Dated: April 1, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–7937 Filed 4–7–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–32–04]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Final Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

In 1998 the Food and Drug Administration (FDA) issued guidelines to blood collection establishments and transfusion services for the notification of persons who received blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen screening assay. Blood collection establishments were to identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services made an attempt to notify the recipients of these products and encouraged recipients to be tested for HCV infection. Recently, the FDA revised their original guidance to extend the lookback period for these multiantigen screened donors, and include in the lookback process donors who tested anti-HCV positive using the earlier single-antigen screening assay.[1]

CDC, in collaboration with the FDA, has been charged with the responsibility of evaluating this nationwide notification process. An interim nationwide survey (Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus, OMB No. 0920–0462) of blood collection establishments and transfusion services was conducted in December 1999 to determine the progress that had been made to date, and to summarize the lookback results. The objective of this currently proposed study is to resurvey the blood collection establishments and transfusion services to obtain final results and assess the overall effectiveness of the targeted lookback for identifying persons infected with HCV. The evaluation has two specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are still alive, the proportion of those alive who were successfully notified, the proportion of those notified who have already been tested, the proportion of those notified who get tested as a result of the notification, and the proportion of those tested who are HCV positive.

2. Determine the cost-effectiveness of targeted lookback, including resources (person-hours, costs of recipient notification and testing, etc.) utilized by blood collection establishments and transfusion services for implementation of the lookback protocol.

The evaluation will include the following components: (1) A nationwide survey of blood collection establishments; (2) A nationwide survey of transfusion services. The estimated annualized burden is 15,480 hours.

Survey site	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Blood Collection Establishment	HCV Targeted Lookback Blood Collection Establishment Final Questionnaire.	160	1	3
Transfusion Services	HCV Targeted Lookback Transfusion Service Final Questionnaire.	5,000	1	3

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BILLING CODE 4163–18–P

[1] Food and Drug Administration. Guidance For Industry. "Lookback'' for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV Rockville, MD: Center for Biologics Evaluation and Research (CBER), December 2001.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Grants for Education Programs in Occupational Safety and Health; Notice of Availability of Funds

Announcement Type: New and Competing Continuation.

Funding Opportunity Number: RFA OH05–001.

Catalog of Federal Domestic Assistance Number: 93.263.

Key Dates:

Letter of Intent Deadline: None.

Pre-Application Technical Assistance Conference Call: May 13, 2004 (see Section VIII of this announcement).

Application Deadline: July 1, 2004.

Executive Summary: The Centers for Disease Control and Prevention (CDC)

announces the availability of fiscal year (FY) 2005 funds for a grant program for institutional training grants in occupational safety and health. The National Institute for Occupational Safety and Health (NIOSH) is mandated to provide an adequate supply of qualified personnel to carry out the purposes of the Occupational Safety and Health Act. Projects are funded to support Occupational Safety and Health Education and Research Center Training Grants (ERCs) and Training Project Grants (TPGs). ERCs are academic institutions that provide interdisciplinary graduate training and continuing education in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields. The ERCs also serve as regional resource centers for industry, labor, government, and the public. TPGs are academic institutions that primarily provide single-discipline graduate training in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields.

I. Funding Opportunity Description

Authority: This program is authorized under section 670(a) of the Occupational Safety and Health Act [29 U.S.C. 670(a)].

Purpose: The purpose of the program is to provide financial assistance to eligible applicants to assist in providing an adequate supply of qualified professional occupational safety and health personnel. This program addresses the "Healthy People 2010'' focus area of Occupational Safety and Health.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Institute for Occupational Safety and Health: Ensure safer and healthier work environments for Americans through information dissemination, knowledge transfer, and training.

