Commerce is in the final stages of issuing regulations out of place on program w/h replace OMB (in. A-134 and implement, P.L. 98-620). They are the principle basis for your being in the business of technology transfer. They define your ownership right. Without them or without their present balance of rights and responsibilities you could not properly conduct your business of bartering university ideas successfully. Why? Management of technology by a federally funded _____ has been implied through the day. Inventing or creating organization must include the ability to evaluate each new technology and determine whether it should be published only, patented, copyrighted, maintained as proprietary information or material, possibly trademarked or some combination of these actions. In a free market economy intellectual property rights must be established and sometimes licensed away to justify the investment of private risk funding in some technologies, like pharmaceuticals and other life science technologies. Failure to establish such rights in a potential marketable product by the creating organization could preclude private sector involvement in completing development to the marketplace.

These regulations recognize that the federally-funded creating or inventing organization must be permitted to manage and own its patentable technology in a manner substantially similar to an organization creating technology with private

These regulations recognize that the federally-funded creating or inventing organization must be permitted to manage and own its patentable technology in a manner substantially similar to an organization creating technology with private

funding. Similar regulations do not yet exist for other forms of managing intellectual property. Government policies that separate management or ownership of technology from the creating organizations and put it in the hands of others who did not have first hand knowledge of the technology and the ability to place a value on it demonstrated failures. The reason was obvious once separation occurs the likelihood of continuing the iterative development process that is necessary to successfully deliver technology to the marketplace is not possible in most part because the most likely champion or advocate of the technology is lost.

1. Commerce Regulations required under P.L. 98-610 will be issued as interim final within a few weeks.

2. There will be a 60 day public comment period which has been necessitated by Agency prompted changes to the regulations published on April of 1985. The changes were negotiated after the close of the 1st public comment period and cannot go final without additional public comment.

3. All new comments, should be sent to me--but frankly, I hope that you will be happy with what we've developed in the face of severe resistance from one of the federal agencies.

4. I hope to mail copies of the new regulations to every person listed on Steve Adkinson's current list of SUPA members.

of severe resistance from one of the federal agencies.

4. I hope to mail copies of the new regulations to every person listed on Steve Adkinson's current list of SUPA members.

Anyone not on that list--give me your card or call.

5. The regulations replace OMB circular A-124 and the standard patent rights clause on the date of their publication and cover all federal awards to U. and S.B. after that period.

6. The regulations closely follow A-124, but do not cover the P.L. 98-620 amendments, universities supported to P.L. 96-517.

Sec. 401.1(a) - Read Page 21

Sec. 401.1(b) - See Note Page 21

Sec. 401.1(c) - Read (Very Important) - Page 21 to University Run D.O.L. Labs

Sec. 401.1(d) - Read Page 22

Sec. 401.1(f) - Provides that standard clause does not apply to inventions made during the progress of private sector use of Government owned research facilities

Sec. 401.2 - No change in definitions in Sec. 401.2 accept that "invention" is expanded to include new plants protectable under the Plant Variety Protection Act.

Sec. 401.3 - Covers permissible exceptions to use of standard clause. Here are some major changes some of

Variety Protection Act.

Sec. 401.3 - Covers permissible exceptions to use of standard clause. Here are some major changes some of

which you will see for the first time when the regulations are published:

1. The exception that permitted agencies GOCO facilities has been eliminated.
2. Agencies are permitted to use substitutes for the standard clause when dealing with foreign-based contractors or grantees.
3. D.O.E. GOCO facilities primarily dedicated to Naval nuclear propulsion or weapons related programs are permitted to use a substitute for the standard patent rights clause.
4. Section 401.3(b) provides that if the exceptional circumstance clause is used to retain rights in the government, the agency still must begin with the standard clause and modify only those sections related to ownership.

Sec. 401.3(b) - Read Important DOE addition Page 26

Sec. 401.3(e) - Any exception must be justified in writing and given to the contractor with a notification of its right to appeal the determination.

Sec. 401.3(f) - Provides that copies must be provided to the Department of Commerce and indicates what action it can take if it does not believe the determination to be consistent with the statutory intent.

it can take if it does not believe the determination to be consistent with the statutory intent.

Sec. 401.4 - Provides the procedure for contractor appeals of Agency use of exceptions to general rule.

