

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, January 4, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at

approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Open Session

Dated: December 23, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-31681 Filed 1-4-93; 11:00 am]

BILLING CODE 6210-01-M

Corrections

Federal Register

Vol. 57, No. 250

Tuesday, December 29, 1992

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 921074-2274]

RIN 0693-AB11

Two Proposed Federal Information Processing Standards; Integration Definition for Function Modeling; Integration Definition Information Modeling

Correction

In notice document 92-30312 beginning on page 59081 in the issue of Monday, December 14, 1992, on page 59082, in the first column, under DATES, in the third line, "March 15, 1992" should read "March 15, 1993".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N-0486]

Pfizer Pharmaceuticals Inc., et al.; Withdrawal of Approval of 45 Abbreviated Antibiotic Drug Applications

Correction

In notice document 92-30491 beginning on page 59840 in the issue of Wednesday, December 16, 1992, make the following corrections:

1. On page 59840, in the third column, the **EFFECTIVE DATE** should read "January 15, 1993".

2. On page 59841, in the first column, in the last line of the paragraph, "January 15, 1992" should read "January 15, 1993".

BILLING CODE 1505-01-D

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 826

Equal Access to Justice Act Fees

Correction

In proposed rule document 92-30940 beginning on page 60785 in the issue of Tuesday, December 22, 1992, in the first column, under DATES, the comment date should read "January 21, 1993".

BILLING CODE 1505-01-D

NUCLEAR REGULATORY COMMISSION

Final Memorandum of Understanding Between the U.S. Nuclear Regulatory Commission and the State of Alabama

Correction

In notice document 92-26627 beginning on page 49725 in the issue of Tuesday, November 3, 1992, make the following corrections:

1. On page 49726, in the second column, in the second full paragraph, in the sixth line "Development" should read "Department".

2. On page 49727, in the first column, in the first partial paragraph, in the eighth line "poser" should read "power".

BILLING CODE 1505-01-D

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 530

RIN 3206-AE22

Pay Rates and Systems (General); Special Salary Rate Schedules for Recruitment and Retention

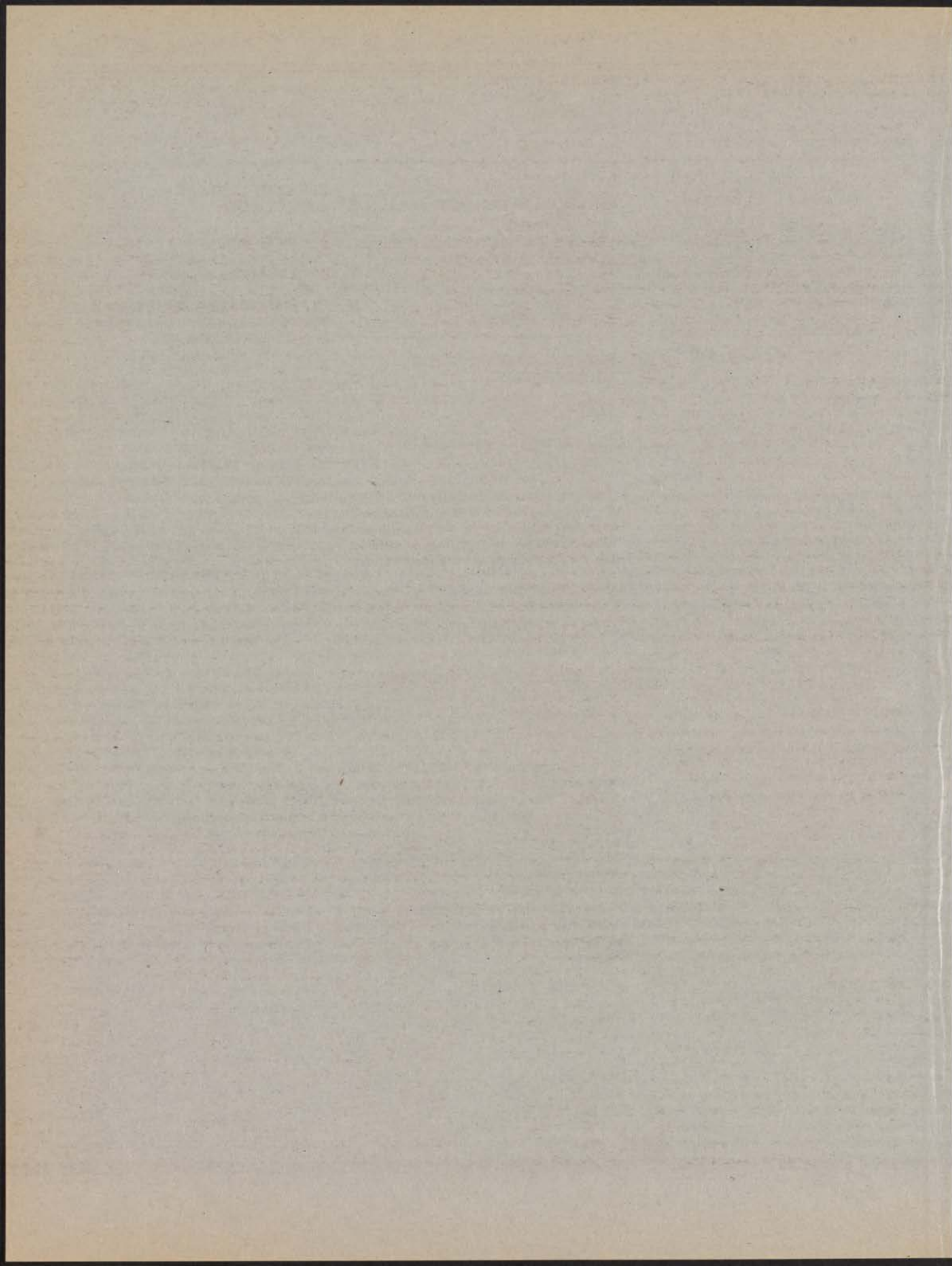
Correction

In rule document 92-30414 beginning on page 59275 in the issue of Tuesday, December 15, 1992, make the following corrections:

1. On page 59275, in the second column, under **EFFECTIVE DATE**, "January 14, 1992" should read "January 14, 1993".

2. On page 59276, in the first column, in the next to last line of the incomplete paragraph, "agencies again" should read "agencies gain".

BILLING CODE 1505-01-D



Environmental Protection Agency

Tuesday
December 29, 1992

Part II

**Environmental
Protection Agency**

40 CFR Part 63

**National Emission Standards for
Hazardous Air Pollutants; Compliance
Extensions for Early Reductions; Final
Rule**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD-FRL-4534-3]

National Emission Standards for Hazardous Air Pollutants; Compliance Extensions for Early Reductions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Regulations governing compliance extensions for early reductions of hazardous air pollutants (HAP's) were proposed in the *Federal Register* on June 13, 1991. This action promulgates these regulations and implements the provisions of section 112(i)(5) of the Clean Air Act (CAA) (as amended in 1990). This rule establishes requirements and procedures for source owners or operators to obtain compliance extensions from section 112(d) standards and for reviewing agencies to follow in evaluating requests for extensions.

DATES: Effective Date, December 29, 1992.

Judicial Review. Under section 307(b)(1) of the CAA, judicial review of the actions taken by this notice is available only by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this rule. Under section 307(b)(2) of the CAA, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: *Background Information Document.* The background information document (BID) for the promulgated standards may be obtained from the U.S. EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone number (919) 541-2777. Please refer to "National Emissions Standards for Hazardous Air Pollutants: Compliance Extensions for Early Reductions—Background Information for Promulgated Standards" (EPA-450/3-92-006b). The BID contains (1) a summary of all the public comments made on the proposed standards and EPA's responses to the comments; and (2) a summary of the changes made to the standards since proposal. Also available from the EPA Library are three additional supporting documents. These documents are:

(a) "Enabling Document for Regulations Governing Compliance Extensions for Early Reductions of

Hazardous Air Pollutants" (EPA-450/3-91-013, July 1991);

(b) "Questions and Answers about the Early Reductions Program" (EPA-450/3-92-005, January 1992); and

(c) "Procedures for Establishing Emissions for Early Reduction Compliance Extensions" (EPA-450/3-91-012a, February 1992).

