized initial costs and recurring annual costs.

Although initial costs for establishing a training file will not be substantial, there will be annual recurring costs because the file must be updated subsequent to training sessions.

Recurring recordkeeping tasks will include recording will be due to the need to include the dates, trainers, and attending trainees for each training session. It was estimated that the time required to update the file will average about 1 minute per trainee. Thus, costs were estimated by the following formula.

(# of trainees) × [1 + (job turnover/2)] × 1/60 hr. × $11.12

(As explained above, job turnover has been divided by two to reflect that, on average, only about one-half of the workers leaving over the course of the year will leave before that year's in-service training. Thus, one-half of the workers eventually leaving will attend one of the sessions provided.)

Since the total first year costs will exceed the costs in succeeding years, this difference is annualized to calculate annual costs. Total annual costs for training records are thus the sum of recurring costs plus the annualization of the difference between first year costs and recurring costs.

Net costs for recordkeeping are summarized in Table VII-18. Annual incremental costs attributable to this provision are $5.6 million. Average cost per facility is expected to be $9.00, ranging from $346 for hospitals to $0.70 for medical equipment repair facilities.

TABLE VIII-18.—SUMMARY OF COMPLIANCE COSTS—RECORD KEEPING

Industry	Annualized initial	Recurring costs	Total annual costs	Total annual costs per facility
Offices of physicians	116,750	364,646	481,395	2.68
Offices of dentists	70,268	243,786	314,054	3.31
Nursing homes	169,515	672,938	842,452	44.98
Hospitals	472,060	1,569,104	2,041,164	345.96
Medical/dental labs	8,890	40,223	49,113	4.03
Outpatient care	80,685	257,575	338,261	11.39
Blood/plasma/tissue centers	4,834	14,255	19,089	29.73
Residential care	17,546	130,097	147,643	7.19
Personnel services	33,938	370,368	404,305	250.34
Funeral services	5,751	26,754	32,505	2.16
Research labs	33,184	184,004	217,188	101.21
Fire and Rescue	43,934	89,214	133,149	35.41
Corrections	21,329	91,153	112,482	48.21
Police	45,446	82,710	128,157	20.65
Health units in industry	59,416	231,748	291,164	1.31
Medical equipment repair	410	1,678	2,088	0.70
Totals	$1,183,956	$4,370,253	$5,554,209	$8.99

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-19-A.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

Industry	Annual cost by type of ownership			Total annual costs	Total annual costs per facility
	Private	Federal	State/loc.		
Offices of physicians	$149,586,276	0	0	$149,586,276	$834
Offices of dentists	223,573,678	0	0	223,573,678	2,354
Nursing homes	118,409,306	0	$4,472,913	122,882,219	6,561
Hospitals	160,602,717	$10,135,123	24,168,370	194,906,210	33,035
Medical/dental labs	5,184,028	0	0	5,184,028	425
Outpatient care	12,708,624	14,206,015	11,479,996	38,394,636	1,292
Blood/plasma/tissue centers	9,063,097	0	0	9,063,097	14,117
Residential care	18,457,633	0	3,180,858	21,638,492	1,054
Personnel services	11,500,173	0	0	11,500,173	7,121
Funeral services	2,121,660	0	0	2,121,660	141
Research labs	8,741,832	682,956	4,234,325	13,659,113	6,365
Fire & rescue	0	0	4,948,495	4,948,495	1,316
Corrections	0	438,794	4,084,857	4,523,651	1,939
Police	0	642,986	3,478,717	4,121,702	664
Health units in industry	45,655,456	0	0	45,655,456	206
Medical equipment repair	421,977	0	0	421,977	142
Totals	766,026,458	26,105,873	60,048,531	852,180,862	1,379

Source: Occupational Safety and Health Administration, Office of Regulatory Anaylsis.

TABLE VII-19-B.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

Industry	Infection control plan	Vaccination/post exposure follow-up	PPE	Training	Housekeeping	Recordkeeping	Totals
Offices of physicians	$4,403,308	$9,786,439	$36,594,622	$53,761,970	$44,558,542	$481,395	$149,586,276
Offices of dentists	2,331,528	4,876,909	161,765,977	11,066,362	43,218,848	314,054	223,573,678
Nursing homes	895,707	14,765,531	69,627,753	9,311,852	27,438,924	842,452	122,882,219
Hospitals	528,647	28,787,707	90,338,514	31,345,685	41,864,493	2,041,164	194,906,210
Medical/dental labs	299,313	681,200	1,250,981	1,347,072	1,556,349	49,113	5,184,028
Outpatient care	745,154	4,459,264	17,961,080	5,622,316	9,268,560	338,261	38,394,636
Blood/plasma/tissue centers	16,494	252,304	6,044,858	850,181	1,880,171	19,089	9,063,097
Residential care	1,008,118	1,464,328	7,347,507	1,883,237	9,787,658	147,643	21,638,492
Personnel services	39,638	2,393,285	0	8,662,944	0	404,305	11,500,173
Funeral services	369,411	425,625	0	821,269	472,850	32,505	2,121,660
Research labs	52,671	2,285,227	4,663,091	1,872,736	4,564,571	217,188	*13,659,113
Fire and resuce	90,174	1,850,542	1,388,457	715,333	770,839	133,149	4,948,495
Corrections	57,261	1,407,964	98,861	1,209,767	1,637,316	112,482	4,523,651
Police	152,295	552,494	814,121	2,219,885	254,751	128,157	4,121,702
Health units in industry	5,440,167	4,331,546	2,550,640	31,438,546	1,603,392	291,164	45,655,456
Medical equipment repair	72,822	53,714	271,255	22,099	0	2,088	421,977
Totals	16,502,710	78,374,079	400,717,716	162,151,255	188,877,264	5,554,209	852,180,862

*Includes $3,628 for signs.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-19-C.—SUMMARY OF COMPLIANCE COSTS—INITIAL COSTS

Industry	Infection control plan	Vaccination/post exposure follow-up	Training	Housekeeping	Recordkeeping	Totals
Offices of physicians	$16,691,841	$22,350,137	$2,566,931	$11,901,992	$997,859	$54,508,760
Offices of dentists	8,838,242	15,347,175	574,621	4,624,329	600,582	29,984,949
Nursing homes	3,395,402	31,205,412	1,106,829	1,113,632	1,448,844	38,270,119
Hospitals	2,003,970	87,644,114	3,489,724	13,371,837	4,034,703	110,544,347
Medical/dental labs	1,134,623	1,672,492	64,352	166,184	75,980	3,113,630
Outpatient care	2,824,694	15,140,174	383,262	6,833,563	689,619	25,871,312
Blood/plasma/tissue centers	62,523	900,844	62,456	791,346	41,316	1,858,484
Residential care	3,821,525	3,230,157	107,669	212,316	149,963	7,521,630
Personnel services	150,260	6,946,786	2,435,538	0	290,065	9,822,648
Funeral services	1,400,345	1,657,855	34,098	0	49,150	3,141,448
Research labs	199,664	6,251,753	138,885	812,246	283,627	*7,745,190
Fire and rescue	341,829	5,181,625	0	884,078	375,506	6,783,039
Corrections	217,062	5,485,724	608,169	0	182,300	6,493,255
Police	577,313	1,573,951	1,513,081	221,345	388,431	4,274,121

TABLE VII–19–C.—SUMMARY OF COMPLIANCE COSTS—INITIAL COSTS—Continued

Industry	Infection control plan	Vaccination/post exposure follow-up	Training	Housekeeping	Recordkeeping	Totals
Health units in industry	20,622,316	9,084,197	923,299	304,081	507,830	31,441,723
Medical equipment repair	276,050	113,860	16,497	0	3,503	409,909
Total	62,557,658	213,786,256	14,025,409	41,236,949	10,119,278	341,784,565

* Includes $59,015 for signs.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII–19–D.—SUMMARY OF COMPLIANCE COSTS—RECURRING COSTS

Industry	PPE	Vaccination/post exposure follow-up	Training	Housekeeping	Recordkeeping	Totals
Office of physicians	$36,594,622	$7,171,473	$53,461,639	$41,418,796	$364,646	$139,011,177
Office of dentists	161,765,977	3,081,289	10,999,131	41,998,950	243,786	218,089,134
Nursing homes	69,627,753	11,114,498	9,182,353	27,145,148	672,938	117,742,689
Hospitals	90,338,514	18,533,346	30,937,388	38,337,002	1,569,104	179,715,353
Medical/dental labs	1,250,981	485,519	1,339,543	1,512,509	40,223	4,628,775
Outpatient care	17,961,080	2,687,864	5,577,474	7,465,866	257,575	33,949,860
Blood/plasma/tissue centers	6,044,858	146,905	842,874	1,671,414	14,255	8,720,306
Residential care	7,347,507	1,086,399	1,870,640	9,731,649	130,097	20,166,293
Personnel services	0	1,580,511	8,377,986	0	370,368	10,328,865
Funeral services	0	231,656	817,280	472,850	26,754	1,548,540
Research labs	4,663,091	1,553,772	1,856,487	4,350,300	184,004	*12,610,227
Fire and rescue	1,388,457	1,244,292	715,333	537,620	89,214	3,974,917
Corrections	98,861	766,134	1,138,612	1,637,316	91,153	3,732,075
Police	814,121	368,341	2,042,854	196,360	82,710	3,504,387
Health units in industry	2,550,640	3,268,695	31,330,520	1,523,176	231,748	38,904,779
Medical equipment repair	271,255	40,392	20,169	0	1,678	333,493
Total	400,717,716	53,361,087	160,510,282	177,998,957	4,370,253	796,960,870

*Includes $2,573 for signs.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Total annual incremental costs for the proposed regulation appear in Tables VII–19–A and VII–19–B. Total costs are expected to be $852 million. It is estimated that offices of dentists will incur the largest share of these costs at $224 million. Medical equipment repair establishments will bear the smallest share, $422,000. The average cost per facility will be $1,379, ranging from $142 per facility for the medical equipment repair sector to $33,035 per facility for hospitals. It is estimated that state and local governments will bear about 8 percent of the costs of the proposed regulation while federally administered facilities will bear about 3 percent. The costs of adequate PPE are expected to amount to almost one-half of total compliance costs.

Tables VII–19–C and VII–19–D provide summaries by sector of initial costs and recurring costs, respectively.

Cost Savings. As an offset to these costs, there are several areas of potential cost savings. First, cost savings attributable to reduced rates of nosocomial infections are likely after implementation of the OSHA rule. JFA reports that average direct charges for nosocomial infections in the U.S. may be greater than $2.5 billion per year [Ex. 13, p. II–47]. Conservative estimates place the potential savings of effective infection control programs at about $250,000 per year for the average U.S. hospital with a patient census of 250 [Ex. 13, p. II–47]. Though most facilities have certainly instituted some kind of infection control program, few are estimated to be at 100% compliance with OSHA's proposed rule. Most facilities, therefore, should realize some reduction in costs attributable to nosocomial infections. Other evidence in the record indicates that other cost savings will be realized. In one hospital, the cost to the hospital per needlestick is estimated to be $110 [Ex. 6–160]. One commenter felt that reducing needlesticks by 40% would greatly reduce the employee health costs of such injuries which are about $300 per employee [Ex. 11–181, p. 4].

F. Economic Impacts. Estimates of the economic impact of the proposed rule are based on the cost figures presented above and on information contained in the public record. Impacts were computed at the industry level and are summarized in Table VII–20. The financial information appearing in columns one and two of the table were obtained from the sources described earlier in the Industry Profile section of this Preliminary Regulatory Impact Analysis.

As shown in the table, compliance costs as a percent of sector revenue/budgets are expected to range up to 0.87% for dentist offices. Estimates of compliance costs as a percent of profits range up to 12.1%, and 11%, respectively, for firms providing health care personnel services, and dentist offices.

The degree to which effected firms will either incur or shift regulatory burdens depends largely on the competitive environment in which the firms operate and on the price elasticity of demand for the firms' products. Where the products offered are not very sensitive to price, affected firms can successfully raise prices to offset increased costs. This description characterizes many health care services because consumers (patients) are frequently given little choice in medical decisions and are partially insulated from price increases by the health care financing system. Although recent cost-containment policies tend to moderate these institutional factors, OSHA believes that many of the establishments affected by this standard will eventually pass through a substantial portion of the cost increases to consumers of health care, government units, and third party payers [Ex. 13, p. IV–5]. Based on these data, OSHA preliminarily concludes that no industry sector will experience severe economic disruption due to the impact of the proposed rule.

TABLE VII-20.—SUMMARY OF ECONOMIC IMPACTS

Industry	Revenue/ budget ($ million)	Profits [1] ($ million)	Annual costs ($ million)	Costs/ revenue (%)	Costs/ profits [7] (%)
Offices of physicians	92,900	[2] 6,900	149.59	0.161	2.168
		[3] 57,500			0.260
Offices of dentists	25,700	[2] 2,030	223.57	0.870	11.013
		[3] 19,000			1.177
Nursing homes	30,600	961	122.88	0.402	9.339
Hospitals	161,000	1,589	194.91	0.121	2.576
Medical/dental labs	7,100	475	5.18	0.073	1.091
Outpatient care	33,750	[4] 1,033	38.39	0.114	2.231
Blood/plasma/tissue centers	1,420	N/A	9.06	0.638	N/A
Residential care	8,700	[5] 254	21.64	0.249	5.784
Personnel services	3,200	96	11.50	0.359	11.979
Funeral services	5,500	390	2.12	0.039	0.543
Research labs	10,300	433	13.66	0.133	2.017
Fire and rescue	4,000	N/A	4.95	0.124	N/A
Corrections	9,900	N/A	4.52	0.046	N/A
Police	16,900	N/A	4.12	0.024	N/A
Health units in industry	([8])	([8])	45.66	N/A	N/A
Medical equipment repair	18,700 [6]	1,000 [6]	0.42	0.002	0.042

[1] Profit totals reflect proprietary firms only.
[2] Profits exclusive of salary.
[3] Profits including salaries.
[4] Based on profit margin of ambulatory facilities.
[5] Based on profit margin of nursing home sector.
[6] Medical equipment supply firms only.
[7] Ratio reflects private firms only.
[8] Health care budgets not estimated.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hospitals. As shown in Table VII-20, OSHA estimates the cost of the standard at 0.12 percent of hospital revenues and 2.6 percent of hospital profits. According to JFA [Ex. 13], hospital profit margins have deteriorated noticeably since 1984, largely due to Medicare's Prospective Payment System (PPS), which sets a predetermined fee for each Diagnostic Rate Group (DRG). To raise prices for these services, hospitals must rely on organizations, such as Medicare, to approve rate increases. Although the added burden of the OSHA standard may eventually be reflected in higher rates for DRGs (which, in turn, would require an increase in federal Medicare/ Medicaid budgets), in the short-term, hospitals will bear the cost increases or pass them on to consumers not covered by DRGs. Hospitals which employ temporary nursing personnel may also experience additional cost increases due to personnel service companies attempting to pass forward compliance costs (see below).

Hospitals are now in a period of consolidation, evidenced by increases in the closing of investor-owned facilities, which accounted for over 43 percent of community hospital closures in 1987, and by accelerated growth in the number of hospitals owned or managed by multi-hospital systems [Prospective Payment Assessment Commission, Report to the Congress, June 1988, pp. 50,51]. Nevertheless, JFA concluded that although the costs of the proposed OSHA standard will increase the financial problems of troubled hospitals, they will not necessarily lead to hospital closures. They noted that rural hospitals, which have the greatest financial problems, often survive because of strong community support, and that the standard's costs are a relatively minor part of the expenditures of larger hospitals.

JFA also calculated that, in 1988, 54% of hospital revenues were provided by government, 36% by private insurers, and only 8% by direct patient outlays [Ex. 13, p. IV-11]. With so much of the cost of hospital care borne by third parties, these price increases would not significantly reduce the long run demand for hospital services. Thus, OSHA expects that the average additional cost of $32,000 per facility might support the current consolidation trend in the hospital sector, but will not substantially alter the general industry structure.

Physicians Offices. Prospective compliance costs are estimated to be 0.16% of physician office revenues and 2.2% of profits. This latter ratio, however, may not be a meaningful indicator of economic feasibility for this sector because most physician offices are owner-managed, and current tax laws provide strong incentives for distributing income as salaries or bonuses. Adjusting this ratio by adding an estimate of average physicians' income to the reported office profit shows that expected compliance costs are only 0.3% of total practitioner's income. Although costs of this magnitude would not bring a marked disruption in this industry even if borne entirely by these employers, this sector will not bear the full cost burden. JFA estimated that under the current reimbursement system, the direct consumer contribution to physicians office receipts is only about 26%, with private insurance and government making up the remainder [Ex. 13, p. IV-11]. Thus, it is probable that physicians will be able to pass through some of the increased costs by raising fees.

Dentist Offices. Dental practices will incur compliance costs averaging almost $2,400 per facility, about 0.87% of revenues and 11% of reported profits. After adjusting this ratio to reflect the average income of dentists, the expected compliance costs amount to 1.2% of the total net income. Several factors have reduced dentist incomes in recent years, including fluoride treated water and better tooth decay prevention and, since the early 1980's, a fall in the number of employees covered by private dental insurance plans. JFA calculates that almost two-thirds of dental revenues are paid by direct consumer outlays [Ex. 13, p. IV-11]. As a result, dentists may be less able than most other health care providers to pass forward ths costs of compliance and may suffer some income decline, and some patients may choose to defer routine preventive care.

Nursing Homes. Compliance costs for nursing homes are estimated at about

0.4% of revenue and at 9.3% of profits. These facilities may face the same problem as hospitals in passing forward cost increases because state and federal agencies are developing similar cost control measures. At this time, however, at least some price increases would be expected because approximately half of nursing home revenues are from government and insurance programs. Moreover, future conditions should favor nursing home profits since the demand for beds is expected to rise sharply as the population ages.

Residential Care Facilities. Compliance costs for residential care facilities average about 0.25% of revenues and 5.8% of profits. Many of these facilities, however, are nonprofit or public institutions. Costs incurred by the non-profit establishments may or may not be fully passed through, depending on financing sources. JFA found that only about one-half of the revenue of these facilities consist of direct consumer payments, so it is likely that some increased rates could be supported. Alternatively, The Hospice Association of America reports that 40% to 100% of hospice funding is derived from donations [Ex. 11–202], and that these facilities would have to absorb a large proportion of the costs of compliance. For the facilities that are publicly owned, additional funds would need to be covered by increases in tax rates or by reduced funding to other government programs.

Other Health Care Facilities. As shown in Table VII–20, compliance costs for the other health care facilites will be less than 1% of revenues. For those sectors where profit data were available, the estimated compliance cost-to-profit ratios for the other affected sectors are below 3%. Although a significant burden within this group may be experienced by some medical and research laboratories, pharmaceutical companies, in which many of the larger laboratories are located, generally have strong profits and favorable expectations for future R&D growth.

Health Units in Industry. The national cost total for health units in other industries is substantial, but the costs for these units are spread over so many industries that the estimated annual cost per facility is only $204. Since health units are typically found in large businesses, these costs will have a negligible impact on market structure.

Personnel Service Companies. Compliance costs for personnel firms supplying medical care staff are estimated at 0.36% of related revenue and 12.1% of related profits. The impact on this sector is substantial because of the large number of affected employees per firm who must be provided with training and with medical evaluations. The estimated cost-to-profit ratio may be overstated, however, because it assumes that profits of firms providing health care personnel are similar to profits of firms providing other categories of personnel. JFA noted that some of these firms may attempt to defray costs by giving preference to hiring vaccinated workers [Ex. 13, p. IV–15]. In many areas, however, it is likely that the shortage of nursing personnel will permit these firms to shift compliance costs forward to hospitals.

Non-Health Care Facilities. Compliance costs for corrections, police, and fire and rescue operations amount to less than 0.2% of the budgets of such organizations. JFA calculates that if these costs were passed on by higher taxes, this would increase the average per capita tax burden by 11 cents [Ex. 13, p. IV–14]. Similarly, the costs of compliance for funeral homes would not disrupt the industry as they are estimated at less than 0.1% of revenues and at about 0.5% of profits.

As noted above, facilities administered by state and local governments were estimated to incur about 8 percent of the total costs of compliance and federal facilities were estimated to incur about 3 percent. The total impact on government finances, however, will be greater, as some of the costs passed forward by health care providers will be financed through government programs such as Medicare. Assuming that the percentage of health care costs financed by government programs in 1988 is an approximation of future financing patterns [Ex. 13, p. IV–11], costs to the federal government would be expected to be about $200 million, representing 23.5% of the total costs of the rulemaking, and costs to state and local governments would be expected to be about $125 million, representing 14.7% of the total costs of the rulemaking.

Regulatory Flexibility Analysis. OSHA finds that the impact of the proposed rule on small businesses will be similar to that found for the affected universe as a whole because the vast majority of businesses affected are small. Table VII–21 lists eleven industry sectors (public services, health units in industry, and blood banks are omitted) and provides estimates reported by JFA [Ex. 13, p. IV–17] of the percentage of firms classified as small (reporting less than $3.5 million in revenue) and the percentage of total sector revenue earned by those firms.

It is evident from the table that for all sectors except hospitals, the high percentage of small firms precludes any significant competitive disadvantage based on size. Thus, for all sectors except hospitals, the impacts developed above will be borne relatively uniformly throughout each respective sector.

As shown in the table, small firms make up about 29% of the hospital sector. These facilities may be at a competitive disadvantage in that small hospitals may have lower operating margins than large hospitals [Ex. 13, p. IV–11; Prospective Payment Assessment Commission, Report to the Congress, June 1988, p. 50], and thus, cost absorption may not be an option for such facilities. This effect will be offset somewhat as smaller hospitals tend to be located in rural areas where there are few competitors.

OSHA concludes that the impact of the proposed standard on small businesses will not differ significantly from that which will be realized by the affected universe as a whole. Also, no differential impact with regard to establishment size is expected, though, as noted earlier in the discussion of overall impacts, the pace of hospital industry consolidation may be accelerated.

