

§ 725.25

under this permit and to assist the permittee in other matters pertaining to the administration of his permit.

§ 725.25 Term and renewal.

(a) Each access permit will be issued for a two year term, unless otherwise stated in the permit.

(b) Applications for renewal shall be filed in accordance with § 725.11. Each renewal application must be complete, without reference to previous applications. In any case in which a permittee has filed a properly completed application for renewal more than thirty (30) days prior to the expiration of his existing permit, such existing permit shall not expire until the application for a renewal has been finally acted upon by the Administrator.

§ 725.26 Assignment.

An access permit is nontransferable and nonassignable.

§ 725.27 Amendment.

An access permit may be amended from time to time upon application by the permittee. An application for amendment may be filed, in triplicate, in letter form and shall be signed by an individual authorized to sign on behalf of the applicant. The term of an access permit shall not be altered by an amendment thereto.

§ 725.28 Administrator action on application to renew or amend.

In considering an application by a permittee to review or amend his permit, the Administrator will apply the criteria set forth in § 725.15. Failure of an applicant to reply to an DOE request for additional information concerning an application for renewal or amendment within 60 days shall result in a rejection of the application without prejudice to resubmit a properly completed application at a later date.

§ 725.29 Suspension, revocation and termination of permits.

The Administrator may revoke or suspend any access permit for any material false statement in the application or in any report submitted to DOE pursuant to the regulations in this part or because of conditions or facts which would have warranted a refusal to

10 CFR Ch. III (1-1-05 Edition)

grant the permit in the first instance, or for violation of any of the terms and conditions of the Atomic Energy Act of 1954 or rules, regulations or orders issued pursuant thereto. A permittee should request termination of his permit when he no longer requires Restricted Data for use in his business, trade or profession.

§ 725.30 Exceptions and additional requirements.

Notwithstanding any other provision in the regulations in this part, the Administrator may deny an application for an access permit or suspend or revoke any access permit, or incorporate additional conditions or requirements in any access permit, upon finding that such denial, revocation or the incorporation of such conditions and limitations is necessary or appropriate in the interest of the common defense and security or is otherwise in the public interest.

§ 725.31 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

APPENDIX A TO PART 725—CATEGORIES OF RESTRICTED DATA AVAILABLE

C-24 Isotope separation.—This category is divided into subcategories A and B.

Subcategory A includes information in summary form concerning the status and potential of the gaseous diffusion and gas centrifuge processes for the separation of uranium isotopes.

Subcategory B includes information on the following:

a. Any aspect of separating one or more isotopes of uranium from a composition containing a mixture of isotopes of that element by the gas centrifuge or gaseous diffusion processes.

b. Design, construction, and operation of any plant, facility or device capable of separating by the gas centrifuge or gaseous diffusion processes one or more isotopes of uranium from a composition containing a mixture of isotopes of that element, including

Department of Energy

Pt. 725, App. A

means and methods of transporting materials from one to another device.

C-44 Nuclear Technology. This category includes classified technical information concerning nuclear technology. It may contain information on the following:

a. Materials, including metals, ceramics, organic and inorganic compounds. Included are such technical areas as the technology and fabrication of fuel elements, corrosion studies, cladding techniques and radiation studies.

b. Chemistry, chemical engineering and radiochemistry of all the elements and their compounds. Included are techniques and processes of chemical separations, radioactive waste handling and feed material processing.

c. Reactor physics, engineering and technology including theory, design, criticality studies and operation of reactors, reactor systems and reactor components.

d. Reserved.

e. Lithium isotope separation technology. This subcategory includes classified technical information on the separation of lithium isotopes by using counter-current flows of lithium amalgam and aqueous lithium hydroxide solution in packed columns. Not included is information regarding plant design and operating conditions from which total production rates or design capacity of the lithium isotope separation plant (Calex) in Oak Ridge, Tennessee, can be inferred. In addition to the other requirements of this part, access permits for Restricted Data in this subcategory will be approved, provided the permittee:

1. Demonstrates that it is not a corporation or entity owned, controlled or dominated by an alien, a foreign corporation, or a foreign government, and