Docket. Docket No. A-90-47, containing supporting information used in developing the promulgated standards, is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, room M-1500, 1st Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the Early Reductions Program regulations, contact Mr. David Beck, telephone (919) 541-5421, or Mr. Richard Colyer, telephone (919) 541-5262. The address for both is Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711. For information concerning Method 301, contact Mr. Tony Wayne, telephone (919) 541-3576, Emission Measurement Branch, Technical Support Division (MD-19), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

- I. General Requirements
- II. Summary of Changes and Impacts of the Final Rule
- III. Supporting Documents
- IV. Public Participation
- V. Significant Comments and Changes to the Proposed Rule
 - A. Definition of Source
 - B. Base Year Emissions
 - C. Enforceable Commitments
 - D. Allowable Emission Reductions
 - E. Demonstration of Early Reductions
 - F. High-Risk Pollutants
 - G. State Authority
 - H. Interface With Title V Permits
 - I. Interface With Section 112(g) Modifications
 - J. Interface With Title I Provisions
 - K. Test Methods and Procedures
 - L. Other Changes to the Proposed Regulation
- VI. Administrative Requirements
 - A. Docket
 - B. Paperwork Reduction Act
 - C. Executive Order 12291
 - D. Regulatory Flexibility Act

I. General Requirements

Today's rule applies to any existing source that seeks a 6-year compliance extension from an applicable section

112(d) standard by achieving early emission reductions of HAP's. The compliance extension would be obtained and authorized in accordance with section 112(i)(5) of the CAA.

Section 112(i)(5) allows an existing source to be granted a 6-year extension of compliance with otherwise applicable section 112(d) standards upon demonstration by the owner or operator of the source that a 90 percent reduction in HAP's (95 percent or more in the case of particulates) has been achieved. An enforceable alternative emission limitation reflecting the reduction will be established for the source by a permit issued under Title V of the CAA.

The 90 (95) percent emission reduction must be achieved before proposal of an applicable section 112(d) standard in most cases. However, a source achieving the reduction after proposal of a standard but before January 1, 1994, may qualify for a compliance extension from section 112(d) standards by making an enforceable commitment before proposal of the standard to achieve such a reduction.

State or local air pollution control agencies with Title V permitting authority will review Title V operating permit applications for compliance extensions. They will issue permits containing alternative emission limitations applicable to sources achieving early reductions in lieu of section 112(d) standards in accordance with approved permit programs under Title V of the CAA. The EPA Regional Offices will review permit applications and issue Title V permits for sources located in States that do not have approved Title V permit programs. States will assume the review and permitting activities upon approval of their Title V permit programs, or may be granted delegation of the Early Reductions Program prior to approval of their Title V permit program.

II. Summary of Changes and Impacts of the Final Rule

Based on comments received during the comment period on the proposed rule, few significant changes have been made to the regulation. The significant changes are listed below.

The most significant change to the rule has been to the high-risk list of pollutants. Seventeen pollutants have been added to the list and five pollutants have been deleted. Weighting factors for seven pollutants have been adjusted. A provision was added to ensure that there are no increases in radionuclides as a result of the emission reduction demonstration. Another

provision was added that would "grandfather" sources that already had approved enforceable commitments or alternative emission limits specified by permit from having to revise their post-reduction demonstration if a new pollutant is added to the high-risk list.

Part of the proposed definition of source, which allowed a combination of sources to be considered an Early Reductions source (§ 63.73(a)(4)) has been removed.

The rule has been revised to restrict the combined percent reduction method in demonstrations involving sources with both gaseous and particulate HAP emissions. This provision now only applies to emission points that emit both gases and particulates; emission points that emit only gaseous HAP or only particulate HAP cannot be used in a combined percent reduction demonstration.

Another change to the rule allows the use of EPA average emission factors for equipment leaks to determine base year emissions only if no reductions in equipment leak emissions are claimed as part of the reduction demonstration. The equipment leak source in appendix B has been clarified to be specific to the individual process equipment component types.

There have also been several less significant changes. The definition of "actual emissions" has been clarified to exclude startup and shutdown emissions due to malfunctions. Requiring evidence that curtailments or shutdowns are permanent for the post-reduction demonstration has been removed; evidence is unnecessary, as such reductions will become permit conditions. The suggested statement of commitment in the enforceable commitment has been revised to be consistent with wording in the demonstration requirements section of the regulation. The length of time allowed to provide source test results to support the post-reduction demonstration has been increased to 120 days from 90 after the permit submittal deadline. The term "post-control" has been changed to "post-reduction" throughout the rule to recognize that reductions can be achieved through means other than control technology. Corrections and changes have been made to Method 301, including a broadening of applicability of the method to other media.

The Early Reductions Program is a voluntary program. The primary goal of the Program is to provide a positive impact to the environment by encouraging early reductions of HAP's prior to mandatory regulatory action. As discussed in the proposal preamble,

significant environmental benefits can be achieved through early reduction of emissions (56 FR 27338). The environmental benefits accrue because over time the total emission reductions achieved by participants exceed those emission reductions which would be achieved by section 112(d) standards imposed at a later date even if the later standards are more stringent.

There are also potential benefits to companies participating in the Program. The compliance extension will give a company an opportunity to design cost-effective emission reduction approaches for their sources and may reduce the cost of compliance over the long term. The Program allows flexible compliance options and encourages pollution prevention solutions. Companies achieving early reductions of HAP's may also be viewed more favorably by the affected public.

III. Supporting Documents

In addition to the background information document, information pertaining to the development and implementation of the Early Reductions Program can be found in other publications developed by EPA. The preamble to the proposed rule (56 FR 27338) includes a detailed discussion of all the provisions of the rule and presents EPA's decision-making process in developing the Program.

The EPA has published three additional documents to assist industries interested in participating in the Program and also to assist regulatory agencies responsible for implementing the Program. The first document, entitled "Enabling Document for Regulations Governing Compliance Extensions for Early Reductions of Hazardous Air Pollutants" (EPA-450/3-91-013, July 1991), presents a more detailed description of the Early Reductions Rule. The enabling document includes information useful in both preparing and reviewing Early Reductions submittals.

The second document is titled "Questions and Answers About the Early Reductions Program" (EPA-450/3-92-005, January 1992), and is a compendium of questions dealing primarily with implementation of the Program. The questions were generated by industry, State and local regulatory agencies, trade associations, and other interested parties.

Finally, EPA has produced a procedures document for establishing base year and post-reduction emissions. This document is titled "Procedures for Establishing Emissions for Early Reduction Compliance Extensions" (EPA-450/3-91-012a, February 1992)

and provides guidance for establishing emissions from specific source categories for which section 112(d) standards will be developed. Source categories included in this document are: The synthetic organic chemical manufacturing industry, ethylene oxide sterilizers, and chrome electroplaters.

IV. Public Participation

In developing the Early Reductions rule, EPA solicited input from representatives of industry, environmental groups, and State and local air pollution control agencies. Options for the rule's major provisions were presented and discussed with these and other interested parties at a meeting of the National Air Pollution Control Techniques Advisory Committee on January 29, 1991, and at four "roundtable" discussions held in January, February, and March 1991.

In addition, EPA solicited public comments on the proposed rule that was published in the *Federal Register* on June 13, 1991 (56 FR 27338). Sixty-seven comment letters were received, with most of the letters containing multiple comments. The EPA's responses to these comments can be found in the Background Information Document referenced in the "ADDRESSES" listing above. The major comments received by EPA and the responses thereto are also addressed in this preamble.

