

Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

**PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES**

**Authority:** 49 U.S.C. app. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

1. The authority citation for part 97 continues to read as follows:

2. Part 97 is amended to read as follows:

**§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]**

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, AND VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

\* \* \* Effective Upon Publication

FDC Date	State	City	Airport	FDC Number	SIAP
12/15/94	GA	Cartersville	Cartersville	FDC 4/6963	NDB or GPS Rwy 19 Amdt 3.
12/15/94	GA	Cartersville	Cartersville	FDC 4/6964	LOC Rwy 19 Amdt 1.
12/15/94	NC	Statesville	Statesville Muni	FDC 4/6972	VOR/DME Rwy 10, Amdt 6.
12/15/94	NC	Statesville	Statesville Muni	FDC 4/6973	NDB Rwy 20 Amdt 8.
12/15/94	SC	Winnsboro	Fairfield County	FDC 4/6965	NDB or GPS Rwy 4 Amdt 3.
12/16/94	IL	Moline	Quad-City Airport	FDC 4/6987	ILS Rwy 9 Amdt 29.
12/16/94	IL	Moline	Quad-City Airport	FDC 4/6988	ILS Rwy 27 Orig.
12/16/94	IL	Springfield	Springfield Capital	FDC 4/6984	Radar-1 Amdt 7A.
12/19/94	NM	Albuquerque	Double Eagle II	FDC 4/7009	ILS Rwy 22 Amdt 1.
12/20/94	ND	Jamestown	Jamestown Muni	FDC 4/7028	ILS Rwy 31 Amdt 7.
12/21/94	SC	Lake City	Lake City Muni/CJ Evans Field	FDC 4/7041	NDB or GPS-A, Amdt 1.
12/23/94	NC	Siler City	Siler City Muni	FDC 4/7061	NDB Rwy 21 Orig.
12/23/94	NC	Siler City	Siler City Muni	FDC 4/7066	VOR-A Amdt 1.

[FR Doc. 95-948 Filed 1-19-95; 8:45 am]  
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**DEPARTMENT OF COMMERCE**

**National Institute of Standards and Technology**

**15 CFR Part 291**

[Docket No. 941097-4363]

RIN 0693-AB36

**Manufacturing Extension Partnership; Environmental Projects**

**AGENCY:** National Institute of Standards and Technology, Commerce.

**ACTION:** Final rule.

**SUMMARY:** The purpose of this rule is to provide for integration of environmental services and resources into the national manufacturing extension system and to codify the process by which NIST will solicit and select applications for cooperative agreements and financial assistance on projects which have the dual benefit of promoting the competitiveness and environmental soundness of smaller U.S. manufacturers. The intended effect is to increase the scope and scale of environmental services provided through the national manufacturing extension system.

**EFFECTIVE DATE:** January 20, 1995.

**ADDRESSES:** Applicants must submit one signed original plus six copies of the proposal along with Standard Form 424, 424A (Rev 4-92) prescribed by the applicable OMB circular and Form CD-511, Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying. SF-424, 424A (Rev 4-92) and Form CD-511 will not be considered part of the page count of the Basic Proposal. Proposals must be submitted to: MEP Environmental Projects, Attention Environmental Projects Manager, National Institute of Standards and Technology Bldg. 224 Room B115, Gaithersburg, MD 20899-0001.

**FOR FURTHER INFORMATION CONTACT:** The Manufacturing Extension Partnership Environmental Projects Manager, 301-975-5020.

**SUPPLEMENTARY INFORMATION:** In the November 14, 1994 **Federal Register**, Volume 59, No. 218, 59 FR 56439, the National Institute of Standards and Technology published a notice of proposed rulemaking to add 15 CFR part 291 to provide for the integration of environmental services and resources into the national manufacturing extension system and to codify the process by which NIST will solicit and select applications for cooperative agreements and financial assistance on projects which have the dual benefit of promoting the competitiveness and

environmental soundness of smaller U.S. manufacturers. No comments on the rules were received. These final rules are the same as the proposed rules with the addition of section 291.6 which clarifies the additional requirements to which recipients and subrecipients are subject.

