

• Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of response.

OMB is required to make a decision concerning the collection of information contained in this notice of proposed eligibility and selection criteria between 30 and 60 days after publication of this document in the **Federal Register**. Therefore to ensure that OMB gives your comments full consideration, it is important that OMB receives the comments within 30 days of publication. This does not affect the deadline for your comments to us on the notice of proposed eligibility and selection criteria.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on process developed by State and local government for coordination and review of proposed Federal assistance.

In accordance with this order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

We invite you to submit comments regarding the rules proposed in this notice. To ensure that your comments have the maximum effect in developing the Secretary's final notice of priorities, application requirements, and selection criteria we urge you to identify clearly the specific section of this notice that each of your comments addresses and to arrange your comments in the same order as the sections appear in the notice.

All comments submitted in response to this notice will be available for public inspection, during and after the comment period, in Room 5C141, 400 Maryland Avenue, SW, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

On request, the Department supplies an appropriate aid, such as a reader or print magnifier, to an individual with a disability that needs assistance to review the comments. An individual with a disability may call (202) 205-8113 or (202) 260-9895. An individual who uses a TDD may call the Federal

Information Relay Service (FIRS) at 1-800-877-8339.

Program Authority: 20 U.S.C. 6661 *et seq.*

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Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://access.gpo.gov/nara/index.html>.

Catalogue of Federal Assistance Number: 84.338

Dated: February 15, 2000.

Michael Cohen,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 00-4084 Filed 2-18-00; 8:45 am]

BILLING CODE 4000-01-U

DEPARTMENT OF ENERGY

Office of Fossil Energy

[Docket Nos. FE C&E 00-02-184]

Notice of Filing of Coal Capability of Reliant Energy Channelview LP Powerplant and Industrial Fuel Use Act

AGENCY: Office of Fossil Energy; Department of Energy.

ACTION: Notice of Filing.

SUMMARY: Reliant Energy Channelview LP has submitted a coal capability self-certification pursuant to section 201 of the Powerplant and Industrial Fuel Use Act of 1978, as amended.

ADDRESSES: Copies of self-certification filings are available for public inspection, upon request, in the Office of Coal & Power Im/Ex, Fossil Energy, Room 4G-039, FE-27, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Ellen Russell at (202) 586-9624.

SUPPLEMENTARY INFORMATION: Title II of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended (42

U.S.C. 8301 *et seq.*), provides that no new baseload electric powerplant may be constructed or operated without the capability to use coal or another alternate fuel as a primary energy source. In order to meet the requirement of coal capability, the owner or operator of such facilities proposing to use natural gas or petroleum as its primary energy source shall certify, pursuant to FUA section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a baseload powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with section 201(a) as of the date filed with the Department of Energy. The Secretary is required to publish a notice in the **Federal Register** that a certification has been filed. The following owner/operator of proposed new baseload powerplant has filed a self-certification in accordance with section 201(d).

Owner: Reliant Energy Channelview LP (C&E 0-04).

Operator: Reliant Energy Channelview LP.

Location: Shedon Road in Channelview, Harris County, TX.

Plant Configuration: Combined-cycle.

Capacity: 786 MW.

Fuel: Natural gas.

Purchasing Entities: Reliant Energy Services, Inc.

In-Service Date: Late 2001.

Issued in Washington, DC, February 14, 2000.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Im/Ex., Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 00-4135 Filed 2-18-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Office of Environment, Safety and Health; Notice of Availability of Funds and Request for Applications for Radiation Health Effects Studies in the Russian Federation

AGENCY: Office of Environment, Safety and Health, DOE.

ACTION: Notice of availability of funds and request for applications.

SUMMARY: The Office of International Health Programs, Office of Health Studies, U.S. Department of Energy (DOE), announces that it is accepting applications to support U.S.-Russian population-based studies on low dose-rate radiation health effects in the Russian Federation. This Notice is issued subsequent to the more general

Continuation of Solicitation for Epidemiology and Other Health Studies Financial Assistance Program published in the **Federal Register** (61 FR 53903) on October 16, 1996.

DATES: The deadline for receipt of applications is May 9, 2000.

ADDRESSES: U.S. Department of Energy, Office of International Health Programs, EH-63/270CC, 19901 Germantown Road, Germantown, Maryland 20874-1290. Seven (7) copies of each application should be provided to the above address.

FOR FURTHER INFORMATION CONTACT:

Requests for further information on this announcement may be directed to Dr. Ruth Neta, telephone: (301) 903-1757; facsimile: (301) 903-1413; electronic mail: ruth.neta@eh.doe.gov; or Ms. Elizabeth White, telephone: (301) 903-7582; facsimile: (301) 903-1413; electronic mail: elizabeth.white@eh.doe.gov.

SUPPLEMENTARY INFORMATION:

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I. Purpose

A. The Office of International Health Programs, in partnership with the Russian Federation, funds research on the health consequences (cancer and other diseases) of exposure to low-dose rate ionizing radiation. These ongoing studies are coordinated through the U.S.-Russian Joint Coordinating Committee for Radiation Effects Research (JCCRER).