Activities

In conducting activities to achieve the purpose of this program, the awardee will be responsible for the following activities that define the ERC and TPG programs to be conducted:

1. *All Applicants* are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various objectives of the grant. Measures must be objective/quantitative and must measure the intended outcomes. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

2. *ERC Applicants* shall be an identifiable organizational unit within the sponsoring organization. Applicants must plan to conduct the following activities in order to be considered for an award. If the activities are not proposed, the application will be considered non-responsive and will be returned to the applicant without a review.

a. Establish cooperative arrangements with a medical school or teaching hospital (with an established program in preventive or occupational medicine), a school of nursing or its equivalent, a school of public health or its equivalent, or a school of engineering or its equivalent. It is expected that other schools or departments with relevant disciplines and resources shall be represented and shall contribute as appropriate to the conduct of the total program, *e.g.*, epidemiology, toxicology, biostatistics, environmental health, law, business administration, and education. Specific mechanisms to implement the cooperative arrangements between departments, schools/colleges, universities, etc., shall be demonstrated in order to assure that the intended interdisciplinary training and education will be engendered.

b. Designate an ERC Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational health and safety education and training. The Director shall oversee the general operation of the ERC Program and shall, to the extent possible, directly participate in training activities. A Deputy Director shall be responsible for managing the daily administrative duties of the ERC and to increase the ERC Director's availability to ERC staff and to the public.

c. Designate Program Directors who are full-time faculty and professional staff representing various disciplines and qualifications relevant to occupational safety and health that are capable of planning, establishing, and carrying out or administering training projects undertaken by the ERC. Each academic program, as well as the continuing education and outreach program, shall have a Program Director.

d. Designate faculty and staff with demonstrated training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

e. Establish a program for conducting education and training for four core disciplines: Occupational physicians, occupational health nurses, industrial hygienists, and occupational safety personnel. ERC core academic programs are intended to provide multi-level practitioner and research training. Core academic programs should offer masters degrees and, in research institutions, doctoral degrees. There shall be a minimum of five full-time students or full-time equivalent students in each of the core programs and a minimum of three full-time students or full-time equivalent students in each of the component programs, with a goal of a minimum of 30 full-time students (total in all of core and component programs together). ERCs are encouraged to recruit and train minority students to help address the under-representation of minorities among the occupational safety and health professional workforce. Although it is desirable for an ERC to have the full range of core programs, an ERC with a minimum of three academic programs of which two are in the core disciplines is eligible for support providing it is demonstrated that students will be exposed to the principles and issues of all four core disciplines. In order to maximize the unique strengths and capabilities of institutions, consideration will be given to the development of new and innovative academic component programs that are relevant to the occupational safety and health field, *e.g.*, ergonomics, industrial toxicology, occupational injury prevention, occupational epidemiology, health services research, and agricultural safety and health; and to innovative technological approaches to training and education. ERCs must also document that the program covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. Each core program curriculum shall include courses from non-core categories as well as appropriate clinical rotations and field experiences with public health and safety agencies and with labor-management health and safety groups. Where possible, field experience shall involve students representing other disciplines in a manner similar to that used in team surveys and other team approaches. ERCs should address the importance of providing training and education content related to special populations at risk, including minority workers and other sub-populations specified in the National Occupational Research Agenda (NORA) special populations at risk category. Further information regarding NORA may be found at the CDC/NIOSH Internet address: *http://www.cdc.gov/niosh/nora/*.

f. Establish a specific plan describing how trainees in core and component

academic programs will be exposed to the principles of all other occupational safety and health core and allied disciplines. ERCs that apply as a consortium (contracting with other institutional partners) generally have geographic, policy and other barriers to achieving this ERC characteristic and, therefore, must give special, innovative, attention to thoroughly describing the approach for fulfilling interdisciplinary interaction between students.

g. Demonstrate impact of the ERC on the curriculum taught by relevant medical specialties, including family practice, internal medicine, dermatology, orthopedics, pathology, radiology, neurology, perinatal medicine, psychiatry, *etc.,* and on the curriculum of undergraduate, graduate and continuing education of primary core disciplines as well as relevant medical specialties and the curriculum of other schools such as engineering, business, and law.

