Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors'' dated July 2001. The guidance document provides recommendations for blood establishments in integrating current CLIA requirements for when to invalidate donor test results based on CLIA required control reagents. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors'' announced in the **Federal Register** of September 1, 1999 (64 FR 47847). The guidance document also supersedes the January 3, 1994 guidance document entitled ''Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking with regard to the invalidation of test results based on the CLIA required control reagents. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of this guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17255 Filed 7–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank; Change in User Fee

The Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS), is announcing a one dollar increase in the fee charged to entities authorized to request information from the National Practitioner Data Bank (NPDB) for all queries. The new fee will be $5.00 and there, will be no change to the $10.00 self-query fee.

The current fee structure ($4.00 per name) was announced in the **Federal Register** on January 29, 1998 (63 FR 4460). All entity queries are submitted and query responses received through the NPDB's Integrated Query and Reporting Service (IQRS) and paid via an electronic funds transfer or credit card.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Public Law 99–660, as amended (42 U.S.C. 11101 *et seq.*). Section 427(b)(4) of the Act authorizes the establishment of fees for the costs of processing requests for disclosure and of providing such information.

Final regulations at 45 CFR part 60 set forth the criteria and procedures for information to be reported to and disclosed by the NPDB. Section 60.3 of these regulations defines the terms used in this announcement.

In determining any changes in the amount of the user fee, the Department uses the criteria set forth in § 60.12 (b) of the regulations, as well as allowable costs pursuant to Title II of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill for Fiscal Year 2001, P.L. 106–554, enacted Dec. 21, 2000. This Act requires that the Department recover the full costs of operating the Data Bank through user fees. Paragraph (b) of the regulations states:

''The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer the actual cost of the special service.''

Based on analysis of the comparative costs of the various methods for filing and paying for queries, the Department is raising all the entity query fees by $1.00 per name. The practitioner self-query fee remains at $10. This price increase is necessitated by increased technical labor costs, equipment upgrades, and improvements to the NPDB's computer system. Since the last fee increase, the system has been migrated from QPRAC, a dial-up client server system, to the web-based IQRS. The IQRS provides a secure mechanism for faster, more convenient, reporting and querying.

This change is effective October 1, 2001.

When a query is for information on one or more physicians, dentists, or other health care practitioners, the appropriate fee will be $5.00 multiplied by the number of individuals about whom information is being requested. For examples, see the table below.

The Department will continue to review the user fee periodically, and will revise it as necessary. Any changes in the fee and their effective date will be announced in the **Federal Register**.

Query method	Fee per name in query	Examples
Entity query (Via Internet with electronic payment).	$5.00	10 names in query. 10x$5=$50.00.
Practitioner self-query	10.00	One self-query=$10.00.

Dated: July 6, 2001.

Elizabeth M. Duke,

Acting Administrator.

[FR Doc. 01–17409 Filed 7–10–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Validation of Questionnaires Used for Occupational Exposure Assessment in Case-Control Studies: Occupational History Questionnaire With Foundry Worker and Textile Industry Job Modules

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 11, 2001, page 2433, Volume 66, No. 8, and allowed 60 days for public comment. No public comments were received. NCI fulfilled only one request for a copy of the study protocol and questionnaire.

The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, and information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Validation of Questionnaires Used for Occupational Exposure Assessment in Case-Control Studies: Occupational History Questionnaire with Foundry Worker and Textile Industry Job Modules. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will investigate the validity and reliability of exposure assessments based on occupational history questionnaires supplemented with industry specific job modules as compared to exposure assessments made based on actual measurement taken in the workplace environments. The results will be used to assess the potential magnitude of exposure misclassification in case-control studies using these types of exposure assessment methods. *Frequency of Response:* One time study. *Affected Public:* Large and small factories in Shanghai, China. *Type of Respondents:* Factory workers. The annual burden is as follows: *Estimated Number of Respondents:* 120; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Respondent:* 0.5 hours; and *Estimated Total Annual Burden Hours Requested:* 60. There are no annualized costs to respondents. There are no Capital Costs to report and no Operating or Maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Joseph Coble, Project Officer, National Cancer Institute, 6120 Executive Blvd, EPS 8110, Rockville, MD, 20892–7240, or call non-toll-free number (301) 435–4702, email your request to *jcoble@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before August 10, 2001.

Dated: July 2, 2001.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01–17281 Filed 7–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Natural Killer Cells in Xenotransplantation and Establishment of a Target Cell Line Producing Porcine Endogenous Retrovirus

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention described below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development.

ADDRESSES: Licensing information for the technology described below may be obtained by contacting John Rambosek, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 270; fax: 301/402–0220; e-mail: rambosej@od.nih.gov.

SUPPLEMENTARY INFORMATION: The worldwide shortage of human organs and tissues for allotransplantation combined with recent advances in transplantation immunobiology, surgery and medicine, have sparked renewed interest in the clinical use of xenotransplantation, the use of living nonhuman animal materials for the treatment of human diseases. In addition to whole organ transplants, cellular implants and ex vivo use of living material from animal sources have been suggested for treatment of disease in human patients. For a variety of reasons, the pig is currently the source animal of choice for xenotransplantation in humans, but there are two major obstacles to successful pig to human xenotransplantation. These are the immune response, responsible for rejecting xenotransplants, and the risk of transmission of infection including porcine endogenous retrovirus, which, at least at the present time, cannot be removed from the xenotransplantation porcine source. Natural killer (NK) cells play an important role in the delayed rejection of xenotransplants, and have been shown to infiltrate rejecting grafts.

Current efforts in the Laboratory of Immunology and Virology, Division of Cellular and Gene Therapies, Center for Biologics Evaluation and Research,