B. The purpose of this Notice is to encourage the submission of applications for new joint U.S.-Russian feasibility studies on cohorts exposed to chronic low-dose rate ionizing radiation as a result of nuclear weapons production in the Russian Federation. Specifically, applications in the following fields will be considered:

1. Epidemiology and related dosimetry/dose reconstruction; and

2. Molecular epidemiology/biomarkers of disease due to radiation exposure.

C. Where possible, applications for joint multi-disciplinary efforts that combine epidemiology and dosimetry are encouraged.

D. At this time, consideration will not be given to applications:

- 1. For research on populations exposed as a result of nuclear power incidents such as the Chernobyl accident;
- 2. For research on populations exposed as a result of testing conducted at the Semipalatinsk Test Site;
- 3. For validation of dosimetry (e.g., through Electron Paramagnetic Resonance, Fluorescent In-Situ Hybridization, and Thermoluminescence, etc.), either as a component of a retrospective physical dose reconstruction effort or as an independent study; or
- 4. For cross-generational studies.

E. DOE anticipates that approximately \$1,000,000 may be available in fiscal year 2000 to support up to five new projects initiated, through cooperative agreements, as a result of this Notice. Information from these studies is expected to be of major importance to DOE's mission to protect U.S. workers and populations from risks of exposures that may be associated with the Department's current and future activities.

F. Addendum XI will provide potential applicants with background information on JCCRER studies conducted to date. Descriptions of cohorts included in this section are limited to those of cohorts subject to ongoing JCCRER studies and are not intended to: (1) Be representative of all related studies in the Russian Federation; or (2) indicate a preference to support studies on these populations over others exposed as a result of nuclear weapons production in the Russian Federation.

II. Background

A. The JCCRER is a bilateral Government committee representing Federal agencies from the United States and ministries from the Russian Federation. It was established to implement the Agreement on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (U.S.—Russian Agreement), signed on January 1, 1994, by U.S. Secretary of State Warren Christopher and Russian Foreign Minister Andrey Kozyrev to support and facilitate joint cooperative research.

B. Radiation health effects research conducted jointly with the Russian Federation provides a unique opportunity to learn more about possible risks to groups of people from lengthy exposure to radiation. This could include people receiving exposure from uranium mining, operations of nuclear facilities, transport and disposal of radioactive materials, the testing and dismantling of nuclear weapons, and grossly contaminated sites or facilities.

C. Currently, the JCCRER and DOE are focusing on population and worker studies in the Southern Urals region of the Russian Federation. In 1948, a nuclear weapons production complex, the Mayak Production Association (MAYAK), was established by the Soviet Union in the Southern Urals, about 100 km northwest of the city of Chelyabinsk. Large amounts of radioactive materials were released into the environment between 1948 and 1957. Liquid discharges into the Techa River from MAYAK occurred from 1949–1956. As a result, thousands of people residing along the Techa River received significant radiation exposures. Furthermore, because of limited and inadequate (by today's standards) radiation protection measures and procedures, thousands of MAYAK workers were overexposed to radiation.

D. The current U.S. JCCRER members are the:

- 1. U.S. Department of Energy (DOE);
- 2. U.S. Nuclear Regulatory Commission (NRC);
- 3. U.S. Department of Health and Human Services (HHS);
- 4. U.S. Department of Defense (DoD);
- 5. U.S. National Aeronautics and Space Administration (NASA); and
- 6. U.S. Environmental Protection Agency (EPA).

E. The current Russian JCCRER members are the:

- 1. Ministry for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM);
- 2. Ministry of Atomic Energy (MINATOM); and
- 3. Ministry of Health (MINZDRAV).

III. Applicants

A. An applicant must be a U.S. organization(s), and applications must include participation by both a U.S. organization(s) and a Russian organization(s). U.S. applicants may include, but are not limited to, nonprofit and for profit organizations, universities, medical centers, research institutions, and other public and private organizations, including small, minority or women-owned businesses,

as well as consortiums of interested organizations. Applications, if accepted, will be awarded through cooperative agreements. Russian participants will be directly funded through implementing arrangements under the auspices of the U.S.-Russian Agreement.

B. Applications submitted by, or on behalf of (1) another Federal agency; (2) a Federally-Funded Research and Development Center sponsored by a Federal agency; or (3) a DOE Management and Operating (M&O) contractor will not be eligible for an award under this RFA. However, as described below in Section IV(C), Application Format, an application that includes performance of a portion of the work by a DOE M&O contractor under a cooperative agreement may be considered for award.

C. Applicants are subject to applicable requirements of 10 CFR part 600, Financial Assistance Rules, and 10 CFR part 602, Epidemiology and Other Health Studies Financial Assistance Program.