Sec. 401.5(d) - Permits agencies to retain rights in order to meet obligations under identified treaties or international agreements. It also permits agencies to add new treaties for international agreement obligations to GOCO constructs but only as to inventions made after the date of the contract amendment adding the new treaties or international agreements.

Sec. 401.5(f) - Provides for specific treatment of royalty income generated by GOCO facilities.

Sec. 401.6 - Sets out the uniform march-in procedures which are substantially the same as the grant march-in procedures from A-124.

Sec. 401.7 - Sets out the Departments's expectation on how university's can meet their responsibility to give preference to small business licensing and what constitutes reasonable efforts to attract small business licensees. To the extent there are complaints about University activities in this area, the regulations limit the Department's involvement to examining the University's policy and precludes intervention

are complaints about University activities in this area, the regulations limit the Department's involvement to examining the University's policy and precludes intervention

in individual licensing activities. The criteria for small business preference is set out in the standard clause.

Sec. 401.8(a) - Ends the Department's attempt to set-up a uniform reporting system on the utilization of University owned inventions by giving general guidance to the agencies on collecting such information if desired. Read if time Page 41.

Sec. 401.8(b) - Provides that if this information is collected, agencies shall maintain it in confidence.

Sec. 401.11 - Covers a list of important right to appeal actions that effect contractor rights:

You have the right to appeal a refusal to grant an extension of the exclusive license period previously capped under P.L. 96-517.

Sec. 401.13(b) - Read Page 45. Further provides that

Sec. 401.13(c) - Requires agencies to maintain invention disclosures in confidence pending the filing of patent applications. Further, no information which is part of a patent application can be disclosed by an agency for 18 months after filing.

The Standard Clause -

disclosed by an agency for 18 months after filing.

The Standard Clause -

Includes the favorable reporting, electing and filing times developed in H-124

Royalty Sharing With Government Employee -

Read Page 59. If rights assigned to university and Government wants to.

Clearly P.L. 96-517 and A-124 have been part of the explosion of private sector investment in commercializing University technology

Quotes from Business Week and Science Week

Analogy--
Real Estate Easements

Basis of drafting--fight off easements--if not make them specific enough so as to not devalue rights.

Unfortunately, the creation of easements seems to be an inherent characteristic of Washington bureaucracy ever present danger.

Billing Code 3510-18

Department of Commerce

Office of the Assistant Secretary for Productivity, Technology and Innovation

37 CFR Part 401

(Docket No. 412878-6009)

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms

AGENCY: Assistant Secretary for Productivity, Technology and Innovation

ACTION: Interim Final Rule

SUMMARY: Public Law 98-620 amended Chapter 18 of Title 35, United States Code, dealing with patent rights in inventions made with Federal funding by nonprofit organizations and small business firms. It also reassigned responsibility for the promulgation of regulations implementing 35 U.S.C. 202-204 and the establishment of standard funding agreement provisions from the Office of Management and Budget (OMB) to the Secretary of Commerce. This regulation, to appear at 37 CFR Part 401, establishes such implementing regulations and standard funding agreement provisions.

EFFECTIVE DATE: (Date of publication of this notice)

COMMENTS BY: (60 days from the date of publication)

FOR FURTHER INFORMATION CONTACT: Mr. Norman Latker, Director, Federal Technology Management Policy Division, Office of

EFFECTIVE DATE: (Date of publication of this notice)

COMMENTS BY: (60 days from the date of publication)

FOR FURTHER INFORMATION CONTACT: Mr. Norman Latker, Director, Federal Technology Management Policy Division, Office of

Productivity, Technology and Innovation, U.S. Department of Commerce, Room 4837, Washington, D.C., 20230.

Phone: 202-377-0659

SUPPLEMENTARY INFORMATION:

Background

Public Law 98-620 amended Chapter 18 of Title 35, United States Code, and assigned regulatory authority to the Secretary of Commerce. The Secretary has delegated his authority under 35 U.S.C. 206 to the Assistant Secretary for Productivity, Technology and Innovation. Section 206 of Title 35 U.S.C. requires that the regulations and the standard funding agreement be subject to public comment before their issuance. Accordingly, on April 4, 1985, the Assistant Secretary published a notice of proposed rulemaking in the Federal Register (50 FR 13524) for public comment. As noted at that time, the regulation closely follows OMB Circular A-124 which the regulation will replace. Differences between the proposed rule and the Circular were highlighted in Supplementary Information accompanying the notice of proposed rulemaking.

