

In accordance with Section 5 U.S.C. 202(b)(1), we have forwarded to the Department of Commerce statements of "exceptional circumstances" determinations. Copies of the statements are transmitted herewith.

The statements cover DOE funding agreements with small businesses or nonprofit organizations relating to three areas:

- storage and disposal of civilian high-level nuclear waste and spent fuel;
- 2) uranium enrichment programs; and
- 3) classified technology and unclassified but sensitive technology under Section 148 of the Atomic Energy Act or DOD Directive 5230.25.

These technology areas were identified by a Departmental task force as the major areas requiring exceptional circumstances determinations.

We anticipate providing formal guidance on implementation of these exceptional circumstances determinations in the near future. In the meantime, should a funding agreement arise with a small business or nonprofit in any of the "exceptional circumstances" areas, you may provide for use of an appropriate patent rights clause providing for title of subject inventions in the Government. Please be advised, however, that in order to implement a contractor's statutory right of appeal of an exceptional circumstance determination, an affected contractor must be provided with notice of the determination and of its right of appeal at the time of contracting.

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Statement of Analysis and Determination of Exceptional Circumstances for Funding Agreements with Nonprofit or Small Business Entities relating to Classified or Sensitive Technology

For the reasons, facts, and justifications set forth below, the Department of Energy (DOE) has determined that exceptional circumstances obtain for DOE funding agreements involving work in technologies which are classified, or sensitive under section 148 of the Atomic Energy Act (42 U.S.C. 2168), or controlled pursuant to federal export control regulations as stipulated in DOD Directive 5230.25. Accordingly, a disposition of patent rights different from that applicable under Pub. L. 96-517 and Pub. L. 98-620 is necessary for funding agreements with small businesses or nonprofit organizations involving these technologies. Allocation of patent rights to the Government for these technologies will better promote the policies and objectives of Chapter 18, Title 35 of the U.S. Code.

Section 148 of the Atomic Energy Act directs the Department of Energy to protect from unauthorized dissemination certain unclassified information pertaining to:

- the design of nuclear production or utilization facilities;
- security measures for the physical protection of such facilities, nuclear material contained in these facilities, or nuclear material in transit; or
- the design, manufacture, or utilization of any atomic weapons or component if the design, manufacture, or utilization of such weapons or component was contained in any information which was declassified from the Restricted Data category.

In revising the Atomic Energy Act to give DOE authority under section 148 to prohibit dissemination of this unclassified but sensitive information, Congress recognized the concern for protection of such information from use by other nuclear powers and small terrorist organizations or non-nuclear states. In many cases, material which had been unclassified or declassified prior to the more recent appreciation of the threat from terrorists could be used for very damaging purposes by such groups or individuals. Consequently, section 148 was included in the Atomic Energy Act to ensure safeguarding of plutonium, enriched uranium, and other special nuclear materials, which might be diverted or stolen through use of this information, as well as to protect sensitive information pertaining to the military uses of nuclear energy (such as naval nuclear propulsion) where it is vitally important that the U.S. maintain its technological lead over adversary countries.

DOD Directive 5230.25, "Withholding of Unclassified Technical Data from Public Disclosure," issued November 6, 1984, is intended to implement a provision in the fiscal 1984 DOD authorization act (10 U.S.C. 140(c)) that gives the Department of Defense the authority to withhold from public disclosure any unclassified technical data with military or space application if the data are subject to export license controls. Those DOE GOCO facilities which perform work in support of nuclear weapons and naval nuclear propulsion matters, also routinely deal with technology which is subject to the above-cited DOD Directive.

The primary rationale for this exceptional circumstances determination is that when the Government decides that an invention (including related technical data) is classified, or is sensitive under Section 148, or meets certain criteria stipulated in DOD Directive 5230.25 concerning technology in which the U.S. holds a lead over foreign adversaries, there is a direct implication that commercialization, uncontrolled disclosure, or proliferation of the technology embodied therein is contrary to the public interest. This applies to inventions whether or not a patent application has been or ever will be filed thereon. Pub. L. 96-517 authorizes an exceptional circumstances determination when appropriate to "better promote the policy and objectives" of the act. The relevant policy and objectives of Pub. L. 96-517 include using the patent system to promote the utilization of inventions arising from federally supported research or development; to promote collaboration between commercial concerns and nonprofit organizations; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; and to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.

Clearly, most of the "policy and objectives" of Pub. L. 96-517 relate to using the patent system to promote utilization, commercialization and free enterprise in the underlying technology. Inventions covered by this exceptional circumstances determination are inherently inventions in which it is in the public interest to <u>discourage</u> commercial utilization. Accordingly, in view of the "exceptional" nature of the technology and the public interest in controlling and discouraging utilization of the technology, automatic contractor election to retain rights in inventions covered by this determination does not appear to be in the public interest.