h. Establish an outreach program to interact with and help other institutions or agencies located within the region. Programs shall be designed to address regional needs and implement innovative strategies for meeting those needs. Partnerships and collaborative relationships shall be encouraged between ERCs and TPGs. Programs to address the under-representation of minorities among occupational safety and health professionals shall be encouraged. Specific efforts should be made to conduct outreach activities to develop collaborative training programs with academic institutions serving minority and other special populations, such as Tribal Colleges and Universities, Historically Black Colleges and Universities, and Hispanic-Serving Institutions. Examples of outreach activities might include: interaction with other colleges and schools within the ERC and with other universities or institutions in the region to integrate occupational safety and health principles and concepts within existing curricula (*e.g.*, Colleges of Business Administration, Engineering, Architecture, Law, and Arts and Sciences); exchange of occupational safety and health faculty among regional educational institutions; providing curriculum materials and consultation for curriculum/course development in other institutions; use of a visiting faculty program to involve labor and management leaders; cooperative and collaborative arrangements with professional societies, scientific associations, and boards of accreditation, certification, or licensure; and presentation of awareness seminars to undergraduate and secondary educational institutions (*e.g.*, high school science fairs and career days) as well as to labor, management and community associations.

i. Establish a specific plan for preparing, distributing and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel from labor-management health and safety committees, in the geographical region in which the ERC is located. The goal shall be that the training be made available to a minimum of 400 trainees per year representing all of the above categories of personnel, on an approximate proportional basis with emphasis given to providing occupational safety and health training to physicians in family practice, as well as industrial practice, industrial nurses, and safety engineers. Priority shall be given to establishing new and innovative training technologies, including distance learning programs and to short-term programs designed to prepare a cadre of practitioners in occupational safety and health. Where appropriate, it shall be professionally acceptable that Continuing Education Units (as approved by appropriate professional associations) may be awarded. These courses should be structured so that higher educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational health and safety personnel working in the workplace. Further, the ERC shall conduct periodic training needs assessments, shall develop a specific plan to meet these needs, and shall have demonstrated capability for implementing such training directly and through other institutions or agencies in the region. The ERC should establish and maintain cooperative efforts with labor unions, government agencies, and industry trade associations, where appropriate, thus serving as a regional resource for addressing the problems of occupational safety and health that are faced by State and local governments, labor and management.

j. Establish a Board of Advisors representing the user and affected population, including representatives of labor, industry, government agencies, academic institutions and professional associations, shall be established by the ERC. The Board should meet at least annually to advise an ERC Executive Committee and to provide periodic evaluation of ERC activities. The Executive Committee shall be composed of the ERC Director and Deputy Director, academic Program Directors, the Director for Continuing Education and Outreach and others whom the ERC Director may appoint to assist in governing the internal affairs of the ERC.

k. Establish a plan to incorporate research training into all aspects of training and, in research institutions, as documented by on-going funded research and faculty publications, a defined research training plan for training doctoral-level researchers in the occupational safety and health field. The plan will include how the ERC intends to strengthen existing research training efforts, how it will integrate research training activities into the curriculum, field and clinical experiences, how it will expand these research activities to have an impact on other primarily clinically-oriented disciplines, such as nursing and medicine, and how it will build on and utilize existing research opportunities in the institution. Each ERC is required to identify or develop a minimum of one, preferably more, areas of research focus related to work environment problems. Consideration should be given to the CDC/NIOSH priority research areas identified in the National Occupational Health Research Agenda (NORA). The research training plan will address how students will be instructed and instilled with critical research perspectives and skills. This training will emphasize the importance of developing and working on interdisciplinary teams appropriate for addressing a research issue. It should also prepare students with the skill necessary for developing research protocols, pilot studies, outreach efforts to transfer research findings into practice, and successful research proposals. Such components of research training will require the ERCs to strive toward developing the faculty composition and administrative infrastructure essential to being Centers of Excellence in Occupational Safety and Health Research Training that are required to train research leaders of the future. The plan should address the incremental growth of such elements and evaluation of the plan commensurate with funds available. In addition to the research training components, the plan will also include such items as specific strategies for obtaining student and faculty funding, plans for acquiring equipment, if appropriate, and a plan for developing research-oriented faculty.