Additionally, to comply fully with Section 206 of Title 35 U.S.C., the Department is requesting public comments on this Final Interim Rule. Comments should be sent to the address listed in the "For Further Information Contact" section above. Comments received by (60 days from date of publication) will be considered in promulgating a final rule.

Copies of all comments received are available for public inspection in the Department's Central Reference Records

Comments received by (60 days from date of publication) will be considered in promulgating a final rule.

Copies of all comments received are available for public inspection in the Department's Central Reference Records

Inspection Facility (CRRIF), room 6628 in the Hoover Building. Information about the availability of these records for inspection may be obtained from Mrs. Hedy Walters at (202) 377-3271.

Treatment of Substantative Comments on Regulation Provisions

Twenty-three comments from seventeen different sources were received on the proposed rule in response to the April 4 notice. The substantative issues raised in the twenty-three comments will first be discussed as they refer to the specific sections of the proposed regulation. General comments on issues not mentioned in the regulation will be discussed later in this Supplementary Information Section.

401.1(a)--Two comments were received on this subject. One suggested adding a sentence alerting readers to the fact that the regulation also includes policy guidance concerning the administration of funding agreements that predate the effective date of this regulation. This was done.

The second comment suggested the reference to the statute implemented by this regulation should be to 35 U.S.C. 200-206 and 212 rather than just 202-204. This suggestion was rejected as authority granted the Secretary of Commerce by 35 U.S.C. 206 is limited to issuing regulations related only to sections 202-204.

401.1(d)--Several comments from federal agencies suggested rewriting the first part of this section to better reflect the relationship of this regulation, agency regulations, and the FAR system. One agency suggested the regulation should permit agency-initiated deviations without approval by the Secretary of

rewriting the first part of this section to better reflect the relationship of this regulation, agency regulations, and the FAR system. One agency suggested the regulation should permit agency-initiated deviations without approval by the Secretary of

Commerce. This was rejected as being inconsistent with the statute's requirement to develop a standard patent rights clause. However, the need to obtain approval by the Secretary of Commerce of certain deviations requested by contractors has been eliminated and it has been made clear that modification and tailoring of clauses, as authorized elsewhere in the regulation, are not considered "deviations."

The suggestion by two agencies that the FAR be used as the regulatory implementation of Chapter 18 of Title 35, U.S.C. was not accepted because it would be inconsistent with the law and Congressional intent.

It was also suggested that limitations on deviations were too strict and that the more liberal deviation procedures of the FAR system should be adopted. This was not accepted.

As a result of one agency comment, section 401.1(d) has been revised to specify when regulations should be submitted to the Secretary for review.

One agency suggested that the opening sentence of section 401.1(d) be deleted or amended as it "may throw the validity of every other regulation implementing Pub. L. 98-620 into doubt since lack of coverage of a point by the Commerce regulations could suggest that no coverage is permitted." It is, in fact, the purpose of section 401.1(d) and the statute to override inconsistent regulations. That is also why it is directed that all regulations supplementing this part be submitted to the Secretary for review for consistency. The Department of Commerce will work with those responsible for Part 27 of the FAR system to

inconsistent regulations. That is also why it is directed that all regulations supplementing this part be submitted to the Secretary for review for consistency. The Department of Commerce will work with those responsible for Part 27 of the FAR system to

ensure that it is consistent with this regulation.

401.2(a)--A comment suggested that the definition of "funding agreement" include language removing 35 U.S.C. 212 from its coverage. This concern has been dealt with in section 401.1(a) and section 401.3(a) which exclude 35 U.S.C. 212 awards.

401.2(h)--A comment suggested that the word "possession" be added in the definition of "nonprofit organizations" after the word "state." This has not been done as the statutory definition does not include the word "possession." The need for seeking an amendment to the act is being studied.