The EPA is strongly committed to the success of the Early Reductions Program. Accordingly, EPA has been actively promoting the Program and been disseminating information to public and private organizations. Since proposal of the rule, EPA has conducted a number of workshops to inform interested parties about the Program. In addition, EPA has met with industries and individual companies interested in participating in the Program and with regulatory agencies who will be involved with the implementation of the rule. These workshops and meetings have served as a forum for EPA to field questions on the proposed rule and to better understand the comments and issues of potentially affected parties.

V. Significant Comments and Changes to the Proposed Rule

Individual companies, trade associations, State and local regulatory agencies, and citizens groups all commented on the proposed rule. The most significant comments and EPA's responses to those comments are discussed below. These comments are grouped under the following headings: Definition of Source, Base Year Emissions, Enforceable Commitments,

Allowable Emission Reductions, Demonstration of Early Reduction, High-Risk Pollutants, State Authority, Interface with Title V Permits, Interface with Section 112(g) Modifications, Interface with Title I Provisions, Test Methods and Procedures, and Other Changes to the Proposed Regulations.

A. Definition of Source

Many comments addressed the source definition. Several commenters contended that the proposed definition was far too broad. They argued that the sources receiving a compliance extension under the Early Reductions Program should be the same sources for which section 112(d) standards are developed.

The commenters' conclusion that EPA should change the definition of source to match that of a section 112(d) source proceeds from an incorrect assumption. The commenter assumes that at the time an owner or operator undertakes to make an early reduction, or enters into an enforceable commitment to do so, he can determine the "source" for purposes of "the otherwise applicable section 112(d) standard."

However, in most instances this will not be possible because of the structure of section 112(i)(5). The Early Reductions provision requires a source owner or operator to make the reductions prior to proposal of a section 112(d) standard, or enter into an enforceable commitment to do so before proposal provided the reductions are demonstrated before January 1, 1994. If the otherwise applicable section 112(d) standard has not yet been proposed and "source" defined for that standard, it would be impossible for an owner or operator to know whether the necessary reductions had been made or could be made to achieve the 90 (95) percent reduction. The only exception is for the equipment leak portion of the upcoming section 112(d) standards for synthetic organic chemical manufacturing plants, discussed below.

As recognized by Senator Durenberger and others, EPA will have broad discretion in defining source for any particular section 112(d) standard. In some cases, a source will be a process unit, in others it will be an entire plant. See 126 Cong. Rec. S16927 (3rd col. daily ed. Oct. 27, 1990). Congress could not have meant to so restrict participation in the Early Reductions Program to those companies who owned or operated emission points that EPA had clearly defined as a source before proposal of a particular section 112(d) standard. Moreover, because it would be impossible at this time to identify all possible sources that may be subject to

section 112(d) standards, it is impossible for EPA to list each and every type of source for the Early Reductions Program. The EPA's definition of "source" recognizes the flexibility set forth in the statute. The EPA, or the State authority if operating under a delegated program, must review the applicant's Early Reductions submittal to ensure that it is consistent with one of the regulatory definitions under the Early Reductions Program. Given the limitation described above, EPA developed a definition of source for this provisions designed to encompass the broad definition of source contained in section 112(a), which incorporates the broad definition of section 111(a).

One commenter contended that EPA's definition of source in § 63.73(a)(1) proceeds from an error in equating "source" and "source category", and interprets sources listed in appendix B as "source categories."

The commenter fundamentally misunderstands EPA's definition of source and how it relates to the "source category." As the commenter suggests, EPA is to identify source categories which emit HAP's. The EPA is not saying, however, that it must know each category before it can make the linkage to section 112(i)(5). A "source category" for the purpose of defining industry types to be regulated and the "source" to which a standard specifically applies may be quite different (e.g., in the new source performance standard for electric utilities the applicable "source" is the steam boiler).

The single "source" listed in appendix B also exemplifies this distinction; this source, equipment leaks, is contained within a source category—the synthetic organic chemical manufacturing industry. Furthermore, equipment leaks are a special situation that EPA believes should be addressed separately, as equipment leak emissions arise from the nearly ubiquitous pumps, valves, connectors, and other equipment integrally associated with more traditional "sources", i.e., building, structure, facility or installation. The outcome of a regulatory negotiation involving equipment leaks published by EPA designated equipment leaks as a separate source (56 FR 9318; March 6, 1991). The EPA indicated that it would propose the rule as part of the hazardous organic NESHAP (HON) which will be promulgated under section 112(d). While this standard has not yet been proposed, the publication of the outcome of the regulatory negotiation sufficiently identifies equipment leaks as a distinct source to separate them for the purposes of Early

Reductions. The EPA will determine the definition of source for the HON in that rule.

The EPA is allowing the option of including equipment leaks as part of a designated source, leaving the equipment leaks out of the source, or identifying equipment leaks solely as the source.

Indeed, once EPA defines a source category, the issue of the source definition may still remain. In some instances, individual facilities within a source category may constitute an entire source, in other instances each "source" subject to a section 112(d) standard may only constitute a portion of the facility within a source category. Thus, it is the regulated "source" that it is important for purposes of determining otherwise applicable section 112(d) standards, not the source category. Because EPA has not defined source for particular section 112(d) standards (except in one instance), EPA's definition reflects the range of possibilities contemplated by the definition of source in the statute.

Several commenters objected to proposed § 63.73(a)(2) and one argued that a plantwide definition of source was expressly prohibited, citing a floor statement by Senator Durenberger.

Section 111(a)(1) (incorporated into the definition of "existing source" in section 112) defines a "stationary source" as "any building, structure, facility, or installation which emits or may emit any hazardous air pollutant." This term is obviously broad enough to encompass an entire plant or facility. In some instances, a section 112(d) standard may encompass an entire "facility," which certainly includes the concept of a plantwide source.

Moreover, the definition of major source, which covers an entire contiguous area under common ownership or control, may consist of a single stationary source. "Major source" is defined as " * * * any stationary source or group of stationary sources * * * " See CAA section 112(a)(1). Thus, contrary to the commenters' assertions, the definition of source under section 112 expressly encompasses a plantwide definition of source, among other configurations. The proposed and final regulations reflect the statutory language.

One commenter also cites a floor statement of Senator Durenberger's as the authoritative basis for the conclusion that a source cannot include an entire plant. However, closer reading of the complete referenced statement also expressly confirms that the source to which a section 112(d) standard might apply could be a specific portion of a facility or encompass an entire

contiguous facility. See 126 Cong. Rec. S 16927 (3rd. col.). If EPA has the discretion to establish a section 112(d) standard for a source that encompasses an entire contiguous facility, then it follows that an entire contiguous facility may be a source under section 112(i)(5).

One commenter objected to the proposed § 63.73(a)(3) because it allows an applicant to define a grouping of points that constitutes a building, structure, facility, or installation as a source. The commenter cites proposal preamble language that explains that emission points having a functional geographical relationship could be defined as a source under this part of the definition and concludes that there is no statutory basis for this type of grouping.

Subparagraph 63.73(a)(3) also directly follows the definition of source in the statute. As noted, a "stationary source" is any "building, structure, facility or installation which emits, or may emit, any hazardous air pollutant." See CAA section 111(a)(3). The phrase "functional or geographical relationship" merely gives meaning to the statutory terms. For example, a "building" suggests a geographical grouping of emission points (it may also have a functional relationship). Likewise, an "installation" suggests some type of unit that undertakes a particular function, such as a wastewater treatment system. As EPA develops section 112(d) standards, it will define "source" for particular standards considering these types of logical groupings of emission points. However, because EPA has not yet defined what will constitute a "source" for any particular section 112(d) standard (with the single exception noted earlier), the language of this rule reflects the range of options available within the statutory definition.

Several commenters contended that subparagraphs (a)(4) and (a)(5) of the proposed definition are contrary to the statute because they allow "bubbling" across two or more separate sources. One commenter noted that previous guidance from EPA precluded the use of "bubbling" to avoid section 112(d) standards.