l. Document evidence of support from other sources, including other Federal

grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

3. *TPG Applicants* must plan to conduct an academic program that covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. There shall be a minimum of three full-time students or full-time equivalent students in each academic program. Applicants should address the importance of providing training and education content related to special populations at risk, including minority and disadvantaged workers. The types of training currently eligible for support are:

a. Graduate training for practice, teaching, and research careers in occupational safety and health. Priority will be given to programs producing graduates in areas of greatest occupational safety and health need. Strong consideration will be given to the establishment of innovative training technologies.

b. Undergraduate and other pre-baccalaureate training providing trainees with capabilities for positions in occupational safety and health professions.

c. Special technical or other programs for long-term training of occupational safety and health technicians or specialists.

II. Award Information

Type of Award: Grant.

Fiscal Year Funds: 2005.

Approximate Total Funding: $6,500,000. See *Funding Preferences* below for a breakdown of funding and awards by category.

Approximate Number of Awards: 20.

Approximate Average Award: $656,000 for ERCs and $83,000 for TPGs. (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: None.

Anticipated Award Date: July 1, 2005.

Budget Period Length: 12 months.

Project Period Length: Maximum of 5 years. Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

Funding Preferences: These awards are intended to augment the scope, enrollment, and quality of training programs rather than to replace funds already available for current operations.

Funding for ERCs: Approximately $4,660,000 of the total funds available will be utilized as follows:

1. Approximately $3,250,000 is available to award five competing continuation or new ERC grants. This includes a total of $190,000 to augment the support of trainees in occupational medicine residency programs. Awards will range from $500,000 to $800,000 with the average award being $650,000.

2. Approximately $180,000 is available to award three competing continuation or new training grants; two of the awards are planned for $120,000 for Hazardous Substance Academic Training (HSAT) Programs and one of the awards is planned for $60,000 for a Hazardous Substance Training (HST) Program. The awards are to support the development and presentation of continuing education and short courses (HST Programs), and academic curricula (HSAT Programs) for trainees and professionals engaged in the management of hazardous substances. Program support is available for faculty and staff salaries, trainee costs, and other costs to provide training and education for occupational safety and health and other professional personnel engaged in the evaluation, management, and handling of hazardous substances.

3. Approximately $70,000 is available to award one competing continuation or new grant to support the enhancement of the ERC research training mission through the support of pilot project research training programs.

4. Approximately $1,160,000 is available to award five competing continuation or new grants to support the enhancement of the ERC research training mission through the support of National Occupational Research Agenda (NORA) research support programs. The ERCs represent a variety of strengths and approaches that are required in order to promote high quality research in occupational safety and health, and are a major vehicle for the development of future leaders in occupational safety and health research. They are structured to foster development of interdisciplinary research skills that are needed to effectively address the NORA priority areas and are a critical link to practicing occupational safety and health professionals and others to translate research findings into interventions that prevent illness and injury in the workplace. Examples of activities that support the implementation of the National Occupational Research Agenda include: Assessing regional needs for research and research training in NORA areas; providing administrative and technical support for conducting research, including the administrative support of Pilot Project Research Training Programs; coordinating interdisciplinary research among graduate students; training graduate students in research principles, including students whose theses are in NORA priority areas, and training students who become occupational safety and health professionals to implement NORA findings in evidence-based practice; and, administering outreach and continuing education activities that bring NORA-related research findings to those who can effect changes that will reduce worker illness and injury.

Funding for TPGs: Approximately $1,200,000 is available to fund fourteen competing continuation or new TPG grants. Awards will range from $40,000 to $250,000, with the average award being $85,000. This includes a total of $75,000 to augment the support of trainees in occupational medicine residency programs. These awards will support academic programs in the core disciplines (*i.e.*, industrial hygiene, occupational health nursing, occupational medicine, and occupational safety and ergonomics) and relevant component programs (*e.g.*, occupational injury prevention, industrial toxicology, and ergonomics).