TABLE VII–21—EFFECT OF THE STANDARD ON SMALL BUSINESS

[1988]

SIC	Facility type	Percent of firms with revenue of less than $3.5 million	Percent of revenue from small business
801 & 3	Offices of MD's & DO's	99.32	88
802	Offices of Dentists	99.97	88
805	Nursing Homes	87.47	48
806	Hospitals	28.64	2
807	Medical and Dental Labs	98.59	58
808	Outpatient Care	98.02	45
836	Residential Care	97.60	75
7362	Personnel Services	90.54	34
726	Funeral Services	99.61	90
7391	Research Labs	91.63	14
	Medical Equip. Repair		NA

Source: Jack Faucett Associates.

VIII. Environmental Impact

The provisions of the proposed standard have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 432, et seq.], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR Part 1500], and OSHA's DOL NEPA Procedures [29 CFR Part 11]. As a result

of this review, OSHA concludes that no evidence exists to suggest that the proposed rule will have a significant environmental impact.

Evidence in the public record indicates that the volume of waste handled as infectious will increase somewhat following promulgation of the OSHA bloodborne pathogens standard. This is because not all generators of infectious waste are currently packaging all types of infectious waste (as defined in the standard) in the manner required by the proposed rule [Ex. 13, Tables II–29, –30]. (The proposed regulation requires infectious waste to be packaged in color coded containers or to bear the universal symbol for infectious waste). As generators come into compliance, infectious waste previously entering the general waste stream will be shifted into one of the major treatment options used for the disposal of infectious waste, namely incineration or autoclaving. Any potential environmental impact associated with the proposed rule would be realized via one of these disposal techniques. To the extent that infectious waste in the general waste stream is currently handled improperly, the proposed rule may improve environmental quality as previously mishandled infectious waste is redirected toward preferred disposal alternatives.

The proposed rule will also increase the volume of waste entering the general waste stream. This will be due to the increase in the use of disposable personal protective equipment. This waste will be disposed of principally by landfill and incineration. OSHA estimates that an increase in tonnage of approximately 67,000 tons per year will be realized across all sectors. Total U.S. solid waste generation is about 150 million tons per year [1987 Stat. Abstract]. Thus, the OSHA proposed regulation is estimated to increase solid waste tonnage by less than 0.1 percent.

It should also be noted that OSHA is aware that the Environmental Protection Agency will publish an interim final rule on infectious waste early in 1989. When published, the rule will be incorporated into the public record for the bloodborne pathogens standard.

IX. Summary and Explanation of the Proposed Standard

OSHA believes that the proposed requirements set forth in this notice are those, based on currently available data, which are necessary and appropriate to provide adequate protection to employees exposed to blood and other potentially infectious materials. In the development of this proposal, OSHA ha carefully considered the comments from interested parties given in response to the Advance Notice of Proposed Rulemaking. In addition, numerous guidelines, reference works, journal articles, and other information, accumulated by OSHA since the initiation of this proceeding have been taken into consideration in the development of this proposed standard.

Paragraph (a) Scope and Application

The standard applies to all occupational exposures to blood and other potentially infectious materials as defined in paragraph (b) of this standard. The risk of infection with bloodborne pathogens is dependent on the likelihood of exposure to blood and other potentially infectious materials wherever that exposure occurs. Any exposure incident may result in infection and subsequent illness. The hazard affects employees in many industries and is not dependent on the type of facility in which an employee works. By conditioning coverage upon exposure potential rather than occupation or industry segment, OSHA hopes to protect all employees at risk regardless of their job titles or place of employment.

Blood has long been recognized as a potential source of pathogenic microorganisms that may present a risk to individuals who are exposed during the performance of their duties. In 1983, the CDC published guidelines for controlling infections in hospitals (Ex. 6–74). One section, entitled "Blood and Body Fluid Precautions," recommended that certain precautions be taken in handling the blood and body fluids of patients who were known or were suspected of being infected with bloodborne pathogens. Special precautions were recommended to be followed with these patients. The patients were identified using special placards, and their blood specimens were labeled in order to alert employees who had contact with the specimens. Under this approach, specimens of blood from patients whose serological status was unknown were collected and analyzed using no special precautions to protect the employee from exposure.

Although some patients could be identified as infected with HIV or HBV, allowing employees to be alerted to the increased risks present, it soon became apparent that many individuals infected with these viruses were either undiagnosed or their infection status was not known to the healthcare employee. Patients being treated for unrelated injuries or illnesses; dental patients; trauma victims; and blood donors are all examples of individuals whose infection status may not be known and whose blood may present a risk to the employees who come in contact with it. The possibility of undiagnosed infection combined with the increasing prevalence of HIV and HBV led many infection control practitioners to recommend that blood and certain other body fluids from all patients be considered potentially infectious and that rigorous infection control precautions be taken to minimize the risk of exposure. This approach is called "universal blood and body fluid precautions" or "universal precautions," and the CDC published this recommendation in its August 1987 guidelines (Ex. 6–153)

"Who is at risk?" and "When?" was the subject of many comments to the record. Information submitted documents both the occupations at risk and the specific tasks and procedures that can result in occupational exposure. Risks associated with certain occupations or procedures have also been singled out by CDC in their guidelines and were mentioned repeatedly by the commenters to the ANPR.

The 1985 CDC guideline recommending HBV vaccination for personnel at risk included these examples of occupational groups having frequent exposure to blood: medical technologists; operating room staff; phlebotomists and I.V. therapy nurses; surgeons and pathologists; oncology and dialysis unit staff; emergency room staff; nursing personnel; and staff physicians. CDC also cites the need for HBV vaccination of students in schools of medicine, dentistry, nursing, laboratory technology and other allied health professions. This set of recommendations also included healthcare workers based outside hospitals such as dental professionals, laboratory and blood bank technicians, dialysis center staff, emergency medical technicians and morticians. A brief discussion follows of some additional types of employees exposed to bloodborne pathogens and the places where they are employed.

Individuals who render emergency medical services are clearly at risk for blood exposure incidents. One study has shown that a high percentage (16%) of male trauma victims between the ages of 25 and 34 at an urban hospital were infected with HIV (Ex. 6–111). The comments received from the International Association of Firefighters included information about a Norwood, Ohio firefighter/paramedic, who became infected with hepatitis B virus when responding to an emergency call. The employee's initial exposure incident

occurred while he was treating the victim of a drug overdose who was infected with hepatitis B. A painful, debilitating illness followed and he eventually died of renal and hepatic failure seven years after the initial exposure (Ex. 11–125).

Prehospital care is often rendered in a hostile or uncontrolled environment. Conditions beyond the control of the employee, ranging from broken glass and sharp metal at an accident scene, weapons at the scene of a violent crime, and inclement weather, may complicate the tasks and make them more hazardous. The CDC has recently completed a set of guidelines for public safety officers that provides special guidance for emergency medical personnel (Ex. 14).

Many of the commenters considered the risk to these providers of emergency medical service to be substantial (ANA Ex. 11–86, AAOHN Ex. 11–111, Int. Assn. of Firefighters Ex. 11–125, Merck Ex.11–165). Moreover, CDC has issued guidelines for personnel rendering emergency medical service (Exs. 6–153, 6–199, Ex. 15). On the other hand, the American Ambulance Association stated that although its members are voluntarily following some of the CDC guidelines, the evidence did not show a need for first responders/ambulance transport personnel to be included in OSHA rulemaking. They also stated that providing the HBV vaccine would be prohibitively expensive (Ex. 11–54).

Employees who work in clinical or diagnostic laboratories which perform a variety of tests to aid in the diagnosis of disease and the management of treatment are at risk for occupational exposure. Although not all laboratory tasks involve blood or other potentially infectious materials, a relatively high potential for exposure exists for employees who analyze and process these substances. Several organizations and groups have devised procedures for reducing risks in the laboratory and these procedures are part of our record (Ex. 11–159, 11–71, 11–280, 6–153). In addition to the traditional hospital clinical laboratory, employees in other laboratories are at potential risk for exposure as well. These include, but are not limited to, free-standing clinical or diagnostic labs, labs in dentists' or physicians' offices, blood and plasma center labs, and laboratories preparing reagents from human blood or blood components.

The housekeeping and laundry workers in healthcare facilities may also be at risk of occupational exposure to bloodborne pathogens. (Ex. 11–18). Individuals who perform housekeeping duties, particularly in patient care and laboratory areas, are at risk for occupational exposure when they perform certain tasks such as cleaning blood spills and handling infectious wastes. Laundry workers may be exposed to laundry contaminated with blood or to contaminated sharps inadvertantly left in the laundry. Most recommendations for minimizing or eliminating these hazards focus on limiting the risk by minimizing handling of soiled laundry. This practice not only reduces the likelihood of skin contact with blood contaminated laundry but also reduces the likelihood of a puncture wound from a needle or other sharp object.

Dentists, dental hygienists, other dental professionals are continually exposed to blood and bloody saliva during almost all dental procedures. Because saliva in dental procedures is so likely to contain blood, the CDC recommends personal protective equipment to practioners for all dental procedures (Ex. 6–490). Most commenters who considered this issue agreed these workers are at risk and supported a standard for dental operations (Exs. 11–162, 11–177, 11–327). The American Dental Association did not question the risk but opposed an OSHA standard because they believe dentists are already taking precautions (Ex. 11–43).

The physician's office is commonly the scene of blood collection, treatment of wounds, and other invasive procedures. Physicians, nurses, nurse practitioners, physician assistants and related healthcare workers may be exposed in this setting. The office may also contain a laboratory where occupational exposure may occur as blood is analyzed. Employees who perform these tasks have the same risk as their hospital-based colleagues.

Nursing homes or other long-term care facilities were frequently cited by commenters as places of employment where employees are at risk for blood and body fluid exposure (Exs. 11–86 ANA, 11–74, 11–172). The American Health Care Association, which represents more than 9,000 long term care facilities and allied health care providers, stated:

> [L]ong term health care facilities should be included, [in the standard] but we believe that recognition should be given to the differences in both type of care and population served in long term care facilities as opposed to acute care facilities. (AHCA Ex. 11–27)

The Service Employees International Union urged OSHA not to exclude nursing homes from the standard:

> An exclusion of nursing homes based on their current low AIDS population is inappropriate. Nursing home workers are as likely as other health care workers to be exposed to HBV. They also face other infectious diseases such as TB. Moreover, such a policy would be dangerously short sighted. CDC estimates that more than 1.5 million individuals are today infected with the HIV virus. The growing numbers of AIDS patients together with soaring hospital-based health costs will spur treatment in alternative healthcare settings like nursing homes and respite homes. (SEIU Ex. 11–61)

A hospice is one of several alternative health care programs open to the terminally ill, including terminally ill AIDS patients. Employees provide services to these patients that place the employee at risk for occupational exposure. The Hospice Association of America, representing more than 1700 hospice programs, noted the risk and requested OSHA to consider their employees and their volunteers for inclusion in any mandated infection control program (Ex. 11–202).

Another alternative to hospital care is home health care. The National Association for Home Care (Ex. 11–203) expressed the concern that using "health care facility" to define coverage would lead to misunderstanding and indicated that it is the services being rendered rather than the location of those services that is connected to the risk. They listed a number of tasks that home health care providers may be expected to perform including collecting a blood specimen, cleaning and dressing wounds, and managing intrathecal, epidural, venous and arterial shunts and catheters. Employees who perform these tasks are clearly at risk for occupational exposure.

In blood banks and plasma centers, the potential for occupational exposure begins with the initial finger stick of the donor and continues until contaminated units are identified and destroyed. The blood and blood products in these facilities are regulated by the Food and Drug Administration (FDA), and all plasma and blood collection facilities have extensive written procedures for donor requirements, donor room procedures, and laboratory testing of the blood with blood components (ABRA Ex. 11–71). However, the FDA does not set standards for the health and safety of the employees.

The American Blood Resources Association (ABRA) has argued that workers in a plasma center are at a reduced risk of exposure to bloodborne pathogens because many plasma donors donate frequently, as often twice a week, and therefore their antibody status is known (Ex. 11–71). Similarly,

the American Red Cross stated that "its healthy blood donor population does not present any increased health risks to its employees and volunteers" (ARC Ex. 11–280). However, despite prescreening, both blood banks and plasma centers have donors who are infected with HIV, HBV, and other bloodborne pathogens including non-A non-B hepatitis. In any discussion of the risk to employees in the processing centers, it is important to note that these facilities dedicate a substantial amount of their resources to identifying these contaminated units and ensuring that they are not released for distribution or for further manufacture. Employees engaged in the collecting and testing of these units are at risk for exposure.

Another potential source of bloodborne pathogens is human tissue that is removed for laboratory analysis or for transplantation. The American Association of Tissue Banks, representing 600 individual and 100 institutional members strongly supported the implementation of a standard and recommended including the category "tissue bank personnel" in the coverage (Ex. 11–50).

Although the overwhelming majority of cases of HBV and HIV infections occur in adults, one group of children have a high risk for hepatitis B infection. This group consists of mentally retarded children who are or have been institutionalized. Surveys conducted in large state institutions indicate that the risk of a child contracting hepatitis B in one of these institutions ranges from 50% to 90% with 5% to 20% of those infected becoming hepatitis B carriers (11–165 p 4). The behavior of these children, including scratching, biting, and self-mutilation, may present a risk to those who teach or otherwise care for them. Mentally retarded adults who are or have been institutionalized also have an increased risk for being infected with HBV. In 1985, the CDC recommended the hepatitis B vaccine for both the clients and the staff of institutions for the mentally retarded (Ex. 6–199).

Many commenters made the point that healthcare is also being provided in industrial and in educational settings. These facilities often provide services such as emergency first aid, collection of blood, and cleaning and dressing of wounds, activities that place the healthcare provider at risk for occupational exposure. Examples of these facilities include occupational health clinics, school health clinics, and first aid stations (Exs. 11–111, 11–86, 11–216).

Research and production facilities that concentrate or otherwise handle concentrated virus are also included within the scope of this standard. There are many researchers in academia, government and industry who are studying HIV and HBV. These individuals may be at even greater risk than health care workers because the concentration of virus is often greater than that found in blood or other body fluids. In addition, the generation of aerosols may increase the risk. The OSHA record contains evidence that two individuals who work with concentrated HIV have become infected as the result of occupational exposure. (Ex. 6–187, 6–368, 6–312).

Although OSHA is not aware of any documented cases of HBV or HIV infection associated with the collection, transportation, and decontamination of infectious wastes, the potential for such an exposure prior to decontamination of the waste is clear. OSHA has recently published a proposed standard entitled "Hazardous Waste Operations and Emergency Response" (*Federal Register;* vol. 52; No. 153; 29620). However, employees dealing with infectious waste are covered under that proposal only if they are involved in emergency response clean-up, such as would result if a truck hauling infectious waste tipped and spilled, or during clean-up of a State or Federally-designated hazardous waste site containing infectious wastes. The Agency proposes, therefore, to extend the scope of the proposed Bloodborne Pathogens standard to include those employees contacting infectious wastes in situations other than emergency response or hazardous waste site clean-up. The Infectious Waste Council of the National Solid Waste Management Association supported the use of personal protective clothing and equipment, medical surveillance and training for infectious waste employees. (Ex. 11–60) There was a consensus among the commenters that employees of mortuaries are at risk because they are exposed to blood and certain body fluids and should be covered by the standard (Exs. 11–293, 11–282, 11–240, 11–181, 11–169, 11–157, 11–165).

For example:

> Mortuary workers are potentially exposed to large quantities of blood during the preparation of cadavers; there is also potential for certain abrasions (SEIU Ex. 11–161).
>
> Embalmers constitute a group of long ignored non-hospital based health care workers. During the embalming procedure they often come into contact with large amounts of uncontainerized blood as the vascular system is drained. Depending on the cause of death and whether an autopsy has been performed, they may be required to handle various body parts and tissues, as well as to make numerous incisions and subsequently suture the incised tissue. These procedures put them at risk of exposure. (AAOHN Ex. 11–111)

Only one commenter, The National Funeral Home Directors, questioned whether there was a significant risk of occupational exposure to HBV and HIV in the industry. Nevertheless, they stated that "Funeral directors are * * * taking precautions regarding known HBV and HIV cases" (NFDA 11–164).

Several commenters pointed out the potential risk to employees who service or repair medical instruments or other types of equipment that may be contaminated with blood or body fluids such as dialysis pumps, pacemakers, liquid chromatographs, and centrifuges (Exs. 11–3, 11–43, 11–97, 11–282). These devices are often contaminated both externally and internally (Exs. 11–43 ADA, 11–7 YSI). An occupational exposure may occur when the equipment is serviced on site (Ex. 11–282) or at the factory or service center prior to decontamination (Ex. 11–7).

Other employees who may be exposed to blood and other potentially infectious materials include firefighters, law enforcement personnel and corrections officers. These employees would be covered under the proposed standard if they have occupational exposure to blood or other potentially infectious materials and if they are employed by the private sector, the federal government, or a state or local government in a state that has an OSHA approved state plan. Employees of state and local governments, including those employed in public hospitals and health clinics, in states without OSHA approved state occupational safety and health plans are not covered by OSHA regulations. (For more information on states and territories with OSHA state plans, see section II—Legal Authority.)

Many commenters urged OSHA to include firefighters and law enforcement personnel, who they considered to be at increased risk. (Exs. 11–86 ANA, 11–15 AFSCME, 11–74 NY State Dept. of Health, 11–111 AAOHN, 11–165 Merck, 11–125 Int'l. Ass'n. of Firefighters). When these individuals act as emergency first responders their risk is similar to that discussed earlier for emergency medical services. In addition, the potential for a hostile or uncontrolled environment at a fire or crime scene mandates special procedures in devising an adequate program of protection. The combination of broken glass, jagged metal and blood may present a hazard to the public safety officer who is attempting to extricate the victim of a vehicle

accident. Even after the victim has been removed from the scene, the employee may have to remain in a blood contaminated environment while the investigation and cleanup continues. For law enforcement officers, weapons (including knives, ice picks and razor blades) and drug paraphernalia (including needles and syringes) may have to be collected as evidence. Also, facilities for personal cleanup can be inadequate or lacking altogether.

OSHA requests specific comments on the protection of employees in the public sector and any circumstances that may be unique to these individuals. One example would be the need to protect the hands from both blood exposure and from cuts by broken glass and jagged metal during the extrication of a victim from an automobile accident. There are a number of circumstances that place corrections officers at risk of exposure. Some examples are body cavity searches and exposure as a result of the violent behavior of the inmates, a group with a high prevalence because of past and present high risk behavior, for example, intravenous drug use.

OSHA's preliminary conclusion is that all employees who have occupational exposure to blood or other potentially infectious materials [as defined in paragraph (b) of the standard] as the result of performing their duties are at risk for infection by bloodborne pathogens. This risk has been most thoroughly documented in healthcare facilities such as hospitals; however, the risk is not confined to hospitals but is present whenever blood or other potentially infectious materials are present. Exposures do occur in a number of industries outside the healthcare industry and to employees who are not necessarily engaged in the direct delivery of healthcare (e.g. medical equipment repair). Therefore, the scope of the standard includes occupational activities that occur both in healthcare and non-healthcare facilities and in permanent and temporary worksites. Examples of health care facilities include, but are not limited to: hospitals, clinics, dentists' and physicians' offices, blood banks and plasma centers, occupational health clinics, nursing (long term care) homes, hospices, urgent care centers, clinical laboratories, mortuaries and funeral homes, and institutions for the mentally retarded. Examples of non-healthcare operations include, but are not limited to the service and repair of equipment, infectious waste disposal, virus research laboratories and production facilities, and correctional institutions. In addition, examples of mobile (temporary) operations where there may be occupational exposure to blood and other potentially infectious materials includes mobile blood banks, crime scenes, and scenes of accidents or other trauma.

OSHA believes that under the proposed scope each employee who has occupational exposure to blood or other potentially infectious materials will be provided the necessary protection afforded by the proposed standard. The Agency requests comment on the breadth of the scope and application of the standard.

Paragraph (b) Definitions

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health or a designated representative of the Assistant Secretary.

"Blood" is defined in this standard as human whole blood; human blood components such as plasma or platelets; and human blood products such as clotting factors.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and that can infect and cause disease in persons who are exposed to blood on other potentially infectious materials containing these pathogens. In addition to hepatitis B virus (HBV), human immunodeficiency virus (HIV), and non-A, non-B hepatitis virus(es), further examples of such microorganisms include, but are not limited to, the pathogens which cause syphilis, malaria, viral hemorrhagic fever, and babesiosis.

"Clinical Laboratory" is defined as a workplace where diagnostic procedures or other screening procedures are performed on blood or other potentially infectious materials. These laboratories may be located within hospitals and clinics, in medical or dental offices, or may be free-standing facilities. Laboratories that perform antibody and antigen screening, such as laboratories in blood and plasma centers, are also considered "clinical laboratories".

"Director" means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or a designated representative of the Director.

"Disinfect" is defined, for the purpose of this standard, as a procedure which inactivates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial endospores) on inanimate objects. This definition is identical to that found in Chapter 13 of the *Manual of Clinical Microbiology* of the American Society for Microbiology. (Ex. 6–343)

"Engineering Controls" are defined as controls that isolate or remove a hazard from a workplace. Biosafety cabinets are examples of engineering controls since they not only remove air contaminants through a local exhaust system but provide the added protection of confining the contaminant within an enclosed cabinet thereby isolating it from the worker. Other examples of engineering controls are sharps disposal containers which isolate contaminated needles or other sharps from employees and plexiglass shields on hematrons to prevent blood spattering into the operator's face during tube segmentation.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. Examples of an exposure incident include blood spattering into the eyes or splashing into the mouth or an injury involving a blood-contaminated needle.

"Infectious Waste" incorporates those items about which there is some agreement of expert opinion that they may present an exposure risk. In July of 1988, the Office of Technology Assessment (OTA) conducted a workshop with hospital, regulatory, and environmental experts at which the status of medical waste management nationwide was discussed. The background paper emanating from that meeting, *Issues In Medical Waste Management* notes that Dr. Nelson Slavik states in his report on the proceedings of the EPA meeting of experts on infectious wastes held in November 1987:

> Not withstanding the risk perceptions and anxieties associated with the fear of contracting AIDS, those categories of infectious wastes that possess the greatest potential to transmit disease are contaminated sharps, human blood and blood products, pathological wastes (primarily body fluids), and laboratory wastes (Slavik, 1987)

The paper goes on to say that since these wastes are consistently recognized as presenting a potential hazard of either disease association or accidental injection, proper handling and disposal are warranted. (Ex. 6–339). Therefore, OSHA has defined "Infectious Waste", to be blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes.