As discussed in the proposed rule, EPA believes that the provisions of § 63.73(a) (4) and (5) are consistent with the statute and the underlying purposes of the Early Reductions provisions. However, EPA is deleting subparagraph (a)(4) because (a)(4) is redundant with the provisions of (a)(5) as any combination of emission points that would meet the requirement of proposed paragraph (a)(4) would also fit with the language of (a)(5).

The EPA has concluded that unrelated emission points may be considered as a single "source" for purposes of the Early Reductions Program, provided that the emission points are all under common ownership or control, are located "within a contiguous area," such as a common plant site, and constitute a significant level of emissions. The individual emission points to be aggregated do not have to be located next to one another or be functionally related in order to be grouped as a source provided that they are all located within the same contiguous facility.

The conclusion that aggregating unrelated emission points is permissible for purposes of the Early Reductions Program is confirmed not only by the statutory language and case law discussed above, but also by the statutory policies and legislative history of the Early Reductions Program. In section 112(i)(5)(E), Congress authorized a form of emissions trading, i.e., by allowing offsetting reductions of one HAP against reductions of other HAP's for purposes of the Early Reductions Program. Aggregation of emission points is merely another form of emissions trading.¹

Nevertheless, the rule is not inconsistent with the general emissions trading policy referenced by the commenter (51 FR 43814; December 4, 1986), i.e., that "bubbling" may not be used to avoid a section 112(d) standard. The Early Reductions provision does not provide a mechanism for a source to avoid applicability of a section 112(d) standard. Rather, it provides for a compliance extension in the form of an alternative emission limit for the source for a period of six years in exchange for the source having achieved a certain emissions reduction level by a specified date (either by January 1, 1994 or before proposal of an otherwise applicable section 112(d) standard). The source must meet the section 112(d) standards when the compliance extension has expired.

Moreover, the legislative history indicates that Congress wanted EPA to encourage participation in the Program. See H.R. Rep. No. 101-490, 101st Cong., 2d Sess. 332 (May 17, 1990) ("In the administration of this provision EPA

¹ This conclusion is limited to the context of the Early Reductions Program for several reasons. In particular, Congress specifically contemplated netting one hazardous pollutant against another for purposes of this program. Congress indicated in the legislative history that it wishes EPA to encourage participation in this program to obtain early reductions (see discussions below); and the statutory requirement for 90 percent reductions raises quite different factual and policy issues than might be applicable elsewhere.

thus should strive to encourage companies to take advantage of this incentive to reduce emissions early.") In addition, the significance threshold (i.e., 10 tons per year, or 5 tons per year at a contiguous plant site less than or equal to 25 tons per year) is designed to ensure that substantial real reductions are achieved and that the Program is not trivialized. The flexibility afforded through aggregating emission points offers greater incentive to participate in the Early Reductions Program. Greater overall participation in the Program combined with the minimum threshold for early reductions achieved will help ensure that the reductions achieved under the Program are both real and substantial and the concomitant environmental benefits maximized.

The commenter argues further that the random pooling approach that allows for credits undertaken in the past demonstrates that subparagraph (a)(5) is inconsistent with the purposes of the statute. The commenter argues that the justification for random pooling—to encourage greater participation in the Program and thereby reduce air toxics emissions—is not present if a source can include past reductions in the pool. The commenter concludes that any pollution reduction measure undertaken prior to the enactment of the law cannot have been dependent on the incentive of pooling. The commenter acknowledges that past reductions can be credited, but that they should not be pooled with unrelated, uncontrolled emission points to demonstrate an early reduction.

The statute affords a six year extension for those sources that achieve a 90 (95) percent reduction in emissions by a specified time. Those emission reductions may have occurred at any time back to 1987, and in limited instances 1985 or 1986. The commenter assumes that the only time applicants will use the grouping of emissions points under proposed paragraphs (a)(4) and (a)(5) is to get credit for past actions, make no additional reductions, and obtain a 6-year extension for remaining uncontrolled emission points within the Early Reductions source. This will not be the case. The EPA has discussed tentative Early Reduction plans with many companies and has received several enforceable commitments which indicate that the flexible definition of source is encouraging prospective emission reduction projects. In many instances, EPA expects that an applicant will group some recently well-controlled emission points with others, some or all of which may have controls installed on them. The ability to apply credits in excess of 90 (95) percent reduction from

one point to a point unable to achieve 90 (95) percent by itself, provides an incentive to control the second point enough to cover the shortfall where it would not have otherwise.

For example, suppose the applicant previously controlled a 100 ton emission point "A" to a 98 percent control level, i.e., it now emits 2 tons of HAP's. The applicant also has a second 100 ton uncontrolled emission point "B." Existing control measures for point B indicate that MACT will likely require at least 90 percent reduction. However, a much less expensive technology can reduce those emissions from point B by 85 percent, i.e., to 15 tons. Furthermore, the owner has determined that he would realize a net savings if he could implement 85 percent control now and 10 years later implement MACT, compared with meeting MACT in four years. The extra time gained from a compliance extension would also allow development of process modifications that would completely eliminate HAP emissions from his source. Without proposed paragraph (a)(5), the applicant will have no incentive to install any controls on point B prior to a section 112(d) standard because that point by itself will not be reduced by 90 (95) percent, short of installing MACT controls anyway. However, if it can "credit" an additional five tons from emission point A, it will have an incentive to participate in the Program for both points A and B, and thereby substantially reduce overall air toxics emissions from that source. Without the option of proposed paragraph (a)(5), the source would not seek a compliance extension for point B and would have no incentive to enter the Program, and the emissions from the two points will be 102 tons; by entering both points in the Program using proposed paragraph (a)(5), the source's emissions will be 17 tons, which is greater than a 90 (95) percent reduction from the original 200 tons being emitted by the two points. Moreover, there is no basis in the law for penalizing those that made reductions between 1987 and the passage of the CAA Amendments in defining a source.

The same commenter also objects to pooling emissions that would have occurred anyway, especially shutdowns, to shield points that otherwise would have had to comply with a section 112(d) standard.

There is no basis to require, as the commenter urges, that an applicant certify that any reductions (in particular any shutdowns) would not have occurred but for the Early Reductions provisions of the law. This comment and others are addressed more fully in

the section entitled "Allowable Emission Reductions" below.

A number of commenters felt the definition of source should be consistent with the source definition proposed in Title V of the CAA, and therefore be consistent with other sections of the CAA.

The definition of source for purposes of section 112(i)(5) is consistent with the definition of source under section 112 of the CAA. Nothing precludes different definitions or interpretations of the term "source" in other parts of the CAA. The Title V permitting authority will be required to establish permit limits for a facility during the permit process required by the Title V permit program. It may well be that one permit for a contiguous facility may contain permit limits for multiple section 112(d) sources. Whether part of the Early Reductions Program or not, many industrial facilities will be subject to more than one section 112(d) standard and thus may have more than one section 112(d) "source" as part of its permit.

One commenter suggested that the source definition be expanded to cover all sources for which EPA is currently developing standards. Similarly, a second commenter requested that the source definition be revised so that it is linked to the list of categories and subcategories for which section 112(d) standards will be developed.

As noted earlier, EPA has not yet determined what groups of emission points will constitute a source for any particular section 112(d) standard.

The definition of source is set forth in a manner consistent with the broad statutory definition. Section 112 will establish standards for hundreds of different types of industrial processes and other sources that emit HAP's. It is impossible to determine at this time how "source" might be defined for any particular source category to be regulated by a section 112(d) standard. As noted above, the list of potential source categories to be subject to regulation does not necessarily aid in the definition of source. In some instances, an industrial source category (e.g., a particular type of manufacturing process) may have one "source" for purposes of a section 112(d) emission limit. In other instances, multiple sources may be included within any source category, e.g., tanks in a process could be one source and wastewater emissions from the same process may constitute another source within the same source category. The EPA has not yet developed any specific definitions of source to all of the categories listed in

56 FR 28548 (preliminary source category listing).

Included in the source definition is a significance threshold (discussed above) to ensure that application of the flexible source definition results in meaningful reductions of emissions. A number of comments were received regarding the significance threshold.