2. Agrees to insertion in his access permit of the terms and conditions:

(i) Set forth in paragraphs (a) and (b) of §725.23 of this part;

(ii) Set forth in paragraph (c) of §725.23 of this part, amended by deleting the phrase "category C-24, isotope separation," and inserting in lieu thereof the phrase "subcategory C-44e, lithium isotope separation technology";

(iii) Set forth in paragraph (d) of §725.23 of this part, amended by:

(A) Deleting the phrases "production or enrichment of special nuclear material" and "separation of isotopes" wherever they appear, and inserting in lieu thereof the phrase "separation of isotopes of lithium";

(B) Deleting the phrase "domestic commercial uranium enriching services are provided by," and inserting in lieu thereof the phrase "domestic lithium isotope separation capacity becomes available to."

This category does not include information which reveals or from which can be calculated actual or planned (as distinguished

from design) capacities, production rates and unit costs for the plutonium production program.

C-65 Plutonium Production. This category includes information on reactor, fuel element and separations technology which reveals or from which can be calculated actual or planned (as distinguished from design) capacities, production rates and unit costs for the Hanford and Savannah River production facilities.

Technology which does not reveal or enable calculation of production rates and unit costs of Hanford or Savannah River production facilities is categorized in C-44 Nuclear Technology.

C-90 Nuclear Reactors for Ram-Jet Propulsion. This category includes information on:

a. Programs pertaining to the development of nuclear reactors for application to ram-jet propulsion systems including theory and/or design, test philosophy procedures and/or results.

b. Fabrication technology and evaluation of performance or characteristics of materials or components for such reactors.

c. Controls, control systems and instrumentation relating to the design or technology of such reactors.

d. Data pertaining to heat transfer, propellant kinetics or corrosion and erosion of materials under conditions of high temperature, high gas flows or other environmental conditions characteristic of ram-jet propulsion systems.

This category does not include information on:

a. Design details of weapons systems or nuclear warheads.

b. Military operational techniques or characteristics.

c. General aspects of nuclear ram-jet missiles, such as payload, aerodynamic characteristics, guidance systems, physical size, gross weight, thrust and information of this kind which is associated with utilization of a nuclear ram-jet propulsion system.

C-91 Nuclear Reactors for Rocket Propulsion. This category includes information on:

a. Programs pertaining to nuclear reactors for rocket propulsion, i.e., missile propulsion, theory and/design, test philosophy procedures and/or results.

b. Design, fabrication technology and evaluation of performance or characteristics of material, components, or subsystems or nuclear rocket reactors.

c. Controls, control systems and instrumentation relating to the design or technology of rocket reactor systems.

d. Data pertaining to heat transfer, propellant kinetics or corrosion and erosion of rocket reactor system materials under conditions of high temperature, high gas flows,

or other environmental conditions characteristic of rocket reactors.

This category does not include information on:

- a. Design details of weapons systems or nuclear warheads.
- b. Military operational techniques or characteristics.
- c. General aspects of payload and aerodynamic characteristics.
- d. Design details and development, information of components and subsystems of the nuclear rocket engine other than that associated with the reactor system.

C-92 Systems for Nuclear Auxiliary Power (SNAP). This category includes information on:

- a. Isotopic SNAP Program, including theory, design, research and development, fabrication, test procedures and results for the device, including power conversion device and the fuels used.
- b. Reactor SNAP Program, including theory, design, research and development, fabrication, test procedures and results for the reactor, including the directly associated power conversion device when developed by DOE.

This category does not include that technical and scientific data developed under the SNAP Advanced Concept Program which should be reported in C-93.

C-93 Advanced Concepts for Future Application.