"Occupational exposure" is one of the key terms upon which this proposed standard rests. It contains the criteria

which trigger application of the provisions of the proposed standard.

As proposed, occupational exposure is:

"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. This definition excludes incidental exposures that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment."

Actual contact would be expected during an autopsy or surgery. In these cases, the blood or other potentially infectious materials come in direct contact with the employee's skin, gloves or other protective clothing. Even though actual exposures may not occur, reasonably anticipated exposures occur in procedures where blood or other potentially infectious materials are an integral part of the task being performed but the procedure does not always result in actual contact. Examples of potential contacts include phlebotomy and changing a surgical dressing.

The occupational exposure must be reasonably anticipated. For example, the employer would reasonably anticipate that exposure to blood either may occur or will occur when an employee is performing dentistry and certain surgical, medical, or laboratory procedures. On the other hand, the employer would not reasonably anticipate that exposure to blood would occur when an employee is processing insurance claims in an office setting.

As indicated these are exposures that the employee is required to incur in the performance of the employee's duties. There are many examples of employees whose jobs require them to come into contact with blood or other potentially infectious materials—most physicians, nurses, dentists, and embalmers. An example of an exposure that an employee is T3not required to incur (i.e., an incidental exposure) happens when an employee takes it upon himself or herself to help another employee, a "Good Samaritan Act." For example, one employee may assist another employee who has a nosebleed or who is bleeding as the result of a fall. This would not be considered an occupational exposure unless the employee who provides assistance is a member of a first aid team or is otherwise expected to render assistance as one of his or her duties. Under the latter circumstance, the exposure would be considered occupational. OSHA seeks comment on whether this definition includes all situations that should be considered occupational exposures.

"Other Potentially Infectious Materials" consists of three primary categories of material which have the potential to transmit bloodborne pathogens. OSHA has used the term "potentially" to acknowledge that body fluids and tissues may or may not contain bloodborne pathogens. However, the provisions of the proposed standard must be followed in any case. Under this definition OSHA has included the body fluids specified by the CDC in their June 1988 update of guidelines to healthcare workers (Ex. 6–316). The fluids covered by this definition are: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, saliva in dental procedures, and any other body fluid that is visibly contaminated with blood. Semen and vaginal fluid have been shown to transmit HIV and HBV. In support of utilizing universal precautions when contacting other fluids, CDC states:

Universal precautions also apply to tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk of transmission of HIV and HBV from these fluids is unknown; epidemiologic studies in the health-care and community setting are currently inadequate to assess the potential risk to health-care workers from occupational exposures to them. However, HIV has been isolated from CSF, synovial, and amniotic fluid, and HBsAg has been detected in synovial fluid, amniotic fluid and peritoneal fluid. One case of HIV transmission was reported after a percutaneous exposure to bloody pleural fluid obtained by needle aspiration (12). Whereas aseptic procedures used to obtain these fluids for diagnostic or therapeutic purposes protect health-care workers from skin exposures, they cannot prevent penetrating injuries due to contaminated needles or other sharp instruments. (Ex. 6–316)

While universal precautions do not generally apply to saliva, exception is made in the case of saliva in dentistry. Addressing this situation, the CDC states:

Special precautions, however, are recommended for dentistry. Occupationally acquired infection with HBV in dental workers has been documented, and two possible cases of occupationally acquired HIV infection involving dentists have been reported. During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood splattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients (Ex. 6–316).

The CDC guidelines for public safety officers state:

The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.

OSHA seeks comment on whether the proposed definition of "other potentially infectious materials," should be amended to make it consistent with the guidelines.

The second category of "other potentially infectious materials" is any unfixed tissue or organs from a human (living or dead). These pose a risk because they may be contaminated with bloodborne pathogens. One example is human bone which has transmitted HIV infection as the result of transplantation (Ex. 6–357). In the same document, CDC also notes reported transmission of HIV through "transplantation of kidney, liver, heart, pancreas, possibly by skin, and by artificial insemination * * *". Although tissues and organs may contain blood and body fluids, which may be the reason for the transmission hazard, they are not in reality "fluids". Therefore, to avoid confusion OSHA has listed them as a separate category. Since casual contact, including touching and hugging, does not pose a risk of transmission, intact skin is not considered to be "other potentially infectious materials."

The third group under "other potentially infectious materials" relates to the culture and propagation of HIV and HBV in laboratory cultures and experimental animals. The group contains HIV- or HBV-containing cell or tissue cultures, organ cultures, and culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. This definition applies to research activities and to production activities where concentrations of virus can be expected to exceed that in blood. The Case Reports Section of HIV Health Effects in this document discusses in detail the infection of two workers that resulted from occupational exposure to high concentrations of HIV virus in a production facility.

"Parenteral" exposure is exposure which occurs through a break in the skin barrier. Examples of parenteral exposure include self-inoculation through an accidental needlestick or a cut with HIV-contaminated glass that may occur when a laboratory technician is picking up a broken centrifuge tube that contained an HIV culture.

"Patient" means any individual (living or deceased) whose blood or other potentially infectious materials may be a source of exposure to the employee. This term includes a wide spectrum of people when one considers both the need for universal precautions and the multitude of healthcare and non-healthcare settings in which occupational exposure may occur. Examples of such individuals include, but are not limited to, hospital and clinic patients; clients of drug and alcohol treatment facilities; accident, gunshot, stabbing, or other trauma victims; residents of nursing homes or hospices; individuals who donate or sell blood, plasma, or blood components; and human remains prior to embalming.

"Personal Protective Equipment" is specialized clothing or equipment worn by an individual to protect him/her from a hazard. For the purposes of this standard, this term includes, but is not limited to, equipment such as (a) gloves; (b) gowns, fluid-proof aprons, laboratory coats, head and foot coverings; (c) faceshields, protective eyewear and masks; and (d) mouthpieces, resuscitation bags, or other ventilation devices.

"Production Facility" and "Research Laboratory" are derived from CDC's *1988 Agent Summary Statement for Human Immunodeficiency Virus.* (Ex. 6–312) "Production Facility" means a facility engaged in activities such as production of industrial-scale, large-volume quantities of HIV or HBV or high concentration and manipulation of concentrated HIV or HBV. In comparison, "Research Laboratory" is defined as a facility engaged in activities such as producing research-laboratory-scale amounts of HIV or HBV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets.

"Sharps" means any object that can penetrate the skin including, but not limited to, needles, lancets, scalpels, and broken capillary tubes.

"Sterilization" follows the American Society of Microbiology's definition for the term as "the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores" (Ex. 6–343).

"Universal Precautions" is a method of infection control in which all human blood and certain other potentially infectious materials are considered infectious for HIV, HBV, and other bloodborne pathogens. In reference to the basis for utilization of universal precautions, the CDC states:

> Since medical history and examination cannot reliably identify all patients infected with HIV or other bloodborne pathogens, blood and body-fluid precautions should be consistently used for *all* patients. This approach, previously recommended by CDC, and referred to as "universal blood and body-fluid precautions" or "universal precautions" should be used in the care of *all* patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown. (Ex. 6–153).

Universal precautions may be a part of a broader program of infection control, such as body substance isolation (BSI), designed to prevent the transmission of many other pathogens in addition to bloodborne pathogens.

"Work Practice Controls" are controls that reduce the likelihood of exposure by altering the manner in which a task is performed. As they relate to this standard, examples of some work practice controls include (1) adherence to the practice of universal precautions in situations of possible exposure; (2) prohibiting the shearing, bending, or breaking of needles and other sharps and not permitting recapping or manipulation of needles or other sharps by hand; and (3) prohibiting pipetting or suctioning by mouth. In each of these instances, the possibility for exposure to blood or other potentially infectious materials has been eliminated or minimized simply by altering the way in which the employee performs the task.

Paragraph (c) Infection Control

Employees incur risk each time they are exposed to bloodborne pathogens. Any exposure incident may result in infection and subsequent illness. Since it is possible to become infected from a single exposure incident, exposure incidents must be prevented whenever possible. It is the goal of the proposed standard to reduce significant risk by minimizing or eliminating exposure incidents.

In order to determine what measures can be taken to minimize or eliminate exposure incidents, the employer must know which tasks or procedures involve occupational exposure. Therefore paragraph (c)(1)(i) requires each employer having employees with occupational exposures to identify and document the tasks and procedures where occupational exposures may occur.

The requirement to perform an exposure determination is similar to the approach taken by the DOL/HHS Joint Advisory Notice (JAN) (52 FR 41818, October 30, 1987) which calls for identifying three categories of tasks: those with actual blood exposure (Category I), those with no blood exposure (Category III), and Category II tasks which, by themselves, entail no blood exposure, though the individual assigned to the task may be called upon to perform an unplanned Category I task. For example, a nurse completing medical records in an emergency room would be expected to immediately assist in the care of a bleeding accident victim who arrives in the emergency room. Therefore, while the paperwork task has no inherent blood exposure, the patient's arrival requires the nurse to perform a Category I task. In addition to categorizing tasks, the JAN calls for development of Standard Operating Procedures (SOPs) for each Category I and II task. These SOPs include mandatory work practices and protective equipment for each task.

In the proposed standard, the employer is responsible only for identifying the tasks equivalent to Category I tasks, and is not required to develop SOPs for all tasks equivalent to Categories I and II. Nevertheless, while SOPs are not required by the proposed standard, some employers may find their development beneficial both for use in training employees in performing routine tasks and procedures in a manner that minimizes or eliminates occupational exposure and as a reference for unusual or infrequently conducted tasks.

The second part of the exposure determination is the identification and the documentation of the positions whose duties include the tasks identified above. This is necessary in order to assure that the employees who hold these positions are included in the training programs, are provided with personal protective equipment, and where appropriate, are provided with post-exposure follow-up and are included in the HBV vaccination program.

Paragraph (c)(1)(iii) requires the exposure determination be made without taking into consideration the use of personal protective clothing or equipment. In other words, a task or procedure that would result in occupational exposure if the employee were not wearing personal protective equipment, must be identified and documented by the employer for

paragraph (c)(1)(i). The reason for this is that several conditions must be met for personal protective equipment to effectively lessen exposures. First, the employee must be trained to use the equipment properly. Second, the personal protective equipment must be used each time the task is performed. Third, the equipment must be appropriate for the task. Fourth, it must be free of physical flaws that could compromise safety. If even one of these conditions is not fully met, protection cannot be assured. For example, if blood covered gloves are not removed correctly, the hands may become contaminated. If utility gloves are torn or cracked, they will not provide protection. Therefore, these tasks need to be included in the exposure determination so that the workers who perform them will receive training, HBV vaccination, and other provisions that will enhance their safety. The exposure determination must be completed within 90 days of the effective date of the standard [see paragraph (i)(2)].

The Infection Control Plan that would be required by paragraph (c)(2) is a key provision of the proposed standard. It must contain the exposure determination discussed above. In addition, it must state when and how the employer will implement the other provisions of the standard in a manner appropriate to the circumstances in the employer's workplace. An annotated copy of the final standard would be sufficient to meet this requirement. The requirement is in performance language, so that each employer can structure the plan to cover the circumstances in the employer's workplace. The time frame for completion of the Infection Control Plan would be within 120 days of the effective date of the final standard as required by paragraph (i)(3). OSHA believes this deadline would permit all employees to receive the benefits of the Infection Control Plan while still allowing employers suffficient time to put their plans in place.

The Exposure Determination must be written. Because infection control must be practiced by everyone—employee and employer—it is imperative that employees be able to find out what provisions are in place in his or her workplace [see paragraph (g)(2)(iv)(D)]. That the program be in writing is also important for enforcement. By reviewing the plan, the OSHA Compliance Officer will be able to become familiar with the employer's determination of the tasks and procedures that place employees at risk of occupational exposure, the employees who perform the tasks, and the implementation and revisions to the Infection Control Plan.

The Infection Control Plan would have to be reviewed and updated to reflect significant changes in tasks or procedures. The purpose of this proposed requirement would be to assure that all new tasks and procedures are evaluated in order to determine whether they will result in occupational exposure. The employer would also have to amend the Infection Control Plan when there are significant changes in tasks or procedures. For example, if a medical center plans to open an HIV research laboratory where none existed before, then the Infection Control Plan would have to be amended to include the provisions specified by paragraph (e).

Paragraph (d) Methods of Compliance

It is generally acknowledged that protection of the employee is most effectively attained by elimination or minimization of the hazard at its source, which engineering controls and work practices are both designed to do. Industrial hygiene doctrine also teaches that control methods which depend upon the vagaries of human behavior are inherently less reliable than well-maintained mechanical methods. For these reasons, OSHA has preferred engineering and work practice controls and required they be used where feasible. Nevertheless, OSHA recognizes that in some situations neither of these control methods is feasible and in these circumstances employee protection must be achieved through the use of personal protective equipment. In other situations, personal protective equipment may have to be utilized in conjunction with engineering controls and/or work practices to obtain a further reduction in employee exposure.

The need to implement and comply with infection control procedures is recognized by nearly all the commenters to the ANPR and is illustrated by the epidemiologic studies on HIV. The CDC has concluded that case reports of healthcare workers who seroconverted to HIV following parenteral, mucous membrane or non-intact skin exposure to blood or concentrated virus provide strong evidence for the transmission of HIV from patients to health care workers and that infection control practices, emphasizing universal precautions, need to be implemented and strictly followed (Ex. 6–365). Marcus and coworkers (Ex. 6–372) and McCray and co-workers (Ex. 4–39) concluded that approximately 37–40% of the exposures in their study cohort would probably not have occurred if the workers had followed recommended infection control procedures. Klein and co-workers (Ex. 6–366) concluded that to minimize the risk of contracting HIV, dental professionals must adhere to recommended infection control procedures. Weiss and co-workers (Ex. 6–187) recommended that laboratories working with HIV and related agents promote continuing educational programs for all employees regarding precautions necessary for working in a laboratory. They concluded that employees must be proficient in and strictly adhere to the recommended infection control procedures and that employee proficiency and compliance with these precautions should be periodically monitored. Gerberding and coworkers (Ex. 6–375) (Ex. 6–353) concluded that although "special infection-control precautions for HIV-infected patients are not required to prevent occupational transmission of HIV * * * it would seem prudent to implement and enforce standard infection-control guidelines designed to reduce exposure to body fluids from all patients, regardless of the probability of HIV infection, to prevent nosocomial transmission of blood-borne pathogens." Henderson and coworkers (Ex. 6–377) (Ex. 6–352) concluded the risk of occupationally acquiring HIV is very small. Kuhl and coworkers (Ex. 6–355) concluded that with the practice of recommended hospital infection control procedures the risk of healthcare workers occupationally contracting HIV infection appears low. Ramsey and coworkers (Ex. 6–373) (See CASE REPORTS, CASE 16) concluded that "almost half of the exposures (41%) were a result of non-compliance with recommended precautions * * * results confirm that needlestick injuries place health-care workers at risk of acquiring HIV–1 infections."

One of the most important methods of compliance is the implementation of "universal precautions" as recommended by CDC. "Universal precautions" requires the employer and employee to assume that all blood, and other potentially infectious materials are, indeed, infectious and must be handled accordingly. The Centers for Disease Control (CDC) bases the rationale of universal precautions on the following:

> Since medical history and examination cannot reliably identify all patients with HIV or other blood-borne pathogens, blood and body fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC, and referred to as "universal blood and body-fluid precautions" or "universal precautions"

should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown. (Ex. 6–153)

This approach is advocated by the majority of the ANPR commenters including the American Hospital Association (Ex. 11–233), the American Dental Association (Ex. 11–43), and the National Committee for Clinical Laboratory Standards (Ex. 11–159). OSHA agrees that universal precautions is necessary to prevent workers from contacting blood or other materials that may be infectious.

As previously stated, universal precautions is a concept of infection control which, in addition to treating blood and other potentially infectious materials as being infectious, encompasses a variety of associated practices other than medical procedures as such, to prevent occupational exposure such as use of personal protective equipment, disposal of sharps in sharps containers, housekeeping, and so forth. Throughout the Methods of Compliance section, OSHA has taken care to specifically provide flexibility. See, for example, the sections on handwashing (d)(2)(ii), disposable gloves (d)(3)(v)(A), and decontamination (d)(4)(ii)(A).

In addition, paragraph (d)(1) of the proposed standard states: "Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials, unless those precautions would interfere with the proper delivery of healthcare or public-safety services, in a particular circumstance, or would create a significant risk to the personal safety of the worker." Since flexibility in following the other practices required under universal precautions is specifically addressed elsewhere in paragraph (d), OSHA expects that the exemption to observing universal precautions stated in the latter portion of paragraph (d)(1), will serve as an exemption to the use of personal protective equipment in appropriate cases and is not intended to provide an excuse for complete non-adherence to the overall concept of universal precautions.

The Agency recognizes that on occasion particular circumstances arise in which the use of personal protective equipment may interfere with the proper delivery of health care or public safety services or create a significant risk to the personal safety of the worker. These "particular circumstances" shall be taken to mean extraordinary situations which are unexpected and threaten the life or safety of the patient or worker.

The following examples illustrate several scenarios to which, OSHA believes, the exemption may apply.

(1) A surgeon's glove tears in the midst of critical surgery;

(2) A sudden change in patient status such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy;

(3) A firefighter rescues an individual who is not breathing from a burning building and discovers that his/her resuscitation equipment is lost/damaged and he/she must administer CPR; and

(4) A suspect who is bleeding unexpectedly attacks an officer with a knife threatening the safety of the officer and/or co-workers.

The first three scenarios are examples of situations which may be immediately life-threatening to the patient while the latter illustrates circumstances in which the personal safety of the worker could be placed at significant risk. In evaluating each of the above situations it may be judged that the time required to don personal protective equipment is critical to saving the patient's life or preventing significant risk to the worker's personal safety. However, use of the exemption is meant to be limited in extent and time. The employee who takes advantage of this exemption in a particular circumstance must continue to take steps to reduce his or her risk. Those practices associated with universal precautions which can be used are to be implemented whenever possible. Moreover, as soon as the situation changes as, for example, when a properly-protected co-worker is available to relieve the employee, the criticality of the patient's condition decreases, or the violent patient/prisoner is subdued, the employee is expected to implement use of full universal precautions.

It is the intent of the Agency that the decision not to utilize personal protective equipment in these types of situations rests with the employee, *not* the employer. Employees must exercise their professional judgment in making such a decision and should be aware that they may be asked to explain the reasons for their course of action. For example, OSHA believes that disregarding use of personal protective equipment because there is concern that the appropriate personal protective equipment may be alarming to the patient or because the patient population is perceived to be "low risk" are not legitimate reasons. Also, a concern that employees may not be able to properly perform their jobs because, for instance, gloves dull their sense of feeling or goggles become fogged is not considered a legitimate reason to use this exemption for routine procedures. These issues are dealt with elsewhere in this preamble.

While "interfere with" may be construed to encompass a broad range of intrusions into one's task performance, OSHA intends for this term to be interpreted in the strictest sense, that is, the prevention of proper delivery of healthcare or public safety services. Therefore, the Agency does not feel that concerns about appearance, perceived low-risk, or personal perception of "interference" are acceptable reasons for not using personal protective equipment.

Some employees may express the concern that gloves, because they do not fit properly, increase their risk of injury. Since the proposed standard requires that personal protective equipment be provided in "appropriate sizes," the employer would be obligated, under paragraph (d)(3)(ii), to provide gloves and other equipment that fit. Therefore, a general concern that the use of gloves, for instance, increases risk to the personal safety of the worker cannot be a basis for an exemption.

It should also be understood that the decision not to use personal protective equipment is to be made by the employee on a case-by-case basis. Also, no work area with the potential for occupational exposure would be exempt from following universal precautions and its associated practices. Therefore, the employer must assure that proper personal protective equipment is readily accessible to employees at all times.

In summary, employees may on occasion find themselves in extraordinary circumstances in which, based upon their professional judgment, they feel that utilizing personal protective equipment will prevent proper delivery of healthcare or public safety services or will create a significant risk to their personal safety. The decision not to use personal protective equipment is to be made by the employee on a case-by-case basis and must be prompted by legitimate and truly extenuating circumstances. In such cases, the employee may temporarily abandon use of personal protective equipment. However, this does not mean that the circumstances surrounding such a decision should not be scrutinized, and it does not relieve the employer of the responsiblity to assure that personal protective equipment is readily accessible at all times. The employer shall not discourage adherance to universal precautions or the appropriate use of personal protective equipment.

OSHA seeks comment on whether the exemption from using universal precautions is appropriate, and, if so, is it clearly stated? Are there situations which require employees to suspend universal precautions as a whole or are the situations that require professional judgment limited to times when personal protective equipment cannot be used? Should the exemption be available to all employees or only those in certain professions? Would it be more appropriate to state the exemption under paragraph (d)(3)(i) "Provision and Use" of personal protective equipment? For example, would the limitations of this exemption be made more clear with the following language:

(3) Personal Protective Equipment

(i) Provision * * *

(ii) Use. The employer shall assure that the employee uses appropriate personal protective equipment unless doing so in a specific instance would, in the professional judgment of the employee, prevent the proper delivery of healthcare or public safety services or pose a greater hazard to the safety of the employee or co-workers.

OSHA believes employees can be fully protected only when the language of the exemption is strictly interpreted to limit the instances in which it applies. Do some of the terms (e.g. "interfere with," "proper delivery," "significant risk") lack precision and clarity? If so, how could the Agency better delineate the particular circumstances? Would substitution of "prevent" for "interfere with" or "greater hazard" for "significant risk" be more easily understood? Is there a generally accepted definition for "proper" delivery of healthcare or public safety services? OSHA seeks comment on whether an exemption is needed, to what situations it should apply, and how it can best be drafted to afford employees the flexibility which may be necessary while assuring adequate protection against occupational exposures.