One commenter believed that § 63.74(b) of the regulation that defines significant emissions unnecessarily restricts participation in the Program by smaller stationary sources. Another commenter agreed that the Early Reductions Program should focus only on major emitters (i.e., 10 tons/yr or 5 tons/yr at less than 25 tons/yr facilities). Another commenter felt that the definition of significant should include only 10 ton/year sources; allowing smaller sources to participate would waste resources on such small sources.

The EPA's definition of source is designed to provide broad flexibility in defining source for purposes of the Early Reduction provisions. The goal is to encourage widespread participation in this Program to achieve early reductions of air toxics emissions. The significance threshold included in 63.73(b) is designed to ensure that significant reductions occur. It is important to point out, however, that the 5/10-ton threshold of significant emissions applies to only subparagraph (a)(4) (formerly (a)(5) in the proposed rule; proposed paragraph (a)(4) has been deleted in the final rule). Thus, any process unit or other entity that meets any definition in (a)(1) through (a)(3) is eligible for an Early Reduction extension, even if it emits less than the 5- or 10-ton threshold. Thus, EPA anticipates that in most instances, even smaller facilities will be able to participate in the Program.

While EPA could have considered other thresholds, such as 3 tons/25 tons per year or 20 percent of any plant's emissions, as suggested by some commenters, the levels chosen are a reasonable attempt to balance the various factors involved, including allowing participation and assuring significant reductions.

One commenter requested clarification of the source definition as it relates to a source that services more than one production unit, such as a wastewater system.

Under § 63.73(a)(3), it is possible to define a unit such as a wastewater treatment system, that serves multiple parts of an entire plant, as a single source.

Given the flexibility of the source definition, one commenter wanted assurance that the source defined for

early reductions would remain constant throughout the compliance extension, regardless of how an applicable section 112(d) standard defined a source. The commenter questioned what would happen if the source defined by an applicable section 112(d) standard is different from the source defined under the Early Reductions Program.

Once an individual source is defined and accepted by EPA as part of the Early Reductions Program, the Early Reduction source will not change as a result of a section 112(d) standard. Any particular section 112(d) standard may apply to the entire Early Reduction source or to a subset of emission points within that source. All emission points included in the defined Early Reduction source are entitled to a 6-year extension from all otherwise applicable section 112(d) standards. At the end of the 6-year period, emission points affected by the earliest applicable section 112(d) standard must meet those standards. Emission points not affected by the earliest section 112(d) standard must continue to meet the alternative emission limitation until 6 years after the compliance date of any section 112(d) standard applicable to the emission point. Any emission points not included in the Early Reduction source definition, but included in the source definition for a section 112(d) standard must achieve reductions according to the compliance schedule in the applicable standard.

Another commenter felt that owners or operators should have the flexibility to redefine sources if significant process changes or production increases were made during the extension period, or if portions of a plant which were shut down restarted.

Once an individual source is defined and accepted by EPA as part of the Early Reductions Program and the source has been granted a 6-year extension by permit, the source cannot be redefined. If a portion of the original source restarts or expands, those emissions must be accounted for in the post-reduction emissions. If part of a source shuts down or curtails production and production capacity is increased at another unit or is replaced by a new unit at the plant site not included as part of the original source, the HAP emissions from the increased production outside of the Early Reduction source must be accounted for as well. This is to ensure that emissions from the source are not simply moved elsewhere in the plant. Owners or operators must give careful consideration to the designation of "source" when applying for the Early

Reductions Program in light of potential future expansions.

If a source anticipates increased production in certain areas of its facility, the owner or operator has several options. The flexibility of the source definition allows the applicant to define a source that does not include the portion of the facility that may expand. The applicant may also reduce emissions from the base year by greater than 90 (95) percent, thereby allowing for subsequent increases in emissions that would still meet the required reduction. If owners or operators can anticipate what changes will be made to the source, they may coordinate with the State in determining the most appropriate type of alternative emission limitation (i.e., a numerical emissions limitation for each emission point or other requirement) that may allow more flexibility for expanding one portion of the source. The EPA recognizes that process changes are necessary, but to participate in this Program, overall source emissions must remain at a level that is 90 (95) percent of the base year emissions. The permitting authority may revise or adjust alternative emission limits through permit modifications as appropriate, provided that the overall 90 (95) percent reduction for the source is maintained during the extension.

Finally, one commenter asked for clarification regarding a situation in which a defined source adds a new line identical to that already included in the source definition.

In most cases, new emission points will not be able to participate in the Early Reductions Program. The CAA specifies that a compliance extension may be granted only to an existing source, e.g., those emission points existing in the selected base year. New emission points (those built after the base year) would thus be outside the scope of the previously defined Early Reduction source, and therefore would be subject to section 112(d) standards, if previously proposed.

The only exception occurs when the entire plant site or an entire enclosed building is defined as the source by the applicant and a "new" process unit is constructed within the plant site or building, respectively, and emits less than 10 tons/yr of a single HAP and 25 tons/yr of total HAP's. The new unit must then be included as part of the Early Reduction source and the source must maintain the original 90 (95) percent emission reduction from base year emissions. Emissions from the existing points in the original source must therefore be reduced to compensate for the additional emissions

from the new points. If, however, emissions from the new unit exceed 10 tons/yr of a single HAP or 25 tons/yr of total HAP's, the new unit is considered, for the purposes of Early Reductions only, a source by itself and thus would not be part of the original Early Reduction source, regardless of the source definition. The EPA will distinguish between existing sources and new sources in other rules. However, early reductions occur before proposal of section 112(d) standards and before other rules that will distinguish between existing and new sources are finalized. Furthermore, the Early Reductions Program applies only to existing sources. Therefore, EPA had to make an administrative determination for the purposes of Early Reductions that new units emitting greater than 10 tons/yr of a single HAP and 25 tons/yr of total HAP's are new sources. The EPA may distinguish between new sources and existing sources differently in other rulemakings.

B. Base Year Emissions

Two commenters suggested that the base year be different than 1987. One commenter wanted 1984 to be an acceptable base year if data had been submitted to EPA during that year. Another commenter suggested that 1990 would be a more relevant base year since 1990 would be consistent with Title I requirements.

The CAA specifically states that the base year not be earlier than 1987 except that the source may choose 1985 or 1986 as the base year only if the source owner or operator can demonstrate that supporting data pursuant to an information request under section 114 of the CAA were received by EPA prior to November 15, 1990. To provide maximum flexibility to sources, EPA is allowing any base year after 1986 that the owner or operator chooses. However, emission data developed during years other than the base year, including years prior to 1985, can be used for determining base year emissions if the data are representative of operating conditions in the base year. Owners or operators will have to demonstrate the applicability of these data to base year conditions.

Two commenters suggested allowing base year emissions that are substantially greater than previous years as long as the emissions were within permit levels.

The CAA specifically states that base year emissions cannot be "artificially or substantially greater than emissions in other years prior to implementation of emissions reduction measures." Permit levels are simply a maximum acceptable

emission limit and may not reflect "actual and verifiable" emission levels as required by the CAA. Therefore, comparison of base year emissions to permit levels does not determine the relationship of base year emissions to emissions in other years. Even emissions well within permit levels, but substantially greater than other years would not be allowable. For example, a permit may be written to allow 100 tons per year, but if the source were emitting 30 tons per year in years other than the base year, base year emissions of 60 tons from the source would not be allowable. It is clearly the intent of the CAA to avoid the use of unusually high emission levels to count toward the base year, which would lead to overstating reductions achieved and minimize the benefits to the environment achieved by the Early Reductions Program.

One commenter requested that the term "substantially greater" be clarified.