Funding for ERCs and TPGs: Approximately $750,000 is available to fund three competing continuation or new grants for occupational health services research training programs. Awards will range from $200,000 to $290,000, with the average award being $250,000. This program is intended to encourage new occupational health services research training programs and will only support doctoral-level training and trainees.

III. Eligibility Information

III.1. Eligible applicants

Any public or private non-profit university, college, educational or training institution that has demonstrated competency in the occupational safety and health field and is located in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, Wake Island, Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act, Johnston Island, and any other U.S. Territory or Trust Territory not named herein are eligible to apply for an institutional training grant.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applicants must demonstrate competency by providing within the grant application, documentation of faculty training and experience in the occupational safety and health field being proposed, and an approved curriculum with course work in the occupational safety and health field.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form CDC 2.145A (OMB Number 0920–0261). Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 15 pages single-spaced per program. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.
- Use standard size, black letters that can be clearly copied. Do not use photo reduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied. Do not include course catalogue and course brochures. When additional space is needed to complete any of the items, use plain white paper (8.5 x 11 inches), leave one inch margins on each side, identify each item by its title, and type the name of the program director and the grant number (if the application is a competitive renewal) in the upper right corner of each page. All pages, including Appendices should be numbered consecutively at least one-half inch from the bottom edge.

Your narrative should address activities to be conducted over the entire project period, and must include the items specified in the "Recommended Outline for Preparation of Competing New/Renewal Training Grant Applications (CDC 2.145A)'' available at the CDC Internet address listed in Section IV.1. The budget and budget justification pages will not be counted in the stated page limit. Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section *VI.2. Administrative and National Policy Requirements.*

IV.3. Submission Dates and Times

Application Deadline Date: July 1, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- At least 50 percent of the funds awarded for each grant must be used for direct trainee expenses. Post-doctoral trainee support is discouraged with the exception of occupational medicine residents. Under this announcement, only one award will be made to any single institution or organization.
- Trainee appointments for support can only be made for students enrolled in academic programs that have been recommended for approval by NIOSH, as noted in the Summary Statement.
- Indirect costs under the training grant program will be reimbursed at 8 percent of total allowable direct costs exclusive of tuition and related fees, and equipment, or at the actual indirect cost rate, whichever results in a lesser dollar amount.
- Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—RFA OH05–001, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goals stated in the "Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

The Special Emphasis Panel will evaluate each application against the following criteria:

1. *ERC Comprehensive Evaluation Criteria* are as follows:

a. Plans to satisfy the regional needs for training in the areas outlined by the application, including projected enrollment, recruitment and current workforce populations. Special consideration should be given to the development of programs addressing the under-representation of minorities among occupational safety and health professionals. Indicators of regional need should include measures utilized by the ERC such as previous record of training and placement of graduates. The need for supporting students in allied disciplines must be specifically justified in terms of user community requirements.

b. Are plans proposed for day-to-day management, allocation of funds and cooperative arrangements designed to effectively achieve the Characteristics of an Education and Research Center (see Activities: 2. ERC Applicants).

c. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration should be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

d. Does the curriculum content and design include formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence, additional related courses open to occupational safety and health students, time devoted to lecture, laboratory and field experience, and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process?

e. Academic training including the number of full-time and part-time students and graduates for each core and component program, the placement of graduates, employment history, and their current location by type of institution (academic, industry, labor, *etc.*). Previous continuing education training in each discipline and outreach activity and assistance to groups within the ERC region.

f. Methods in use or proposed methods for evaluating the effectiveness of training and outreach including the use of placement services and feedback mechanisms from graduates as well as employers, innovative strategies for meeting regional needs, critiques from continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

g. Competence, experience and training of the ERC Director, the Deputy ERC Director, the Program Directors and other professional staff in relation to the type and scope of training and education involved.

h. Institutional commitment to ERC goals. An example of institutional commitment to the long-term stability of ERC programs is the commitment of tenured or tenure-track faculty positions to each participating academic program.

