the order after twenty years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 757]

National Institute for Occupational Safety and Health; Epidemiologic Studies To Evaluate Health Effects of Uranium Milling; Notice of Availability of Funds for Fiscal Year for 1997

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement program to design and conduct epidemiologic studies evaluating the health effects of uranium milling.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000, see the section Where To Obtain Additional Information.)

Authority

This program is authorized under Section 501 of the Federal Mine Safety and Health Act (30 U.S.C. 951).

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, non-profit and for-profit organizations and governments, and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority-and/or women-owned businesses are eligible to apply.

Note: Public Law 104–65, dated December 19, 1995, prohibits an organization described in section 501(c)(4) of the IRS Code of 1986, that engages in lobbying activities to influence the Federal Government, from receiving Federal funds.

Availability of Funds

Approximately $300,000 is available in FY 1997 to fund one award. It is expected that the award will begin on or about September 1, 1997, and will be made for a 12-month budget period with a one year project period.

Preapplication Teleconference

Applicants are invited by CDC/NIOSH to attend a preapplication technical assistance teleconference on Monday, June 16, 1997, at 2:00 p.m.(EDT) to discuss the programmatic issues and time constraints regarding this program, and to ask question regarding its content. This teleconference is expected to last approximately one hour. All conference calls are scheduled on Eastern time. The conference name is ''Uranium Millers Technical Assistance''. The telephone bridge number for Federal participants is 404/639–4100 and for Non-Federal participants it is 800/713–1971. Participants will need the conference code, 575934, to be connected.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104–208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996).

Background

The National Institute for Occupational Safety and Health (NIOSH) is developing and conducting a study of the health effects associated with uranium milling and will be awarding cooperative agreement funds to support this effort.

NIOSH is conducting this research pursuant to an agreement with the United States Army Environmental Hygiene Agency in follow-up to a 1994 Congressional mandate to the Department of Defense. Public Law 103–139 provides that the Department of Defense shall conduct ''* * * a study of the health effects of uranium milling, including the effects of exposure to radon chemicals and uranium, on the health of those individuals employed in uranium mills in the southwestern United States during the period beginning on January 1, 1947, and ending on December 31, 1971.''

NIOSH has been evaluating available personnel and exposure records for uranium mills which operated in Colorado, New Mexico, Utah, and Arizona between 1947 and 1971 to determine which types of epidemiologic studies of the health effects of uranium milling would be feasible given the

nature and extent of records available on uranium milling operations. To date, NIOSH has determined that a cross sectional study of renal and/or pulmonary disease among uranium millers would be feasible. In addition, such a study is scientifically appropriate since prior research has indicated that uranium millers may be at increased risk of renal disease and non-malignant respiratory disease.

Purpose

The purpose of this cooperative agreement is to utilize the special resources of the research community to conduct studies evaluating the renal and/or pulmonary health effects of uranium milling, including the effects of exposure to uranium dust, silica dust, inorganic acids, organic solvents, and ionizing radiation. The project results should be applicable to individuals employed in uranium mills in the southwestern United States between January 1, 1947 and December 31, 1971. This project could include: (a) A morbidity study of renal disease, (b) a morbidity study of non-malignant respiratory disease, and/or (c) a morbidity study of other health outcomes if substantial justification is given for evaluating other endpoints. Personnel and/or exposure records from U.S. uranium mills may be utilized to the extent available. The recipient should develop an epidemiologic study design which specifies the methods that will be used to select former uranium millers and a non-uranium miller comparison group for the study.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC/NIOSH will be responsible for activities under B. (CDC/NIOSH Activities).

A. Recipient Activities

1. Develop a study to evaluate the health effects of uranium milling among individuals employed in uranium mills in the southwestern United States during the period between January 1, 1947, and December 31, 1971.

2. Evaluate potential sources of recruitment of uranium millers including company records, the registry kept by the Office of Navajo Uranium Workers, and other sources in order to propose a recruitment strategy.

3. Develop a final study protocol that reviews the pertinent literature on potential health effects of uranium milling and historical exposure data, describes the study methodology including the selection of an unexposed (non-uranium miller) comparison group, the data to be collected, and the proposed analysis of the data.

4. Present the protocol to a panel of scientific peer reviewers and revise the protocol as required for final approval.

5. Perform data collection and management. Data collected may include worker symptomatology, results of medical tests evaluating renal and/or pulmonary function, and available exposure data.

6. Conduct statistical analyses of the data collected.

7. Report study results to the scientific community via presentations at professional conferences and articles in peer-reviewed journals. All reports should undergo appropriate scientific peer review prior to public release.

8. Maintain the confidentiality of individually identifiable data. Provide written assurance to the CDC that there are adequate technical and administrative safeguards in place to protect the confidentiality of such records and that the confidentiality of the records will be maintained.

9. Notify study participants of their individual and overall study results.

B. CDC/NIOSH Activities

1. Provide technical assistance with program development, implementation, maintenance, priority setting, evaluation efforts, and information and dissemination activities.

2. Provide scientific, epidemiologic, and medical collaboration for the successful completion of this project.

3. Provide, obtain, and/or assist in obtaining available personnel and/or exposure records from uranium mills located in the southwestern United States that operated during the period between January 1, 1947 and December 31, 1971.

4. Assist in reporting study results to the scientific community via presentations at professional conferences and articles in peer-reviewed journals. Assist, if needed, in reporting individual and overall study results to study participants.

