

## **STATEMENT OF CONSIDERATIONS**

### **Advance Test Reactor Class Waiver W(C)-2008-004**

The Advanced Test Reactor (ATR) is a pressurized water test reactor at the Idaho National Laboratory (INL) that operates at low pressure and temperature. The ATR was originally designed to study the effects of intense radiation on reactor material and fuels. It has a "Four Leaf Clover" design that allows a diverse array of testing locations. The unique design allows for different flux in various locations and specialized systems also allow for certain experiments to be run at their own temperature and pressure.

The U.S. Department of Energy (DOE) designated the Advanced Test Reactor (ATR) as a National Scientific User Facility (NSUF) in April 2007. This designation will allow the ATR to become a cornerstone of nuclear energy research and development within the U.S. by making it easier for universities, the commercial power industry, other national laboratories, and international organizations to conduct nuclear energy R&D. These sectors have a common need for experimental capabilities, whether for basic scientific investigations, applied research concerning existing nuclear fuels and materials, validation of data for regulatory agencies, or research underpinning the development of advanced nuclear energy systems.

In the past, DOE has issued a variety of class waivers, both proprietary and non-proprietary, to users of designated DOE user facilities. However, those class waivers do not specifically cover the ATR, nor the type of collaborative work that is contemplated at the ATR. It is anticipated that Users will be using the Facility either to advance a specific commercial interest, to gain a familiarity with the capabilities of the ATR, or to advance their own general state of knowledge. Further, the ATR, unlike typical user facilities where a beam line or a tool can be made available to the User with very little interaction from the Laboratory, almost all of the work must be done in collaboration with the Laboratory. The collaboration can range from arranging for a simple irradiation task on behalf of the sponsor to providing full scientific assistance and analysis to the user.

While such collaborative uses could be covered under the statutory authority for Cooperative Research and Development Agreements (CRADA's) in 15 U.S.C. § 3710a, that authority does not exclude other contractual arrangements for collaborative research. Both before and after the enactment of the CRADA law, DOE authorized other types of agreements that covered work that also could have been performed under CRADAs. These include Non-proprietary and Proprietary User Facility Agreements and the Deployment User Facility Agreement. In order to maximize access and utilization of the ATR, there is a need to have a streamlined approach to permit users the flexibility to engage in general collaboration without having to negotiate a formal CRADA, which can cause significant delays. Use of CRADA's for all collaborative work may also limit access to and use of the ATR. Also, INL might be reluctant to enter into CRADA's with some parties insofar as the Laboratories would be obligated to negotiate exclusive licenses in Laboratory inventions for certain fields of use. Such exclusive licenses, to the extent they encumber Laboratory inventions, might diminish the further availability of the ATR for others to engage in collaborative research in the same or closely related fields of art, and could also

restrict the Laboratory's ability to license its technology to others or perform work for others in the technology it develops. As described below, the issuance of this waiver would not preclude collaborative research being done at the ATR under a CRADA. Use of a similar class waiver at DOE's Nanoscale Science Research Centers has demonstrated that providing for this type of precompetitive User agreement, in addition to the more commercial CRADA, maximizes third party access to and use of a facility.

Agreements that are the subject of this waiver do not take the form of a research contract, cooperative agreement, or grant as these terms are used in the Federal Grant and Cooperative Agreement Act of 1977 (31 U.S.C. §§ 6303-05) and implementing guidance by OMB and OFPP. Also, the requirements of DOE's regulations covering contracts, cooperative agreements and grants are not followed. As a result, these agreements do not fall within the definition of "funding agreement" of 35 U.S.C. § 200 *et seq.* (commonly referred to as the Bayh-Dole legislation), and the patent policy set forth therein as applicable to small businesses and nonprofit organizations does not apply. For the same reason, the Presidential Memorandum on Government Patent Policy of February 18, 1983, which made the policies of Bayh-Dole applicable to all other organizations to the extent permitted by law, does not apply. The Laboratory scope of work will be performed under the prime contract with DOE, and those terms and conditions apply to the Laboratories.

Although not falling within the normal concept of R&D acquisition or assistance, for the user, these agreements nevertheless fall within the broad definition of "...contract, grant, agreement, understanding, or other arrangement, which includes research..." of section 9 of DOE's Federal Nonnuclear Energy Research and Development Act of 1974 (Nonnuclear Act) and the concept of "...any contract, subcontract, or arrangement entered into with ...(DOE) ..., regardless of whether the contract, subcontract or arrangement involved the expenditure of funds by the ... (DOE) ..." of Section 152 of the Atomic Energy Act of 1956, as amended (Atomic Energy Act). As a result of this broad statutory language, agreements that fall outside of normal R&D acquisition and assistance policies nevertheless fall within DOE's title-taking patent policy legislation. It is the purpose of this waiver to utilize the flexibility of the Atomic Energy and Nonnuclear Acts, the statutory intent of Bayh-Dole, and the guidance of the Presidential Memorandum on Government Patent Policy of 1983 in order to provide a balanced and equitable patent policy that will encourage the utilization of ATR.

This waiver is directed to non-proprietary research at the ATR for users who are seeking to gain a familiarity with ATR or to advance their own general state of knowledge. Users will have a scope of work in which the user's tasks and deliverables will be set forth in an appendix attached to the ATR User Agreement. The Laboratory's scope of work will be approved through its Field Task Proposal. The scope of work will be directed toward non-proprietary research that advances the state of the art in the user's area of interest, rather than toward producing a specific commercial end result (e.g., a marketable product); (2) intend to publish their research results in the open scientific literature; and (3) do not require the data protection available in a CRADA. The converse of each of these factors would be an indication that the work to be performed is beyond the non-proprietary stage and would be more appropriately covered under a CRADA. In addition, users interested in proprietary work at the ATR can also use the non-federal WFO mechanism available at the INL.