i. Academic and physical environment in which the training will be conducted, including access to appropriate occupational settings.

j. Is the budget adequate, justified, and consistent with the intended use of the grant funds? This includes a separate budget for the academic staff's time and effort in continuing education and outreach.

k. Evidence of the integration of research experience into the curriculum, and field and clinical experiences. In institutions seeking funds for doctoral level research training, evidence of a plan describing the research and research training the ERC proposes. This should include goals, elements of the program, research faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

l. Evidence of success in attaining outside support to supplement the ERC grant funds including other Federal grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

m. Evidence of a strategy to evaluate the impact that the ERC and its programs have had on the region served by the Center. Examples could include a continuing education needs assessment and action plan, a workforce needs survey and action plan, consultation and research programs provided to address regional occupational safety and health problems, the impact on primary care practice and training, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

n. Past performance based on evaluation of the most recent CDC/NIOSH Peer Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

2. *ERC Specialty Program Evaluation Criteria are as follows:*

a. Hazardous Substance Training Program in Education and Research Centers:

(1) Relevance of the proposed project to each element of the characteristics of a hazardous substance training program.

(2) Comprehensiveness and soundness of the training plan developed to carry out the proposed activities. This is based on a documented need for the training and evidence to support the approach used to provide the required training. It includes descriptions of the scope and magnitude of the hazardous substance problem in the region served by the ERC and current activities and training efforts.

(3) Education and experience of the Project Director, faculty, and staff assigned to this project with respect to handling, managing or evaluating hazardous substance sites and to the training of professionals in this field.

(4) Creativity and innovation of the project leadership with respect to marketing the courses, structure in attracting trainees and/or providing incentives for training.

(5) Has the applicant considered the work of relevant agencies involved in hazardous substance activities, including EPA, and cooperated with

these agencies in developing and implementing this training program?

(6) Suitability of facilities and equipment available for this project.

(7) Is the budget adequate, justified, and consistent with the intended use of the grant funds?

b. Hazardous Substance Academic Training Program in Education and Research Centers:

(1) Evidence of a needs assessment directed to the overall contribution of the proposed training program toward meeting the needs of the job market, especially within the applicant's region. The needs assessment should consider the regional requirements for hazardous substance training, information dissemination and special industrial, labor or community training needs that may be peculiar to the region.

(2) Evidence of a plan to satisfy regional needs for training in the areas outlined by the application, including Program projected enrollment and recruitment and current workforce populations.

(3) Does the HSAT curriculum content and design include: formalized training objectives; minimal course content to achieve a degree or successful completion of the specialty area requirements; course descriptions; course sequence; additional related courses open to occupational safety and health students; time devoted to lecture, laboratory, and field experience; and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process?

(4) Evidence that all trainees supported in the HSAT program have successfully completed a 40-hour Hazardous Waste Operations training course, or equivalent, to meet the requirements of 29 CFR 1910.120 (e)(3)(i). This training requirement may be accomplished prior to enrollment in the HSAT program of study.

(5) Previous record of academic and/or short course training delivered in the hazardous substances field, including the number and type of students trained. Previous record of hazardous substances outreach activity and assistance to hazardous substance groups within the ERCs region.

(6) Methods in use or proposed for evaluating the effectiveness of training and services including the use of placement services and feedback mechanisms from graduates as well as employers, student evaluations from academic and continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

(7) The competence, experience and training of the Program Director and other professional staff in relation to the type and scope of training and education involved.

(8) Institutional commitment to HSAT Program goals.

(9) Academic and physical environment in which the training will be conducted.

(10) Is the budget adequate, justified, and consistent with the intended use of the grant funds? This includes the budget required to support the training courses developed, as well as accounting for the academic staff's time.

(11) Evidence of a plan describing the hazardous substances academic training the Center proposes. This should include goals, elements of the program, faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

(12) Evidence of success in attaining outside support to supplement the ERC grant funds including other federal grants, support from states and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

(13) Has the applicant collaborated with state and federal agencies having hazardous substance management functions, including the U.S. Environmental Protection Agency, and has the applicant cooperated with the agencies in developing and implementing this program?

c. ERC Pilot Project Research Training Programs:

(1) Relevance of the proposed program, including objectives that are specific and consistent.