The House Report concerning H.R. 5003 (a predecessor bill to Pub. L. 98-620), in discussing the "exceptional circumstances" exemption, specifically cites DOE programs such as uranium enrichment or reprocessing as areas where a determination of "exceptional circumstances" would be justified, because "for public policy reasons such as nuclear proliferation the business is considered too sensitive to be operated with private sector ownership." A similar rationale prevails for technologies covered by this determination. Considerable overlap exists between the subject matter covered by this determination and that covered by the statutory exemption provided in 35 U.S.C. 202(a) (iv) for DOE Government-owned, contractor-operated facilities primarily dedicated to the Department's naval nuclear propulsion or weapons related programs, and by similar "exceptional circumstances" determinations covering uranium enrichment activities and activities related to handling and disposal of civilian high level radioactive waste. The public interest in discouraging proliferation of the underlying technologies is a common thread in precluding automatic contractor retention of rights in the above areas.

Accordingly, it is hereby determined that exceptional circumstances exist in the field of classified or sensitive technologies discussed herein. As a result, DOE funding agreements with small businesses or nonprofit organizations shall contain patent provisions providing for Government retention of rights to inventions to the extent that such inventions are in classified or sensitive areas. However, this exceptional circumstances determination does not preclude a contractor from seeking patent waivers in accordance with established policies and procedures.

35 U.S.C. 203(2) provides a contractor a right of appeal of any agency's exceptional circumstances determination. Accordingly, each contractor to which this determination applies will be provided with notice of this determination and its right of appeal at the time of contracting.

Statement of Analysis and Determination of Exceptional Circumstances for DOE funding agreements relating to Federal storage and disposal of civilian high-level nuclear waste and spent nuclear fuel.

For the reasons, facts, and justifications set forth below, the Department of Energy (DOE) has determined that the circumstances surrounding DOE's program for Federal storage— and disposal of civilian high-level nuclear waste and spent nuclear fuel are exceptional. Accordingly, a disposition of patent rights different from that applicable under Pub. L. 96-517 and Pub. L. 98-620 for funding agreements with small businesses or nonprofit organizations under this program is necessary. Allocation of patent rights to the Government under this program will better promote the policies and objectives of Chapter 18, Title 35 of the U.S. Code.

As one of its primary missions, the Department of Energy conducts a program directed toward storage and disposal of radioactive waste and spent nuclear fuel. In the Nuclear Waste Policy Act of 1982 (NWPA) (Pub. L. 97-425), Congress found that a national problem had been created by the accumulation of (A) spent nuclear fuel from nuclear reactors; and (B) radioactive waste from (i) reprocessing of spent nuclear fuel; (ii) activities related to medical research, diagnosis, and treatment; and (iii) other sources. It determined that the Federal Government has the responsibility to provide for the permanent disposal of high-level radioactive waste and such spent nuclear fuel as may be disposed of in order to protect the public health and safety and the environment. However, according to the NWPA, the costs of activities related to such disposal should be the responsibility of the generators and owners of such waste and spent fuel, e.g. the utilities, and are collected by special fees levied on the utilities.

Typically, funding agreements under the civilian high-level nuclear waste program are with organizations other than the utilities. Since the program is funded by special fees levied on the utilities, it would be inequitable in many cases if the utilities were precluded from obtaining even license rights to use the technology developed under the program. Without this "exceptional circumstances" determination, small business or nonprofit contractors would automatically be entitled to retain invention rights, with the result that utilities, which by law are required to fund the program, would not be assured of license rights to use the technology.

1/ For purposes of this determination, "Federal storage" shall mean the Interim Storage Program as authorized by 42 U.S.C. 10151 et seq. and Monitored Retrievable Storage as authorized by 42 U.S.C. 10161 et seq.

This reasoning was endorsed in the House Report concerning H.R. 5003 (a predecessor bill to Pub. L. 98-620). In discussing the "exceptional circumstances" exemption, the Department of Energy's terminal repository program for high-level nuclear waste was specifically cited as an example of a situation where "exceptional circumstances" would obtain. The House Report noted that the program is an example of a "non-routine business relationship," and that since the program is funded through special fees levied on the utility industry, the Department may decide that that industry should have a say in the allocation of rights in that program's subject inventions. Providing for Government retention of rights pursuant to this "exceptional circumstances" determination preserves the Government's flexibility to grant licenses to utilities, as appropriate, or to solicit utility industry participation in any rights allocation to contractors, as suggested in the House Report.

In the Senate Judiciary Committee Report on S.414 (which resulted in Pub. L. 96-517, which originally authorized "exceptional circumstances" determinations) use of the "exceptional circumstances" exemption was discussed. In that report it was stated that an example of a situation in which "exceptional circumstances" might be used is when the funding agreement calls for a specific product that will be required to be used by regulation. In such a case, the report states, it is presumed that patent incentives would not be required to bring the product to the market. The report further states that if a funding agreement calls for developmental work on a product or process that the agency plans to fully fund and promote to the marketplace, use of the exception might be justified. Work in the field of high-level radioactive waste storage and disposal has in the past been substantially funded by the Government. As noted above, the NWPA provides for costs of nuclear waste disposal to be assumed by the generators and owners of such waste. The substantial support of the technology by the Government and the utilities is pertinent from the standpoint that, as suggested in the Judiciary Committee Report, patented inventions and the incentives inherent in the patent system are not promoting commercialization of this technology to any significant extent, at least at this time. Instead, it is congressional mandates, regulatory requirements, and Federal and utility support that are promoting development of this technology.