The purpose of the National Institute of Standards and Technology Manufacturing Extension Partnership is to promote the competitiveness of smaller U.S. manufacturers. This is done primarily through technical assistance provided by a network of nonprofit manufacturing extension centers. The purpose of this rule is to provide for the integration of environmental services and resources into the national manufacturing extension system and to codify the process by which NIST will solicit and select applications for cooperative agreements and financial assistance on projects which have the dual benefit of promoting the competitiveness and environmental soundness of smaller U.S. manufacturers. Proposals from qualified organizations will periodically be solicited for projects which accomplish any one of the following objectives:

*Integration of Environmental Services Into Manufacturing Extension Centers:* to support the integration of environmentally-focused technical assistance, and especially pollution prevention assistance, for smaller manufacturers into the broader services

provided by manufacturing extension centers.

*Development of Environmentally Related Technical Assistance Tools and Techniques:* to support the initial development and implementation of tools or techniques which will aide manufacturing extension organizations in providing environmentally-related services, and especially pollution prevention services, to smaller manufacturers and which also may be of direct use by the smaller manufacturers themselves. Specific industry sectors and categories of tools and techniques may be specified in solicitations.

*Pilots for National Industry-Specific Pollution Prevention and Environmental Compliance Information Centers:* to support the pilot implementation of national centers for specific industry sectors specified in solicitations. The centers will provide easy access to relevant, current, reliable and comprehensive information on innovative technologies, pollution prevention opportunities and regulatory compliance.

Integration projects are open to existing manufacturing extension affiliates of the NIST Manufacturing Extension Partnership.

Projects for development of tools or techniques and national information centers are open to all nonprofit organizations including universities, community colleges, state governments, and independent nonprofit organizations.

Announcements of solicitations will be made in the Commerce Business Daily.

In accordance with the provisions of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)(1) and (c)(3) and 2781), as amended, NIST will provide assistance to integrate environmentally-related services and resources into the national manufacturing extension system. This assistance will be provided by NIST often in cooperation with other federal agencies such as the EPA. Under the NIST Manufacturing Extension Partnership (MEP), NIST will periodically make merit-based awards to existing MEP manufacturing extension affiliates for integration of environmental services into extension centers and to non-profit organizations for development of environmentally-related tools and techniques. In addition, NIST will initiate pilot centers providing environmental information for specific industrial sectors to be specified in solicitations. MEP assumes a broad definition of manufacturing, and recognizes a wide range of technology and concepts, including durable goods production; chemical, biotechnology, and other materials processing; electronic component and system fabrication; and engineering services associated with manufacturing, as lying within the definition of manufacturing.

### Classification

This notice relating to public property, loans, grants, benefits, or contracts is exempt from all requirements of section 553 of the Administrative Procedure Act (5 U.S.C. 553(a)(2)) including notice and opportunity for comment. Therefore, a Regulatory Flexibility Analysis is not required and was not prepared for this notice for purposes of the Regulatory Flexibility Act (5 U.S.C. 603 and 604). The program is not a major Federal action requiring an environmental assessment under the National Environmental Policy Act. This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612. This notice contains collection of information requirements subject to the Paperwork Reduction Act which have been approved by the Office of Management and Budget (OMB Control Number 0693-0010, 0348-0043 and 0348-0044). Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address shown above; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

It has been determined that this rule is not significant for purposes of EO 12866.

### List of Subjects in 15 CFR Part 291

Environmental projects, Environmental compliance assistance, Manufacturing extension, Pollution prevention assistance, Technical assistance.

Dated: January 13, 1995.

**Samuel Kramer,**  
*Associate Director.*

For the reasons set out in the preamble, 15 CFR part 291 is added as set forth below.

### PART 291—MANUFACTURING EXTENSION PARTNERSHIP; ENVIRONMENTAL PROJECTS

Sec.

- 291.1 Program description.
- 291.2 Environmental integration projects.
- 291.3 Environmental tools and techniques projects.

- 291.4 National industry-specific pollution prevention and environmental compliance resource centers.
- 291.5 Proposal selection process.
- 291.6 Additional requirements.