The determination of "substantially greater" is necessarily subjective. "Substantially greater" will be determined in large part by historical emissions variations of the source and the reasons for the variations. If an application is denied because base year emissions are found to be "substantially greater" than other surrounding years, the reviewer will provide rationale for this determination. Each base year review will be judged on a case-by-case basis. The enabling document ("Enabling Document for Regulations Governing Compliance for Early Reductions of Hazardous Air Pollutants," EPA-450/3-91-013, July 1991) provides guidance to reviewers and submitters to better understand what is "substantially greater." To avoid later problems with this issue, it is recommended that the applicant request a preapplication conference to discuss the specific details surrounding its base year emissions. The preapplication meeting should be held with the appropriate EPA Regional Office and State.

One commenter questioned EPA's requirements for establishing base year emissions. Specifically, the commenter felt applicants should not be required to submit evidence that base year emissions are not artificially high or that emissions reductions due to lower production rates or shutdowns are permanent. The commenter contended that the seriousness of violating section 114 requirements and the threat of enforcement would make it unnecessary to show this type of evidence.

Early reduction applicants will be required to submit evidence demonstrating that base year emissions are not artificially high. Submission of

this information provides reasonable assurance desired by the applicant that base year emissions will be acceptable for an Early Reductions demonstration, except in the case of error or submittal of fraudulent information. Prior approval of base year emissions facilitates the Title V review process, where the actual reduction demonstration is made.

The regulation has been changed with regard to providing evidence of lower production rates and shutdowns. Sources will not be required to show evidence that lower production rates or shutdowns are permanent for the extension duration. This will be accomplished by making the shutdown or lower production rate conditions of the Title V permit.

Two commenters also requested guidance in assessing the presence of trace quantities of HAP's. They suggested that there should be a minimum quantity of HAP's present before having to account for these emissions in the base year.

Trace pollutants and impurities will be handled on a case-by-case basis. General policy would be difficult to develop for all pollutants. For example, small quantities of dioxin may be considered significant while the same quantity of another non high-risk pollutant would be considered an inconsequential trace amount. Based on process and product knowledge, owners or operators should be aware of the possible presence of HAP's in their emissions. If trace quantities of HAP's are expected or known to be emitted, owners or operators should account for their presence.

The actual determination of the quantity of emissions may be similar to the determination of small, insignificant emission points. Generally, testing will not be required. The source owner or operator may make conservative assumptions in his calculations to determine the quantity that may be emitted. If trace HAP's are neither expected nor known to be present, then there is no need to make an assessment. The EPA expects participants in the Program to quantify all HAP's reasonably expected to be present.

A number of commenters requested that Toxics Release Inventory (TRI) data be acceptable for base year emissions.

The TRI data alone are not sufficient to support base year emissions. The Early Reductions Program requires more rigorous support for emissions data than is required by the TRI. If the supporting information for the TRI data meets all the requirements of the Early Reductions Program, then that information will be acceptable.

Supporting documentation for the Early Reductions Program must stand on its own merit.

Various commenters representing industry asked that EPA allow the use of average emission factors when estimating base year emissions from equipment leaks.

Average EPA equipment leak emission factors generally may not be used in establishing base year emissions. Use of EPA average emission factors for base year emissions would artificially inflate the base year estimate. Subsequent use of a more source-specific method for the post-reduction demonstration would result in lower estimated emissions, but in fact would only be a "paper" reduction. As mentioned in the preamble to the proposed regulation, source owners or operators can establish emission levels for equipment leaks using any procedure except for average emission factors established in the document entitled "Protocols for Generating Unit Specific Emission Estimates for Equipment Leaks of VOC and VHAP," EPA-450/3-88-010, October 1988.

The EPA has reconsidered disallowing use of average emission factors to establish equipment leak emissions only in the case where no equipment leak emission reduction will be claimed; i.e., equipment leak emissions are the same in the base year and the post-reduction year.

The EPA is allowing this exception because it will result in greater actual emission reductions from the source. The source will have to control non-equipment leak emission points to a greater extent to compensate for the over-estimate of the post-reduction equipment leak emissions. In addition, it is noted that equipment leaks must be less than 10 percent of base year source emissions, or the source could not achieve a 90 percent overall reduction.

Appendix B has also been clarified to better describe the equipment leak "source." The negotiated regulation for equipment leaks (56 FR 9315, March 6, 1991) will require that certain equipment in HAP service within a process unit to which the equipment leak standards are applicable must be viewed as a whole. This is the case for valves, pumps, and connectors within a process unit, which must be considered together, as the regulation is written in terms of percent leaking components across a process unit. That is, valves, pumps, and connectors cannot be split up such that some of the valves in a process unit have an Early Reduction alternative emission limitation and the rest meet the section 112(d) standard. For example, it must be that either all

valves within a process unit are in the Early Reduction Program or none are.

The logic for requiring inclusion of all the valves, pumps, or connectors from a process unit, does not extend to the other equipment covered by the equipment leak rule, such as pressure relief devices or product accumulator vessels, which will be subject to individual standards applicable to each device or vessel, and not all devices or vessels as a group. Equipment subject to such "piece-specific" standards could individually be assigned alternative emission limits as part of an Early Reductions source or meet the section 112(d) standard, and are not constrained by the process unit coverage.

Two commenters were concerned that the review process would result in delays and suggested that base year emissions be accepted if EPA did not complete the review in a specified time frame.

It is EPA's goal to review all enforceable commitments and submittals within the times identified in the rule. However, EPA intends to adequately review all submittals, and will take whatever time is necessary to ensure that the applications are complete and verifiable. The EPA will not automatically accept base year emissions that have not been reviewed due to time constraints. The purpose of reviewing base year emissions early is to provide some assurance to the submitter that the base year emissions for Early Reductions will be approved at permit review.

Finally, a number of commenters suggested that once base year emissions are accepted by EPA, there should be no further review or auditing of the data.

Acceptance of base year emissions data does not provide an absolute shield against revision should the data later be found incorrect. Reviewers and commenters are urged to present any criticisms during the early review period regarding base year data. Applicants can make appropriate modifications at that point and proceed with reasonable confidence that their emissions are acceptable. Base year emissions that have been reviewed and approved are still subject to additional review if errors or fraud are discovered at a later date. Discovery of incorrect or fraudulent information in the emission data or supporting materials after initial approval could potentially invalidate the base year and/or require the applicant to make revisions.

C. Enforceable Commitments

Two commenters suggested that there be no penalty for failure to meet an enforceable commitment. They

proposed that sources failing to meet the commitment simply be allowed to revert back to the requirements of an applicable section 112(d) standard.

Sources that make an enforceable commitment to achieve early reductions can revoke the commitment without penalty up to December 1, 1993. These sources would thus be subject only to the applicable section 112(d) standard. This allows the source a considerable amount of time to attempt to achieve the promised reductions. But, if the source is unable to achieve those reductions, they may terminate their participation in the Early Reductions Program without sanction, provided they do so by the required deadline. Other participants in the discussions leading up to proposal of this rule expressed the concern that Congress intended that commitments are to be kept, and that once made, they could never be revoked. To give any meaning to the "enforceable" part of enforceable commitment, there must be something that is enforceable. The EPA believes that if after given every opportunity to revoke the commitment if necessary, the unrevoked commitment is enforceable. The EPA feels that the suggested compromise between the competing positions is reasonable.

If those who achieve the committed reductions prior to January 1, 1994 subsequently increase emissions in violation of their Title V permit conditions (or in violation of the enforceable commitment if the permit has not yet been issued), they would not have to revert to meeting the section 112(d) standard. They would be subject to an appropriate penalty, but would continue to maintain the considerable benefits of continuing in the Early Reductions Program. Likewise, those who indicate that they are continuing in the Program by not revoking their commitment prior to December 1, 1993, but who fail in their performance by not achieving the reductions committed to prior to January 1, 1994, will likewise be subject to an appropriate penalty. The EPA will use enforcement discretion to determine the severity of penalties, based on the efforts made to achieve the reductions.

One commenter recommended that a grace period be allowed for sources that cannot make their enforceable commitments on time due to external forces such as delays in test results.

