

Comment: The requirement in 10 CFR part 784 for substantial manufacture in the United States for a patent title waiver remains unchanged. DOE should consider loosening this restriction, since most large for-profit corporations today are global and have partnerships with many overseas suppliers.

Response: The requirement for substantial manufacture in the United States for assignees and exclusive licensees of a waived invention is embodied in a "Preference for U.S. Industry" clause implementing a statutory requirement applicable to funding agreements with small business and nonprofits (35 U.S.C. 204) and made applicable to for-profit large businesses by the FAR and DOE Patent Waiver regulations, 10 CFR part 784. That "preference for U.S. Industry" provision includes authority for a waiver, under certain circumstances. In addition, DOE generally requires a "U.S. Competitiveness" provision as an additional condition for a patent waiver. This "U.S. Competitiveness" provision is negotiable, depending on circumstances surrounding the particular technology involved and DOE programmatic concerns. Inclusion of the "U.S. Competitiveness" provision is a programmatic decision, and therefore may be deleted with the concurrence of the DOE program official. However, where commercialization of DOE supported technology is the goal, promoting a U.S. economic benefit is an essential consideration.

III. Revisions Incorporated in This Final Rule

In addition to the changes made in response to public comments, DOE made the following revisions:

1. In the proposed rule, section 600.311 encouraged recipients to use existing financial management systems established for doing business in the commercial marketplace to the extent that the systems comply with Generally Accepted Accounting Principles (GAAP) and the minimum standards in this section. In the final rule, we have deleted the words "established for doing business in the commercial marketplace." Recipients are encouraged to use any existing systems (*i.e.*, systems used in the commercial marketplace or systems established for other government business) as long as the systems comply with GAAP and the standards in this section.

2. In the proposed rule, section 600.316 would require recipients that expend \$500,000 or more in a year under Federal awards to have an audit made for that year by an independent auditor. We have added language to

paragraph (a) of that section to clarify that if a recipient is performing under another Federal award that requires an audit by its Federal cognizant agency (*e.g.*, Defense Contract Audit Agency), the recipient must also use that agency to conduct the audit of the DOE award. The recipient and its Federal cognizant agency should develop a coordinated audit approach to ensure that the DOE award is included in the recipient's annual Federal audit.

3. In the proposed rule, section 600.325, paragraph (b) is entitled, "Patent rights—small business concerns and nonprofit organizations." As this paragraph is within subpart D, which applies to for-profit organizations, the title may be misleading or confusing. The final rule deletes the references to nonprofit organizations in the title and first sentence of paragraph (b), but retains the reference in the title of the clause in Appendix A, because this clause implements the Bayh-Dole Act (35 U.S.C. 206) and will be used by both small businesses and nonprofit organizations.

4. In section 600.325, paragraph (c)(1) the words "a large business" have been changed to "a for-profit organization other than a small business concern, as defined in 35 U.S.C. 201(h)" to comfort with the language in the statute. In addition, the words "pursuant to statute" have been added to clarify that this is a statutory requirements.

5. In the proposed rule, appendix A to subpart D, "Patent Rights (Small Business Firms and Nonprofit Organizations)" clause, paragraph (g)(2) made a reference to, but did not identify, the "DOE implementing regulations" and did not clearly address subcontracting requirements and rights. The final rule clarifies paragraph (g)(2) by deleting the reference to "DOE implementing regulations" and inserting "10 CFR 600.355(c)." In addition, a new paragraph (g)(3) has been added to this clause to establish requirements for subawards, as follows: "(3) In the case of subawards/contracts at any tier, DOE, the Recipient, and the subrecipient/contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subrecipient/contractor and DOE with respect to those matters covered by the clause."

6. In appendix A to subpart D, "Rights in Data—Programs Covered Under Special Protected Data Statutes" clause, paragraph (g)(1) has been modified to add the following phrase to the end of the first sentence: "that would have been treated as a trade secret if developed at private expense." This change was made because the Energy

Policy Act of 1992 limits such protection to data that would have been treated as trade secret if developed at private expense (42 U.S.C. 13293).

7. In the proposed rule, section 600.351(a)(4) allowed DOE to terminate a cooperative agreement for convenience of the government. While the Federal Acquisition Regulation includes a termination for convenience requirement, this is not a standard requirement in financial assistance. Neither OMB Circular A-110 nor A-102 includes a termination for convenience requirement. After further consideration, we have decided to delete paragraph (a)(4) in section 600.351 because DOE cooperative agreements are virtually always cost-shared, and applicants, lenders, and equity contributors may be reluctant to finance these projects if the award includes such a provision. We do not want to unnecessarily reduce the number of applicants applying for DOE assistance programs.

8. Minor editorial corrections were made to sections 600.302, 600.304, and 600.325.

IV. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be "a significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (October 4, 1993). Accordingly, this action is not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Because DOE is not required by the Administrative procedure Act (5 U.S.C. 553) or any other law to propose financial assistance rules for public comment, DOE did not prepare a regulatory flexibility analysis for this rule.

C. Review Under the Paperwork Reduction Act

This regulatory action will not impose any new reporting or record keeping requirements under the Paperwork Reduction Act. Reporting and record keeping requirements in subpart D have