401.3(a)(ii)--One agency comment raised the question of whether the exceptional circumstance provision of 35 U.S.C. 202(a)(ii) can be used to except from contractor ownership a class of research contracts and all their resulting inventions on the grounds that national security may require classification of some of the results of the research. Three responding agencies believed the general principle of contractor ownership should be preserved as it does not preclude the advanced classification of research contracts and their resulting inventions for national security reasons under provisions of law other than 35 U.S.C. 202(a)(ii). Agencies are encouraged to use established national security classification procedures set out in regulation and Executive Order to protect from public disclosure those inventions which pose security risks. The procedures allow the contractor to elect to retain title to such inventions. Thus, if at some later date security classification is lifted the contractor can immediately commence commercialization. However,

inventions which pose security risks. The procedures allow the contractor to elect to retain title to such inventions. Thus, if at some later date security classification is lifted the contractor can immediately commence commercialization. However,

it is recognized that in some limited situations agencies may be able to use national security to justify an alternate ownership provision under the exceptional circumstance paragraph of 35 U.S.C. 202(a)(ii). In such cases provision must be made to permit the contractor to elect ownership if there is no security classification of a reported invention by the agency within six months. Accordingly, section 401.3(b) provides that should an agency exercise an exceptional circumstance exception under 401.3(a)(ii) and include provisions to own inventions on the basis of national security, the contractor shall be entitled to own any invention if the agency does not classify the contractor's invention report within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law, Executive Order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempt from this paragraph.

401.3(b)--Two agency comments suggested that the requirement to use the standard clause with modifications, even when exceptions under subsection 202(a) are invoked, is too restrictive. The language of the Act, particularly the introduction to 35 U.S.C. 202(c), makes no distinction between funding agreements under which the contractor retains the right to elect title and those in which this right has been curtailed through one of the exceptions. A standard clause will promote maximum uniformity and assurance that small business and

funding agreements under which the contractor retains the right to elect title and those in which this right has been curtailed through one of the exceptions. A standard clause will promote maximum uniformity and assurance that small business and

nonprofit contractors understand their obligations.

401.3(e)--Comments were requested on whether determinations of class exceptions should be allowed. One comment stated that the law contemplates case-by-case exceptions and felt that only rarely could a class exception be justified. On the other hand, one agency comment stated that class determinations are needed to reduce paperwork. That agency suggested the use of a single determination be authorized for multiple contracts involving identical circumstances to facilitate contracting so long as each contractor is accorded its right of appeal. This suggestion was accepted.

In response to one comment, language has been added requiring an agency to advise a contractor of its appeal rights when it notifies the contractor that one of the exceptions at 35 U.S.C. 202(a) are being invoked.

401.3(g)--One agency comment expressed concern about this section's requirement to provide information to the Comptroller General. The requirement has been retained as it was developed during the drafting of OMB Circular A-124 at the request of an in consultation with the GAO.

401.4(b)(3)--In response to one comment, the word "present" has been changed to "rely upon."

401.4(b)(6)--In response to one comment, language has been added requiring the agency head to detail the basis for the rejection of facts found during the fact-finding process.

401.5(a)--One agency comment pointed out that, particularly in grants or cooperative agreements where an agency has a policy

added requiring the agency head to detail the basis for the rejection of facts found during the fact-finding process.

401.5(a)--One agency comment pointed out that, particularly in grants or cooperative agreements where an agency has a policy

of applying the standard clause in all subcontracts, paragraph (g)(3) is not needed and the standard clause could be simplified by eliminating paragraph (g)(2). This has been done by expanding section 401.5(a) to authorize such modification of the subcontract provisions of the standard clause at section 401.14.

401.5(d)--At the suggestion of one agency, several minor changes to this section have been made. The most significant of these changes is the additional language that agencies are authorized to add to the standard clauses which allow agencies to identify international agreements that are "to be entered into." This change is needed to enable future agreements to be entered into during contract performance and is only to be applied to subject inventions made after the date of contract amendment.

In response to agency comments, the number of situations in which the language at the end of the subsection related to international agreements can be used has been increased to include all long-term contracts such as those frequently used for funding operation of Government-owned research facilities, and not just those involving a series of task orders.

401.5(e)(ii)--One comment suggested adding "or other form of protection of intellectual property" to this requirement. This has not been done because it goes beyond the scope of the Act.

401.5(e)(iii)--In response to several agency comments, the option of the agencies to obtain annual listings of reported subject inventions has been retained.

401.5(f)--One university comment raised the question of whether a university licensing office on the same campus but

option of the agencies to obtain annual listings of reported subject inventions has been retained.

401.5(f)--One university comment raised the question of whether a university licensing office on the same campus but

organizationally separate from a university-operated, Government-owned facility would meet the "most effective technology transfer" standard in the last sentence of paragraph (k)(3) which is prescribed at section 401.5(f). The situation described meets the standard.