The CAA requires that the reductions specified in the commitment must be achieved by January 1, 1994 to receive a section 112(d) compliance extension. The Early Reductions regulation allows test data to be received as late as March 31, 1994 to demonstrate that the

reductions have been achieved. The reductions, however, must have been achieved by the date specified by the CAA. If a source cannot achieve the reductions required by the enforceable commitment, the applicant may rescind the commitment as late as December 1, 1993 without penalty. Therefore, the applicant should have adequate time to assess whether or not the source can achieve the reductions and to take whatever action he deems appropriate.

Another commenter suggested that the rule should assure that companies that make good faith efforts to comply with the requirements of the Early Reductions Program not be subject to enforcement action if errors or mistakes are discovered in the enforceable commitment either by EPA or the company.

The EPA will use its enforcement discretion for cases where companies make an honest mistake in their estimation of the base year emission data or supporting materials. In such instances, companies may be required to revise their base year and make additional reductions in order to achieve 90 (95) percent emission reductions. Alternatively, they may rescind their commitment without penalty prior to December 1, 1993. Sources found submitting false or fraudulent information in their commitment for early reductions, even after initial approval of their base year submission, shall be subject to enforcement action under section 113 of the CAA or other Federal statutes.

One commenter questioned the authority of the reviewing agency to challenge the control plan proposed as part of an enforceable commitment.

The control plan outlined in the enforceable commitment is a general, nonbinding strategy that the source will implement to reduce emissions and is not enforceable. The owner or operator develops the plan with the goal of reducing emissions by 90 (95) percent. As the owner or operator implements the plan, however, he may discover that the emission reduction can be better met with another control strategy. The control plan presented in the enforceable commitment must, therefore, remain somewhat flexible. The general plan is required to assure the reviewing authority that the reductions can be achieved and that the source owner has given serious consideration to achieving early reductions. The control plan will not likely be questioned or the cause for denial unless it indicates that the required reductions will not be met or the plan does not appear reasonable. The ultimate test will not be whether or

not the described control plan will be followed, but a demonstration that the reductions have actually occurred.

One commenter requested clarification of the time limit given for submitting revised data for an enforceable commitment.

Within 90 days of receiving comments indicating deficiencies in a submittal, a source owner or operator must either revise and resubmit the submittal or notify the permitting authority that a revised submittal eventually will be sent; otherwise the submittal will be considered by EPA to be withdrawn. This allows the reviewing agency to recognize in a timely fashion which commitments will be revised and which will be rescinded. Because of the large number of applications expected to be received by EPA, a deadline for resubmittal or notification of intent to continue in the program is necessary to expedite the review process and to identify those sources that do not wish to pursue their reduction demonstration. A withdrawal alerts the reviewing agency not to pursue penalties after January 1, 1994 if the source fails to meet the required reductions. Base year emissions that are submitted for early review and not as part of an enforceable commitment do not have a deadline for resubmittal. The regulation has been clarified to distinguish the difference between resubmittal schedules.

D. Allowable Emission Reductions

Several regulatory agencies and citizens groups felt that only voluntary reductions should be credited toward demonstration of early reductions.

It is clearly the intent of the CAA to credit sources for emissions reductions accomplished by any means, as long as the emission reductions are actual and verifiable and made prior to proposal of an applicable standard or, in the case of an enforceable commitment, by January 1, 1994. According to the legislative history of the CAA, the Early Reductions Program initially was limited to voluntary reductions. Some commenters on the draft legislation suggested that limiting qualified reductions was unfair. For example, facilities located in States with extensive air toxics programs would not be able to benefit from early reductions. After considering this and other comments there was a deliberate change to the CAA Amendments to allow any reductions in emissions after the base year. The EPA interprets this change as the intent of Congress to expand the Program to allow all early reductions, regardless of how they are achieved.

One commenter felt that HAP emission reductions resulting from State or Federal regulatory programs designed to control VOC (such as New Source Performance Standards or PSD) should not be credited towards Early Reduction demonstrations. The commenter suggested that only reductions achieved to control air toxics should be used for this Program, not reductions achieved to reduce non-toxic VOC. Another commenter asked for clarification as to whether offsets used in New Source Review are creditable for the Early Reductions Program.

The statute provides that the Administrator shall issue a permit to a source that achieves a 90 (95) percent reduction in emissions of HAP's that allows the source to meet an alternative emission limit reflecting the 90 (95) percent reduction in lieu of the otherwise applicable standard issued under section 112(d) if the reduction is made before the proposal of a section 112(d) standard or if the source enters into an enforceable commitment before proposal of the standard and makes such reductions before January 1, 1994. The statute further provides the reduction will be determined with respect to verifiable and actual emissions in a base year not earlier than calendar year 1987. There is no limitation in the statute as to the reasons those reductions were made.

There were also comments pertaining to the definition of "malfunction," particularly with regard to how startups and shutdowns will be credited towards base year emissions.

Scheduled startups and shutdowns are considered routine. Emissions created by these routine operations can be counted toward base year emissions. However, startups and shutdowns associated with malfunctions are not routine and cannot be included with base year emissions. "Actual emissions" as defined in the proposed rule do not include excess emissions from a malfunction. Likewise, other emissions from startups and shutdowns directly attributed to the malfunction should not be included. In order to clarify this exclusion, the definition of actual emissions in the Early Reduction regulation has been modified to read " * * * does not include excess emissions from a malfunction or any startups and shutdowns associated with a malfunction."

Another commenter contended that the definition of malfunction would allow sources to earn credit for poor maintenance. Since the definition states that failures caused by poor maintenance shall not be considered malfunctions, the commenter felt

sources could inflate base year emissions and also obtain reductions by performing maintenance on neglected process units.

Sources will not be allowed to credit emission reductions if the base year emissions were in violation of emission standards. However, emissions that result from poor maintenance, careless operation, or any other preventable upset conditions or preventable equipment breakdown that are not in violation of any emission standard are not considered malfunctions and can be credited toward base year emissions. Thus, the Early Reductions Program provides an incentive for sources to improve their maintenance and operation practices (which would not otherwise be required), resulting in a net benefit to the environment.

E. Demonstration of Early Reductions

Sources will be granted compliance extensions if they demonstrate reductions of HAP's of 90 (95) percent. A number of comments were received on how that demonstration should be made.

One commenter suggested that sources be granted compliance extensions if they achieve 90 (95) percent reduction of one or more specific HAP's.

The CAA specifies that 90 (95) percent reduction of all HAP's from the defined source must be achieved. Selective HAP reduction is not allowed. The Early Reductions Program allows flexibility in defining the source, but that flexibility cannot be extended to specific pollutants within the source, with the exclusion of others.

Two commenters recommended that emissions be expressed as emissions/pound of product rather than a specific quantity per year. They felt that this would overcome problems with fluctuating production rates, particularly when establishing the base year emission level.

The statute requires 90 (95) percent reduction from base year emissions. Thus, the Early Reductions Program is concerned with absolute reductions from base year emissions, not a percent reduction from what current emissions would have been. The alternative emission limit will reflect a specific emission level that is 90 (95) percent less than base year. Sources with fluctuating production must consider future increases in emissions, and make adjustments accordingly.

Several commenters urged EPA to require particulates to be controlled to 95 percent, and not allow averaging with gaseous pollutants. Other commenters supported the weighted

average approach for gaseous and particulate mixtures.

At proposal EPA recognized that there may be sources that have already achieved 95 to 99 percent reduction in particulates through control measures employed prior to the earliest allowable base year, but that have significant potential reductions from relatively uncontrolled gaseous HAP emissions. If, for an Early Reductions demonstration, such sources were required to reduce gaseous HAP's by 90 percent as well as reduce the remaining particulate emissions by another 95 percent, the source may find it impossible to reduce particulate emissions further or find that further reductions likely would exceed requirements of an applicable section 112(d) standard for the particulate emissions. In either case the source would not seek a compliance extension and thus would not make early reductions of the gaseous HAP's.