(2) Adequacy of the plan proposed to conduct the pilot projects program, including procedures for reviewing and funding projects, the scientific review mechanism, and program quality assurance.

(3) Does the applicant demonstrate collaboration with other research training institutions in the region, including NIOSH Training Project Grantees?

(4) Education and experience of the proposed Research Training Program Director and faculty in the occupational safety and health field, including the utilization of pilot projects as a research training mechanism.

(5) Is the budget adequate, justified, and consistent with the intended use of the grant funds?

(6) Adequacy of the plan to evaluate the effectiveness of the proposed pilot projects program.

(7) Gender and minority issues—Are plans to include women, ethnic, and racial groups adequately developed (as appropriate for the scientific goals of the pilot projects)? (See AR–2, Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.)

d. ERC NORA Research Support Programs:

(1) Adequacy of a detailed plan at the ERC level that will promote high quality NORA research and research training activities within the ERC and the region.

(2) Does the plan outline the approaches and mechanisms that will be used by the ERC to carry out interdisciplinary research and research training activities?

(3) Education and experience of the proposed Program Director, faculty, and staff in the occupational safety and health research training field.

(4) Academic and physical environment, including laboratories and equipment, in which research training will be conducted.

(5) Is the budget adequate, justified, and consistent with the intended use of the grant funds? Training grant funds may not be used to fund research projects. Some examples of how funds may be used for NORA-related research project technical support include laboratory supplies, training-related equipment, data entry/analysis, and technicians who work on multiple projects and thus enhance faculty ability to carry out training.

3. *TPG Evaluation Criteria* are as follows:

a. Need for training in the program area outlined by the application. This should include documentation of a plan for student recruitment, projected enrollment, job opportunities, regional need both in quality and quantity, and for programs addressing the under-representation of minorities in the profession of occupational safety and health.

b. Potential contribution of the project toward meeting the needs for graduate or specialized training in occupational safety and health.

c. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration should be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

d. Curriculum content and design which should include formalized

program objectives, minimal course content to achieve degree, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, nature and the interrelationship of these educational approaches. There should also be evidence of integration of research experience into the curriculum, and field and clinical experiences.

e. Previous records of training in this or related areas, including placement of graduates.

f. Methods proposed to evaluate effectiveness of the training.

g. Degree of institutional commitment: Is grant support necessary for program initiation or continuation? Will support gradually be assumed? Is there related instruction that will go on with or without the grant? An example of institutional commitment to the long-term stability of TPG programs is the commitment of tenured or tenure-track faculty positions to each academic program.

h. Adequacy of facilities (classrooms, laboratories, library services, books, and journal holdings relevant to the program, and access to appropriate occupational settings).

i. Competence, experience, training, time commitment to the program and availability of faculty to advise students, faculty/student ratio, and teaching loads of the program director and teaching faculty in relation to the type and scope of training involved. The program director must be a full-time faculty member.

j. Admission Requirements: Student selection standards and procedures, student performance standards and student counseling services.

k. Advisory Committee: Membership, industries and labor groups represented; how often they meet; who they advise, role in designing curriculum and establishing program need. The Committee should meet at least annually to provide advice and periodic evaluation of TPG activities.

l. Evidence of a strategy to evaluate the impact that the program has had on the region. Examples could include a workforce needs survey and action plan, consultation and research programs provided to address regional occupational safety and health problems, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

m. Past performance based on evaluation of the most recent CDC/NIOSH Peer Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

n. Is the budget adequate, justified, and consistent with the intended use of the grant funds?