D. Intellectual property created or furnished under any cooperative agreements awarded pursuant to this request for applications will be subject to the intellectual property annex to the U.S.-Russian Agreement, set forth in Section IX. In addition, generated data will be treated in accordance with the JCCRER General Data Access Provisions set forth in Section X. The applicable terms and conditions of the data clauses of 10 CFR 600.27 also will apply if included in the cooperative agreements. It is not anticipated that inventions will be made in performance of work under the cooperative agreements and, therefore, the patent rights clauses of 10 CFR 600.27 will not be included in the cooperative agreements.

IV. Applications

A. General

This Notice of Availability is issued pursuant to DOE regulations contained in 10 CFR part 602: "Epidemiology and Other Health Studies Financial Assistance Program," as published in the **Federal Register** on January 31, 1995 (60 FR 5841). The Catalog of Federal Domestic Assistance number for 10 CFR part 602 is 81.108, and its solicitation control number is EOHSFAP 10 CFR part 602. 10 CFR part 602 contains the specific requirements for applications, evaluation, and selection criteria. Only those applications following these specific criteria and forms will be considered.

B. Structure of Cooperative Agreements

1. Cooperative agreements funded under this announcement may have two phases. Initial funding for each new cooperative agreement will be for a Phase I feasibility assessment and, if requested by DOE, development of a Phase II proposal. Phase I will last up to eighteen (18) months. Phase II, if warranted, will be funded through continuation awards. Phase II could continue up to four (4) years, renewable annually. Continuation awards for Phase II, if made, will be based on the results from Phase I, the availability of funds, and negotiation of the costs for Phase II. Only those who participate in Phase I will be eligible to participate in Phase II.

2. Phase I: During Phase I, awardees will conduct a feasibility assessment. The feasibility assessment will include a review of site-specific information and an analysis of this and other information to demonstrate the feasibility of conducting the proposed research. During Phase I, investigators will conduct the following tasks:

a. Demonstrate the feasibility of conducting the proposed project and determine any significant impediments to conducting the proposed project, as well as proposed strategies to overcome them;

b. Attend periodic DOE-coordinated meetings to share information on projects; and

c. Upon notification by DOE following review of the feasibility assessment, develop a detailed technical proposal and budget for Phase II.

3. Using the information developed in Task a, investigators will be expected to produce a feasibility assessment to be delivered one (1) year after the award is made. Based on the external review of the feasibility assessment by DOE's standing bi-national Scientific Review Group (an advisory panel for DOE-funded U.S.-Russian radiation health effects research), as well as an internal review by DOE's Office of International Health Programs, DOE will make a determination as to whether to request a long-term proposal for Phase II. Upon notification by DOE, the Phase II technical proposal and proposed budget should be prepared. The complete proposal should be submitted at least ninety (90) days prior to the conclusion of Phase I. The process and criteria used by the DOE to review these documents will be described in detail in the award documents for Phase I. The process is intended to provide a seamless transition to Phase II.

4. Phase II: DOE will determine the need for Phase II activities as described

above and, if appropriate, will support these efforts through continuation awards. Where Phase II plans are approved by DOE, the investigators will perform the following tasks:

a. Conduct the research project developed in Phase I;

b. Periodically communicate results to DOE;

c. Publish the research results in peer reviewed scientific journals; and

d. Attend periodic DOE-coordinated meetings of researchers to share information on projects.

C. Application Format

1. An application shall be submitted by the U.S. organization(s). The application shall contain two sections, technical and cost.

a. Technical applications must contain separate technical descriptions for Phase I and Phase II, which are described in Section IV(B), Structure of Cooperative Agreements. Because the scope of Phase II is dependent on the results of Phase I, the technical description for Phase II may be less specific than that for Phase I, but must clearly demonstrate a capability to conduct Phase II. The technical application shall be no longer than 25 pages in length. Resumes of proposed key personnel should be submitted as an appendix to the technical proposal and will not be counted against the page limit. The following format must be followed for the technical application:

i. *Abstract*—Provide a 1-page summary of the specific aims, background, significance, and research design and methods.

ii. *Specific Aims*—State the long-term objectives and describe what the specific research in this plan is intended to accomplish and the hypothesis to be tested.

iii. *Project Description*—Describe the research design and the procedures to be used to accomplish the specific aims of the project. At a minimum, the tasks listed under Section IV(B), Structure of Cooperative Agreements, must be described (in detail for Phase I tasks and more generally for Phase II tasks). The project description must include clear statements of what is known, what is uncertain, and what new knowledge would be added by the proposed study.

iv. *Resources*—Demonstrate the competency of research personnel and the adequacy of resources. Applications must demonstrate that the applicant has the experience and capability to plan, organize, manage, and implement the proposed work. Applications must identify the technical and scientific staff who will conduct the studies and detail their professional experience and other

sources of support. Applications must demonstrate that the offeror has a demonstrated skill in planning and scheduling projects of comparable magnitude to the project it is proposing under this Notice.

b. Cost proposals shall have no page limit and shall include, for Phase I, a summary breakdown of all costs and provide a detailed breakdown of costs on a task-by-task basis. Costs for Phase II tasks may be more general estimates since the initial award will be for Phase I only. The cost proposal for Phase I shall include an estimate of the costs of the Russian participating organization(s).