A further rationale for invoking "exceptional circumstances" for the program is the preservation of the option to privatize the technology developed under the program. As stated above, under current law the Federal Government has the primary responsibility for the conduct of the program. At some future time, it may be found desirable and feasible to have industry commercialize the technology. In that event, subject to Federal laws and regulations, private commercialization efforts can be undertaken by industry. If "exceptional circumstances" are not invoked, ownership of technology rights in this field will become fragmented among a number of contractors. This fragmentation of rights might well frustrate the Government's ability to transfer the technology to the private sector if and when such transfer is deemed desirable and feasible since licensing arrangements would likely need to be negotiated with a number of firms.

It should be noted that this "exceptional circumstances" determination is limited to the DOE's <u>Civilian</u> Radioactive Waste Management Program, as distinct from DOE programs solely for handling of <u>defense</u> wastes. While much of the rationale of this determination regarding civilian wastes would be applicable to defense wastes, it is felt that broadening of the scope of this determination to include defense wastes is unnecessary in view of the exemption provided in Pub. L. 98-620 for Government-owned, contractor-operated facilities that are primarily dedicated to weapons-related programs.

For these reasons the Department has determined that exceptional circumstances exist as provided in Section 202(a)(ii) of Chapter 18 of Title 35, United States Code, and that funding agreements with small businesses or nonprofit organizations in the field of Federal storage and disposal of civilian high-level nuclear waste and spent nuclear fuel shall contain patent provisions providing for Government retention of rights to inventions. However, this "exceptional circumstances" determination does not preclude a contractor from seeking patent waivers in accordance with established policies and procedures.

35 U.S.C. 203(2) provides a contractor a right of appeal of any agency's exceptional circumstances determination. Accordingly, each contractor to which this determination applies will be provided with notice of this determination and its right of appeal at the time of contracting.

Statement of Analysis and Determination of Exceptional Circumstances for DOE's Uranium Enrichment Programs

For the reasons, facts, and justifications set forth below, the Department of Energy (DOE) has determined that the circumstances surrounding DOE's Uranium Enrichment programs are exceptional. Accordingly, a disposition of patent rights different from that applicable under Pub. L. 96-517 and Pub. L. 98-620 for funding agreements with nonprofit organizations under these programs is necessary. Allocation of patent rights to the Government under these programs will better promote the policies and objectives of Chapter 18, Title 35 of the U.S. Code.

DOE's uranium enrichment programs, which include enrichment by gaseous diffusion, and anticipated advanced development of the gas centrifuge and laser isotope separation technologies, are largely classified, Government-controlled programs involving technology which has been funded almost exclusively by the Government. The gaseous diffusion program dates back over 40 years and represents a Government investment of over \$3.8 billion. The Government has invested about \$730 million so far in the gas centrifuge program with a potential additional commitment of about \$5 billion to be invested in a gas centrifuge enrichment plant to be built in Portsmouth, Ohio. The Government has spent about \$600 million developing advanced processes such as laser isotope separation technology and the Dawson process.

Access to uranium enrichment technology to date has been controlled by the Government since, for public policy reasons such as nuclear proliferation, the technology at this time is considered too sensitive to be utilized with private sector ownership. Since the Government is the the only legal customer of the technology, there is no present justification for allowing the private sector to own the patent rights. This rationale for invoking of "exceptional circumstances" for uranium enrichment technology was specifically endorsed in House Report 98-983 accompanying H.R. 5003 (a predecessor bill to Pub. L. 98-620).

There have been studies on whether to "privatize" uranium enrichment technology in the future. While the future roles of the Government and private industry in this regard are in a state of flux at this time, the Department believes that the Government should continue to retain the rights to the technology. If transfer of the technology to private industry in the future is to be made, it is anticipated that the Government would need to transfer the rights as a whole to the purchaser of the technology. If "exceptional circumstances" are not invoked, ownership of uranium enrichment technology rights will become fragmented among a multiplicity of contractors. This fragmentation of rights could frustrate the Government's ability to transfer the technology to the private sector if and when such transfer is deemed in the public interest, since licensing arrangements would likely need to be negotiated with a number of

firms. General Accounting Office Report GAO/RCED-84-26 (February 28, 1984) endorses this reasoning.

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For the foregoing reasons, funding agreements and contracts under DOE's uranium enrichment programs are determined to be subject to exceptional circumstances as provided in Section 202(a) (ii) of Chapter 18 of title 35 United States Code. However, this determination does not preclude a contractor from seeking patent waivers in accordance with established policies and procedures.

35 U.S.C. 203(2) provides to a contractor a right of appeal of any agency's exceptional circumstances determination. Accordingly, each contractor to which this determination applies will be provided with notice of this determination and its right of appeal at the time of contracting.