**Authority:** 15 U.S.C. § 272(b)(1) and (c)(3) and § 2781.

#### § 291.1 Program description.

(a) In accordance with the provisions of the National Institute of Standards and Technology Act (15 U.S.C. § 272(b)(1) and (c)(3) and § 2781), as amended, NIST will provide financial assistance to integrate environmentally-related services and resources into the national manufacturing extension system. This assistance will be provided by NIST often in cooperation with the EPA. Under the NIST Manufacturing Extension Partnership (MEP), NIST will periodically make merit-based awards to existing MEP manufacturing extension affiliates for integration of environmental services into extension centers and to non-profit organizations for development of environmentally-related tools and techniques. In addition, NIST will initiate pilot centers providing environmental information for specific industrial sectors to be specified in solicitations. MEP assumes a broad definition of manufacturing, and recognizes a wide range of technology and concepts, including durable goods production; chemical, biotechnology, and other materials processing; electronic component and system fabrication; and engineering services associated with manufacturing, as lying within the definition of manufacturing.

(b) *Announcements of solicitations.* Announcements of solicitations will be made in the Commerce Business Daily. Specific information on the level of funding available and the deadline for proposals will be contained in that announcement. In addition, any specific industry sectors or types of tools and techniques to be focused on will be specified in the announcement.

(c) *Proposal workshops.* Prior to an announcement of solicitation, NIST may announce opportunities for potential applicants to learn about these projects through workshops. The time and place of the workshop(s) will be contained in a Commerce Business Daily announcement.

(d) *Indirect costs.* The total dollar amount of the indirect costs proposed in an application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award or 100 percent of the total proposed direct costs dollar amount in the application, whichever is less.

(e) *Proposal format.* The Proposal must not exceed 20 typewritten pages in length for integration proposals.

Proposals for tools and techniques projects and national information centers must not exceed 30 pages in length. The proposal must contain both technical and cost information. The Proposal page count shall include every page, including pages that contain words, table of contents, executive summary, management information and qualifications, resumes, figures, tables, and pictures. All proposals shall be printed such that pages are single-sided, with no more than fifty-five (55) lines per page. Use 21.6 x 27.9 cm (8½" x 11") paper or A4 metric paper. Use an easy-to-read font of not more than about 5 characters per cm (fixed pitch font of 12 or fewer characters per inch or proportional font of point size 10 or larger). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left and right) must be at least 2.5 cm. (1"). The applicant may submit a separately bound document of appendices, containing letters of support for the Basic Proposal. The basic proposal should be self-contained and not rely on the appendices for meeting criteria. Excess pages in the Proposal will not be considered in the evaluation. Applicants must submit one signed original plus six copies of the proposal along with Standard Form 424, 424A (Rev 4/92) and Form CD-511.

(f) *Content of basic proposal.* The Basic Proposal must, at a minimum, include the following:

- (1) An executive summary summarizing the planned project consistent with the Evaluation Criteria stated in this notice.
- (2) A description of the planned project sufficient to permit evaluation of the proposal in accordance with the proposal Evaluation Criteria stated in this notice.
- (3) A budget for the project which identifies all sources of funds and which breaks out planned expenditures by both activity and object class (e.g., personnel, travel, etc.).
- (4) A description of the qualifications of key personnel who will be assigned to work on the proposed project.
- (5) A statement of work that discusses the specific tasks to be carried out, including a schedule of measurable events and milestones.
- (6) A Standard Form 424, 424A (Rev 4-92) prescribed by the applicable OMB circular and Form CD-511, Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying, SF-424, 424A (Rev 4-92) and Form CD-

511 will not be considered part of the page count of the Basic Proposal.

(7) The application requirements and the standard form requirements have been approved by OMB (OMB Control Number 0693-0010, 0348-0043 and 0348-0044).

(g) *Applicable federal and departmental guidance.* This includes: Administrative Requirements, Cost Principles, and Audits. [Dependent upon type of Recipient organization: nonprofit, for-profit, state/local government, or educational institution]

(1) *Nonprofit organizations.*

(i) OMB Circular A-110—Uniform Administrative Requirements of Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A-122—Cost Principles for Nonprofit Organizations.

(iii) 15 CFR part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations [implements OMB Circular A-133—Audits for Institutions of Higher Education and Other Nonprofit Organizations].

(2) *State/local governments.*

(i) 15 CFR part 24—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

(ii) OMB Circular A-87—Cost Principles for State and Local Governments.