2. An application that includes performance of a portion of the effort by a DOE M&O contractor will be evaluated and considered for award pursuant to Section V, Phase I Application Evaluation and Award, provided that the application meets the following criteria:

a. Prior to submission of an application to DOE, the DOE Contracting Officer for the M&O contractor must provide written authorization for the DOE M&O contractor to perform the proposed scope of work. Pursuant to this authorization, the DOE Contracting Officer must determine that performance by the M&O contractor: (1) Is consistent with or complementary to DOE missions and the missions of the facility to which the work is to be assigned; (2) will not adversely impact execution of the assigned programs of the facility; (3) will not place the facility in direct competition with the domestic private sector; and (4) will not create a detrimental future burden on DOE resources. The DOE Contracting Officer's authorization shall be included in the application.

b. An application must include a description of: (1) The scope of work to be performed by the applicant and the scope of work to be performed by the M&O contractor; and (2) the managerial arrangement between the applicant and the M&O contractor. The scope of work to be performed by the M&O contractor may not be more significant than the scope of work to be performed by the applicant and the Russian participating organization(s). Prior to submitting an application for review as set forth in Section V, Phase I Application Evaluation and Selection, DOE will review the application to determine that it meets this criteria and reserves the right to reject any application that fails to do so.

c. DOE intends to fund an approved M&O contractor scope of work through a DOE Field Work Proposal from the

Office of International Health Programs to the DOE Operations Office overseeing the M&O contractor at issue. The M&O contractor's work scope, therefore, should not be accomplished through a contract with a recipient as defined in 10 CFR Part 600.3. Applications must include a form DOE F 4620.1 and budget page for the applicant's portion of the project, and a Field Work Proposal cover page and budget pages (see DOE Order 5700.7C) for the M&O contractor's scope of work.

3. If an applicant uses an M&O contractor to perform a portion of the work under the cooperative agreement, the applicant will be the responsible authority, without recourse to DOE, regarding the settlement and satisfaction of all contractual and administrative issues, including, but not limited to, disputes and claims, arising out of any agreement between the applicant and the M&O contractor.

V. Phase I Application Evaluation and Selection

1. Applications will be subjected to merit review (ad hoc peer review) and will be evaluated against the following criteria listed in descending order of importance and codified at 10 CFR 602.9(d):

- a. Scientific and technical merit of the proposed research;
- b. Appropriateness of the proposed method or approach;
- c. Competency of research personnel and adequacy of proposed resources; and
- d. Reasonableness and appropriateness of the proposed budget.

2. Applications will be peer reviewed by evaluators apart from DOE employees and contractors described in the Office of Environment, Safety and Health's Merit Review System (57 FR 55524, November 25, 1992) and at 10 CFR 602.9(c). The review will consist of an initial comprehensive review by an ad hoc group of experts in the field, followed by a second-tier independent review of the most highly ranked proposals by DOE's standing bi-national Scientific Review Group.

3. Following the feasibility phase, DOE's standing bi-national Scientific Review Group will evaluate the promise of feasibility studies for long-term (Phase II) study. This group will also serve to evaluate, every six (6) months, progress of all DOE-funded long-term studies and the success of completed projects.

VI. DOE's Policy on Protection of Human Subjects Reviews

A. The Federal Policy for the Protection of Human Subjects, in 10

CFR part 745 (the "Common Rule"), has special provisions for international research which apply to any awards made under this Notice of Availability. DOE approval of research conducted outside the United States is subject to the "Common Rule," or equivalent laws and regulations of the country in which research is conducted, whichever represents the greater level of protection for the research subject.

B. DOE will work with awardees during Phase I, as necessary, to ensure that research conducted with Russian participant(s) comports with the required level of protection of human subjects and adequately addresses the issue of informed consent. Information on protecting human research subjects (within DOE) can be obtained from Dr. Susan Rose at the address listed above.

VII. DOE's Role

For DOE to use cooperative agreements for these studies, there must be substantial involvement between DOE and each awardee. DOE established the subject area for these projects, the core tasks for Phase I and prepared this Notice of Availability. DOE will ensure a two-tier external evaluation and will make final selections and awards for applications submitted pursuant to this Notice. DOE, with input from its standing bi-national Scientific Review Group, will evaluate the results of Phase I and, where warranted and subject to available funding, authorize and fund Phase II continuation awards. Finally, DOE will monitor and evaluate the results of the projects to determine how these studies will contribute to DOE's ongoing efforts to improve health and safety programs for its workers.