Engineering and Work Practice Controls. Engineering controls serve to reduce employee exposure in the workplace by either removing the hazard or isolating the worker from exposure. These controls encompass process or equipment redesign (e.g. self-sheathing needles), process or equipment enclosure (e.g. biosafety cabinets), and employee isolation. In general, engineering controls act on the source of the hazard and eliminate or reduce employee exposure without reliance on the employee to take self-protective action. Once implemented, engineering controls protect the employee permanently, subject only, in some cases, to periodic replacement or preventive maintenance. Examples of engineering controls that would protect employees from exposure to bloodborne pathogens include sharps disposal containers, biosafety cabinets, and splashguards, such as might be placed over the segmenting unit of a Hematron to prevent blood spattering into the operator's face. Relative to this, section (d)(2)(i) of the proposed standard requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm that engineering controls such as protective shields have not been removed or broken; that ventilation systems such as those in biosafety cabinets are operating properly; that filters, sharps disposal containers, and so forth are being replaced on a sufficiently frequent interval; and that any other physical, mechanical, or replacement-dependent controls are functioning as intended.

In comparison, work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed. While work practice controls also act on the source of the hazard, the protection they provide is based upon employer and employee behavior rather than installation of a physical device such as a protective shield. In many instances these two control methodologies work in tandem as it is often necessary to employ work practice controls to assure effective operation of engineering controls. For example, a sharps disposal container provides no protection if an employee persists in recapping needles by hand and disposing of them in the waste basket. Proper work practices and engineering controls must both be utilized to ensure safe, acceptable sharps disposal.

In developing the methods of compliance section for this proposal, OSHA recognized the uniqueness of many of the work environments which have the potential for producing occupational exposures. Since the source of the hazard is frequently a living person or tissue, typical industrial methods of reducing or eliminating the hazard at the source are often not feasible. For example, in an industrial operation a process may be entirely enclosed and operated/monitored by an employee at a remote location. Clearly, this is not possible in patient-care settings, in circumstances of violence in correctional institutions, and so forth. The Agency believes, therefore, that prevention of exposures to blood or other potentially infectious materials can require use of a combination of control methods to achieve adequate protection of employees.

Returning to the previous example of using a Hematron (a device for segmenting blood-containing tubing in plasmaphoresis centers, blood collection sites, etc.), methods of exposure control could include a plexiglass shield over the segmenting/sealing unit to prevent blood spattering into the operator's face—an engineering control; positioning of the employee's face over the shield during operation—a work practice; and use of personal protective equipment such as gloves, a lab coat, and/or other personal protective equipment depending on where blood could spatter onto the employee. In the above example, engineering controls, work practice controls, and personal protective equipment were necessary to provide proper protection. Each control method plays a part in reducing and/or protecting against exposure; however, none of them taken singly can be said to eliminate or significantly lessen the need for other methods of control.

When dealing with primary hazard sources that are often living persons, transplant tissues, and so forth, use of engineering controls may not always be feasible. However, OSHA would like to know about situations where engineering controls alone or in combination with work practices will sufficiently protect workers so that personal protective equipment would not be necessary.

OSHA recognizes that the conditions of exposure to bloodborne pathogens are substantially different from those of exposure to other hazards which OSHA regulates. Considering the primary hazard sources involved in this proposal, it is OSHA's belief that combinations of controls (varying greatly by task) are best used to prevent exposure incidents. OSHA seeks comment on how the Agency can best assure employers institute the appropriate combinations of controls.

In paragraph (d)(2)(ii) OSHA proposes to require employers to assure that employees wash their hands immediately or as soon as possible following activities that may result in exposure. OSHA has recognized that a major precept of infection control is thorough handwashing. A number of commenters supported the requirement that hands be washed immediately or as soon as possible 1) after removal of gloves or protective clothing (Exs. 6–153, 11–71, 11–159, 11–233(d), 11–280), and 2) after hand contact with blood or other potentially infectious materials (Exs. 6–153, 6–316, 11–71, 11–111, 11–159, 11–233(d)). This frequency of handwashing

should minimize the amount of time that blood is in contact with the skin of the hands and potential routes of exposure including areas of dermatitis or microcuts in the skin. Several commentors suggested that hands be washed upon leaving the work area. While this requirement has not been included in the proposal, OSHA seeks comment as to whether there are instances in which an employee would not be wearing gloves in a work area presenting the potential for hand contamination. Will requiring washing of hands upon leaving the work area serve to reduce contaminant migration and/or better protect employees? Should it be a stated requirement?

With regard to managing and further limiting the possible spread of contamination, OSHA proposes to require that all personal protective equipment be removed immediately upon leaving the work area or as soon as possible if overtly contaminated (Exs. 6–153, 6–338, 11–159, 11–280). The former requirement will prevent migration of contamination beyond the work area to such places as lunchrooms and offices. The latter will limit contact contamination within the work environment and reduce the possibility for contaminant soak-through which would result in contamination of the employee's underlying garments and/or skin.

Placement of the contaminated equipment in an appropriately designated area or container for storage, washing, decontamination, or disposal will help ensure that the potentially contaminated clothing and equipment will only be handled by employees who have been properly trained in the safe handling of this material.

One of the greatest hazards to workers is from needles and other sharp objects contaminated with blood or other potentially infectious materials. Of the 25 Case Reports presented in the HIV Health Effects section of this proposal, 15 of the seroconversions are associated with needlestick injuries (Cases 1,2,6,7,9–16,19,22,23). In addition, as stated previously in the hepatitis B Health Effects section, the chance of becoming infected after a single needlestick from a hepatitis B source patient ranges from 7% to 30%. Therefore, handling of needles and sharps must be minimized. The AHA affirmed this hazard in their statement:

> As with other blood-borne diseases, the potential for transmission is greatest when needles and other sharp instruments are used in patient care (Ex. 6–75)

In view of this, the AHA and a number of other commenters recommend that needles and other sharps not be sheared, bent, broken, recapped or resheathed by hand and that needles not be removed from disposable syringes (Exs. 11–71, 11–159, 11–233(d), 11–280). OSHA agrees and is proposing to require that these restrictions be followed when sharps are handled.

While there is no documented evidence showing transmission of HIV by environmental surfaces, there is evidence that surface contamination is a mode of HBV transmission. Therefore, the Agency feels that the following paragraphs, (d)(2)(v) and (d)(2)(vi), are necessary provisions of the proposed standard. In paragraph (d)(2)(v), OSHA proposes to prohibit eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in work areas where there is the potential for occupational exposure (Exs. 6–75, 11–159, 11–280). This requirement is consistent with other OSHA standards [Coke oven emissions 29 CFR 1910.1029 (i)(5)(i); Acrylonitrile 29 CFR 1910.1045 (f)(4); Asbestos 51 FR 22612] and is simply good industrial hygiene practice. While the first four stipulations have been set by OSHA in previous standards, the last, which refers to prohibiting the handling of contact lenses was supported by the American Red Cross's comment (Ex. 11–280). OSHA believes that bloodborne pathogens could be introduced onto the lens through handling in the work area and the contaminated lens would then be placed and held in intimate contact with both the eye's surface and the mucous membranes of the eye. Since bloodborne pathogens can infect through mucosal contact (i.e. the eye), it is felt that prohibition of lens handling is a prudent practice. The rationale for prohibiting these activities is consistent with the following statement from *Laboratory Safety: Principles and Practices:*

> Hepatitis transmission, especially type B hepatitis, can occur by indirect means via common environmental surfaces in a laboratory, such as test tubes, laboratory benches, laboratory accessories, and other surfaces contaminated with infective blood, serum, secretions, or excretions which can be transferred to the skin or mucous membranes. The probability of disease transmission with a single exposure of this type may be remote, but the frequency of such exposures makes this mechanism of transmission potentially an efficient one over a long period of time. Activities in laboratories such as nail biting, smoking, eating, and a variety of hand-to-nose, -mouth, and -eye actions contribute to indirect transmission. (Ex. 6–344).

CDC/NIH also recommend that these activities be prohibited for all 4 Biosafety Levels in their guidelines *Biosafety in Microbiological and Biomedical Laboratories* (Ex. 6–338).

Consistent with the above, OSHA proposes in paragraph (d)(2)(vi) to prohibit the storage of food and drink in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored or in other areas, such as laboratories, where these foodstuffs may become contaminated. While contamination of the mucous membranes of the mouth is of concern, one must also consider that food and beverage containers may also become contaminated, resulting in unsuspected contamination of the hands.

In addition to being recommended by CDC/NIH laboratory guidelines (Ex. 6–338) and by commenters such as the National Committee for Clinical Laboratory Standards (Ex. 11–159) and the American Red Cross (Ex. 11–280), this requirement is also consistent with the following statement from *Laboratory Safety: Principles and Practice:*

> Because blood tubes can be contaminated on the outside as well as contain infective blood, they must be handled and stored with care. If blood tubes must be refrigerated, they should be capped and placed in a designated refrigerator or in a designated portion of a refrigerator. Blood tubes should never be kept in a refrigerator that contains food or beverages. (Ex. 6–344)

In paragraph (d)(2)(vii), OSHA proposes to require that all procedures involving blood or other potentially infectious materials be performed in such a manner as to minimize splashing, spraying, and aerosolization of these substances. This requirement will decrease the chances of direct exposure of employees to these substances through means such as spraying into the eyes or splashing onto the face or arms, while also reducing general work area contamination of benchtops, instruments, and so forth caused by errant splashes, sprays, or aerosols (Exs. 6–75, 6–338, 11–159, 11–280). The American Hospital Association in their recommended precautions for clinical laboratories wrote that:

> Procedures that have a high potential for creating aerosols or infectious droplets, including centrifugation, blending, sonicating, vigorous mixing, and harvesting infected tissue from animals or embryonated eggs, should be carried out in biological safety cabinets (class II). (Ex. 6–75)

Minor spattering may be controlled in other ways. For example, the National Committee for Clinical Laboratory Standards states:

> Removing rubber stoppers from specimen tubes frequently causes minor spattering of blood or serum. This may be minimized by

covering the tube with gauze pad while removing stopper. (Ex. 11–159)

It is the responsibility of the employer to evaluate such tasks and institute the measures necessary to minimize splashing, spraying, and production of aerosols.

In paragraph (d)(2)(viii), OSHA proposes to adopt the good laboratory and infection control practice of prohibiting pipetting or suctioning by mouth. The use of cotton plugs or other barriers does little to reduce the hazards of mouth pipetting. Even a technician who is skilled in mouth pipetting may inadvertently suck blood or other potentially infectious materials into the mouth which could result in bloodborne pathogens coming in contact with the mucous membranes of the mouth as well as any blisters, cuts, abrasions or other lesions in the mouth or on the lips.

Personal Protective Equipment. OSHA's proposed requirements for personal protective equipment, paragraph (d)(3), have been set to assure adequate protection based upon the type of exposure expected during task performance. In their response to the ANPR, the National Institute for Occupational Safety and Health (NIOSH) stated:

> The purpose of personal protective clothing and equipment is to prevent or minimize the entry of materials into the worker's body. This includes entry via apparent or inapparent skin lesions or entry through the membranes of the eye, nose or mouth * * * Appropriate protective clothing and equipment should * * * be selected based on the specific work and exposure conditions that will be encountered and the anticipated level of risk. (Ex. 11–187)

This approach to the selection of protective barriers is echoed by CDC in the statement in their June 1988 guidelines:

> The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated. (Ex. 6–316)

The proposed standard requires the employer to provide personal protective equipment to employees who have the potential for occupational exposure. Examples of such personal protective equipment are gloves, gowns, fluid-proof aprons, laboratory coats, head and foot coverings, face shields, eye protection, masks, and respiratory ventilation devices such as mouthpieces, pocket masks, or resuscitation bags.

While the reasons for providing protective clothing such as gowns, gloves, and faceshields should be obvious, some question may arise as to the necessity of emergency ventilation devices. OSHA bases this requirement on the possibility of employee exposure to blood or other potentially infectious materials in the mouth or in fluids that may be expelled by the patient during resuscitation. As little as one cubic centimeter (cc) of HBsAg positive blood can contain one hundred million infectious doses of hepatitis B virus (see Hepatitis B Health Effects section). In their August 1987 guidelines, the CDC states:

> Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable. (Ex. 6–153)

The American Federation of State, County, and Municipal Employees (AFSCME) expressed a similar, but more detailed justification in their comments:

> Resuscitation devices should be included with other types of required personal protective equipment. Although there is no evidence of transmission of bloodborne pathogens from administering Cardiopulumonary Resuscitation, such transmission remains a theoretical possibility and other pathogens can definitely be transmitted in this way. CDC also recommends the use of such devices in its August 1987 document. Resuscitation devices are very inexpensive, some models well under $10.00. Affected employees should be trained in the use of such equipment and the equipment needs to be strategically stationed in order to facilitate its use. Prisons, mental health facilities, and public safety occupations are obvious candidates for such equipment. Anywhere a large group of people are housed, or where there is likelihood that emergency assistance may have to be rendered should have resuscitation devices on hand. (Ex. 11–157)

OSHA agrees with CDC and AFSCME on the need to minimize mouth-to-mouth resuscitation, and believes the most effective way to do so is to require ventilation devices be provided for resuscitation.

In addition, the employer shall assure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or issued to employees who may be exposed to blood or other potentially infectious materials during performance of their work duties. Resuscitation bags, pocket masks, mouthpieces, and other ventilation devices must be readily assessible to employees who can reasonably be expected to resuscitate a patient (Exs. 6–153, 11–71, 11–111, 11–157, 11–159, 11–233(d)). These devices are to be readily accessible for use at sites where the need for emergency resuscitation is likely or issued to employees for use at mobile non-fixed worksites as required by paragraph (d)(3)(ii). It is of great importance that personal protective equipment is easily accessible and of proper size. The consistent use of such items hinges, in part, upon the employee's motivation and acceptance. If access to the equipment is difficult, its use may be perceived as too time consuming and burdensome. Proper fit of personal protective equipment also plays a major role in its utilization by employees. If it is too large or small it may be uncomfortable or could interfere with proper task performance, resulting in frustration and non-use. Proper employee protection rests upon utilization of this equipment, therefore provision of proper sizes and accessibility must be maintained to ensure and promote their use.

The Agency is aware that use of gloves as a protective barrier is a major part of this proposal's methods of preventing occupational exposure. In addition, it is known that some employees may exhibit an allergic dermal reaction to the gloves normally provided to workers or the powder they contain. To prevent exacerbation of such allergic dermatitis and thereby permit these individuals to continue working, the proposed standard requires that employers make hypoallergenic gloves readily accessible to those employees who are allergic to the gloves normally provided.

The employer's responsibility to assure accessible personal protective equipment for employees at non-fixed worksites, such as emergency medical technicians, cannot be over emphasized. Adequate planning and reinventory should assure that the necessary equipment is present on the response vehicle in a portable "kit" or on the employee's person.

The proposed standard also requires that the employer shall provide for the cleaning, laundering, or disposal of personal protective equipment required by paragraphs (d) and (e). This is to insure that these items remain within the control of the employer and, therefore, will be properly disposed of, cleaned, or laundered consistent with that employer's infection control program. This will prevent contamination outside of the work area (e.g. non-work areas such as the employee's home) and insures that only those personnel trained in proper work practices will handle potentially contaminated equipment during cleaning or disposal.

In paragraph (d)(3)(iv), the proposed standard requires that the employer repair or replace personal protective equipment required by this standard as

needed to maintain their effectiveness. The requirement to repair or replace the protective equipment is needed to insure proper functioning of these items and, thereby, proper employee protection. Moreover, requiring that the employer be responsible for this activity provides further insurance that the items will remain under the control of the employer who will make this a part of his or her infection control program.

OSHA proposes to require that the employer assure that the employee wear gloves whenever the employee has the potential for direct skin contact (of the hand) with blood or other potentially infectious materials, mucous membranes or non-intact skin of patients, and when handling items or surfaces soiled with blood or other potentially infectious materials. Glove use in these situations is advocated in whole or in part by a number of commenters and sources including the American Hospital Association (Exs. 6–75, 11–233(d)), the American Dental Association (Ex. 11–43), the National Committee on Clinical Laboratory Standards (Ex. 11–159), the American Red Cross (Ex. 11–280), and the American Blood Resources Association (Ex. 11–71).

Examples of tasks which require the use of gloves include dentistry, surgery, phlebotomy, laboratory analysis of blood or body fluids, clean-up of blood or body fluid spills, and rendering emergency medical assistance to individuals with traumatic injury.

Along with the provisions for glove usage discussed above, certain work practices are necessary concerning when gloves are to be replaced in order to assure adequate protection for the employee and limit contamination, [paragraphs (d)(3)(v) (A) and (B)]. Disposable gloves must be changed as soon as possible when they are visibly soiled to reduce inadvertent contamination of items throughout the work area such a door knobs, telephones, computer keyboards, and so forth (Ex.6–344). Since the glove acts as the primary physical barrier between potentially infectious materials and the employee's skin, any tear, puncture, or similar defect compromises the integrity of this barrier, dictating replacement to insure maintenance of protection (Exs. 6–153, 11–71, 11–280).

Disposable gloves, often called surgical or examination gloves, shall not be washed or disinfected for re-use. The CDC in its June 24, 1988, *Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings* (Ex. 6–316) states that disinfecting agents may cause deterioration of the glove material while washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected holes, thereby transporting potentially infectious materials into contact with the hand. Utility gloves, often called "rubber" gloves, such as those which may be used for housekeeping chores are of more substantial construction than surgical or examination gloves. OSHA agrees with CDC's recommendation permitting decontamination and reuse of utility gloves but requires that they be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration. (Ex. 6–316)

Paragraph (d)(3)(vi) of the proposed standard states that masks and eye protection or chin-length face shields shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials (e.g. bone chips) may be generated and there is a potential for mucous membrance (eye, nose, mouth) contamination. If protective eyewear is chosen over use of a faceshield, the eyewear must be worn in conjunction with a face mask since the aim of this requirement is to provide protection for the eyes, nose, and mouth. A number of commenters expressed support for this requirement (Exs. 6–153, 10, 11–43, 11–71, 11–111, 11–159, 11–233(d), 11–280). For example, the American Hospital Association stated:

> The use of protective eyewear, such as goggles in connection with masks, is recommended in situations in which splatter with blood, body secretions, or body fluids is possible. This is particularly recommended in the performance of procedures such as endotracheal intubation, bronchoscopy, or GI endoscopy. Precautions during other procedures should be judged on an individual basis. (Ex. 6–75)

Mucous membrane and skin exposures are recognized routes of transmission of HBV (see the Hepatitis B Health Effects section) and HIV. In fact, the CDC (Ex. 6–109) has documented a phlebotomist's HIV seroconversion after blood spattered on her face and in her mouth when the top flew off of a 10 ml vaccuum tube of blood. The individual lacked other identified risk factors and the case is considered the result of occupational exposure. Although she had no open wounds, facial acne was present. While it is uncertain if mouth or skin exposure was the direct route of transmission, facial protection would have eliminated the hazard of infection via mucous membrane exposure.

In paragraph (d)(3)(vii), OSHA proposes to require that appropriate protective clothing be worn when the employee has a potential for occupational exposure. The type of clothing (e.g., lab coat, gown, apron) and its associated characteristics (e.g., fluid-resistance) will depend upon the task being performed and the degree of exposure anticipated (e.g., soiling, splashing, soaking). In this provision, the proposed standard gives the employer flexibility in complying. Rather than requiring complete barrier protection in all situations, the proposed standard allows the employer to evaluate the task and the exposure expected to be associated with its performance and, based upon this determination, select protective clothing and equipment appropriate to the task. In order to fulfill the requirement of "appropriate" for this standard, the clothing selected shall form an effective barrier under the anticipated conditions of exposure. In their comment to the ANPR, Kimberly-Clark Corporation submitted results of their research and development efforts in the area of blood strike-through potential of various types of protective clothing materials (Ex. 11–353). Kimberly-Clark emphasized the importance of design, breathability, and fluid resistance of the garments. The Agency seeks comment on whether the performance oriented approach will provide adequate protection to employees or whether OSHA should specify characteristics of construction or fabric for particular tasks.

In paragraph (d)(3)(vii)(A), OSHA proposes to require gowns, labcoats, aprons, or similar clothing shall be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials (Exs. 4–25, 6–75, 6–338, 11–71, 11–159). These items are commonly made of tightly woven or fused materials that will prevent the employee's underlying clothing from becoming contaminated. The contaminated overgarment can be easily removed at the end of the work shift or when access to a non-work area is required and will remain within the work area for cleaning, laundering, or disposal.

If splashing or spraying of blood or other potentially infectious liquids is possible, the proposed standard requires the employee to wear clothing such as gowns, aprons, or coveralls that is fluid-resistant (Exs. 4–25, 6–153, 11–111, 11–159, 11–233(d)). Since a larger volume of blood and other potentially infectious materials (and consequently a greater chance of soak-through and skin contact) accompanies these modes of exposure, a more protective type of barrier clothing is dictated. If extreme splashing or spattering is anticipated, surgical caps or hoods are required to

prevent potentially infectious materials from reaching the scalp (Exs. 6–75, 11–159).

In some situations, such as autopsies, there is a possibility of clothing becoming soaked with blood or other potentially infectious materials. When a potential for soaking is anticipated, the proposed standard requires that fluid-proof clothing such as gowns, aprons, sleeve covers, or coveralls, be worn (Exs. 6–153, 10, 11–159, 11–233(d), 11–280, 11–283). Fluid-proof shoe covers are required to be worn if there is a potential for shoes becoming contaminated or soaked with blood or other potentially infectious materials to prevent possible contact exposure of the foot. (Exs. 6–75, 11–159, 11–283). Shoe covers, like all personal protective equipment, must be removed prior to leaving the work area thereby limiting migration of contamination via shoes into other areas.

Some employees may feel that personal protective equipment interferes with their ability to perform their routine duties. OSHA seeks comments on how these concerns can be addressed without compromising the safety provided by barrier protection.

In paragraph (d)(4)(i), OSHA proposes to require that employers assure that the worksite is maintained in a clean and sanitary condition. The term "worksite" refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, and so forth but also covers temporary non-fixed workplaces. Examples of such facilities include, but are not limited to, ambulances, bloodmobiles, temporary blood collection centers, and any other non-fixed worksites which have a reasonable possibility of becoming contaminated with blood or other potentially infectious materials. OSHA recognizes that different types of surfaces and soiling exist throughout a facility and that the employer is in the best position to evaluate the condition of his or her facility. Therefore, the standard requires that the employer determine and implement the appropriate written schedule of cleaning and method of disinfection based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed (Exs. 11–283, 11–71, 6–153).

The proposed standard also requires that employers ensure that all equipment and environmental and working surfaces are properly cleaned and disinfected after contact with blood or other potentially infectious materials (Exs. 11–159, 11–283).