This class waiver applies to inventions of the user conceived or first actually reduced to practice in the course of or under a non-proprietary agreement for the use of ATR. Since the user is not providing full cost recovery, the Government will receive a royalty free, nonexclusive license to each invention, the standard march-in rights, U.S. Preference, and other restrictions and obligations set forth in Sections 202-204 of Bayh-Dole, as implemented by applicable regulations. In the event that the user does not elect title to a subject invention under this waiver, the Laboratory contractor may then take title. The waiver does not cover inventions of the Laboratory contractor, or apply when the user is working under an agreement with DOE or another federal agency which requires a different disposition of patent rights. Additionally, all parties will have unlimited rights in the data generated from work under the agreement and the right to publish the results of the sponsored research.

This waiver is also available to foreign entities, provided they are granted access to the ATR pursuant to other applicable laws and regulations the scope of work will be directed towards.

The availability of this class waiver for non-proprietary transactions at the ATR shall be automatic upon a determination by the DOE Patent Counsel responsible for the ATR, either directly or through delegation to the ATR user facility management, that the user is qualified and selected to have access to the facility. Delegation to the ATR user facility management is appropriate where there is an established set of criteria for user access, subject to peer review, and where the ATR user facility management has a management plan, for use of the facility. On the other hand, the applicability of this waiver to a proprietary user shall be by approval of the cognizant DOE Patent Counsel responsible for the ATR.

Work performed under this waiver will be pursuant to a Non-proprietary ATR User Facility Agreement, which will be reviewed and approved by the cognizant DOE Field Patent Counsel. The Agreement will be consistent with previously approved DOE user facility agreements and any user facility agreements that are being circulated for comment. The ATR Non-proprietary User Agreement may be updated periodically at the discretion of the DOE Field Patent Counsel.

Further, it is understood that DOE is in the process of updating class waivers for non-proprietary and proprietary users of DOE facilities to simplify and promote consistency for User Agreements at DOE facilities. When these new standard DOE class waivers are issued by DOE, the ATR class waiver will be superseded/replaced by the new waivers, and the ATR User Facility Agreement will be modified to reflect the new class waivers. Substantive changes are not expected in the new standard class waivers for DOE user facilities.

Because of the unique nature of the ATR operations which support various Department and National programs as well as users, a tailored pricing model has been developed by the Laboratory. All work at the ATR will be conducted in accordance with this pricing model. The costs have been broken down into the areas of core capacity costs, irradiation charges, and program costs. In general, non-proprietary users will be authorized to do their work at no charge for research that is of Department programmatic interest and approved by Laboratory management.

To the extent that the user is supported by funding from another federal agency or an international agreement, the agreement with that agency or the international agreement will provide for the disposition of patent rights deemed necessary to satisfy the agency's statutory or regulatory requirements. In view of Bayh-Dole, and the 1983 Presidential Memorandum on Government Patent Policy, the disposition of rights in a funding agreement with the Government will normally be identical to those of this class waiver.

It is within DOE's programmatic purposes to encourage widespread utilization of the ATR in the support of nuclear energy research. It is believed that providing exclusive rights to patentable inventions made by the users of the ATR would best encourage such utilization, as well as further development of the technology by the user. Further, proprietary rights in the data and inventions produced under the work at the ATR will be useful in encouraging the investment of the required capital expenditures for commercialization of the technology. The waiver should, therefore, promote the commercial utilization of subject inventions and make the benefits of the ATR widely available to the public in the shortest practicable time. Accordingly, this waiver is consistent with the objectives and considerations of DOE's waiver regulations.

In summary, the ATR has been designated as user facility to provide a world-class facility for nuclear energy research that facilitates the advancement of nuclear science and technology. This allows for advancing research and collaboration by offering the unique capabilities of the ATR to the research efforts of profit and nonprofit organizations, as well as other governmental entities. The grant of this waiver, therefore, will not only be consistent with the legislative intent of Bayh-Dole, but also will reflect the guidance provided to DOE in Section 9 of the Nonnuclear Act, as implemented by DOE regulations governing the granting of patent waivers, and in the 1983 Presidential Memorandum on Government Patent Policy.

Accordingly, in view of the objectives to be attained and the factors to be considered under DOE's statutory waiver policy, all of which have been considered, it is recommended that a waiver of U.S. and foreign patent rights, to the class of users, and in the situations described above, will best serve the interests of the United States and the general public. It is therefore recommended that the waiver be granted.



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Date: 4/23/08

Pursuant to the authority provided in Section 152 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2182), Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, as amended (42 U.S.C. 5908), and the implementing regulations promulgated thereunder for waivers of patent rights, it is concluded that it is in the best interests of the United States and the general public to grant a waiver of patent rights to the class represented by Users at the ATR. Therefore, it is ordered that a waiver of U.S. and foreign patent rights to the class of Users described in the foregoing Statement of Considerations is hereby granted. The waiver is limited to inventions which are conceived or first actually reduced to practice in the course of or under an agreement for the use of the ATR, and is subject to all the limitations, terms, and conditions set forth in the foregoing Statement of Considerations. The Assistant General Counsel for Technology Transfer and Intellectual Property shall be responsible for issuing instructions for implementation of this waiver in accordance with DOE regulations for the waiver of patent rights.

CONCURRENCE:



Dennis Miotto  
Deputy Assistant Secretary  
for Nuclear Power Deployment

Date: 5/5/08

APPROVAL:



Paul A. Gottlieb  
Assistant General Counsel  
for Technology Transfer  
and Intellectual Property

Date: 5-21-08