Technical Reporting Requirements

An original and two copies of semi-annual progress reports are required. Timelines for the semi-annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Semi-annual progress report should include:

A. A brief program description.

B. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.

C. If established goals and objectives to be accomplished were delayed, describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

D. Other pertinent information, including the status of completeness, timeliness and quality of data.

Final Report summarizing the methodology; results obtained, conclusions reached, and recommendations regarding effectiveness and costs of components of the Epidemiologic Studies to Evaluate Health Effects of Uranium Milling program.

Application Content

The entire application, including appendices, should not exceed 40 pages and the Proposal Narrative section contained therein should not exceed 25 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8½″ by 11″ paper, with at least 1″ margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets.

The applicant should provide a detailed budget, with accompanying justification of all operating expenses, that is consistent with the stated objectives and planned activities of the project. CDC may not approve or fund all proposed activities. Applicants should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; described the services to be performed and provide an itemized breakdown and justification for the estimated cost of the contract; the kinds of organizations or parties to be selected; the period of performance; and the method of selection. Place budget narrative pages showing, in detail, how funds in each object class will be spent, directly behind form 424A. Do not put these pages in the body of the application.

The applicant should provide a detailed description of all activities.

A. Title Page

The heading should include the title of the program, project title, organization, name and address, project director's name and telephone number.

B. Abstract

A one page, singled-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract should include a work plan identifying activities to be developed, activities to be completed, and a timeline for completion these activities.

C. Proposal Narrative

The narrative of each application must:

1. Briefly state the applicant's understanding of the need or problem to be addressed and the purpose of this cooperative agreement. This should be reflected in a draft protocol for the study.

2. Describe clearly the objectives, the steps to be taken in planning and implementing this project, and the respective responsibilities of the applicant for carrying out those steps. Provide timelines for accomplishing each objective and a method of evaluating the activities.

3. Inclusion of women, ethnic, and racial groups: Describe how the CDC policy requirements will be met regarding the inclusion of women, ethnic, and racial groups in the proposed research. (See Women, Racial and Ethnic Minorities in the Evaluation Criteria and Other Requirements sections.)

4. Provide documentation of access to potential study sites with the sample characteristics specified in the Program Requirements Section, and provide documentation of anticipated involvement of management, labor, and community representatives in the study.

5. Document the applicant's expertise in the area of occupational health, industrial hygiene, health physics, and project management.

6. Document the applicant's ability to provide staff, knowledge, and other resources required to perform the responsibilities in this project.

7. Provide the name, qualifications, and proposed time allocation of the Project Director who will be responsible for administering the project. Describe staff, experience, facilities, equipment available for performance of this project, and other resources that define the applicant's capacity or potential to accomplish the requirements stated above. List the names (if known), qualifications, and time allocations of the existing professional staff to be assigned to (or recruited for) this project, the support staff available for performance of this project, and the available facilities including space.

8. Human Subjects: State whether or not Humans are subjects in this proposal. (See Human Subjects in the Evaluation Criteria and Other Requirements sections.)

9. Provide a detailed budget which indicates: (a) Anticipated costs for personnel, travel, communications, postage, equipment, supplies, etc., and (b) all sources of funds to meet those needs.

10. Provide a detailed security plan to ensure that there are reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of records.

Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

A. Understanding of the Problem (15%)

Responsiveness to the purpose of this announcement including:

1. Applicant's understanding of the general objectives, and

2. Evidence of the ability to understand the problem and to propose effective methodologies for evaluating renal and/or pulmonary effects.

B. Program Personnel (30%)

1. Applicant's technical experience (e.g., in the areas of occupational health, industrial hygiene, health physics, and project management),

2. The qualifications (e.g., in the areas of industrial hygiene, health physics, and occupational safety and health) and time allocation of the professional staff to be assigned to this project, and

3. The applicant's ability to describe the approach to be used in carrying out the responsibilities of the applicant in this project.

C. Study Design (30%)

1. Steps proposed in planning and implementing this project and the respective responsibilities of the applicant for carrying out those steps,

2. The adequacy of the applicant's evidence of access to study populations, and

3. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research.

D. Project Planning and Evaluation (15%)

The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable. The extent to which the methods are sufficiently detailed to allow assessment of whether the objectives can be achieved for the budget period. Clearly stated evaluation method for evaluating the accomplishments and a detailed security plan to safeguard and prevent disclosure of records. The extent to which a qualified plan is proposed that will help achieve the goals stated in the proposal.

E. Facilities and Resources (10%)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

F. Human Subjects (Not Scored)

Whether or not exempt from the Department of Health and Human Services (DHHS) regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate, and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

G. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number for this project is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by this cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the DHHS Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Application Submission and Deadline

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to Victoria F. Sepe, Grants Management Specialist, Grants Management Branch, CDC at the address listed in this section. It should be postmarked no later than July 11, 1997. The letter should identify the Program Announcement number 757 and the name of principal investigator. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Application

The original and four copies of the application PHS Form 398 (Revised 5/95, OMB Number 0925–0001) must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before July 25, 1997.

1. Deadline: Applications will be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 757. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 757 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Lynne E. Pinkerton, M.D., M.P.H., Medical Officer, Epidemiology 1 Section, Industrywide Studies Branch, Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop R–15, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 841–4344, Internet: lep5@.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Dated: June 4, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 738]

National Institute for Occupational Safety and Health; Assessment of Respiratory Exposure Hazards in Composting

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997