VIII. Notices on Lobbying Restrictions and American-Made Products

A. Lobbying Restrictions (Energy and Water Act, 2000)

The awardee agrees that none of the funds obligated this award shall be expended, directly or indirectly, to influence congressional action on any legislation or appropriation matters pending before Congress, other than to communicate to Members of Congress as described in 18 U.S.C. 1913. This restriction is in addition to those prescribed elsewhere in statute and regulation.

B. Notice Regarding the Purchase of American-Made Equipment and Products—Sense of Congress

It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased

with funds made available under this award should be American-made.

IX. Intellectual Property Annex to the U.S.-Russian Agreement

Pursuant to Article VI of this Agreement:

The Parties shall ensure adequate and effective protection of intellectual property created or furnished under this Agreement and relevant implementing arrangements. The Parties agree to notify one another in a timely fashion of any inventions or copyrighted works arising under this Agreement and to seek protection for such intellectual property in a timely fashion.

Rights to such intellectual property shall be allocated as provided in this Annex.

I. Scope

A. This Annex is applicable to all cooperative activities undertaken pursuant to this Agreement, except as otherwise specifically agreed to by the Parties or their designees.

B. For purposes of this Agreement, intellectual property shall have the meaning found in Article 2 of the Convention establishing the World Intellectual Property Organization, done at Stockholm, July 14, 1967.

C. This Annex addresses the allocation of rights, interests, and royalties between the Parties. Each Party shall ensure that the other Party can obtain the rights to intellectual property allocated in accordance with the Annex, by obtaining those rights from its own participants through contracts or other legal means, if necessary. This Annex does not otherwise alter or prejudice the allocation between a Party and its nationals, which shall be determined by the Party's laws and practices.

D. Disputes concerning intellectual property arising under this Agreement should be resolved through discussions between the concerned participating institutions or, if necessary, the Parties or their designees. Upon mutual agreement of the Parties, a dispute shall be submitted to an arbitrate tribunal for binding arbitration in accordance with the applicable rules of international law. Unless the Parties or their designees agree otherwise in writing, the arbitration rules of the UNCITRAL shall govern.

E. Termination or expiration of the Agreement shall not affect rights of obligations under this Annex.

II. Allocation of Rights

A. Each Party shall be entitled to a non-exclusive, irrevocable, royalty-free license in all countries to translate,

reproduce, and publicly distribute scientific and technical journal articles, reports, and books directly arising from cooperation under this Agreement. All publicly distributed copies of a copyrighted work prepared under this provision shall indicate the names of the authors of the work unless an author specifically declines to be named.

B. Rights to all forms of intellectual property, other than those rights described in Section II(A) above, shall be allocated as follows:

1. Researchers and scientists visiting in furtherance of their education shall receive intellectual property rights under the existing rules of the host institution. In addition, each visiting researcher or scientist named as an inventor shall have the right to national treatment regarding awards, benefits or other compensation, including royalties, in accordance with the existing rules of the host institution.

2. (a) For intellectual property created during joint research, for example, when the Parties, participating institutions, or Participating personnel have agreed in advance of the scope of work, each Party shall be entitled to obtain all rights and interests in its own territory. Rights and interests in third countries will be determined in implementing arrangements. The rights to intellectual property shall be allocated with due regards for the economic, scientific and technological contributions from each Party to the creation of intellectual property. If research is not designated as "joint research" in the relevant implementing arrangement, rights to intellectual property arising from the research will be allocated in accordance with Paragraph II(B)(1). In addition, each person named as an inventor shall have the right to national treatment regarding awards, benefits and other compensation, including royalties, in accordance with the existing rules of the host institution. (b) Notwithstanding Paragraph II(B)2(A), if a type of intellectual property is available under the laws of one party but not the other Party, the Party whose laws provide for this type of protection shall be entitled to all rights and interests worldwide. Persons named as inventors of the property shall nonetheless be entitled to royalties as provided in Paragraph II(B)2(a).

III. Business-Confidential Information

In the event that information identified in a timely fashion as business-confidential is furnished or created under the Agreement, each Party and its participants shall protect such information in accordance with applicable laws, regulations and

administrative practice. Information may be identified as "business-confidential" if a person having the information may derive an economic benefit from it or may obtain competitive advantage over those who do not have it, the information is not generally known or publicly available from other sources, and the owner has not previously made the information available without imposing in a timely manner an obligation to keep it confidential.

X. U.S.-Russian Joint Coordinating Committee for Radiation Effects Research (JCCRER) General Data Access Provisions

Introduction

The purpose of this data access agreement is to ensure that scientists of the Russian Federation and American scientists working on projects under the *U.S.-Russian Agreement* have equal access to all primary and original Russian and American data necessary to conduct the work described under Directions 1 and 2 of the Agreement. Such access will ensure the highest quality of scientific research conducted in an atmosphere of mutual trust and cooperation.

General Provisions

1. For the purposes of this agreement on data access, data is defined as all information, in whatever format or media, that is identified by any of the Principal Investigators and Directors of participating institutes as necessary to carry out the project.