(iii) 15 CFR part 29a—Audit Requirements for State and Local Governments [implements OMB Circular A-128—Audit of State and Local Governments].

(3) *Educational institutions*

(i) OMB Circular A-110—Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A-21—Cost Principles for Educational Institutions.

(iii) 15 CFR part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations [implements OMB Circular A-133—Audits for Institutions of Higher Education and Other Nonprofit Organizations].

#### § 291.2 Environmental integration projects.

(a) *Eligibility criteria.* Eligible applicants for these projects are manufacturing extension centers or state technology extension programs which at the time of solicitation have grants, cooperative agreements or contracts with the NIST Manufacturing Extension Partnership. Only one proposal per organization per solicitation is permitted in this category.

(b) *Project objective.* The purpose of these projects is to support the integration of environmentally-focused technical assistance, and especially pollution prevention assistance, for smaller manufacturers into the broader services provided by existing MEP manufacturing extension centers. Proposers are free to structure their project in whatever way will be most effective and efficient in increasing the ability of the center to deliver high quality environmental and pollution prevention technical assistance (either directly or in partnership with other organizations). Following are some examples of purposes for which these funds could be used. This list is by no means meant to be all inclusive. A center might propose a set of actions encompassing several of these examples as well as others.

(1) *Environmental needs assessment.*

Detailed assessment of the environmentally-related technical assistance needs of manufacturers within the state or region of the manufacturing extension center. This would be done as part of a broader plan to incorporate environmentally related services into the services of the manufacturing extension center. The center might propose to document its process and findings so that other centers may learn from its work.

(2) *Partnership with another organization.* The center might propose to partner with an existing organization which is providing environmentally-focused technical assistance to manufacturers. The partnership would lead to greater integration of service delivery through joint technical assistance projects and joint training.

(3) *Accessing private-sector environmental resources.* The center might propose to increase its ability to access environmental technical services for smaller manufacturers from environmental consultants or environmental firms.

(4) *Training of field engineers/agents in environmental topics.* Funding for training which empowers the field engineer/agent with the knowledge needed to recognize potential environmental, and especially pollution prevention, problems and opportunities. In addition, training might be funded which empowers the field engineer/agent with the knowledge needed to make appropriate recommendations for solutions or appropriate referrals to other sources of information or expertise. The over-arching goal is for the field engineer/agent to enable the manufacturer to be both environmentally clean and competitive.

(5) *Access to environmentally related information or expertise.* A center might propose to fund access to databases or other sources of environmentally-related information or expertise which might be necessary to augment the environmentally focused activities of the manufacturing extension center.

(6) *Addition of environmentally focused staff.* It may be necessary for manufacturing extension centers to have an environmental program manager or lead field engineer/agent with environmental training and experience. Funds could be requested to hire this person. However, the proposer would have to demonstrate a clear and reasonable plan for providing for the support of this person after the funds provided under this project are exhausted since no commitment is being made to on-going funding.

(c) *Award period.* Projects initiated under this category may be carried out over multiple years. The proposer should include optional second and third years in their proposal. Proposals selected for award may receive one, two or three years of funding from currently available funds at the discretion of DOC. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. A separate cooperative agreement will be written with winning applicants. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC. It is anticipated that successful projects will be given the opportunity to roll the funding for these efforts into the base funding for the extension center. Such a roll-over will be based on a performance review and the availability of funds.

(d) *Matching requirements.* No matching funds are required for these proposals. However, the presence of matching funds (cash and in-kind) will be considered in the evaluation under the Financial Plan criteria.

(e) *Environmental integration projects evaluation criteria.* In most solicitations, preference will be given to projects which are focused on a single industry sector. This is desired to build on the expertise and resources which are being built in tools and resources projects in these industry sectors. Industry focus will be specified in the solicitation announcement. However, actual services need not be limited exclusively to this sector. In addition preference may be given to extension centers which do not have extensive environmentally-related services already in place. In addition to these preferences, the criteria for selection of awards will be

as follows in descending order of importance:

(1) *Demonstrated commitment to incorporating environmentally related services.* The extension center must demonstrate its commitment to incorporate environmentally-related technical services into its overall manufacturing extension services even after funding for this project is exhausted. It is not the objective of this effort to establish completely autonomous environmentally focused extension centers. Rather, the goal is to ensure that such services are integrated directly with general manufacturing extension services focused on competitiveness. The center must demonstrate that such integration will take place. Factors that may be considered include: The amount of matching funds devoted to the efforts proposed as demonstration of the center's commitment to the activity; indication that environmental services are a significant aspect of the organization's long range planning; strength of commitment and plans for continuing service beyond funding which might be awarded through this project; the degree to which environmental services will become an integral part of each field engineers' portfolio of services; the level of current or planned education and training of staff on relevant environmental issues; and the extent of environmentally related information and expert resources which will be easily accessible by field engineers.

(2) *Demonstrated understanding of the environmentally related technical assistance needs of manufacturers in the target population.* Target population must be clearly defined. The manufacturing center must demonstrate that it understands the populations environmentally related needs or include a coherent methodology for identifying those needs. The proposal should show that the efforts being proposed will enable the center to better meet those needs. Factors that may be considered include: A clear definition of the target population, its size and demographic characteristics; demonstrated understanding of the target population's environmental technical assistance needs or a plan to develop this understanding; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(3) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are providing high quality environmentally-related services to manufacturers in the

same target population or which have relevant resources which can be of assistance in the proposed effort. If no such organizations exist, the proposal should build the case that there are no such organizations. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication of services in providing assistance to small and medium-sized manufacturers. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant for providing technology assistance related services to the target population; adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(4) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed program and for ensuring continuous improvement of program activities. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and "customer satisfaction" measures of performance.

(5) *Management experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; appropriateness of the organizational approach for carrying out the proposed activity; evidence of involvement and support by private industry.

(6) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget both in income and expenses; strength of commitment and amount of the proposer's cost share, if any; effectiveness of management plans for control of budget; appropriateness of matching contributions; and plans for

maintaining the program after the cooperative agreement has expired.

### § 291.3 Environmental tools and techniques projects.

(a) *Eligibility criteria.* Eligible applicants for these projects include all nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. Organizations may submit multiple proposals under this category in each solicitation for unique projects.

(b) *Project objective.* The purpose of these projects is to support the initial development and implementation of tools or techniques which will aide manufacturing extension organizations in providing environmentally-related services to smaller manufacturers and which may also be of direct use by the smaller manufacturers themselves. Specific industry sectors to be addressed and sub-categories of tools and techniques may be specified in solicitations. These sectors or sub-categories will be specified in the solicitation announcement. Examples of tools and techniques include, but are not limited to, manufacturing assessment tools, environmental benchmarking tools, training delivery programs, electronically accessible environmental information resources, environmental demonstration facilities, software tools, etc. Projects must be completed within the scope of the effort proposed and should not require on-going federal support.

(c) *Award period.* Projects initiated under this category may be carried out over up to three years. Proposals selected for award will receive all funding from currently available funds. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

(d) *Matching requirements.* No matching funds are required for these proposals. However, the presence of matching funds (cash and in-kind) will be considered in the evaluation under the Financial Plan criteria.

(e) *Environmental tools and techniques projects evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstrated understanding of the environmentally-related technical assistance needs of manufacturers and technical assistance providers in the*

*target population.* Target population must be clearly defined. The proposal must demonstrate that it understands the population's environmentally related tool or technique needs. The proposal should show that the efforts being proposed meet the needs identified. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's environmental tools or techniques needs; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(2) *Technology and information sources.* The proposal must delineate the sources of technology and/or information which will be used to create the tool or resource. Sources may include those internal to the center (including staff expertise) or from other organizations. Factors that may be considered include: Strength of core competency in the proposed area of activity; and demonstrated access to relevant technical or information sources external to the organization.

(3) *Degree of integration with the manufacturing extension partnership.* The proposal must demonstrate that the tool or resource will be integrated into and will be of service to the NIST Manufacturing Extension Centers. Factors that may be considered include: Ability to access the tool or resource especially for MEP extension centers; methodology for disseminating or promoting use of the tool or technique especially within the MEP system; and demonstrated interest in using the tool or technique especially by MEP extension centers.