Though there exist a broad range of work environments and circumstances where a work surface may become contaminated, OSHA has preliminarily concluded that there are certain common circumstances where decontamination procedures must be implemented to maintain cleanliness and minimize migration of contaminants. Therefore, the proposed standard requires that work surfaces shall be decontaminated with an appropriate disinfectant 1) after completion of procedures (Exs. 6–338, 11–159,); 2) when surfaces are overtly contaminated (Ex. 11–159); 3) immediately after any spill of blood or potentially infectious materials (Exs. 6–153, 6–338) and; 4) at the end of the work day (Exs. 6–153, 6–312, 11–159, 11–280). With reference to hepatitis B, these requirements are supported by the following statement from *Laboratory Safety: Principles and Practices:*

> The primary mode of transmission is by direct contact with blood and serum specimens and environmental surfaces which are contaminated. The presence of blood or serum on hands, whether from direct or indirect sources, can result in the HBV gaining access to the vascular system subcutaneously by needle sticks or contamination of lesions or by nasal, oral, or ocular exposure (Ex. 6–344).

The above are minimum requirements and additional decontamination may be performed any time that it is deemed necessary.

Paragraph (d)(4)(ii)(B) of the proposed standard allows equipment and environmental surfaces to be covered with protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper (Exs. 6–153, 6–338, 9–7(c), 11–43, 11–159). Examples of such an instance would be covering dental light handles with foil or a dental x-ray unit head with plastic film (Ex. 6–153). The standard requires that if these covers are used, they must be removed and replaced when they become overtly contaminated and at the end of the work shift.

The proposed standard also requires that equipment (e.g. blood gas analyzers, mechanical pipetters, suctioning devices, centrifuges, liquid chromatographs) which may become contaminated with blood or other potentially infectious materials shall be checked routinely for contamination and decontaminated as necessary. The NCCLS (Ex. 11–159) pointed out that automated analyzers with sampling probes that move rapidly can generate a fine mist which can accumulate on the equipment, necessitating periodic inspection and decontamination.

In their comments, Waters Chromatography Division of Millipore Corporation (Ex. 11–3) and YSI Incorporated (Ex. 11–7), both of whom are involved with instrument servicing, address the potential for exposure of repair personnel. In addition, several sources recommend the decontamination of instruments and equipment before being repaired in the laboratory or shipped to the manufacturer for servicing (Exs. 6–153, 11–71, 11–159). On the basis of these recommendations, OSHA has proposed to require that employers check all equipment which may be contaminated with blood or other potentially infectious materials prior to servicing or shipping and decontaminate as necessary. OSHA anticipates that this requirement will minimize the possibility of servicing and shipping personnel becoming exposed due to leakage of potentially infectious fluids from the equipment or contact with interior/exterior contamination.

In some cases bins, pails, cans, and so forth, which are intended for re-use may be utilized in a manner which presents the potential for their becoming contaminated with blood or other potentially infectious materials. For example, a reuseable metal trash can may be lined with a disposable plastic infectious waste bag. By virtue of a plastic bag's construction, the possibility of leakage is inherent and the can could become contaminated. If the can is not cleaned and disinfected the contamination may be spread by leakage or spillage from the can or by fouling the outside of succeeding bags. Therefore, paragraph (d)(4)(ii)(D) of the standard requires that all bins, pails, cans, and similar receptacles intended for re-use and which have the potential for becoming contaminated with blood or other potentially infectious materials must be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination. This is consistent with OSHA's current standard regarding maintenance of waste disposal containers 29 CFR 1910.141 (a)(4)(i).

The Case Studies portion of the preamble's HIV Health Effects section (Case 8) describes the HIV seroconversion of an NIH worker as a result of viral innoculation through a cut from a broken glass vial containing HIV-infected blood. This provides an example of the relationship between infection and breaks in the skin barrier caused by contaminated, broken glass. The Agency concludes that broken glass which may be contaminated with infectious bloodborne pathogens shall not be handled directly by employees. In the *1988 Agent Summary Statement for*

Human Immunodeficiency Virus, the CDC states:

> In the laboratory, the skin (especially when scratches, cuts, abrasions, dermatitis, or other lesions are present) and mucous membranes of the eye, nose, mouth, and possibly the respiratory tract should be considered as potential pathways for entry of virus. Needles, sharp instruments, broken glass, and other sharp objects must be carefully handled and properly discarded. (Ex. 6–312).

Accordingly, this standard requires that broken glassware which may be potentially contaminated shall not be cleaned up with the hands. Since gloves do not provide adequate protection against cuts, OSHA proposes to require that all clean-ups be accomplished using mechanical means. Various mechanical means can be used. For example, the Red Cross states that clean-up may be performed with a brush and dustpan or a vacuum cleaner (Ex. 11–280). Pieces in difficult to reach places, such as sinks, can be removed by using tongs for large pieces and cotton swabs or forceps for chips and slivers.

Several sources made a number of recommendations concerning the handling of specimens (Exs. 6–75, 6–153, 11–71, 11–159, 11–233(d)). After reviewing these recommendations in conjunction with the current OSHA regulations on labelling, this proposed standard requires that specimens of blood or other potentially infectious materials shall be placed in a closable, labeled or color-coded, leakproof container prior to being stored or transported. If outside contamination of the container is likely a second closable, labeled or color-coded, leakproof container shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport. If puncture of the primary container is likely, it shall be placed within a leakproof puncture-resistant secondary container. These requirements serve to warn the employee of the potential hazard and minimize unintentional worker exposure and migration of contaminants.

Reusable equipment, such as glassware and hand instruments, which may be contaminated are required to be decontaminated prior to washing and/or reprocessing. By ridding such items of contamination before they enter the overall cycle of washing and reprocessing, the number of employees who must handle potentially contaminated items can be limited to those performing the decontamination procedures.

The Agency has defined infectious waste to be blood and blood products, pathological wastes, microbiological wastes, and contaminated sharps. This is identical to CDC's definition as stated in *Recommendations for Prevention of HIV Transmission in Health-Care Settings* (Ex. 6–153). Included under this definition are the wastes of "other potentially infectious materials" as defined in paragraph (b) of this section. The standard requires that all such wastes destined for disposal shall be placed in closable, labeled or color-coded, leakproof containers or bags. If outside contamination of the container or bag is likely to occur then a second leakproof container or bag which is closable and labeled or color-coded shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport. This requirement is supported by several sources (Exs. 4–25, 6–35, 11–71, 11–159, 11–283).

A leakproof container or bag is required to prevent leakage of the contents into the work area while closability is necessary to ensure that the waste is contained in the event of the container or bag becoming tipped or upended. If outside contamination is anticipated, as would occur if potentially infectious materials were spilled on the exterior of the bag as it is being filled, then a second bag placed over the first will contain the contamination. This prevents an employee's handling the contaminated exterior and limits spread of contamination throughout the work area as the bag is handled, stored, and transported. The outside bag must also be labeled or color-coded to assure that a warning of biohazardous contents is readily observable to employees.

The National Solid Wastes Management Association sums up the logic for proper containment of sharps and infectious waste in their statement:

> * * * the essential elements to control the risk posed by this waste stream are to create a physical barrier around the waste until it has been treated. This includes double-bagging for "soft" wastes and containment in rigid containers for "sharps" (Ex. 11–60).

It should be remembered that anything which compromises the physical barrier, such as torn bags resulting from rough handling or compaction or punctures caused by pointed or sharp objects being placed in plastic waste bags, also compromises the benefit which would be gained by proper infectious waste handling and increases the chance of employee exposure and work area contamination.

The CDC recommends that facilities which produce the aforementioned wastes, such as hospitals, blood banks, and clinical or research laboratories, develop an infectious waste management plan which includes identification, collection, proper handling, transport, infectious waste pre-treatment, and disposal of the treated infectious waste (Ex. 6–395). While the proposed standard puts forth minimum requirements for containing potentially infectious waste to protect employees against exposure, it is not the intent of the proposal to set rigid regulations regarding infectious waste handling and disposal. OSHA is aware that additional requirements may apply to this waste under the jurisdiction of other governing bodies. Therefore, the standard requires that disposal of all infectious waste shall be in accordance with applicable Federal, state, and local regulations (Exs. 4–25, 11–71, 11–187, 11–283).

Needles and sharps have been documented as a prime mechanical agent of employee innoculation with both HIV and HBV. Therefore, their handling and disposal warrants special attention. Needles and sharps are capable of transferring infectious bloodborne pathogens directly into the bloodstream through accidental injuries such as needlesticks or scratches. The AHA states in their recommendations *Management of HTLV–III/LAV Infection in the Hospital:*

> As with other bloodborne diseases, the potential for transmission is greatest when needles and other sharp instruments are used in patient care. Therefore, needles and syringes should be disposed of in rigid, puncture-resistant containers (Ex. 6–75).

Several CDC documents also address disposal of sharps and needles (Ex. 6–27, 6–153, 6–312) including *The Centers for Disease Control's Recommendations on Infective Waste* which says:

> Disposable syringes with needles, scalpel blades, and other sharp items capable of causing injury should be placed intact into puncture-resistant containers located as close as is practical to the area in which they were used. If predisposal autoclaving is performed, the container should maintain its impermeability after autoclaving in order to avoid subsequent physical injuries (Ex. 6–395).

In addition, the American Federation of State, County, and Municipal Employees (AFSCME) commented:

> Currently, one of the most important work practices for preventing needlesticks is the disposal of uncapped unbroken needles and other sharps into puncture resistant needle boxes. In order to facilitate adherence to this practice, adequate numbers of needle boxes must be supplied in convenient locations. All patient rooms and other patient care areas where needles or other sharps are used should be supplied with needle boxes. In

institutions where security is a consideration, such as prisons or mental health facilities, needle boxes may have to be kept on a cart and accompany the person giving injections (Ex. 11-157).

AFSCME, in continuing their comment, raised an important point:

> Based on our experience from visits to facilities and information we receive from members it is apparent that needle boxes are often not within easy reach. There may only be one box on a ward or floor, if that, which is usually located at the nurses station. The distance between where the needle is used and should be disposed can be very substantial and make proper disposal very inconvenient. (Ex. 11-157)

Disposal boxes must be easily accessible to personnel. When sharps disposal is perceived as inconvenient, then chances are increased that needles and sharps will be left in bed linens, on night stands, or thrown into waste baskets, making them potential hazards for other staff such as laundry workers and housekeepers. In addition, the possibility of an accidental needlestick is greater if an employee must carry an uncapped needle or sharp to a remote location for disposal. Therefore, paragraph (d)(4)(iii)(B)(1) requires the disposal containers to be located as close as possible to the point of use to encourage proper disposal and minimize the distance that uncovered sharps must be transported.

Of equal concern when utilizing sharps disposal containers is that they be replaced routinely and not allowed to overfill. The reason for this is twofold. First, a full container necessitates disposal of the sharp in some manner other than in the proper container, again leading to sharps being placed on night stands, thrown into waste baskets, and so forth. Second, the employee may be tempted to get "just one more" sharp into the container by forcing it in by hand. In doing so, the potential for an accidental needlestick increases, particularly if some of the disposed needles or sharps are pointed toward the mouth of the container. Therefore, replacement of the containers before overfilling occurs reduces the chance for accidental needlestick by promoting proper sharps handling and disposal.

Several stipulations in the proposed standard deal directly with the design of the disposal containers. Paragraph (d)(4)(iii)(B) requires them to be puncture-resistant to prevent the points of needles or other sharps from puncturing the container and protruding through the side of the container where they can present a hazard to unsuspecting staff (e.g. nurses, technicians, housekeepers). The containers must also be closable as further required by paragraph (d)(4)(iii)(B) in order to assure that contaminated sharps remain inside the disposal unit while it is being transported and handled prior to terminal disposal. In addition, the containers must be leakproof on the sides and bottom. This requirement is aimed at preventing residual liquids draining from the syringes and pooling in the container from leaking out onto countertops, floors, cart tops, and so forth, thereby spreading contamination. It also prevents employee hand contact with liquids which could otherwise leak through and contaminate the outside of the container. The design of the tops of a number of sharps disposal containers will permit leakage if the container is tipped on its side or turned upside down. This is acceptable if the container meets all other requirements (puncture-resistance, closability, etc.) and will not be tipped or turned over in normal use. If leakage is a possibility during disposal of these containers (i.e. handling, storage, transport) they shall be disposed of as outlined in paragraph (d)(4)(iii)(A). A proper closing will ensure that if the container should become tipped or overturned employees will not be exposed to needles or other sharps which may otherwise spill out. Also, the containers must be labeled or color-coded as described in paragraph (g)(1)(ii) of this proposed standard. This requirement essentially serves two purposes: (1) it allows the containers to be easily identified by employees having needles/sharps to dispose of by clearly distinguishing the containers from others in the area, and (2) it gains the attention of other staff, such as housekeepers, by virtue of the readily recognizable label or color thereby warning them of the potential hazard and signaling that special handling precautions may be necessitated.

A number of commenters and sources made recommendations on disposal of needles and sharps which closely follow (or support) OSHA's proposed regulations (Exs. 4-25, 6-35, 6-75, 6-153, 6-316, 6-338, 10, 11-43, 11-71, 11-111, 11-157, 11-159, 11-233(d), 11-280, 11-283). In summary, the proposed standard requires that sharps (e.g., needles, syringes, capillary tubes, scapels) shall be disposed of in closable, leakproof, puncture-resistant, labeled or color-coded, disposable containers immediately after use. These containers shall be easily accessible to personnel; located in the immediate area of use such as the emergency room, surgery, patient floors, and other settings where blood is drawn and needles used; and shall be replaced routinely and not allowed to overfill.

Employees responsible for laundering items that are either contaminated with blood or other potentially infectious materials or which may contain needles or other sharps must be protected from potential exposure. Proper protection of these employees depends upon, at a minimum, using safe work practices when handling these materials and the appropriate containers and personal protective equipment. Based on comments and collected information the standard delineates several basic provisions for handling contaminated laundry (Exs. 4-25, 6-75, 6-153, 6-312, 11-159, 11-233(d), 11-259, 11-280).

Laundry from workplaces with employees covered under paragraph (a) of this section that is contaminated with blood or other potentially infectious materials or may contain contaminated sharps shall be treated as if it were contaminated and shall be handled as little as possible with a minimum at agitation. Minimizing handling and agitation of this laundry will not only reduce contact-acquired contamination of the employee and the work area but will also decrease mechanical injuries such as needlesticks, cuts and scratches from sharps accidentally left in linens.

Paragraph (d)(4)(iv)(A)(1) of the proposed standard requires that all contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient-care areas. Contaminated laundry is required by paragraph (d)(4)(iv)(A)(2) to be placed and transported in bags that are labeled or color-coded as described in paragraph (g)(1)(ii) in order to indicate contents which are contaminated. Whenever this laundry is wet and presents the potential for soak-through of or leakage from the bag, it shall be placed and transported in leakproof bags (Exs. 4-25, 6-153, 6-75).

By requiring bagging of laundry at its location of use and prohibiting sorting and rinsing in patient-care areas, the amount of manual handling of laundry by staff, other than laundry personnel, is limited to only that which is necessary for removal and bagging. Contamination of additional surfaces such as sinks and floors is also reduced in comparison to that which may occur if sorting and rinsing were permitted in areas other than the laundry.

The intent of labeling or color-coding the bags is to inform employees who may handle the bags of their contaminated contents and that special handling procedures may be in order. This labeling/color-coding system is supported by the AHA in their recommendations *Management of HIV-*

III/LAV Infection in the Hospital which states:

> Soiled linens and other laundry should be bagged, appropriately labeled or color-coded, and processed according to the hospital's existing policy regarding linens from patients on isolation precautions (Ex. 6–75).

In some circumstances, laundry may contain enough blood or potentially infectious materials that soak-through of or leakage from the bag could occur. This situation dictates use of a leakproof laundry bag. Bags which prevent leakage minimize not only environmental migration of contaminants but also reduce employee exposure which would occur during handling of wet or leaking bags.

In paragraph (d)(4)(iv)(B) OSHA proposes to require that the employers assure that laundry workers wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure during handling or sorting (Exs. 4–25, 11–18(c)). The Joint Commission on Accreditation of Hospitals, in their 1986 monograph *Managing Hazardous Wastes and Materials*, reported:

> Other hazards found in soiled sorting could include drugs, drug-contaminated materials, and contamination from "undiagnosed" infectious soiling (e.g., blood from the broken arm of a patient in physical therapy who has as yet undiagnosed infectious hepatitis B). (Ex. 11–18(c))

Gloves will not protect against needlesticks, however, they will reduce contact exposure to blood or other potentially infectious materials that are found in contaminated laundry. Therefore, glove usage to prevent skin contact with contaminated laundry is warranted until the laundry is properly cleaned. At the present time, OSHA is assuming that normal laundering procedures successfully disinfect contaminated linen. Is this assumption correct? Should specific laundering procedures be stated and required? If so, what are these procedures?

In addition, other appropriate personal protective equipment such as fluid-proof aprons, gowns, and protective eyewear may be necessary. For example, if an employee must handle laundry which is wet with contaminated fluids and the likelihood for arm and body exposure exists, then a fluid-proof gown, fluid-proof apron and sleeve covers, or similar protective clothing would be necessary. If the potential for spattering to the eyes was present then protective eyewear would also be required.

Paragraph (e). HIV and HBV Research Laboratories and Production Facilities.

This paragraph addresses additional requirements that must be met by research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV. The risks associated with direct and routine work with pathogens have long been recognized :

> Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Personnel have contracted infections in the laboratory throughout the history of microbiology (Ex. 6–338).

HIV and HBV research laboratories and production facilities are no exception, and the risks associated with work in such facilities warrant additional protective measures.

Prior to 1984, no single code of practice, standards, guidelines or other publication providing detailed descriptions of techniques or equipment for laboratory activities involving pathogens was available. In that year, the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) published guidelines entitled "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6–338). These biosafety guidelines were based on combinations of standard and special practices, equipment, and facilities recommended for use when working with various infectious agents in laboratory settings.

The basic format for the biosafety guidelines categorizes infectious agents and laboratory activities into four classes or levels denoted as biosafety levels 1 through 4. These biosafety levels (BSL) are comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed. The Guidelines indicate the BSL to be used when working with various infectious agents and infected animals. Recommended BSL for working with HIV were not included in the orginal biosafety guidelines.

In 1988, CDC issued an "Agent Summary Statement for Human Immunodeficiency Virus" (Ex. 6–312) which outlined biosafety levels for various activities involving HIV. Activities performed in clinical laboratories were categorized at BSL 2 which covers standards and practices for handling all clinical specimens. For HIV research laboratories and production facilities, Agent Summary statement states:

> Activities such as producing research-laboratory-scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets should be performed in a BSL 2 facility with the additional practices and containment equipment recommended for BSL 3.
>
> Activities involving industrial-scale, large-volume production or high concentration and manipulation of concentrated HIV should be conducted in a BSL 3 facility using BSL 3 practices and equipment (Ex. 6–312).

These recommendations with some modifications were adopted by OSHA to cover HIV/HBV research laboratories and production facilities. Accordingly, the Guideline's BSL 3 text for standard microbiological practices, special practices, and containment equipment was converted to regulatory language and comprises paragraph (e)(2) of the standard. Requirements for the facilities for research laboratories [paragraph (e)(3)] were derived from the text for BSL 2, while those for production facilities [paragraph (e)(4)] were derived from the text for BSL 3.

While general training requirements for employees working with pathogens are given in paragraph (g), OSHA feels that additional specialized training should be provided for employees of the research laboratories and production facilities covered by paragraph (e). HIV infection of a worker in an HIV production facility as a result of "undetected skin contact with virus culture supernatant" was attributed to inexperience coupled with "on-the-job training in a setting in which episodes of contamination may have occurred frequently" (Ex. 6–312). Therefore, the training recommendations of the NIH committee convened to investigate the incident were incorporated into paragraph (g)(2)(v) of this standard as special training requirements.

OSHA recognizes the valuable contribution that is being made by research laboratories that are studying the human immunodeficiency virus and the hepatitis B virus. The Agency also understands the need to produce extremely high concentrations of these viruses to prepare reagents and other products needed for research, diagnosis and, if an HIV vaccine is developed, prevention. The Agency has no desire to impede these efforts. However, there is clearly documented risk to individuals working with blood containing HIV and HBV. When the concentration of these viruses is increased as the result of growing virus in cell culture or artifical concentrate on, then the risk to employees increases.

The two cases of HIV infection that occurred in HIV production facilities are discussed in the Health Effects section of this preamble. The requirements in

paragraph (e) are derived primarily from the CDC/NIH recommendations found in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6–338). Only those provisions that relate to the health and safety of the employee are required by the standard. Since the employer is responsible for following the entire standard, requirements stated elsewhere in the standard (e.g. the prohibition of mouth pipetting) are not repeated. The special training requirements in paragraph (g)(2)(v) are based on the conclusions and recommendations of an expert team convened by the Director of the National Institutes of Health.

This section applies to two types of facilities that we have designated "research laboratories" and "production facilities." For the purpose of this standard, "research laboratories" means a facility in which HIV or HBV is being grown in cell, tissue or organ culture in the laboratory or manipulation. Although attempts to grow HBV in this manner have not been successful in the past, researchers are attempting to culture HBV and the *in vitro* culture of HBV may soon be possible. This proposed standard does not require research laboratories such as laboratories using unconcentrated blood or blood components as the source of HIV or HBV to follow these additional requirements. However, they must follow the other provisions of the standard and avoid the production of aerosols.

For purposes of the standard, facilities that are engaged in the concentration of large quantities and/or high concentrations of HBV or HIV are called "production facilities". These facilities reduce many liters of plasma or culture fluid into a concentrate of a few milliliters. These concentrated preparations are used for a number of purposes including as testing reagents and, in the past for HBV and perhaps in the future for HIV, for vaccines. In many cases, the production of concentrated virus is a byproduct of the process and not the goal, for example, in the production of HbsAg.

Paragraph (e)(2)(i) describes standard microbiological practices, most of which are found in other provisions of the standard. The single requirement listed here, the decontamination of infectious liquid or solid waste, is to prevent the accidental exposure of other employees to the concentrated virus.