2. Privacy statutes in Russia and the United States generally restrict access to data which includes personal identifiers. Individual data, however, is the basis of much of the research work of the JCCRER. Therefore, where necessary, adherence to these statutes will be ensured by substituting unique numerical identifiers which protect individual privacy while allowing analysis of individual and aggregate data.

3. Data covered by this access agreement include original or raw data, compiled data created before these projects were begun, and second generation or summarized data and information compiled according to project requirements. The specific project agreement provisions will specify the actual data which fall under each of these categories. Appropriate access to all these data must be ensured; however, original or raw data, and compiled data created before these projects were begun remain the property of that organization and that country

where the data were obtained and are currently maintained.

4. Secondary data created as part of JCCRER projects, which are a joint scientific product, will be jointly owned by the Russian and the American institutions participating in the project. Each project will determine what is a scientific product of the collaboration and, therefore, subject to joint ownership.

5. Project participants have the right to appropriate access to original, compiled and secondary data on the territory of the organization which owns and maintains the data.

6. The specific project agreement provisions will identify the kind and extent of unpublished primary, compiled, and secondary data that may be transferred out of the country of ownership to achieve specific project goals such as technical analyses, modeling, etc., at the home institution of researchers. When such data transfers occur, they must also be approved in writing by the Director of the institute or organization to which the data belong. Transferred data cannot be used for purposes other than those specified by the agreement, even after the project is completed or the researcher is no longer associated with the JCCRER. In cases where such data are transferred to people who are not participants in the project for the purposes of furthering the project, the same conditions and limitations on use of data apply. Such transfers will be carefully scrutinized.

7. No transfers, publications, presentations, press releases or any other form of communication to the outside world regarding details of the unpublished data or the unpublished results of studies conducted under the authority of the JCCRER will be made without the written consent, and participation of the institutions maintaining the data sets and the scientists involved in the research. Any agreement to make data publicly available must be approved by the Directors of organization performing the research. Scientists and specialists participating as current members of the JCCRER Joint Committee, Executive Committee, and Scientific Review Groups have a right to review data and unpublished results of studies as appropriate to their responsibilities, but are similarly bound by the restrictions on communication as described in this paragraph.

8. Dissemination of scientific results, in the form of presentations at scientific meetings and publications in referred journals, is regarded as an essential product of the JCCRER work. To ensure that such communications take place

while complying with the requirements of the participating institutions and funding agencies, procedures will be developed for the expeditious review and approval of such communication requests from the principal investigators.

9. Data published in the open, peer-reviewed literature shall be referenced and used according to generally understood and accepted conventions of scientific conduct; it is expected that proper reference and credit to the origin of the published material will be made.

10. After the publication of reports, third parties may request access to unpublished study data that does not contain individual identifiers, in order to conduct independent analyses. Third parties are defined as experts in the field of radiation health effects and dosimetry who are not part of any JCCRER project. Procedures will be developed for requesting and approving third party access to primary data.

XI. Addendum—Ongoing U.S.-Russian Joint Coordinating Committee for Radiation Effects Research (JCCRER) Studies

A. Description of Ongoing JCCRER Projects

The Russian scientific institutions currently conducting radiation health effects research under the auspices of the JCCRER include the:

- Branch Number 1 of the Biophysics Institute (FIB-1), Ozersk (Dr. Sergey Romanov, Director, romanov@fib1gnc.chel-65.chel.su);
- Mayak Production Association, Ozersk; (Dr. Evgenii Vasilenko, Senior Engineer, rel@envc.chel.su); and
- Urals Research Center for Radiation Medicine (URCRM), Chelyabinsk (Dr. Alexander Akleyev, Director, akleyev@urcrm.chel.su).

1. Description of Cohorts Currently Under Study

Two different epidemiologic research directions currently are supported by the JCCRER: (1) Studies of populations who live near the Techa River; and (2) studies of workers at the MAYAK facility.

a. Techa River Population Cohort.

The liquid discharges to the Techa River from MAYAK (due to inadequate storage of radioactive waste) occurred from 1949–56, with 95 percent released in an eighteen (18) month period (March 1950 to November 1951), for a total release of about 3 million Ci.

The cohort registry consists of individuals born in 1949 or earlier, who lived for at least one (1) month during 1950 to 1952 in the villages along the

Techa River. The cohort includes 28,000 individuals, about 20 percent of which have been estimated to have had average effective doses of exposure of more than 0.5 sievert (Sv). Thirty (30) percent of the cohort members were 0 to 14 years old at the time of exposure.

The external exposure was due from contaminated sediments in the river; the internal exposure (measured by whole body counts and conducted for half of the members of the cohort) was mainly due to intake of river water and milk and included Sr 89, 90, and Cs 137.

Published reports indicate a statistically significant increase in leukemia in the exposed versus control populations. Other cancers, including stomach, esophagus, and lung were also studied, but the results have not been conclusive.

b. MAYAK Workers Cohort.