4. *ERC and TPG Evaluation Criteria for Occupational Health Services Research Training Programs* are as follows:

a. Evidence of a plan to satisfy the need for training in the area outlined by the application, including projected enrollment, recruitment and job opportunities. Indicators of need may include measures utilized by the Program such as previous record of training and placement of graduates. Indicate the potential contribution of the project toward meeting the need for this specialized training.

b. Are plans included for day-to-day management, allocation of funds and cooperative arrangements designed to effectively achieve the program requirements.

c. Evidence of a plan describing the academic and research training the program proposes. This should include goals, elements of the program, research faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

d. Does the curriculum content and design include formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence, additional related courses open to students, time devoted to lecture, and clinical and research experience addressing the relationship with didactic programs in the educational process?

e. Is the program effort capable of supporting the number and type of students proposed?

f. Has the program initiated collaborative relationships with external agencies and institutions to expand and strengthen its research capabilities by providing student and faculty research opportunities?

g. Evidence of previous record of training in health services research and occupational safety and health, including placement of graduates and employment history.

h. Does the program document methods in use or proposed methods for evaluating the effectiveness of the training, including the use of feedback mechanisms from graduates and employers, placement of graduates in research positions, research accomplishments of graduates and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies?

i. Competence, experience and training of the Program Director, faculty and advisors in relation to the type and scope of research training and education involved.

j. Degree of institutional commitment to Program goals.

k. Adequacy of the academic and physical environment in which the training will be conducted, including access to appropriate occupational health research resources.

l. Is the budget reasonable, adequately justified, and consistent with the intended use of the grant funds?

m. Evidence of a plan for establishment of an Advisory Committee, including meeting times, roles and responsibilities.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Institute for Occupational Safety and Health. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

The initial peer review will be conducted by a Special Emphasis Panel (SEP) appointed by CDC. SEP members are extramural peer reviewers with occupational safety and health expertise in the program areas under review. An application will be considered a complete document for review purposes. Thus, there will not be any other form of communication between the applicant and the reviewers. In special circumstances, site visits may be made by a SEP for all applications of a given type, but such site visits are not routine or anticipated and will only be conducted where it is essential to observe activities of the applicants that NIOSH determines are necessary for an adequate review. Such site visits would not be for the applicants to add new information or clarify issues in their applications. Each of the review criteria will be addressed and considered by the peer reviewers in assigning the overall priority score, weighting them as appropriate for each application. If an application is deemed responsive, a priority score will be assigned using a range of 100–500 representing adjectival equivalents from outstanding (100) to acceptable (500). Note that an application does not need to be strong in all categories to be judged likely to have a major scientific impact and receive a good priority score.

The secondary peer review will be conducted by the NIOSH Secondary Review Committee which evaluates how the applications will contribute to the purpose for this program as stated at the beginning of this announcement.

V.3. Anticipated Announcement and Award Dates

Award notification dates are expected to be June 1, 2005 with award start dates of July 1, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1* Human Subjects Requirements
- AR–2* Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–3* Animal Subjects Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions

*Applies only to ERC Pilot Project Research Training Program.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Initial interim progress report is due December 1, 2004. This report is required on December 1, on an annual basis. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget and justification.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report, no more than 90 days after the end of each budget period. The initial report is due September 30, 2006.

3. Final financial and performance reports, no more than 90 days after the end of the project period. These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact:

John T. Talty, Program Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 4676 Columbia Parkway, Mailstop C–7, Cincinnati, OH 45226–1998, Telephone: (513) 533–8241, E-mail: *jtt2@cdc.gov.*

For financial, grants management, or budget assistance, contact: Cynthia Y. Mitchell, Grants Management Specialist, CDC Procurement and Grants Office, 626 Cochrans Mill Rd., Mailstop P05, Pittsburgh, PA 15236, Telephone: (412) 386–6434, E-mail: *CMitchell@cdc.gov.*

VIII. Other Information

A pre-application technical assistance conference call will be held from 2 to 3 p.m. (eastern time) on May 13, 2004, to allow potential applicants the opportunity to ask questions about this announcement. The call in number is 1–866–524–1250, and the participant passcode is 469181.

Dated: April 2, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–7936 Filed 4–7–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0093]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 the (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

DATES: Submit written or electronic comments on the collection of information by June 7, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.39(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the