(4) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise on similar tools or techniques. If no such organizations exist, the proposal should show that this the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; Adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(5) *Program evaluation.* The applicant should specify plans for evaluation of

the effectiveness of the proposed tool or technique and for ensuring continuous improvement of the tool. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and "customer satisfaction" measures of performance.

(6) *Management experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(7) *Financial plan:* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considerable include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposers' cost share, if any; effectiveness of management plans for control of budget appropriateness of matching contributions; and plan for maintaining the program after the cooperative agreement has expired.

### § 291.4 National industry-specific pollution prevention and environmental compliance resource centers.

(a) *Eligibility criteria.* Eligible applicants for these projects include all nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. Only one proposal per organization is permitted in this category.

(b) *Project objective.* These centers will provide easy access to relevant, current, reliable and comprehensive information on pollution prevention opportunities, regulatory compliance and technologies and techniques for reducing pollution in the most competitive manner for a specific industry sector or industrial process. The sector or industrial process to be addressed will be specified in the

solicitation. The center will enhance the ability of small businesses to implement risk based pollution prevention alternatives to increase competitiveness and reduce adverse environmental impacts. The center should use existing resources, information and expertise and will avoid duplication of existing efforts. The information provided by the center will create links between relevant EPA Pollution Prevention programs, EPA and other technical information, NIST manufacturing extension efforts, EPA regulation and guidance, and state requirements. The center will emphasize pollution prevention methods as the principal means to both comply with government regulations and enhance competitiveness.

(c) *Project goal.* To improve the environmental and competitive performance of smaller manufacturers by:

(1) Enhancing the national capability to provide pollution prevention and regulatory requirements information (federal, state and local) to specific industries.

(2) Providing easy access to relevant and reliable information and tools on pollution prevention technologies and techniques that achieve manufacturing efficiency and enhanced competitiveness with reduced environmental impact.

(3) Providing easy access to relevant and reliable information and tools to enable specific industries to achieve the continued environmental improvement to meet or exceed compliance requirements.

(d) *Project customers.* (1) The customers for this center will be the businesses in the industrial sector or businesses which use the industrial process specified as the focus for the solicitation. In addition, consultants providing services to those businesses, the NIST Manufacturing Extension Centers, and federal state and local programs providing technical, pollution prevention and compliance assistance.

(2) The center should assist the customer in choosing the most cost-effective, environmentally sound options or practices that enhance the company's competitiveness. Assistance must be accessible to all interested customers. The center, wherever feasible, shall use existing materials and information to enhance and develop the services to its customers. The centers should rarely, if ever, perform research, but should find and assimilate data and information produced by other sources. The center should not duplicate any existing distribution system. The center should distribute and provide information, but should not directly

provide on-site assistance to customers. Rather, referrals to local technical assistance organizations should be given when appropriate. Information would likely be available through multiple avenues such as phone, fax, electronically accessible data bases, printed material, networks of technical experts, etc.

(e) *Award period.* The pilot initiated under this category may be carried out over multiple years. The proposers should include optional second and third years in their proposal. Proposals selected for award may receive one, two or three years of funding from currently available funds at the discretion of DOC. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC. Successful centers may be given an opportunity to receive continuing funding as a NIST manufacturing center after the expiration of their initial cooperative agreement. Such a roll-over will be based upon the performance of the center and availability of funding.

(f) *Matching requirements.* A matching contribution from each applicant will be required. NIST may provide financial support up to 50% of the total budget for the project. The applicant's share of the budget may include dollar contributions from state, county, industrial or other non-federal sources and non-federal in-kind contributions necessary and reasonable for proper accomplishment of project objectives.

(g) *Resource center evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstrated understanding of the environmentally-related information needs of manufacturers and technical assistance providers in the target population.* Understanding the environmentally-related needs of the target population (i.e., customers) is absolutely critical to the success of such a resource center. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's environmentally-related information needs or a clear plan for identifying those customer needs; and methodologies for continually improving the understanding of the target population's environmentally-related information needs.

(2) *Delivery mechanisms.* The proposal must set forth clearly defined,

effective mechanisms for delivery of services to target population. Factors that may be considered include: Potential effectiveness and efficiency of proposed delivery systems; and demonstrated capacity to form the effective linkages and partnerships necessary for success of the proposed activity.