Paragraph (e)(2)(ii) describes special practices to be followed and paragraph (e)(2)(ii) (A),(C) and (D) serve to further limit access to the laboratory and would warn of the hazards associated with bloodborne pathogens. These paragraphs ensure that unauthorized individuals are not placed at risk, and that they do not distract or otherwise interfere with the activity of the authorized employees. This works in concert with the requirement for signs in paragraph (g). This ensures that only those individuals who meet special requirements, such as training, clothing and/or immunization, would enter the area. The requirement proposed in paragraph (e)(2)(ii)(B) that contaminated material removed from the work area be placed in a durable, leakproof container that is closed before being removed from the work area is to assure there are no accidental spills or other contamination that may place other employees at risk.

The requirement in paragraph (e)(2)(ii)(E) that all activities involving infectious materials be conducted in a biological safety cabinet or equivalent containment is to ensure that material containing virus will be contained and away from the worker's mucous membranes, unprotected skin, and breathing zone (in the case of aerosols).

Paragraphs (e)(2)(ii) (F) and (G) specify personal protective clothing to be worn to prevent contact of the infectious materials with the employee's skin.

The requirements for decontamination of wastes [paragraph (e)(2)(ii)(H)] and the use of HEPA filters and traps on vacuum lines, paragraph (e)(2)(ii)(I), are to prevent the spread of contamination to other work areas.

Since needlestick injury is one of the most efficient methods of accidental infection, paragraph (e)(2)(ii)(J) requires that the use needles and other sharp objects be kept to a minimum, handled carefully and disposed of in containers that prevent accidental injury.

Exposure incidents must be reported (paragraph (e)(2)(ii)(K)) so that post exposure follow-up required by paragraph (f)(3) can be initiated.

The requirement for a biosafety manual, paragraph (e)(2)(ii)(L), ensures that any necessary additional procedures are developed to address situations that are unique to a particular facility and to provide appropriate protection to potentially exposed employees.

Paragraph (e)(2)(iii) specifies that specific containment equipment (engineering controls) are required to minimize or eliminate exposure to the viruses. Biological safety cabinets must be certified to ensure that they will provide the proper protection.

Paragraph (e)(3) contains requirements specific for HIV and HBV research facilities. This paragraph requires a sink for hand washing and an autoclave. Handwashing reduces both the likelihood of infection and the contaminantion of environmental surfaces, and the availability of a handwashing sink near the work area is essential. The availability of an autoclave is required for inactivating or destroying HIV or HBV in or on a variety of media, including culture fluids, plastic ware, and equipment.

The specific requirements for HIV and HBV production facilities are found in paragraph (e)(4). Paragraph (e)(4)(i) would require that in production facilities work areas be separated from other areas by two sets of doors. This reduces the likelihood of accidental entry into the work area and means that entry into the area is a deliberate action. This further reduces the likelihood that untrained individuals will enter the work area as does the requirement that the doors be self-closing [paragraph (e)(4)(iv)].

The requirement for easy cleaning and decontamination of the work area [paragraph (e)(4)(ii)] is necessary because of the high concentration of the virus that may be present and the need to decontaminate the work area to reduce the possibility of infection.

The requirement for a handwashing sink [paragraph (e)(4)(iii)] is to allow for handwashing prior to exiting the work area and to keep environmental contamination to a minimum by requiring that the sink be foot, elbow and automatically operated.

The requirement for an autoclave in or very near the work area [paragraph (e)(4)(iv)] is necessitated because of the very high concentration of virus in these facilities. Transporting contaminated fluids, plastic ware and other equipment would result in a high potential for accidental exposure to other employees.

The requirement that production facilities have a directional airflow into the work area [paragraph (e)(4)(vi)] is to ensure air is drawn into the work area in order to maintain the containment of the facility.

Paragraph (e)(5) alerts the employees to the special, additional training requirements found in paragraph (g)(3)(v) for employees in research laboratories and production facilities.

OSHA seeks comments on its designations "research laboratory" and "production facility." Should there be additional requirements or should any of the proposed requirements be modified? Could alternative provisions provide equivalent protection?

Paragraph (f) HBV Vaccination and Post Exposure Follow-up

The provisions in this paragraph of the proposed standard are designed to protect employees from infection caused by bloodborne pathogens by requiring the employer to (1) make the HBV vaccination available to employees to prevent HBV infection and subsequent illness and death and (2) ensure that the employee receives appropriate medical follow-up after an exposure incident. Early intervention, including testing, counseling and appropriate prophylaxis can reduce the risk of infection, in the case of HBV, and prevent further transmission if an infection should occur.

The proposed standard calls for a hepatitis B vaccination and post-exposure follow-up program to be made available to all employees who are covered by paragraph (a) of this section. Since a single exposure may result in an infection, the Agency believes its coverage is reasonably related to achieving benefits to the health of these employees as well as being technologically and economically feasible.

The proposed standard requires all medical evaluations and procedures to be performed by or under the supervision of a licensed physician. Although a licensed physician must supervise and interpret a medical evaluation(s), certain parts of the evaluation(s) do not necessarily require the physician's expertise, and these may be conducted by other suitably qualified health care personnel under the supervision of the physician.

The proposed standard requires that all laboratory tests be performed by an accredited laboratory. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. This accreditation process is required to ensure a measure of quality control so that employees receive accurate information concerning their laboratory tests and tends to assure long-term stability and consistency among laboratory test procedures and interpretations of results.

The proposed standard requires all evaluations, procedures, vaccinations, and post-exposure prophylaxis to be provided at a reasonable time and place, and according to standard recommendations for medical practice. In order to increase the likelihood that employees receive the benefits provided by the standard, the evaluations must be convenient to them and the above requirements ensure that they will be. Moreover, OSHA has included this provision in other standards (e.g., EtO, 49 FR 25798 (1984) and Asbestos, 51 FR 22737 (1986).) The requirement for adherence to standard recommendations for medical practice assures that employees are afforded the benefit of receiving all procedures according to currently accepted medical standards.

The requirements for the hepatitis B vaccination and post exposure follow-up program are sufficiently detailed to ensure the employees will receive appropriate protection from bloodborne pathogens, while affording the treating physician flexibility to exercise professional judgment in the management of particular cases. The physician will be able to determine whether the employee has any condition that would prevent the employee from receiving the hepatitis B vaccination and will have access to information such as the documentation required following an exposure incident in order to evaluate, counsel and provide appropriate prophylaxis to employees who have experienced an exposure incident.

HBV Vaccination. The proposed standard requires that the vaccine shall be offered to all employees occupationally exposed on average one or more times per month unless it has been determined through antibody testing that an employee is immune or has previously received the vaccine. In addition, the vaccine shall be provided to any such employee who initially declines HBV vaccination but later, while still covered under the standard, decides to accept the HBV vaccine. Should booster dose(s) be recommended at a future date, they shall be provided. An employee who is exposed to potentially infectious materials such as concentrated preparations of HIV concentrate, that do not contain HBV and who has no exposure to blood has no reason, on the basis of employment, to receive HBV vaccine. Therefore, it is not required that HBV vaccine be offered to these employees.

In the past, the CDC has published lists of occupations identified by epidemiologic studies as placing employees at risk for hepatitis B infection and has recommended the vaccination of these groups. If this approach were to be followed for regulatory purposes, some occupations with routine exposure to blood may be excluded because epidemiologic studies may not be available to quantify the risk. Since this standard seeks to minimize or eliminate exposure to blood and other potentially infectious materials, the mechanism for occupational transmission of bloodborne pathogens, OSHA proposes to base HBV vaccination on frequency of exposure rather than occupation. This allows greater flexibility and provides protection for those individuals whose occupation may not be included on the recommended list but may nonetheless have frequent occupational exposure.

OSHA is proposing that employers offer the vaccine to those employees who are occupationally exposed on average one or more times per month. If, for example, once a month or twice every other month, an employee dons gloves to perform a phlebotomy procedure, then for the purpose of paragraph (f)(2)(i) the requisite occupational exposure has occurred and the employee must be offered the vaccine. Since the basis for specifying the frequency of this occupational exposure is lifetime risk, an employee who has 12 occupational exposures in a day or in a week but has no additional exposures for several months is eligible to receive the vaccine.

The requirement that the HBV vaccine be administered "according to standard recommendations for medical practice" refers to such considerations as dosage, route, site and technique of immunization (Ex. 6–489). It does not refer to any recommendation that conflicts with OSHA's proposed requirement that the employer make the HBV vaccine available to employees occupationally exposed on average one or more times per month.

Since OSHA is charged with protecting a worker over his or her entire working lifetime (45 years), an exposure frequency of once a month means that the employee will have potential exposure to the blood of 540 different individuals over a working lifetime. Although it is not possible to predict exactly how many of these exposures involve blood or body fluids from HBV infected individuals, estimates of the prevalence of HBV carriers are available in the literature. For example, approximately 0.2% of the white population, 1% of hospital patients, and 13% of immigrants from areas of high endemicity are infected (HBsAg positive) and capable of transmitting the virus (Ex. 6–390, 6–427, 6–199). Using these figures, one can estimate that a hospital employee who is exposed once a month for 45 years (540 exposures) will be exposed to the blood of an HBV infected individual approximately 5 to 6 times over a working lifetime. The actual number of exposures to blood or other potentially infectious materials containing HBV could be higher if the contact population consists of individuals from high risk

groups or those with a higher HBV carrier rate. If these exposures are by needlestick, then the probability of infection would be expected to range from 7% to 30% for each exposure. Exposure by other routes would have a lower probability of infection. For additional estimates of lifetime risk to workers with an average of one exposure per month, see Exhibit 6–491.

It is the goal of the standard to minimize or eliminate significant risk using engineering and work practice controls and personal protective equipment. However, accidents occur, equipment may fail or be defective, the employee may have unsuspected cuts or may develop dermatitis and infection may follow exposure. Therefore, OSHA believes that the risk of infection is sufficient to mandate that the employer make the HBV vaccine available to those employees whose exposure occurs an average of once a month or more. Employees with fewer exposures are also at some risk and may not be adequately protected from HBV by the other provisions of the standard. OSHA seeks comment on whether the group of employees who would receive the vaccine under this proposal should be expanded and upon what criteria should the expansion be based?

The requirement that employers make the vaccine available to employees who initially decline vaccine but who later decide to accept the vaccine, assures that employees who initially are reluctant to accept vaccine but who later change their minds as the result of information or experience are accorded the opportunity to receive such vaccine. The signing of a waiver by the employee does not relieve the employer of the requirement to provide the vaccine at a later date if the employee requests the vaccine. This is consistent with OSHA's goal of encouraging employees to be vaccinated.

Since the plasma-derived HBV vaccine has been available in the U.S. only since 1982, with the recombinant DNA HBV vaccine licensed in 1986, future follow-up of vaccinees may demonstrate that HBV antibody levels fall to a level at which they are no longer protective. At that time, booster doses of vaccine may be recommended to ensure protection. Should such doses be recommended, the provision for booster doses assures that employees will continue to be protected.

HBV vaccination has been endorsed in an ANPR comment by NIOSH (Ex. 11–187) and recommended by CDC (Ex. 6–200). The Departments of Labor and Health and Human Services endorsed HBV vaccination in the Joint Advisory Notice (Ex. 10). In addition, the ADA has recommended that all dental health care workers with possible exposure to blood or direct patient contact obtain HBV vaccination (Ex. 11–43), and AFSCME has recommended that HBV vaccine be offered (Ex. 11–157). The ANA (Ex. 11–86) and AACN (Ex. 11–117) have endorsed provision of HBV vaccination by the employer, and the American College of Obstetricians and Gynecologists (Ex. 11–158) has recommended that health care workers be vaccinated against HBV.

The proposed standard requires that HBV antibody testing shall be made available to an employee who desires such testing prior to deciding whether to receive HBV vaccination. OSHA believes that it is the right of employees to have such information so that they can make a fully informed choice regarding HBV vaccination. The manufacturer of the vaccine has stated that antibody screening prior to vaccine is not warranted (Ex. 11–165). However, the agency believes that employees who are already immune to HBV should have the opportunity to obtain that information so that they can choose whether or not to be vaccinated based on knowledge of their HBV immune status. In addition, if adequate HBV antibody titer is demonstrated in an employee, there is no reason for the employer to offer the HBV vaccine to that employee. In addition, in many cases, the employer will find it cost effective to prescreen prior to vaccination (Ex. 6–199).

OSHA seeks to gather additional information related to hepatitis B vaccination during the written comment period and the public hearing. Since the employee's participation in the hepatitis B vaccination program is voluntary, OSHA is particularly interested in existing HBV vaccination programs that have achieved a high degree of voluntary employee compliance. The Agency will attempt to identify those elements that are common to successful programs and will provide this information to all employers. In addition, we are also seeking information on availability, cost and any potential distribution problems that may be associated with initiating the vaccination of large numbers of employees within the 150 day period following the effective date of the standard.

The Agency intends to designate several days of the Washington, DC hearing to focus on the issues surrounding HBV vaccination. We encourage hearing participants who are concerned about this matter or who have pertinent information to participate either by requesting to testify on one of the designated days or by submitting a statement to be entered into the record on the days set aside to focus on Hepatitis B vaccination. Specific information on this matter can be found in Section X. Public Participation.

Post Exposure Evaluation and Follow-up

Following a report of occupational exposure, medical evaluation and monitoring are to be made available to the employee. Such evaluation and monitoring, as well as maintaining the required medical records, are to be done in a manner which protects the confidentiality of the employee's identity and test results. OSHA believes that medical evaluation and monitoring following an exposure incident are necessary to provide appropriate prophylaxis to prevent HBV infection, to take appropriate precautions to prevent possible perinatal transmission, and to ensure that such employees are able to take necessary precautions to ensure that sexual contacts are protected from infection. Post-exposure medical evaluations have been recommended by NIOSH (Ex. 11–187), NCCLS (Ex. 11–159), AHA (Ex. 6–75), NIH/CDC (Ex. 6–312), AAOHN (Ex.11–358), and AFSCME (Ex. 11–157). The ADA has stated that CDC guidelines should be followed (Ex. 11–43).

Determination of and Documentation of exposure incident. The route of exposure, the source patient's antibody status (if known), and the circumstances under which the exposure occurred are to be documented. Such determinations enable the employer to discharge further responsibilities in providing information to the physician by determining the infection status of the source patient. In addition, through documentation of such exposure the employer can receive feedback regarding the most prevalent circumstances and routes of exposure of employees so that efforts can be focused on decreasing or eliminating the circumstances involved (e.g., providing protective equipment that is acceptable to employees and that they will more likely use, increasing training efforts regarding certain procedures which seem to be associated with exposure incidents). Such determination of and documentation of exposure incidents and circumstances has been recommended by ABRA (Ex. 11–71) and the Hospital Association of Greater Des Moines (Ex. 11–23). Additionally, NCCLS (Ex. 11–159) and NIH/CDC (Ex. 6–312) have recommended that institutions develop and maintain post-exposure documentation.

Testing of source patient. If the source patient of an employee's occupational

exposure can be determined, permission for antigen or antibody testing of the source patient's blood shall be obtained, if possible, and testing shall be performed to determine HBV and HIV infection status. In any case, management of the exposed employee shall be according to standard recommendations for medical practice. OSHA believes that testing of source patient(s) for infection status provides exposed employees with information that will assist them in their decisions regarding testing of their own blood, complying with other elements of post-exposure management, and using precautions to prevent possible infection in others. The American Red Cross has recommended that the employer make an early attempt to evaluate the infectivity of the implicated material after an employee exposure (Ex. 11–280). SEIU has stated that it is the right of workers to know the HIV and HBV status of patients if exposed to their blood or body fluids (Ex. 11–161). The need to obtain the consent of the source patient prior to testing is recognized. Many organizations and associations support testing of source patient(s) only after obtaining consent of such patient(s). These associations and groups include CDC (Ex. 6–153), NIOSH (Ex. 11–187), AAOHN (Ex. 11–358), NCCLS (Ex. 11–159), and AHA (Ex. 6–75). The AMA (Ex. 11–163) has endorsed the implementation of CDC recommendations. Consistent with the opinion expressed by the CDC and the majority of commenters, OSHA proposes that testing of source patients following an employee exposure be accomplished after consent is obtained from the source patient. It is to be expected that some patients will not consent to testing, and OSHA does not expect the employer to test the source patient against his or her wishes.

Blood collection and antibody/antigen testing. Blood from the exposed employee is to be collected as soon as possible after the exposure incident for the determination of HIV and/or HBV status. Actual antibody/antigen testing of the blood may be done at that time or at a later date if the employee so requests.

By offering blood collection and antibody testing to the exposed employee as soon as possible after an exposure incident, the employer assures that the employee has the opportunity to have antibody testing to serve as a baseline value with which to compare future test results in order to narrow the point in time at which any infection resulting from exposure was acquired. The option is given to the employee to have the blood tested at a later date so that exposed employees will not be forced to decide in a short time about whether they desire to know their antibody status at the time of exposure. OSHA believes that the provision of opportunity for future testing rather than a demand for an immediate decision by the employee will encourage employees to accept blood collection at the time of exposure. The offering to exposed employees of voluntary blood collection and testing for evidence of infection has been recommended by NIOSH (Ex. 11–187), the Hospital Association of Greater Des Moines (Ex. 11–23), Joint Advisory Notice (Ex. 10), AAOHN (Ex. 11–358), NCCLS (Ex. 11–159), AHA (Ex. 6–75), ABRA (Ex. 11–71), and SEIU (Ex. 11–161). The American Red Cross has recommended that employee blood samples be held until the employee requests testing and that samples not tested be held for at least 5 years (Ex. 11–280). The American Dental Association has recommended that blood of exposed employees be tested only if the source patient has AIDS or is HIV infected (Ex. 11–43). OSHA seeks comments on whether this provision will increase the likelihood that the employee will be willing to participate in a post exposure follow-up program.

Further follow-up of the exposed employee includes counseling and illness reporting. OSHA believes that further follow-up of an exposure incident is vital to assure that employees are afforded further information and counseling regarding their condition as a result of exposure. The American Blood Resources Association (Ex. 11–71) has recommended that follow-up testing be encouraged and that the employee be referred, if a test is positive for infection, for further evaluation and follow-up. The American Red Cross (Ex. 11–280) has recommended referral to a physician of an exposed employee if the source material is infectious. The Centers for Disease Control and the National Institutes of Health (Ex. 6–312) have recommended surveillance of exposed employees in laboratories and production facilities. The American Association of Occupational Health Nurses (Ex. 11–358) has recommended follow-up antibody tests at 6 weeks and 6–12 months post exposure. A number of commenters including NIOSH (Ex.11–187), AFSCME (Ex. 11–157), the Hospital Association of Greater Des Moines (Ex. 11–23) and AMA (Ex. 11–163), endorsed CDC current recommendations of follow up antibody testing of exposed employees at 6 weeks, 12 weeks and 6 months (Ex. 6–153). However, AHA has recommended the addition of a 12 month test (Ex. 6–75) to the CDC recommendations, and the NCCLS (Ex. 11–159) has recommended follow-up testing, in addition to 6 weeks, 12 weeks, and 6 months, at 9, 12, and 24 months post exposure. Since follow-up testing is a rapidly changing and developing field, OSHA believes that current standard recommendations for medical practice at the time of exposure offer the best protection for employees covered by such a standard at the present time as well as in the future.

The requirement for the employer to advise employees to report illness to the responsible physician assures that such employees will have the benefit of early medical evaluation and can accept in a timely manner any currently recommended treatment of such disease. This illness reporting provision has been recommended by CDC (Ex. 6–153) and is supported by ABRA (Ex. 11–71), CDC/NIH (Ex. 6–312), AMA (Ex. 11–163), AAOHN (Ex. 11–358), and NCCLS (Ex.11–159).

OSHA believes that counseling of exposed employees is a vital component of the post-exposure follow-up procedures. Counseling concerning the infection status (results and interpretation of all tests) will assist the employee in understanding the potential risk of infection and in making decisions regarding the protection of personal contacts. Post exposure counseling has been recommended by CDC (Ex. 6–153), DOL/CDC (Ex. 10), NIOSH (Ex. 11–187), ARC (Ex. 11–280), AAOHN (Ex. 11–358), SEIU (Ex. 11–161), AHA (Ex. 6–75), ABRA (Ex. 11–71), AMA (Ex. 11–163), NCCLS (Ex. 11–159), and AFSCME (Ex. 11–157).

OSHA believes that it is essential that exposed or infected employees be offered post-exposure follow-up according to standard recommendations for medical practice. This provision guarantees employees the benefit of currently recommended measures to help prevent infection and disease immediately after occupational exposure. The offering of such measures in a timely manner assures that maximum effectiveness is achieved. Post exposure follow-up for exposed employees has been recommended by SEIU (Ex. 11–161). The American Federation of State, County and Municipal Employees (Ex. 11 157) and AAOHN (Ex. 11–111) have endorsed prophylaxis for HBV as recommended by CDC, and the ACIP has recommended HBIG, along with HBV vaccine, for unvaccinated exposed employees (Ex. 6–199). In addition to treatment of the exposed employee,

AAOHN has recommended that if a pregnant employee is exposed, the baby should be treated if necessary (Ex. 11–111).

Information Provided to the Physician. The proposal requires that the employer provide the evaluating physician with certain information [paragraph(f)(4)]. This information includes:

(i) A copy of this regulation and its appendices, and

(ii) A description of the affected employee's duties as they relate to the employee's occupational exposure.

The purpose of making this information available to the physician is to inform the physician of the requirements of the standard and to aid the physician in understanding the employee's assigned duties.

Physician's Written Opinion

For each evaluation required under this section the employer shall obtain and provide the employee with a copy of the evaluating physician's written opinion within 15 working days of the evaluation. The written opinion shall be limited to the following information:

(i) The physician's recommended limitations upon the employee's ability to receive the HBV vaccination.

(ii) A statement that the employee has been informed of the results of the medical evaluation and 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.

(iii) Specific findings or diagnoses, which are related to the employee's ability to receive the HBV vaccine. Any other findings and diagnoses shall remain confidential.

The purpose of requiring the evaluating physician to supply the employer with a written opinion is to provide the employer with a documentation of a medical assessment of the employee's ability and need to receive HBV vaccination. The requirement that the employee be provided with a copy of the physician's written opinion within 15 working days ensures that the employee is informed in a timely manner of the results of the evaluation and the need for any additional follow-up, and of the receipt by the employer of the information contained in the physician's written opinion. The purpose of limiting the information the employer receives is to encourage employees to participate in the medical evaluation by removing concern that the employer will obtain information about their physical condition and specific findings or diagnoses that are unrelated to the employees ability to receive vaccine.