One agency comment suggested that language be added at the end of section 401.5(f) as follows: "However, in the case of facilities of the Department of Energy, the paragraph shall be used in contracts designated by the Department of Energy as management and operating contracts for such facilities in accordance with Subpart 17.6 of the Federal Acquisition Regulations as supplemented by the Department of Energy Acquisition Regulations." This suggestion has not been accepted because it is inappropriate to include language that is tied to other regulations that could change and which may contain definitions based on other objectives and purposes. However, DOE may designate such contracts, and to the extent it finds that the proposed language is consistent with 35 U.S.C. 204(c)(7)(E) and section 401.5(f) it may prescribe such language it its supplementary regulations or instructions.

Several comments suggested the deletion of the words "at the facility" from the clause language prescribed by section 401.5(f). The basis for this suggestion was that limiting the use of income to research at the facility will act as a deterrent to university investment in the promotion of inventions. This change has been made because it is more appropriate to leave the question of royalty sharing with the facility to negotiations

use of income to research at the facility will act as a deterrent to university investment in the promotion of inventions. This change has been made because it is more appropriate to leave the question of royalty sharing with the facility to negotiations

among the interested parties.

401.5(g)--For clarity, a paragraph has been added authorizing agencies to require that contractors operating Government-owned facilities furnish certain information concerning their invention reporting and disclosure procedures.

401.6(c)--For clarity, a change has been made that agencies are expected to give notice only if they have actual knowledge of assignees or licensees.

401.6(f)--For clarity, the words "or adopt" have been added to the subsection.

401.6(g)--To conform with Section 401.4(b)(6), language has been added requiring the agency head to detail the reasons for rejecting facts found during the fact-finding process.

401.6(k)--For clarity, a paragraph has been added providing that exclusive licensees include "partially exclusive licensees" for purposes of march-in proceedings.

401.7--Several comments expressed concern that it should be made clear that the small business preference not be construed to prevent a university from providing a right of first refusal or other type of option to a larger business that is providing support under a long-term agreement for research related to the invention. This change has been made because small business preference is not intended to inhibit industrial support of university research.

One agency comment suggested that the Secretary's role may conflict with that of the agency in matters pertaining to the "domestic preference" in licensing agreements. Therefore, it was

university research.

One agency comment suggested that the Secretary's role may conflict with that of the agency in matters pertaining to the "domestic preference" in licensing agreements. Therefore, it was

suggested that "matters in regard to the contractor's licensing practices would be better handled by the contractor agency." This comment was rejected because the role of the Secretary will not include involvement in an individual licensing decision.

One comment suggested that the regulations "need to reflect that no individual small business will have standing to attack any particular license agreement." This suggestion was not accepted because it is already reflected in the subsection and the clause.

401.8(a)--One agency comment suggested relaxing the requirement that agencies receive periodic information on the utilization of inventions pending instructions by this Department. In response, a change has been made that agencies refrain, to the extent feasible, from specifying specific formats for the information and instead rely on information in the form in which it is customarily prepared by the contractor for its own internal reporting purposes. The Paperwork Reduction Act will apply to any information gathering efforts. If further experience under the regulations indicates that agencies' requests to contractors are developed on an uncoordinated basis or create undue burden, a uniform reporting system may be instituted.

401.8(b)--In response to one agency comment, a provision has been added requiring contractor marking of utilization data which they wish to have protected.

401.10--Several agencies suggested revising this subsection so that agencies may apply additional conditions. This has been

been added requiring contractor marking of utilization data which they wish to have protected.

401.10--Several agencies suggested revising this subsection so that agencies may apply additional conditions. This has been

permitted, providing the additional conditions are consistent with sections 201-206 of the statute. In addition, the royalty-sharing requirement with Government employee/inventors under paragraph (k)(2) of the clause at section 401.14(a) has been eliminated. Agencies may still require royalty-sharing with their employee/inventors on a case-by-case or other broader basis.

One university comment suggests that the coverage of this subsection be expanded so that disparate regulations do not develop among the various agencies. Agency activities will be monitored in order to attain consistency.

401.12--One university comment suggests adding language to section 401.12 requiring the payment of reasonable royalties when licensing of background inventions is required. This change was not accepted because such payments can be negotiated in connection with the use of such provisions.