The computerized registry of 19,000 MAYAK workers contains: occupational histories; vital status; current place of residence or date and causes of death; annual and cumulative data doses; plutonium body burdens; and internal doses to the main organs (lungs, liver and bone marrow). As of 1994, 90 percent of this cohort had known vital status; 5,000 were dead; 1,000 had died of cancer; and more than 4,000 had known plutonium body burdens. The average value of the equivalent dose to the lung for all workers with measured plutonium (Pu 239) body burden is 7.06 Sv, with external gamma doses of 0.88 gray (Gy) for all workers included in the registry. Radiation doses decreased significantly with time, for example:

| Years hired | Average exposure |
|---------------|------------------|
| 1948–53 | 1.57 Gy. |
| 1954–58 | 0.57 Gy. |
| 1959–63 | 0.27 Gy. |
| 1964–72 | 0.15 Gy. |

More than 1,800 occupational diseases were diagnosed by 1959, 92 percent of which were noted between 1949 and 1953. Eighty-three (83) percent of these were diagnosed as chronic radiation sickness caused by radiation exposures of 1 to 10 Gy. Forty-one (41) cases were diagnosed as acute radiation syndrome, four of which were fatal. Burns and other local radiation injury were reported for 188 workers. In addition, 110 cases of pneumosclerosis (66 in individuals whose internal lung exposure exceeded 4.0 Gy) were diagnosed.

2. Tissues Available for Study from the Deceased Techa River Population and MAYAK Worker Cohorts

Tissues available for study on the Southern Urals populations include those of the deceased Techa River population, stored at URCRM in Chelyabinsk, as well as those of the deceased MAYAK workers, located at

FIB-1 in Ozersk. DOE is currently supporting an effort to establish a tissue repository at FIB-1, as described below.

a. *Establishment of Russian Human Radiobiology Tissue Repository at FIB-1 for Exposed MAYAK Workers.*

The repository consists of organs and tissues of 600 deceased MAYAK workers. Blood sample donations obtained with informed consent from

living members of worker cohort, 1,200 of whom are currently residing in the city of Ozersk, will be added to this repository. Additionally, information on internal and external exposure records, on medical records, and on work history will be included in a computerized inventory currently under development for the tissues included in the repository.

Background Information on Formalin-fixed Tissue Materials From 180 Donors Inventoried to Date

(a) Internal organs:

| | Lung | Heart/aorta | Stomach | Pancreas | Liver | Intestine | | Spleen | Kidneys | Urinary bladder |
|-----------------------|------|-------------|---------|----------|-------|-----------|-----|--------|---------|-----------------|
| | | | | | | Sm | Lg | | | |
| Number of cases | 180 | 172/103 | 132 | 135 | 180 | 24 | 117 | 159 | 176 | 30 |

(b) Brain and other organs/tissues:

| | Brain | | Thyroid | Adrenals | Reproductive organs | | | | Lymph nodes |
|-----------------------|-------------|------------|---------|----------|---------------------|----------|-------|--------|-------------|
| | Hemispheres | Cerebellum | | | Testes | Prostate | Ovary | Uterus | |
| Number of cases | 173 | 109 | 126 | 143 | 100 | 40 | 8 | 19 | 69 |

Accumulated Doses of External y-exposure for the 180 Registrants

| | Cumulative doses, Gy | | | | | | Non-monitored |
|-----------------------|----------------------|-----------|---------|----------|----------|------|---------------|
| | <0.05 | 0.051-0.5 | 0.5-1.0 | 1.01-2.0 | 2.01-4.0 | >4.0 | |
| Number of cases | 11 | 15 | 7 | 67 | 63 | 27 | 10 |

Plutonium Body Burden for the 180 Registrants

| | Body burden, kBq | | | | | | | No information |
|-----------------------|------------------|----------|-----------|----------|------------|-------------|--------|----------------|
| | 0-0.75 | 0.76-1.5 | 1.51-2.95 | 2.96-5.9 | 5.91-11.84 | 11.85-47.36 | >47.36 | |
| Number of cases | 34 | 19 | 24 | 19 | 8 | 31 | 18 | 47 |

Ad hoc histology examination of tissue samples of 15 individuals showed preservation of structure of tissue materials stored in formalin for 10-20 years and their adequacy for utilization in morphology studies. Additionally, work with 10 paraffin blocks has shown promise for future DNA studies.

3. Current JCCRER Research Directions

The JCCRER has initiated areas for study called Directions. Direction 1 focuses on the Techa River population and Direction 2 focuses on the MAYAK workers. All projects are jointly conducted by both U.S. and Russian principal investigators and their

respective teams of researchers, and are summarized below.

A third JCCRER Direction, which is not related to this announcement, is focused on U.S.—Russian emergency preparedness/response activities. The Russian Ministry for Emergencies is leading these activities for the Russian side.