Hepatitis B Vaccination and Post Exposure Follow-up Recordkeeping. Medical records shall be maintained in accordance with paragraph (h)(1) of this section. The above notation is included in this discussion so that the employer and interested parties reviewing this discussion of the proposed medical surveillance requirements are made aware that there are requirements for medical surveillance recordkeeping elsewhere in the standard. These records must remain confidential.

Paragraph (g) Communication of hazards to employees

This proposed standard includes paragraph (g) entitled: "Communication of Hazards to Employees." This paragraph addresses the issue of transmitting information to employees about the hazards of bloodborne pathogens through the use of signs, labels and information and training. This paragraph of the proposed standard on bloodborne pathogens would apply to all operations where there is potential for exposure to blood and other potentially infectious materials. OSHA's primary intent in this paragraph of the proposed standard is to ensure that employees will receive adequate warning (signs and labels) and training necessary to minimize or eliminate exposure to bloodborne pathogens.

Signs and labels

Paragraph (g)(1) of the proposed bloodborne pathogens standard provides the specific labeling and sign requirements that would have to be used to warn employees of the hazards to which they are exposed. The requirements for signs and labels are consistent with Section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed. There was also strong support in the record for such requirements (see for example, Exs. 11–159, 11–233).

The proposed standard would require that the entrance to research laboratories or production facilities be posted with signs specifically stating "Biohazard" and showing the universal biohazard symbol in the color black. Should there be any additional requirements that relate to the color or contrast of these signs? The sign would also have to identify the infectious agent and specify any special requirements for entering the area. For example, if personal protective equipment is required, this information would have to be included on the sign. In addition, the name and telephone number of the laboratory director or other responsible person would be displayed. Such warning signs would have to be posted at the entrance to a research laboratory or a production facility as defined by paragraph (b) of this proposed standard. The proposed standard intends that the posting of these signs will serve as a warning to employees who may otherwise not know they are entering a restricted area. Signs would warn employees not to enter the area unless there is a need, unless the employee has been properly trained, and unless the employee also meets all other appropriate entrance requirements listed on the sign.

The proposed standard dictates certain wording on the warning signs for regulated areas to assure that appropriate and universally recognized warning is given to employees. The specific requirement to use the word "Biohazard" and the universal biohazard symbol is considered appropriate because epidemiological evidence indicates that HIV and HBV have been transmitted to laboratory workers in circumstances where these hazards existed. The universal biohazard symbol indicates the nature of the hazard in a manner readily recognized by laboratory workers, and it emphasizes the importance of the message that follows. The requirement that the name of the infectious agent be listed on the sign would assure that employees are aware of the specific biohazard involved. The requirement that any special provisions for entry into the regulated area be listed on the sign posted at the entry to the work area will assure that authorized individuals who enter the area are properly protected. The requirement that the name and telephone number of the laboratory director or other responsible individual be posted on the sign will ensure that, in the event of an emergency or other unforeseen event, a trained and knowledgeable individual will be available to provide guidance and ensure that procedures are followed to minimize or eliminate exposure.

The provisions for signs in paragraph (g)(1)(i) are virtually identical to the recommendations for signs found in Special Practices for Biosafety Levels 2 and 3 in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6–338). The only exception is the additional requirement that the word "Biohazard" be used. OSHA has added this requirement because of the likelihood that some individuals who are present in the general work area may be unfamiliar with the meaning of the biohazard symbol.

The hazard warning signs are intended to supplement the training which employees are to receive under the other provisions of paragraph (g)(2), since even trained employees need to be reminded of the location of regulated areas and of the precautions to be taken before entering these hazardous areas.

Paragraph (g)(1)(ii) would require that labels or other appropriate forms of warning be provided on containers of infectious waste; on refrigerators or freezers that are used to store blood or other potentially infectious materials and on other containers used to store or transport either blood or other potentially infectious materials. The only exception would be substitution of red bags or red containers for infectious waste and the use of containers of blood or blood components that are labeled as to their contents and have been released for distribution. (The reasons for these exemptions are discussed below.)

This is to alert employees of possible exposure since the nature of the material or contents will not always be readily identified as blood or other potentially infectious materials. The proposed labeling requirement reads as follows: BIOHAZARD, followed by the universal biohazard symbol in the color black, and any other appropriate designation, e.g., Infectious Waste. The purpose of the term "Biohazard" and the universal biohazard symbol are as described above for signs. Any "other appropriate designation" is also required because this would ensure that employees know the contents of the bag or container without opening it and risking possible exposure.

One result of the implementation of universal precautions is that, in most facilities, signs and labels that indicate the patient's HIV or HBV infection status are no longer used. Under this method, for example, blood from all patients is treated as if it contains HBV or HIV, and there is no need for these particular signs and labels. In addition, the labeling of some blood specimens and not others may set up a dual system in which employees take fewer precautions with unlabelled specimens than with those labeled "HIV" or "HBV." On the other hand, some employees may feel that if they are required to provide care to a patient who is known to be infected with HIV or HBV, the employee has a right to know that the patient is infected.

The proposed standard would neither require nor prohibit the posting of signs or labeling of specimens to specify the patients's HIV or HBV infection status as long as the employer has implemented universal precautions. Should OSHA continue to leave the decision to use labels and signs designating the patient's infection status to the employer? Should OSHA *prohibit* the use of signs and labels stating the patient's HIV or HBV infection status? Should OSHA *require* the use of these particular signs and labels?

The proposal would require labels to be fluorescent orange, orange-red or predominantly so with lettering or symbols in a contrasting color. This requirement would ensure that the label attracts the attention of the employee and that the letters and symbols are legible. The color requirement is identical to that contained in Appendix A of OSHA's standard for accident prevention tags (29 CFR 1910.145(f)). OSHA seeks comment on this color requirement.

The proposed standard would allow the substitution of red bags for labels on bags or containers of infectious wastes. OSHA recognizes the accepted current practice of "red bagging" infectious wastes. Paragraph (g)(2)(iv)(k) of the proposed standard would require that employees be trained to understand the meaning of all symbols used on signs and labels. This would include information on the meaning of red bags, thus assuring that OSHA's intent, to inform employees of hazards present at their worksite, would be achieved by the use of red bags.

Although some products are available that have biohazard labels as an integral part of the container, the proposed standard would allow a label to be affixed to the container. This flexibility is particularly important since objects, such as refrigerators or freezers, would have to be labeled under certain circumstances.

The proposed standard would exempt containers of blood and blood components, labeled as to their contents and released for distribution, from the labeling provision of this standard. This exemption is justified because the standard would require the implementation of universal precautions (as defined in paragraph (b)) so that containers bearing a specific label which identifies blood or blood components would provide sufficient information to ensure that employees will know to take appropriate infection control measures. For example, the labeling requirements of the Food and Drug Administration for blood and blood products provide sufficient warning for a trained employee so that no additional labeling would be necessary. The Agency specifically seeks additional comments from the public on the appropriateness of this exemption.

Employee Information and Training

According to paragraph (g), the employer would be required to provide all employees exposed to bloodborne pathogens with training about the hazards associated with blood, and potentially infectious materials and the protective measures to be taken to minimize the risk of occupational exposure. Effective training is a critical element of any overall infection control program. It will ensure that employees understand hazards associated with bloodborne pathogens, the modes of transmission, the infection control plan, and the use of engineering controls, work practices, and personal protective clothing. Employees would also be trained in the appropriate actions to take in an emergency, and they would be informed of the reasons that they should participate in medical surveillance programs. This training would help reduce the risk of occupational exposure, consequently reducing exposure-related infection, illness, and death.

The proposed standard would require the employer to provide an explanation of the contents of the final standard on bloodborne pathogens including appendices. This ensures the employee will know the standard exists and will become familiar with its provisions.

The proposed provisions for employee training are performance oriented, listing categories of information that must be provided to employees. This ensures that important information is communicated to employees while allowing employers the most flexible approach to providing training.

Training of employees would have to be accomplished at the time of initial assignment or within 150 days of the effective date of the final standard for bloodborne pathogens, whichever comes later. Employee training would be repeated and updated at least annually thereafter.

It is OSHA's position, in general, that it is essential for employees to understand the nature of the hazards they may face in the course of their employment and the procedures to follow to minimize or eliminate the risks associated with their exposure to these hazards. This is particularly important in the case of bloodborne pathogens because a single exposure incident may result in an infection, illness or death. Because of the severity of the diseases and the potential to contact them from a single event, it is also important to retrain workers exposed to bloodborne pathogens on an annual basis. Annual retraining reinforces initial training and

provides an opportunity to present new information that had not been available at the time of initial training.

In the November 27, 1987 ANPR, OSHA requested public comment and other pertinent information on how employees are currently informed of the occupational hazards associated with HBV and HIV; how employees should be trained to ensure that they understand the nature of HIV and HBV infections and the ways to reduce the likelihood of occupational exposure to these viruses; the number of employees who already have received training; how often training should be repeated; any model training programs available and whether employee training should address occupational exposures only or whether it should address personal behavior that increases risks as well. The more than 350 comments OSHA received comprise a record that strongly supports the need for employee training programs and endorses the conclusion that employee training should be mandated as an integral part of OSHA's standard on bloodborne pathogens. The comments also provided many suggestions regarding the types of information that should be included in a specific requirement for training, and OSHA has relied heavily on these comments in developing the proposed training requirements listed below. (See, for example, Exs. 11–1, 11–7, 11–51, 11–57, 11–58, 11–86, 11–111, 11–156, 11–161, 11–165, 11–169, 11–187, 11–233, 11–280, 11–327.)

Typical of the comments received is that of the American Federation of State, County and Municipal Employees (AFSCME) (Ex. 11–157) which addresses the need for training as follows:

> A critically important part of preventing injuries or illnesses in the workplace is training workers about potential hazards and safe working conditions. Workers shall have the same right to know about communicable disease hazards to their health that they now have for chemical hazards (Ex. 11–157).

The American Dental Association (ADA) noted that such training is already received as part of a dental education. "Dental professionals are trained and educated in the delivery of quality dental care. Training and education include infection control practices" (Ex. 11–43).

Like the proposed requirements for signs and labels, OSHA's proposal for employee training is based on the conclusion that workers potentially exposed to bloodborne pathogens should follow universal precautions. The CDC (Ex. 6–316) noted the need for training health care workers in "the routine use of universal blood and body-fluid precautions for all patients." In addition, the majority of commenters to the ANPR considered "universal precaution" to be the correct approach for reducing occupational exposure to bloodborne pathogens.

For example, the Hospital Association of Greater Des Moines (Ex. 11–23) commented:

> An aggressive program of * * * education and enforcement of universal and specific infection control precautions is vitally important to assure the effectiveness of the safeguards.

The American Occupational Medicine Association (AAOM) (Ex. 11–111) cited a specific example of employee training in universal precautions, commenting that:

> Employee education in the proper use and disposal of needles combined with proper placement of disposable equipment is the most effective approach to minimizing needlestick injuries.

The proposed standard would require training material to be of professional quality that is appropriate in content and vocabulary to education level, literacy and language background of employees. This would ensure that all employees, regardless of their cultural or education background, will receive adequate training on infection control procedures. Many commenters suggested such a provision, as seen in the citations below:

> Training materials shall be of professional quality and may involve a variety of media (Merck, Sharpe & Dohme, Ex. 11–165).
>
> Education must be appropriate to education level, literacy and cultural or language background * * * clarify materials to workers at all levels with varying cultural, ethnic and literacy backgrounds (American Association of Occupational Health Nurses (AAOHN), Ex. 11–111).
>
> Program depth, content and frequency might vary widely depending on audience characteristics (such as prior training, educational background, job duties, nature and degree of risk) (American Hospital Association (AHA), Ex. 11–233).

The Service Employees International Union (SEIU) provided similar suggestions in recommending that the following factors be taken into consideration for training employees exposed to bloodborne pathogens:

> [Employee] attitudes and knowledge about these diseases; educational level of workers and potential barriers to training (i.e., language difficulties of non-English speaking workers, limited literacy on the part of some workers * * *) (Ex. 11–161).

The proposed standard would require that the training program include an explanation of the epidemiology, symptomatology, and modes of transmission of the diseases. This ensures a basic understanding of the diseases and the need to observe precautions to prevent disease transmission. There is general agreement in the record that such information would be needed in a training program for bloodborne pathogens. For example, the SEIU envisioned a training program where "there will be sessions on the general epidemiology of diseases as well as a clinical explanation of the disease" (Ex. 11–161). As a more general statement of the same principle, the National Institute of Occupational Safety and Health (NIOSH) commented that "[w]orkers require complete understanding of the modes of transmission of HBV and HIV to observe properly the protective measures required of them" (Ex. 11–187). Similarly, the State of Maryland (Ex. 11–283), AFSCME (Ex. 11–157), and the American Red Cross (ARC) (Ex. 11–280) endorsed the need for training workers to understand the diseases that could be transmitted by exposure.

Certain individuals, for example, infection control practitioners and some virologists, might be expected to be thoroughly familiar with some of the material in the training program. Is it appropriate to substitute some measure of competency in leiu of training for these individuals? OSHA seeks comment on this matter.

OSHA believes that it is important for each worker to recognize how he or she specifically might be occupationally exposed to bloodborne pathogens and under which circumstances infection control precautions will be necessary. The proposed standard, therefore, would require employee training to include an explanation of the infection control program and of the appropriate methods for recognizing tasks that may involve exposure to blood, and other potentially infectious materials.

Several groups who have commented to OSHA's record on bloodborne pathogens stressed the need for workers to be able to recognize when they may be at risk of exposure. For example, the ARC (Ex. 11–280) commented:

> Descriptions of staff duties must indicate whether duties routinely involve potential for exposure to infectious agents * * * whether such exposure might occasionally occur due to extra-ordinary circumstances * * * or whether duties do not include potential for exposure.

Likewise, AFSCME (Ex. 11–157) pointed out that "[t]raining should ensure that all workers * * * can identify tasks that may involve exposure to blood or other potentially infectious body fluids." In suggesting a specific training program, the SEIU (Ex. 11–161)

proposed that "* * * workers will learn the exposure associated with specific occupations and tasks in health care facilities."

The proposed standard would require that employees be provided information on appropriate methods for recognizing tasks and other activities that could involve exposure to blood or potentially infectious materials. This would ensure that workers will be prepared for unusual or extraordinary circumstances that include the potential for exposure to bloodborne pathogens. Typical of the support in the record for this provision is the following comment from the ARC (Ex. 11–280):

> Staff must understand * * * actions to be taken when confronted with a situation of potential exposure that had not been anticipated by the employee. Such training might include knowledge of the existence of safety procedures applicable to the situation and the availability of assistance.

To ensure that employees will be able to identify and implement methods of reducing or preventing occupational exposure to bloodborne pathogens, the proposed training requirements would require an explanation of the use and limitations of appropriate engineering controls, work practice controls, and personal protective equipment.

The proposed standard would require that employees be provided information on the types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment as well as an explanation of the basis for selection and limitations of protective equipment and clothing. This would ensure that employees are knowledgeable about the proper use of personal protective equipment to achieve appropriate barrier protection.

Comments in the record support inclusion of information on personal protective equipment and clothing in the training program for employees. For example, AFSCME (Ex. 11–157) suggested the following:

> Training should ensure that all workers * * * know where all protective equipment is kept, how to remove, handle, decontaminate, maintain and dispose of contaminated equipment.

The ARC (Ex. 11–280) noted that:

> Staff must understand * * * protective clothing and equipment (is) available and their proper use * * * all proper practices and pertinent Standard Operating Procedures, including handling, decontamination, and disposal of contaminated clothing and equipment.

NIOSH (Ex. 11–187) stressed the need for employee training on measures to control exposure to bloodborne pathogens, recommending that "[a]ll workers * * * receive detailed training on engineering controls, personal protective clothing and equipment and work practices required for their duties." According to NIOSH, this training would have to cover not only the proper use of protective devices, but also the inherent limitations of those devices.

The proposed standard would require that employees be provided with information on the hepatitis B vaccine to ensure that they are aware of its efficacy and safety as well as its benefits. The vaccine is the best available means of preventing HBV in the vast majority of workers. Nevertheless, a disappointingly large percentage of employees at risk remain unvaccinated, many because of a lack of knowledge about the vaccine including an unfounded fear of contracting HBV or HIV from the vaccine. According to the vaccine's manufacturer, a number of studies on worker acceptance attribute the "underutilization of the vaccine" to a "lack of information about the disease and the vaccine safety and effectiveness" (Ex. 11–165). In fact, a study conducted at three teaching hospitals found that "the amount of information received concerning the need for and safety of the vaccine correlated significantly with the level of vaccination among employees. Approximately 50% of employees who reported receiving adequate information were vaccinated, whereas fewer than 20% who indicated they did not receive adequate information requested the vaccine (Ex. 11–165)." Merck (Ex. 11–165) concluded that successful vaccination programs combined "proper education about the disease and the vaccine, [with] * * * active support for employee vaccinations from the managerial staff, and * * * vaccine(s) without cost to the employees."

OSHA believes informing employees about the HBV vaccine is a critical component of any training program. The Agency seeks comment on how this can best be achieved and requests interested parties to inform OSHA of specific methods that have proven successful in encouraging employees to accept the vaccine.

It is important that employees understand the actions to be taken if an occupational exposure does occur as well as what medical follow-up is available for exposed individuals to ensure that they seek appropriate medical treatment, prophylaxis and/or post-exposure follow-up. Therefore, the proposed standard would require an explanation of the procedure to follow if an occupational exposure to bloodborne pathogens occurs, including the method of reporting the incident and a description of the medical follow-up that would be made available.

Support for including training about exposure reporting and post-exposure follow-up after an exposure incident was given by several commenters to the record, such as the ARC (Ex. 11–280) who stressed that "[s]taff must understand * * * proper procedures to be followed in case of an accident or exposure." Elaborating on this position, AFSCME (Ex. 11–157) stated:

> Training should ensure that all workers * * * know the corrective actions to take in the event of * * * personal exposure to fluids or tissues, the appropriate reporting procedures and the medical monitoring recommended in cases of suspected parenteral exposure.

The AAOHN (Ex. 11–111) took an even more explicit position regarding training on the need for follow-up medical care in stating that:

> All health care workers should receive education about the counseling of occupationally exposed individuals, monitoring and surveillance activities, current management of the disease process and legal, ethical issues.

The proposed standard would require an explanation of the required signs and labels, including color codings and "red bagging", to ensure that employees understand the warning messages presented and the need for appropriate infection control procedures.

Employees in HIV/HBV research laboratories and HIV/HBV production facilities may be at especially high risk of infection following occupational exposure because they handle concentrated preparations of these viruses. OSHA has concluded that the risk is sufficiently high to warrant a requirement for additional training in the handling of HIV/HBV. The proposed standard, therefore, would require that employees in such facilities who have occupational exposures be trained in and demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility *before* being allowed to work with HIV/HBV.

The proposal would also require employees in HIV/HBV research laboratories and HIV/HBV production facilities to be experienced in the handling of human pathogens or tissue cultures prior to working with HIV or HBV. Employees with no prior experience in handling human pathogens would have to participate in an on-the-job training program where initial work activities would not include the handling of infectious agents. A progression of work activities would be

permitted as techniques are learned and proficiency is developed. An employee would be permitted to participate in work activities involving infectious agents only after proficiency has been demonstrated to ensure that the worker is able to handle HIV or HBV as safely as possible, thereby minimizing the risk of occupationally related infection and illness.

OSHA's provisions proposing to require additional training for employees in HIV/HBV research laboratories and HIV/HBV production facilities are patterned after the recommendations made by an expert team convened by the Director of the National Institutes of Health (Ex. 6–312). This expert team made the following recommendations to help assure a safe and healthful work environment for employees who handle concentrated preparations of HIV:

A. Strictly adhere to standard microbiologic practices and techniques:

The most important recommendation is to adhere strictly to standard microbiologic practices and techniques. Persons working with HIV must be aware of potential hazards and must be trained and proficient in practice and techniques necessary for self-protection. Employees must be informed that parenteral exposure is the most serious potential hazard for causing a laboratory-acquired infection. They must be able to recognize how such exposures occur and how they can be prevented. Although on-the-job training is an acceptable approach for learning techniques and practices, it is imperative that proficiency be obtained before virus is actually handled. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed.

B. Assure that workers are proficient in virus-handling techniques:

Selection criteria for employees who will work in production operations or with concentrated preparations of HIV should require experience in the handling of human pathogens or tissue cultures. If an employee has not had such experience, s/he should participate in carefully structured, well-supervised on-the-job training programs.

The director or person in charge of the laboratory or production facility must ensure that personnel are appropriately trained and are proficient in practices and techniques necessary for self-protection. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed. Virus should only be introduced into the work activities after the supervisor is confident it can be handled safely.

Paragraph (h) Recordkeeping

The proposed rule would require that employers maintain records related to hepatitis B vaccination and post exposure follow-up and training. These requirements are in accordance with section 8(c) of the Act which authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act, or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain medical and training records is necessary and appropriate. In addition, medical records are necessary for the proper evaluation of the employee's immune status and for proper medical management following an exposure incident.

The proposed standard would require employers to maintain medical records which include: (1) The name and social security number of the employee; (2) a copy of the employee's hepatitis B vaccination records and medical records relative to the employee's ability to receive the HBV vaccine or the circumstances of an exposure incident; (3) a copy of all results of physical examinations, medical testing and follow-up procedures as they relate to the employee's ability to receive vaccination or to post-exposure evaluation following an exposure incident; (4) the employer's copy of the physician's written opinion; and (5) a copy of the information provided to the physician as required by paragraph (f) of this proposed standard.

The proposed standard requires that the employer keep the employee's medical record confidential. OSHA has attempted to reduce barriers to exposure reporting by requiring that medical records, including all test results, be kept confidential except as otherwise required by law. Fear that coworkers or others may see test results may discourage the reporting of exposure incidents and seeking follow-up care. OSHA recognizes the sensitive nature of HIV testing and the possible repercussions should that test be positive. Unfortunately, some individuals have suffered the loss of their jobs, homes, medical and life insurance, and have been otherwise stigmatized as a result of testing positive for antibody to HIV. This provision would assure that testing results would not be disclosed and would encourage exposure reporting.