401.13--One comment suggested that we add language to section 401.13 to state that the duration of an exclusive license granted by a university can extend for the life of the patent plus an extension of the patent term granted under the Drug Price Competition and Patent Term Restoration Act of 1984. As the Act now contains no restrictions on licensing, no such language is required.

One comment also requested the inclusion of language in section 401.13 making clear that a long-term license granted by a university to a small business firm prior to the enactment of Pub. L. 98-620 can be transferred to a large business firm

One comment also requested the inclusion of language in section 401.13 making clear that a long-term license granted by a university to a small business firm prior to the enactment of Pub. L. 98-620 can be transferred to a large business firm

without agency approval as part of the acquisition of the smaller firm. This suggestion was not accepted because under the current law, such a transfer does not require agency approval. The approvals required under OMB Circular A-124 for long-term licenses to other than small business firms are not applicable when a small business firm assigns this as part of a transfer of the firm to a larger firm.

401.13(b)--In response to suggestions, advice in subsection 401.13(b) has been expanded to cover contract clauses predating P.L. 96-517.

Two university comments suggested waiving any requirement for agency approvals under funding agreements predating Pub. L. 98-620. This comment was not accepted as there is no authority to apply the law retroactively.

401.13(c)--One agency suggested that the requirement that agencies not disclose information, which is part of a patent application, be limited to a period of no more than 18 months. This suggestion was accepted.

401.14(a)(Standard Clause)--

Paragraph (c)(1)--One comment suggested this subparagraph should specifically state that a proposed patent application would meet the disclosure requirements. This suggestion was not accepted as a proposed patent application, by definition, would meet the disclosure requirement.

Paragraph(c)(3)--In response to one suggestion, language has been added to make clear that filing in supranational patent offices will satisfy the foreign filing requirements.

meet the disclosure requirement.

Paragraph(c)(3)--In response to one suggestion, language has been added to make clear that filing in supranational patent offices will satisfy the foreign filing requirements.

Several comments suggested:

(a) The requirement to make foreign within ten months of the corresponding initial patent application forces a university to make a commitment to file foreign much earlier than such a decision would normally be made.

(b) Amending the subsection to either "authorize the filing" or "make a commitment to file."

(c) Adding "will file or authorize the preparation and filing."

One agency comment opposed the above changes noting that a contractor may withdraw its authorization to file at a time too late to permit the agency to protect its reversionary interests.

The issue raised by the above comments has been deferred pending a more comprehensive cost-benefit analysis. Contractors are reminded that paragraph (c)(4) of the standard clause [Sec. 401.14(a)] allows contractors to request extensions of time to file patent applications.

Paragraph (d)(ii)--One comment suggested that it is unreasonable to expect a contractor to file in every patent office in the world in order to protect its foreign rights. No change has been made because the statute clearly specifies the steps a contractor must take to secure title against reversion to the agency.

Paragraph (e)(4)-(6)--One agency comment recommended that the content of these clauses be moved into the preamble to the standard clause in the same manner as OMB Circular A-124. This has been done.

Paragraph (e)(4)-(6)--One agency comment recommended that the content of these clauses be moved into the preamble to the standard clause in the same manner as OMB Circular A-124. This has been done.

Paragraph (f)--One agency comment suggested adding language to paragraph (f) requiring contractors to submit, without agency request, a confirmatory license and a copy of any U.S. patent. This suggestion was not accepted as paragraph (f)(1) already requires a confirmatory license and the optional language at section 401.5(e) allows agencies to add language so they can obtain patent numbers.

Paragraph (h)--One agency comment suggested altering the last sentence of this paragraph to follow the statutory language more closely. Alternatively, the comment suggested that "without permission of the contractor" be inserted at the end of that sentence. The alternative suggestion has been adopted as disclosure with the permission of the contractor would appear consistent with the statutory intent and language.

Paragraph (i)--One comment noted that other countries have local manufacture regulations and that in some cases there could be conflicts with the domestic manufacturing requirement. The comment suggested that some provision should be made in this subsection than an agency will automatically ameliorate the U.S. manufacture requirement if there is a direct conflict with a similar clause in another country and a single commercial embodiment would involve inventions from both countries. This suggestion was not accepted as there is sufficient latitude under the existing language to allow an agency to waive its requirements under such circumstances and therefore explicit discussion in the regulation is not warranted.