Direction 1: Medical Aspects of Radiation Exposure Effects on Population

1. Project 1.1: Dose Reconstruction for the Population Subjected to Radiation in the Urals.

Objectives: To reconstruct, validate and analyze data on individual radiation doses received by the population so that these can be used in studies assessing the risks of developing cancer in exposed populations. (U.S. support from DOE, with supplements from NASA and EPA—scheduled for completion in March 2000)

2. Project 1.2: Risk Estimation of the Carcinogenic Effects in the Population Residing in the Region of the Mayak Production Association.

Objectives: To conduct studies to determine the risk of cancer in population groups exposed to radioactive contaminants in the region, to characterize the quality and validity of the data for conducting such studies, and to preserve the existing data using modern technologies. (U.S. support from DOE on cancer incidence, the first component of which is scheduled for completion in March 2000, and data preservation projects; from National Cancer Institute (HHS) on cancer mortality project.)

3. Project 1.3: Retrospective Reconstruction of Radionuclide Contamination of Techa River Caused by Liquid Waste Discharge from Radiochemical Production at the Mayak Production Association: 1949–1956.

Objectives: To supplement the population dose reconstruction study by providing additional information on the source term of radioactive materials released into the Techa River. (U.S. support from DOE—completed in 1998.)

Direction 2: Medical Consequences of Occupational Exposure to Radiation

1. Project 2.1: Metabolism and Dosimetry of Plutonium Industrial Compounds.

Objectives: To conduct a joint analysis of the data collected by the U.S. Transuranium and Uranium Registry (USTUR) and the dosimetry registry at FIB–1/MAYAK on deceased people with occupational exposure to radiation. (U.S. support from DOE—scheduled for completion in March 2000.)

2. Project 2.2: Risk Estimation for Stochastic (Carcinogenic) Effects of Occupational Exposure.

Objectives: To determine risk estimates for cancer as a result of prolonged occupational exposure to radiation, from both external sources and internally-deposited radioactive compounds. (U.S. support from DOE.)

3. Project 2.3: Non-cancerous Effects of Occupational Exposure to Radiation.

Objectives: To validate and analyze the data on acute and chronic effects of radiation, other than cancer, observed in a large number of workers at the Mayak Production Association. (U.S. support from NRC.)

4. Project 2.4: Reconstruction of Individual Doses of Exposure to Mayak Production Association Workers.

Objectives: To develop an electronic database of reconstructed doses for external and internal exposures received by the MAYAK worker cohort. (U.S. support from DOE.)

Additional DOE Office of International Health Programs-Funded Direction 2 Studies

The Office of International Health Programs awarded five cooperative agreements in August 1998 for fifteen (15) month feasibility studies to support ongoing joint U.S.-Russian studies in the Southern Urals on low dose-rate radiation health effects. These new studies were aimed at adding a molecular epidemiology/biodosimetry component to the ongoing epidemiologic and dose reconstruction work of the JCCRER. The feasibility studies have been jointly conducted by the FIB–1 in Ozersk and U.S. institutions, and the following two have proceeded as Phase II studies.

1. Improved Dosimetry and Risk Assessment for Plutonium-Induced Lung Disease Using a Microdosimetric Approach

Objectives: To determine plutonium distribution in relation to pathology in preserved tissues.

2. Establishment of a Repository Containing Tissues and Organs of Deceased Workers of the Mayak Production Association Who Were Exposed to Actinide Elements.

Objectives: To establish a human tissue repository for cytogenetic and molecular biological research at FIB–1 in Ozersk.

Issued in Washington, D.C., on February 11, 2000.

Paul J. Seligman, M.D., M.P.H.,

Deputy Assistant Secretary for Health Studies.

[FR Doc. 00–4136 Filed 2–18–00; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–53–000]

Black River Limited Partnership; Errata of February 16, 2000; Notice of Filing Issued February 8, 2000

By this notice, the due date for interventions and protests in the above-referenced proceeding is hereby shortened to and including February 28, 2000.

David P. Boergers,
Secretary.

[FR Doc. 00–4093 Filed 2–18–00; 2:18 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00–76–000]

Black River Limited Partnership; Errata of February 15, 2000; Notice of Amendment to Application for Commission Determination of Exempt Wholesale Generator Status Issued February 11, 2000

By this notice, the due date for interventions and protests in the above-referenced proceeding is hereby shortened to and including February 25, 2000.

David P. Boergers,
Secretary.

[FR Doc. 00–4056 Filed 2–18–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–1317–000]

Central Vermont Public Service Corporation; Notice of Filing

February 10, 2000.

Take notice that on February 7, 2000, Central Vermont Public Service Corporation (Central Vermont), tendered for filing revised Network Integration Transmission Service Agreements with Vermont Electric Cooperative, Inc.; Woodsville Fire District Water and Light Department (Woodsville); Village of Johnson Water and Light Department; Rochester Electric Light and Power Company; Village of Ludlow Electric Light Department of serve under Central Vermont's Open Access Transportation