(3) *Technology and information sources.* The proposal must delineate the sources of information which will be used to create the informational foundation of the resource center. Sources may include those internal to the Center (including staff expertise), but it is expected that many sources will be external. Factors that may be considered include: Strength of core competency in the proposed area of activity; demonstrated access to relevant technical or information sources external to the organization.

(4) *Degree of integration with the manufacturing extension partnership and other technical assistance providers.* The proposal must demonstrate that the source center will be integrated into the system of services provided by the NIST Manufacturing Extension Partnership and other technical assistance providers. Factors that may be considered include: Ability of the target population including MEP Extension Centers to access the resource center; and methodology for disseminating or promoting use of the resource center especially within the MEP system.

(5) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise on similar tools or techniques. If no such organizations exist, the proposal should show that this is the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; and adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities.

(6) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed resource center and for ensuring continuous improvement. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the

activity, and "customer satisfaction" measures of performance; and the proposer's plan must include documentation, analysis of the results, and must show how the results can be used in improving the resource center.

(7) *Management experience and Plans.* Applicants should specify Plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications and experience of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(8) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's *cost share*; effectiveness of management plans for control of the budget; and appropriateness of matching contributions.

#### § 291.5 Proposal selection process.

The proposal evaluation and selection process will consist of three principal phases: Proposal qualification; proposal review and selection of finalists; and award determination.

(a) *Proposal qualification.* All proposals will be reviewed by NIST to assure compliance with the proposal content and other basic provisions of this notice. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) *Proposal review and selection of finalists.* NIST will appoint an evaluation panel composed of NIST and in some cases other federal employees to review and evaluate all qualified proposals in accordance with the evaluation criteria and values set forth in this notice. A site visit may be required to make full evaluation of a proposal. From the qualified proposals, a group of finalists will be numerically ranked and recommended for award based on this review.

(c) *Award determination.* The Director of the NIST, or her/his designee, shall select awardees based on total evaluation scores, geographic distribution, and the availability of funds. All three factors will be considered in making an award. Upon the final award decision, a notification will be made to each of the proposing organizations.

#### § 291.6 Additional requirements; federal policies and procedures.

Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 211

[Docket No. 90N-0376]

RIN 0905-AA73

#### Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Amendment of Certain Requirements for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revising certain requirements of the current good manufacturing practice (CGMP) regulations for finished human and veterinary pharmaceuticals. The changes include clarifying the degree of discretion provided to manufacturers to determine whether separate or defined areas of production and storage are necessary, clarifying the standard used to determine the degree of scrutiny necessary to check the accuracy of the input to and output from computer systems, exempting investigational new drug products from bearing an expiration date, permitting the use of a representative sampling plan for the examination of reserve samples, and clarifying the manufacturer's responsibilities regarding batch records during the annual evaluation of drug product quality standards. These revisions will reduce regulatory burdens.

**EFFECTIVE DATE:** February 21, 1995.

#### FOR FURTHER INFORMATION CONTACT:

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William G. Marnane, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville MD 20855, 301-594-0678.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of July 14, 1981 (46 FR 36332), FDA announced that it was undertaking a review of existing regulations with the goal of minimizing regulatory burdens while maintaining an acceptable level of consumer protection. The public was invited to submit information to assist the agency in deciding the priority of review. FDA invited data that would enable the agency to identify specific existing regulations or groups of regulations perceived to be unnecessarily costly, burdensome, or without public benefit, and on the potential savings to be derived from revising or removing regulations.

In the **Federal Register** of July 2, 1982 (47 FR 29004), FDA announced its review priorities based on comments from 125 individuals and organizations. One area selected for regulatory review was part 211 (21 CFR part 211), the regulations that govern CGMP for finished pharmaceuticals.

This, in turn, led to an internal retrospective review that resulted in recommendations to the agency. As a result of the agency review, in the **Federal Register** of February 12, 1991 (56 FR 5671), FDA issued a proposed rule incorporating the recommendations resulting from the review (hereinafter referred to as the proposed rule). Consideration of these comments and any resulting revisions have been incorporated into this final rule and are discussed in detail below.

The agency's review of CGMP regulations is ongoing and FDA anticipates further revisions based on the agency's experience with the regulations, enforcement efforts, and communications with industry and the general public.