Paragraph (k)(2)--Several agency comments have pointed out

the existing language to allow an agency to waive its requirements under such circumstances and therefore explicit discussion in the regulation is not warranted.

Paragraph (k)(2)--Several agency comments have pointed out

that by requiring royalty-sharing with agency employees, there may be situations in which the employee would be placed in a violation of the conflict-of-interest statutes. This change has been accepted by adding to the paragraph the words "where the agency deems it appropriate."

One university comment suggested "inventor" be changed to "inventors" and that "we would like to hold open the possibility of sharing royalties with close technical associates of the inventor(s)." For clarity the first change has been made. The second change has not been made as such payments can be made and considered as "expenses incidental to the administration of subject inventions."

401.14(b)--For clarification, several changes have been made to the alternative language prescribed for use by DOE when the exception at section 401.3(a)(iv) is invoked and title to inventions made under the Navy nuclear propulsion or nuclear weapons programs are retained by DOE. These changes included elimination of the exclusive license provided to the contractor in fields of use other than Navy nuclear propulsion or nuclear weapons. While the statute does not mandate this right to contractors, DOE is urged to take a liberal approach in providing such right on a case-by-case basis as being within the spirit of the statute.

One university comment suggested that the requirement to assign title to inventions under paragraph (c)(1)(B) as prescribed at 401.14(b)(2) be limited to subject inventions that are "nuclear weapons, naval propulsion systems, components

One university comment suggested that the requirement to assign title to inventions under paragraph (c)(1)(B) as prescribed at 401.14(b)(2) be limited to subject inventions that are "nuclear weapons, naval propulsion systems, components

thereof, or directly therein." This suggestion has been rejected because it is not consistent with the statute. DOE is urged to take a liberal approach to granting waivers to inventions that fall within paragraph (c)(1)(B) as it is written but which are not within the scope of this suggested language, since we believe that to be within the spirit and intent of the statute.

At the request of DOE, provision has been made for the use of an alternative clause. Provisions for record keeping and reporting requirements will be submitted to OMB for review under the Paperwork Reduction Act.

401.15(a)--This section has been revised to allow the Department of Energy to use their existing waiver procedures in lieu of the procedures prescribed in this section.

Treatment of Comments on Issues Not Mentioned in the Regulation

Successor Contracts--The notice of proposed rulemaking requested comments on the issue of transfer of patent rights to successor contractors in contracts for the operation of Government-owned facilities. One agency favored authorizing agencies to add provisions dealing with this. Several universities and nonprofit organizations opposed transfer of their ownership as not being authorized by law. The Department believes the best solution to this issue would be to allow the federal agency and each of the contractors involved to negotiate issues of allocation of royalties, continuation of commercialization efforts, and other related issues taking into account the equities of the parties.

Cooperative Research Arrangements and "de minimus" Support--

issues of allocation of royalties, continuation of commercialization efforts, and other related issues taking into account the equities of the parties.

Cooperative Research Arrangements and "de minimus" Support--

Several commenters suggested that some "de minimus" standard be established to define a threshold contribution of Government funding to the making of a jointly funded invention below which the regulations should not apply. There is no authority to make this change because the Act does not define "subject invention" in terms of the size of the Government financial contributions in making the invention.

Plant Variety Protection--One university comment suggested that separate regulatory coverage was needed in this area and indicated an intent to discuss this with the Department of Agriculture and to submit suggested changes later. A second comment expressed concern that, if literally read, the disclosure and election requirements could require substantial paperwork for plant varieties that were not found to be commercially viable. The Department of Agriculture indicates that they have no intent to require such paperwork. The Department of Commerce is working with the Department of Agriculture to determine whether changes in the clause may be appropriate for plant varieties.

Rulemaking Requirements--

As stated in the proposed notice this regulation is not a major rule as defined in Executive Order 12291, and it adds no paperwork burdens. In fact, it reduces certain paperwork requirements of the regulations it replaces. And, as discussed in connection with the proposed rule, the General Counsel of the Department of Commerce has certified to the Small Business Administration that this rule will not have a substantial economic impact on a substantial number of small entities.

in connection with the proposed rule, the General Counsel of the Department of Commerce has certified to the Small Business Administration that this rule will not have a substantial economic impact on a substantial number of small entities.