The time period for retention of medical records is the duration of employment plus thirty years which is consistent with 29 CFR 1910.20. The transfer of employee medical records is to be in accordance with the provisions of paragraph (h) of 29 CFR 1910.20. If an employer ceases to do business and there is no successor employer, the employer is to notify NIOSH at least three months prior to the disposal of the records and to transmit them to the Director for retention, if requested. The employer may cease to do business before or during this time period. However, the records must be retained for at least 3 months after NIOSH is notified.

The proposed rule would require employers to maintain training records which include: (1) The dates of the training sessions; (2) the contents or a summary of the training session; (3) the names of the persons conducting the training; and (4) the names of all persons attending the training sessions. The time period for retention of training records is five years. Maintaining these training records for five years will facilitate review of the content, consistency, and completeness of the training program by OSHA and the employer. The transfer of training records is to be in accordance with the provisions of paragraph (h) of 29 CFR 1910.20. OSHA believes that these records are necessary and appropriate to the enforcement of the standard.

The access provisions of this proposed standard are consistent with 29 CFR 1910.20. Employees and their designated representatives are, in general, allowed unrestricted access to training records. Access to medical records is also provided for employees and, if the employee has given specific written consent, for the employee's designated representative. OSHA retains unrestricted access to both these medical and training records, but the Agency's access to personally identifiable medical records is subject to regulations designed to protect privacy which have been published at 29 CFR 1913.10 (see 45 FR 35584).

Paragraph (i). Dates

As proposed, the final rule would become effective thirty (30) days after publication in the **Federal Register.** This will allow time for public distribution and give employers time to familiarize themselves with the standard. The various provisions have phased-in effective dates.

The employers initial duty under the standard is the exposure determination required by paragraph (c)(1) of this section and would have to be completed within ninety days of the effective date of the standard. The employer would then have an additional 30 days (120 days after the effective date) to complete the infection control plan required by paragraph (c)(2).

Thirty days later, 150 days after the effective date of the standard, paragraphs (d)(2) engineering controls and work practice controls, (d)(3) personal protective equipment, (d)(4) housekeeping, (e) HIV and HBV research laboratories and production facilities, (f) hepatitis B vaccination and post-exposure follow-up, (g) communication of hazards to the employee, and (h) recordkeeping would take effect.

Since many employers have many of these provisions already in effect through current infection control plans and the implementation of universal precautions, OSHA believes that these dates provide adequate time for compliance.

X. Public Participation—Notice of Hearing

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at three informal public hearings scheduled to begin at 10:00 a.m. at places and on dates as follows:

Washington, DC: September 12, 1989. The Auditorium, Frances Perkins Department of Labor Building, 200 Constitution Avenue, NW., Washington, DC 20210.

Chicago, IL: October 17, 1989. Parlor A, Palmer House, 17 East Monroe Street, Chicago, IL 60603.

San Francisco, CA: October 24, 1989. The Crystal Ballroom, San Franciscan Hotel, 1231 Market Street, San Francisco, CA 94103.

Notice of Intention to Appear

All persons desiring to participate at the hearing must file in quadruplicate a Notice of Intention to Appear, postmarked on or before August 14, 1989, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket H–370, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 523–8615. A Notice of Intention to Appear also may be transmitted by facsimile to (202) 523–5046 or (for FTS) to 8–523–5046, provided the original and 4 copies of the Notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office, Room N–2625, 200 Constitution Avenue NW., Washington DC 20210, telephone (202) 523–7894, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A statement of the position that will be taken with respect to each issue addressed;

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(7) Whether the party wishes to testify on the days set aside to focus on hepatitis B vaccination.

(8) At which hearing or hearings the party wishes to testify.

Filing of Testimony and Evidence Before Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of his testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be received by August 31, 1989, for the Washington, DC hearing and September 29, 1989, for the Chicago, IL and San Fransisco, CA hearings, and it will be available for inspection and copying at the Technical Data Center Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper notices of intention to appear at the hearing will be entitled to ask questions and otherwise participate fully in the proceeding.

Conduct and Nature of Hearing

The hearing will commence at 10 a.m., on September 12, 1989. At that time any procedural matters relating to the proceeding will be resolved.

The nature of the informal rule making hearings to be held is established in the legislative history of section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, it is clear that the proceeding shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentation by interested persons which can be carried out expeditiously and in the absence of rigid procedures which might unduly impede or protract the rulemaking process.

The hearings will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR 1911 including the powers:

(1) To regulate the course of the proceedings;

(2) To dispose of procedural requests, objections and comparable matters;

(3) To confine the presentation to the matters pertinent to the issues raised;

(4) To regulate the conduct of those present at the hearing by appropriate means;

(5) In the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

(6) In the Judge's discretion, to keep the record open for a reasonable, stated time to receive written information and additional data, views, and arguments from any person who has participated in the oral proceedings.

Written Comments

Interested persons are invited to submit written comments on the issues raised in the proposal and summarized in this notice. Written comments must be postmarked on or before August 14, 1989, and submitted in quadruplicate to the Docket Office, Docket Number H–370, Room N–2625, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210. The telephone number of the Docket Office is (202) 523–7894, and its hours of operation are 8:15 a.m. to 4:45 p.m. Monday through Friday except Federal holidays. Comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 523–5046 or (for FTS) to 8–523–5046, provided the original and 4 copies of the comment are sent to the Docket Officer thereafter. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken on each issue.

All materials submitted will be available for inspection and copying at

this address. All timely submissions will be part of the record of the proceeding.

Information on Hepatitis B Vaccination Issues for the Public Hearing

OSHA seeks to gather additional information related to hepatitis B vaccination during the written comment period and the public hearing. Since the employee's participation in the hepatitis B vaccination program is voluntary, OSHA is particularly interested in existing HBV vaccination programs that have achieved a high degree of voluntary employee compliance. The Agency will attempt to identify those elements that are common to successful programs and will provide this information to all employers. In addition, we are also seeking information on other issues including availability, cost and any potential distribution problems that are associated with initiating the vaccination of large numbers of employees within the 150 day period following the effective date of the standard.

The Agency intends to designate several days of the Washington, DC hearing to focus on the issues surrounding HBV vaccination. We encourage hearing participants whose primary testimony will involve hepatitis B vaccination to indicate this in their Notice of Intention To Appear, and OSHA will attempt to schedule these participants on the days of the hearing that are set aside to focus on Hepatitis B vaccination. Other participants whose testimony will not be primarily on HBV vaccination issues but who wish to address HBV vaccination will be scheduled on another day, but they may enter a separate statement in the record during this period. In any case, participants are free to discuss hepatitis B vaccination or any other issue related to this standard whenever they present their testimony.

Certification of Record and Final Determination After Hearing

Following the close of the hearing, the presiding Administrative Law Judge will certify the record of the hearing to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all testimony and written submissions received as part of the record, and a standard will be issued, based on the entire record of the proceeding, including the written comments and data received from the public.

XI. Authority and Signature

This document was prepared under the direction of Alan C. McMillan, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Accordingly, pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), 29 CFR Part 1911 and Secretary of Labor's Order No. 9–83 (48 FR 35736), 29 CFR Part 1910 is proposed to be amended as set forth below.

List of Subjects in 29 CFR Part 1910

AIDS, Hepatitis B, Human Immunodeficiency Virus, Blood, Blood diseases, Communicable disease, Health, Healthcare, Health professions, Hospitals, Protective equipment, Immunization, Medical research, Occupational safety and health.

Signed at Washington, DC on this 19th day of May, 1989.

Alan C. McMillan,

Acting Assistant Secretary of Labor.

XII. The Proposed Standard

General Industry

Parts 1910 of Title 29 of the Code of Federal Regulations are proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for Subpart Z of 29 CFR Part 1910 continues to read as follows and a new citation for § 1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

Section 1910.1030 also issued under 29 U.S.C. 653.

* * * * *

2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne pathogens.

(a) *Scope and application.* This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) *Definitions.* For purposes of this section, the following shall apply:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

"Blood" means human blood, human blood components and products made from human blood.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Disinfect" means to inactivate virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial endospores) on inanimate objects.

"Engineering Controls" means controls that isolate or remove the hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Infectious Waste" means blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes.

"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. This definition excludes incidental exposures that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment.

"Other Potentially Infectious Materials" means

(1) The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid , amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood.

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead) and

(3) HIV- or HBV-containing cell or tissue cultures, organ cultures, and culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV or HBV.

"Parenteral" means exposure occurring as a result of piercing the skin barrier (e.g. subcutaneous, intramuscular, intravenous routes).

"Patient" means any individual, living or dead, whose blood, body fluids, tissues, or organs may be a source of exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the mentally retarded; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains prior to embalming; and individuals who donate or sell blood or blood components.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee to protect him/her from a hazard.

"Production Facility" means a facility engaged in industrial-scale, large-volume production of HIV or HBV or in high concentration production of HIV or HBV.

"Research Laboratory" means a laboratory producing research-laboratory-scale amounts of HIV or HBV.

"Sharps" means any object that can penetrate the skin including, but not limited to, needles, scalpels, and broken capillary tubes.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Universal precautions" is a method of infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

(c) *Infection control*— (1) *Exposure Determination.* (i) Each employer who has employees with occupational exposure as defined by paragraph (b) of this section shall identify and document those tasks and procedures where occupational exposures may take place.

(ii) Each employer shall identify and document all positions with occupational exposure.

(iii) This exposure determination shall be made without regard to the use of personal protective equipment.

(2) *Infection Control Plan.* (i) Each employer having employees whose reasonably anticipated duties may result in occupational exposure shall establish a written infection control plan designed to minimize or eliminate employee exposure.

(ii) This infection control plan shall contain the following as a minimum:

(A) The exposure determination required by paragraph (c)(1) and

(B) The schedule and method of implementation for each of the applicable paragraphs of this standard.

(iii) This infection control plan shall be reviewed and updated as necessary to reflect significant changes in tasks or procedures.

(iv) The infection control plan shall be made available to the Assistant Secretary and the Director for examination and copying.

(d) *Methods of Compliance*— (1) *General.* Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials, unless those precautions would interfere with the proper delivery of health care or public safety services in a particular circumstance, or would create a significant risk to the personal safety of the worker.

(2) *Engineering and work practice controls.* (i) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(ii) Employees shall wash their hands immediately or as soon as possible after removal of gloves or other personal protective equipment and after hand contact with blood or other potentially infectious materials.

(iii) All personal protective equipment shall be removed immediately upon leaving the work area or as soon as possible if overtly contaminated and placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(iv) Used needles and other sharps shall not be sheared, bent, broken, recapped, or resheathed by hand. Used needles shall not be removed from disposable syringes.

(v) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure.

(vi) Food and drink shall not be stored in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored or in other areas of possible contamination.

(vii) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, and aerosolization of these substances.

(viii) Mouth pipetting/suctioning is prohibited.

(3) *Personal protective equipment*— (i) *Provision and Use.* When there is a potential for occupational exposure, the employer shall provide and assure that the employee uses appropriate personal protective equipment such as, but not limited to, gloves; gowns, fluid-proof aprons, laboratory coats, and head and foot coverings; face shields or masks and eye protection; and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

(ii) *Accessibility.* The employer shall assure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or issued to employees. Hypoallergenic gloves shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iii) *Cleaning.* The employer shall provide for the cleaning, laundering or disposal of personal protective equipment required by paragraphs (d) and (e) of this standard.

(iv) *Repair and replacement.* The employer shall repair or replace required personal protective equipment as needed to maintain its effectiveness.

(v) *Gloves.* Gloves shall be worn when the employee has the potential for the hands to have direct skin contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, and when handling items or surfaces soiled with blood or other potentially infectious materials.

(A) Disposable (single use) gloves, such as surgical or examination gloves, shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. They shall not be washed or disinfected for re-use.

(B) Utility gloves may be disinfected for re-use if the integrity of the glove is not compromised, however they must be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

(vi) *Masks, Eye Protection, and Face Shields.* Masks and eye protection or chin-length face shields shall be worn whenever splashes, spray, spatter, droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.

(vii) *Gowns, Aprons, and Other Protective Body Clothing.* Appropriate protective clothing shall be worn when the employee has a potential for occupational exposure. The type and characteristics will depend upon the task and degree of exposure anticipated; however, the clothing selected shall form an effective barrier.

(A) Gowns, lab coats, aprons, or similar clothing shall be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials.

(B) Fluid-resistant clothing shall be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials.

(C) Surgical caps or hoods shall be worn if there is a potential for splashing or splattering of blood or other potentially infectious materials on the head.

(D) Fluid-proof clothing shall be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials.

(E) Fluid-proof shoe covers shall be worn if there is a potential for shoes to become contaminated and/or soaked with blood or other potentially infectious materials.

(4) *Housekeeping*—(i) *General.* Employers shall assure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement the appropriate written schedule for cleaning and method of disinfection based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed.

(ii) *Cleaning and Disinfection.* All equipment and environmental and working surfaces shall be properly cleaned and disinfected after contact with blood or other potentially infectious materials.

(A) Work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; when surfaces are overtly contaminated; immediately after any spill of blood or other potentially infectious materials; and at the end of the work shift.

(B) Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper may be used to cover equipment and environmental surfaces. These coverings shall be removed and replaced at the end of the work shift or when they become overtly contaminated.

(C) Equipment which may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary.

(D) All bins, pails, cans, and similar receptacles intended for reuse which have a potential for becoming contaminated with blood or other potentially infectious materials shall be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination.

(E) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, a vacuum cleaner, tongs, cotton swabs or forceps.

(F) Specimens of blood or other potentially infectious materials shall be placed in a closable, leakproof container labeled or color-coded according to paragraph (g)(1)(ii) prior to being stored or transported. If outside contamination of the primary container is likely, then a second leakproof container that is labeled or color-coded according to paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, or transport. If puncture of the primary container is likely, it shall be placed within a leakproof, puncture-resistant secondary container.

(G) Reusable items contaminated with blood or other potentially infectious materials shall be decontaminated prior to washing and/or reprocessing.

(iii) *Infectious Waste Disposal.* (A) All infectious waste destined for disposal shall be placed in closable, leakproof containers or bags that are color coded or labeled as required by paragraph (g)(1)(ii) of this standard.

(*1*) If outside contamination of the container or bag is likely to occur then a second leakproof container or bag which is closable and labeled or color-coded as described in paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport.

(*2*) Disposal of all infectious waste shall be in accordance with applicable Federal, state, and local regulations.

(B) Immediately after use, sharps shall be disposed of in closable, puncture resistant, disposable containers which are leakproof on the sides and bottom and that are labeled or color-coded according to paragraph (g)(1)(ii).

(*1*) These containers shall be easily accessible to personnel and located in the immediate area of use.

(*2*) These containers shall be replaced routinely and not allowed to overfill.

(iv) *Laundry.* (A) Laundry from workplaces with employees covered under paragraph (a) of this section that is contaminated with blood or other potentially infectious materials or may contain contaminated sharps shall be treated as if it were contaminated and shall be handled as little as possible and with a minimum of agitation.

(*1*) Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient-care areas.

(*2*) Contaminated laundry shall be placed and transported in bags that are labeled or color-coded as described in paragraph (g)(1)(ii). Whenever this laundry is wet and presents the potential for soak-through of or leakage from the bag, it shall be placed and transported in leakproof bags.

(B) The employer shall ensure that laundry workers wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure during handling or sorting.

(e) *HIV and HBV Research Laboratories and Production Facilities.* (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) *Standard microbiological practices.* All infectious liquid or solid waste shall be decontaminated before being disposed of.

(ii) *Special practices.* (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons only. Policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with the provisions outlined in paragraph (g)(1)(i) of this standard.

(E) All activities involving potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work shall be conducted in open vessels on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work

area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contamination with potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with potentially infectious materials is unavoidable.

(H) All waste from work areas including animal rooms shall be decontaminated before disposal.

(I) Vacuum lines shall be protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of potentially infectious fluids. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before being discarded or reused.

(K) Spills and accidents that result in overt exposures of employees to potentially infectious materials shall be immediately reported to the laboratory director or other responsible person.

(L) A biosafety manual shall be prepared or adopted. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) *Containment equipment.* (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a sink for hand washing.

(ii) An autoclave for decontamination of infectious laboratory waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The interior surfaces of walls, floors and ceilings shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination of the work area.

(iii) Each work area shall contain a sink for washing hands. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of infectious waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) Training requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(v).

(f) Hepatitis B Vaccination and Post Exposure Follow-up—(1) *General.* (i) The employer shall make available hepatitis B vaccination to all employees who have occupational exposure on average one or more times per month and post-exposure follow-up for all employees with an occupational exposure incident.

(ii) The employer shall assure that all medical evaluations and procedures are performed by or under the supervision of a licensed physician and that all laboratory tests are conducted by an accredited laboratory.

(iii) The employer shall assure that all evaluations, procedures, vaccinations, and post-exposure management are provided to the employee at a reasonable time and place, and according to standard recommendations for medical practice.

(2) *HBV Vaccination.* (i) HBV vaccination shall be offered to all employees occupationally exposed on an average of one or more times per month to blood or other potentially infectious materials, unless the employee has a previous HBV vaccination or unless antibody testing has revealed that the employee is immune. If the employee initially declines HBV vaccination but at a later date while still covered under the standard decides to accept the HBV vaccine, the employer shall provide the vaccine at that time. Should a booster dose(s) be recommended at a future date, such booster dose(s) shall be provided according to standard recommendations for medical practice.

(ii) HBV antibody testing shall be made available to an employee who desires such testing prior to deciding whether or not to receive HBV vaccination. If the employee is found to be immune to HBV by virtue of adequate antibody titer, then the employer is not required to offer the HBV vaccine to that employee.

(3) *Post exposure evaluation and follow-up.* Following a report of an exposure incident, the employer shall make available to each employee covered by paragraph (a) a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, HBV and HIV antibody status of the source patient(s) (if known), and the circumstances under which the exposure occurred.

(ii) If the source patient can be determined and permission is obtained, collection of and testing of the source patient's blood to determine the presence of HIV or HBV infection.

(iii) Collection of blood from the exposed employee as soon as possible after the exposure incident for the determination of HIV and/or HBV status. Actual antibody or antigen testing of the blood or serum sample may be done at that time or at a later date if the employee so requests.

(iv) Follow-up of the exposed employee including antibody or antigen testing, counseling, illness reporting, and safe and effective post-exposure

prophylaxis, according to standard recommendations for medical practice.

(4) *Information provided to the physician.* The employer shall provide the following information to the evaluating physician:

(i) A copy of this regulation and its appendices and

(ii) A description of the affected employee's duties as they relate to the employee's occupational exposure.

(5) *Physician's written opinion.* For each evaluation under this section, the employer shall obtain and provide the employee with a copy of the evaluating physician's written opinion within 15 working days of the completion of the evaluation. The written opinion shall be limited to the following information:

(i) The physician's recommended limitations upon the employee's ability to receive hepatitis B vaccination.

(ii) A statement that the employee has been informed of the results of the medical evaluation and 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.

(iii) Specific findings or diagnoses, which are related to the employee's ability to receive HBV vaccination. Any other findings and diagnoses shall remain confidential.

(6) *Medical recordkeeping.* Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) *Communication of Hazards to Employees*—(1) *Signs and Labels*—(i) *Signs.* The employer shall post signs at the entrance to work areas specified in paragraph (e) of this standard which shall bear the following legend:

BIOHAZARD



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

(ii) *Labels.* (A) Warning labels shall be affixed to containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials except as provided in paragraph (g)(1)(ii) (E) and (F).

(B) Labels required by this section shall include the following legend:

BIOHAZARD



(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by paragraph (g)(1)(ii) shall either be an integral part of the container or shall be affixed as close as safely possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels on containers of infectious waste.

(F) Containers of blood or blood components that are labeled as to their contents and have been released for distribution are exempted from the labeling requirements of paragraph (g).

(2) *Information and Training.* (i) Employers shall ensure that all employees with occupational exposure participate in a training program.

(ii) Training shall be provided at the time of initial employment or within 90 days after the effective date of this standard and at least annually thereafter.

(iii) Material appropriate in content and vocabulary to educational level, literacy, and language background of employees shall be used.

(iv) The training program shall contain the following elements:

(A) A copy of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's infection control program.

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

(F) An explanation of the use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated.

(J) Information on the appropriate actions to take and persons to contact in an emergency;

(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. Also information on the medical counseling that the employer is providing for exposed individuals; and

(L) An explanation of the signs and labels and/or color coding required by paragraph (g)(1).

(v) Additional training. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following training in addition to the above training requirements:

(A) Employees shall be trained in and demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) Employees shall be experienced in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.

(C) A training program shall be provided to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed.

The employee shall participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) *Recordkeeping*—(1) *Medical records.* (i) The employer shall establish and maintain an accurate record for each employee subject to paragraph (f) of this section, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) A copy of the employee's hepatitis B vaccination records and medical records relative to the employee's ability to receive vaccination or the circumstances of an exposure incident;

(C) A copy of all results of physical examinations, medical testing, and follow-up procedures as they relate to the employee's ability to receive vaccination or to post exposure evaluation following an exposure incident;

(D) The employer's copy of the physician's written opinion; and

(E) A copy of the information provided to the physician as required by paragraphs (f)(4).

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (f) are:

(A) Kept confidential; and

(B) Are not disclosed or reported to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain this record for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records.* (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names of persons conducting the training; and

(D) The names of all persons attending the training sessions.

(ii) These records shall be maintained for 5 years.

(3) *Availability.* (i) The employer shall assure 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.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical and training 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, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) *Transfer of records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(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.

(i) *Dates*—(1) Effective Date. The standard shall become effective on [Insert date 30 days after publication in the **Federal Register**].

(2) Exposure Determination. The exposure determination required by paragraph (c)(1) of this section shall be completed within 90 days of the effective date of this standard.

(3) Infection Control Plan. The Infection Control Plan required by paragraph (c)(2) of this section shall be completed within 120 days of the effective date of this standard.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping shall take effect 150 days after the effective date of this standard. OSHA expects that the employer will have initiated, but perhaps not completed, the HBV vaccination series within this time period.

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