C-93a Reactor Experiments. This category includes classified technical information developed in the pursuit of work on new or advanced concepts of reactors or components which DOE considers essential to future growth or for general application to future generations of reactors. Classified information developed in the pursuit of work on the lithium cooled reactor experiment is an example of the type of information to be reported in this category, i.e., information resulting from an experimental reactor project or component development which may have many future applications but which is not currently being pursued to meet the specific needs of an approved requirement for which other information categories have been provided. For example, classified technical information developed in the pursuit of work on Naval, Ram-Jet or Rocket nuclear reactors would not be reported here but under their respective specific categories. This category will include classified technical information on the following:

- a. Theory, design, and performance, either estimated or actual.
- b. Design details, composition and performance characteristics of major components (e.g., fuel media, reflectors, moderators, heat exchangers, pressure shells or containment devices, control rods, conversion devices, instrumentation and shielding).

c. Material (metals, ceramics and compounds) development, alloying, cladding, corrosion, erosion, radiation studies and fabrication techniques.

d. Chemistry, including chemical engineering, processes and techniques. Reactor physics, engineering and criticality studies.

C-93b Conversion Devices. This category includes classified technical information developed in the pursuit of studies, designs, research and development, fabrication and operation of any energy conversion device to be used with nuclear energy sources which is not being applied to a specific system development project.

C-94 Military Compact Reactor (MCR). This category includes classified technical information on the actual or planned Military Compact Reactor and its components developed in the pursuit of studies, designs, research and development, fabrication, and operation of the reactor system or its components.

Examples of the areas of information included are:

- a. Reactor core physics.
- b. Fuel elements and fuel element components.
- c. Moderator and reflector details.
- d. Data on primary coolant system.
- e. Radiation shield.
- f. Controls and instrumentation.

This category does not include information on military operational characteristics or techniques.

[41 FR 56778, Dec. 30, 1976, as amended at 44 FR 37939, June 29, 1979]

APPENDIX B TO PART 725—DOE'S OPERATIONS OFFICES AND GEOGRAPHICAL AREAS OF RESPONSIBILITIES

Albuquerque Operations Office, U.S. Department of Energy, P.O. Box 5400, Albuquerque, New Mexico 87115: Arizona, Kansas, New Mexico, Oklahoma, and Texas.

Chicago Operations Office, U.S. Department of Energy, 9800 South Cass Avenue, Argonne, Illinois 60439: Connecticut, Delaware, District of Columbia, Illinois, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, North Dakota, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Dakota, Vermont, and Wisconsin.

Richland Operations Office, U.S. Department of Energy, P.O. Box 550, Richland, Washington 99352: Alaska, Oregon, and Washington.

Oak Ridge Operations Office, U.S. Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830: Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Panama Canal Zone, Puerto Rico, Tennessee, Virginia, Virgin Islands, and West Virginia.

Department of Energy

§ 745.101

San Francisco Operations Office, U.S. Department of Energy, 2111 Bancroft Way, Berkeley 4, California 94612; California, Colorado, Hawaii, Idaho, Montana, Nevada, Utah, Wyoming, and U.S. Pacific Territories.

Savannah River Operations Office, U.S. Department of Energy, P.O. Box A, Aiken, South Carolina 29810; Alabama, Florida, Georgia, North Carolina, and South Carolina.

[41 FR 56778, Dec. 30, 1976, as amended at 44 FR 37939, June 29, 1979]

PART 745—PROTECTION OF HUMAN SUBJECTS

Sec.

- 745.101 To what does this policy apply?
- 745.102 Definitions.
- 745.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 745.104–745.106 [Reserved]
- 745.107 IRB membership.
- 745.108 IRB functions and operations.
- 745.109 IRB review of research.
- 745.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 745.111 Criteria for IRB approval of research.
- 745.112 Review by institution.
- 745.113 Suspension or termination of IRB approval of research.
- 745.114 Cooperative research.
- 745.115 IRB records.
- 745.116 General requirements for informed consent.
- 745.117 Documentation of informed consent.
- 745.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 745.119 Research undertaken without the intention of involving human subjects.
- 745.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 745.121 [Reserved]
- 745.122 Use of Federal funds.
- 745.123 Early termination of research support: Evaluation of applications and proposals.
- 745.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28018, June 18, 1991, unless otherwise noted.

§ 745.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 745.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 745.102(e) must be reviewed and approved, in compliance with § 745.101, § 745.102 and § 745.107 through § 745.101 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through