List of Subjects in 37 CFR Ch. IV

Inventions, Patents, Nonprofit Organizations, Small Business Firms.

Date:

D. Bruce Merrifield
Assistant Secretary for Productivity,
Technology and Innovation

Accordingly, Chapter IV of Title 37 of the Code of Federal Regulations is amended by the addition of a new Part 401, to read as follows:

**PART 401**

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements

Section


401.1 Scope.

401.2 Definitions.

401.3 Use of the Standard Clauses at Section 401.14.

401.4 Contractor appeals of exceptions.

401.5 Modification and tailoring of clauses.

401.6 Exercise of march-in rights.

401.7 Small business preference.

401.8 Reporting on utilization of subject inventions.

401.9 Retention of rights by contractor employee inventor.



401.6 Exercise of march-in rights.

401.7 Small business preference.

401.8 Reporting on utilization of subject inventions.

401.9 Retention of rights by contractor employee inventor.

401.10 Government Assignment to contractor of rights in invention of Government employee.

401.11 Appeals.

401.12 Licensing of background patent rights to third parties.

401.13 Administration of patent rights clauses.

401.14 Standard clauses.

401.15 Deferred determinations.

401.16 Submissions and Inquiries.

Authority - 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary for Productivity, Technology and Innovation at Section 3(g) of DOO 10-1.

Section 401.1 Scope.

(a) This regulation is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of the regulations, except for a funding agreement made primarily for educational purposes. Some sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with P.L. 98-620, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

**DOES THIS GO HERE OR IN (B)???**

Solves old problem of fellows contaminating privately funded patents.

Federal agency any rights to inventions made by the awardee.

**DOES THIS GO HERE OR IN (B)???**

Solves old problem of fellows contaminating privately funded patents.

(b) Creates a uniform march-in procedure following the A-124 grant procedure for all grants and contracts. This eliminates the dual grant and contract procedure under A-124.

(c) At the request of the contractor, a funding agreement for the operation of a Government-owned facility which is in effect on the effective date of the regulations shall be promptly amended to include the standard patent rights clause unless the agency determines that one of the exceptions to the general rule applies. Probably the most emotional change--impacts maybe $2 million.

(d) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and P.L. 98-620.

NEW SECTION

(2) The <u>contractor</u> will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the <u>contractor</u> with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the

(3) The balance of any royalties or income earned by the <u>contractor</u> with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the

support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) Communications.

[Complete According to Instructions at 401.5(b)]

(b) When the Department of Energy (DOE) determines to use alternative provisions under section 401.3(a)(iv), the standard clause at section 401.14(a), above, shall be used with the following modifications unless a substitute clause is drafted by

(b) When the Department of Energy (DOE) determines to use alternative provisions under section 401.3(a)(iv), the standard clause at section 401.14(a), above, shall be used with the following modifications unless a substitute clause is drafted by

DOE:

1. The title of the clause shall be changed to read as follows:

Patent Rights to Nonprofit DOE Facility Operators

2. Add an "(A)" after "(1)" in paragraph (c)(1) and add subparagraphs (B) and (C) to paragraph (c)(1) as follows:

(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of DOE, then the provisions of this subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). In such cases the contractor agrees to assign the Government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e), below. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. DOE will process such a request in accordance with procedures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h)-(k) of this clause and such additional conditions, if any, deemed to be appropriate by the Department of Energy.

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or

Department of Energy.

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or

not the invention occurred under a naval nuclear propulsion or weapons-related program of the Department of Energy. If this statement is not filed within this time, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to subparagraph (c)(1)(B).

3. Paragraph (k)(3) of the clause will be modified as prescribed at section 401.5(f).

Section 401.15 Deferred Determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at section 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any

and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any

event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under Government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances or concerns which originally led the agency to invoke an exception under section 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at section 401.14(a) had been used originally.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded Government license rights in such applications.

(d) A determination not to allow the contractor to retain

imposed upon the contractor's use of the invention for such applications or with expanded Government license rights in such applications.

(d) A determination not to allow the contractor to retain

title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at section 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under section 401.11 of this part.

Section 401.16 Submissions and Inquiries.

All submissions or inquiries should be directed to Federal Technology Management Policy Division, telephone number 202-377-0659, Room H4837, U.S. Department of Commerce, Washington, D.C., 20230.