A telephone query from a potential applicant exemplified this problem. This source coats metal parts and has vents that release both gases and particulates. In this case particulates are very tightly controlled (prior to the earliest possible base year) but gases are not. The source was interested in making early reductions by reducing the gases by 90 percent, but if it also had to achieve an additional 95 percent reduction in the already tightly controlled particulates, it would not be able to enter the Program.

The EPA recognized that it would be beneficial from an environmental standpoint to allow a reduction in the gases without requiring an additional 95 percent for the particulates; i.e., without some allowance for this situation, the source would not enter the Program and no reductions would be achieved in the gaseous HAP's until required by a section 112(d) standard. The EPA therefore proposed to allow a source to average the required reductions for gases and particulates; particulates could be reduced by less than 95 percent as long as compensating reductions were achieved in gaseous HAP's. The overall target reduction to be achieved would be between 90 and 95 percent and would be determined by the relative amounts of gases and particulates emitted from the source in the base year. This averaging method still would require the same amount of overall HAP emission reduction as would the separate 90 and 95 percent requirements.

The proposed averaging method could have been used at any source, whether the gases and particulates were emitted from different emission points or the same emission point. However, based

on commenters' concerns, EPA has reconsidered the applicability of the averaging method, and has narrowed the scope.

The statutory language, in section 112(i)(5), explicitly requires 95 percent reduction of particulate HAP's and 90 percent of gaseous HAP's. The EPA, however, feels that Congress did not consider or was not aware of emission points that emitted both gases and particulates and that different controls are required for each, and therefore did not provide for this situation. Furthermore, EPA believes that it would be beneficial to allow a weighted average for gases and particulates, when emitted from the same points, especially where only small quantities of one are emitted with respect to the other, in light of the alternative of no early emission reduction.

Therefore, the final rule allows the use of averaging at sources in which the gases and particulates are emitted from the same points. For example, if 3 emission points at the source emit both gases and particulates, these emission points could be aggregated to establish a combined percent reduction between 90 and 95 percent, e.g., the 3 points could achieve 94 percent reduction overall. The combined percent reduction would depend on the relative amounts of gases and particulates emitted by the points. By restricting the use of averaging gaseous and particulate emission reductions, EPA notes that some sources emitting either gases or particulates from different vents may now be unable to achieve the required early reduction if averaging were not allowed. In these cases, because emissions are emitted from different points, the source should be defined to exclude those points that create the difficulty in emission reduction. However, the source must still conform to one of the allowable definitions in the regulation.

One commenter stated that EPA should not expect emissions testing as the basis for demonstrating post-reduction emissions.

Sources will be required to adequately document post-reduction emissions before being granted an alternative emission limit. The EPA requires the best available data to demonstrate emissions. Direct measurement of emissions is the presumed best demonstration for many cases. However, test data will not be required to demonstrate all emissions. Calculations based on engineering principles, emission factors, or material balances may be acceptable if the applicant demonstrates to the satisfaction of the permitting authority that: (1) No test

method exists; (2) it is not technologically or economically feasible to perform source tests; (3) it can be demonstrated that the accuracy of a calculated estimate is comparable to source testing; or (4) emissions from one or more set of points are insignificantly small compared to total source emissions. The EPA agrees that in some situations (e.g., storage tank emissions or batch operations using solvent HAP's) calculations or mass balances generally will be acceptable and may be the preferred method of establishing emissions.

Another commenter opposed any efforts by EPA to require continuous emissions monitoring to document early reductions.

Continuous emission monitoring (CEM) is not a general requirement of the Early Reductions Program to document that the source has achieved sufficient reductions. General monitoring requirements for permit provisions, including, but not specifically, alternative emission limitations established for the Early Reductions Program, will be established according to the requirements of Title V of the CAA. Section 504 of Title V states that continuous emissions monitoring need not be required if alternative methods are available that provide sufficiently reliable and timely information for determining compliance. Therefore, if other acceptable means for determining compliance are available, CEM will not be required. Nothing in the CAA, however, prevents the requirement of CEM for the Early Reductions Program and if no other acceptable methods are available, CEM may be required.

Two commenters requested clarification of the term "sufficiently variable" used in § 63.78(b)(4) as the basis for denial. The commenters were concerned that batch processes would not be able to qualify for compliance extensions because of the inherent variability of batch systems.

The term "sufficiently variable" has been removed from the language of the regulation. The EPA recognizes that batch processes are inherently variable, and that variability alone should not be a reason for denial. The reason for denial will now read: "The emission of hazardous air pollutants or the performance of emission control measures is unreliable so as to preclude determination that the required reductions have been achieved or will continue to be achieved during the extension period."

F. High-Risk Pollutants

1. Summary

Section 112(i)(5)(E) specifies that with respect to pollutants for which high risks of adverse public health effects

may be associated with exposure to small quantities, the Administrator shall limit the use of offsetting reductions in emissions of other HAP's from the source as counting towards the 90 (95) percent reduction in such high-risk

pollutants. In the final rule, the number of pollutants on the high-risk list is 47, rather than 35 as proposed. The additional pollutants are listed in Table 1.

TABLE 1. LIST OF POLLUTANTS ADDED TO HIGH-RISK LIST

CAS No.	Chemical	Weighting factor
53963	2-Acetylaminofluorene	100
532274	2-Chloroacetophenone	100
334883	Diazomethane	10
96128	1,2-Dibromo-3-chloropropane	10
79447	Dimethylcarbamoyl chloride	100
122667	1,2-Diphenylhydrazine	10
151564	Ethylene imine (Aziridine)	100
77474	Hexachlorocyclopentadiene	10
0	Manganese compounds	10
60344	Methyl hydrazine	10
0	Nickel compounds	10
684935	N-Nitroso-N-methylurea	1000
62759	N-Nitrosodimethylamine	100
56382	Parathion	10
7803512	Phosphine	10
7723140	Phosphorus	10
8001352	Toxaphene	100

These pollutants have been added to the list since proposal for a number of reasons including changes to the methodology EPA used to select the pollutants and updated health effects information. Five pollutants which were proposed for the high-risk list have been deleted. These are benzotrichloride; chloroprene; 1,1,2,2-tetrachloroethane; 2,4-toluene diisocyanate; and vinylidene chloride. The final list of high-risk pollutants and their weighting factors are shown in Table 2.

TABLE 2. LIST OF HIGH-RISK POLLUTANTS

CAS No.	Chemical	Weighting factor
53963	2-Acetylaminofluorene	100
107028	Acrolein	100
79061	Acrylamide	10
79107	Acrylic acid	10
107131	Acrylonitrile	10
0	Arsenic compounds	100
1332214	Asbestos	10
71432	Benzene	100
92875	Benzidine	1000
0	Beryllium compounds	10
542881	Bis(chloromethyl) ether	1000
106990	1,3-Butadiene	10
0	Cadmium compounds	10
57749	Chlordane	100
532274	2-Chloroacetophenone	100
0	Chromium compounds	100
107302	Chloromethyl methyl ether	10
0	Coke oven emissions	10
334883	Diazomethane	10
132649	Dibenzofuran	10
96128	1,2-Dibromo-3-chloropropane	10
111444	Dichloroethyl ether (Bis(2-chloroethyl)ether)	10
79447	Dimethylcarbamoyl chloride	100

TABLE 2. LIST OF HIGH-RISK POLLUTANTS—Continued

CAS No.	Chemical	Weighting factor
122667	1,2-Diphenylhydrazine	10
106934	Ethylene dibromide	10
151564	Ethyleneimine (Aziridine)	100
75218	Ethylene oxide	10
76448	Heptachlor	100
118741	Hexachlorobenzene	100
77474	Hexachlorocyclopentadiene	10
302012	Hydrazine	100
0	Manganese compounds	10
0	Mercury compounds	100
101688	Methylene diphenyl diisocyanate (MDI)	10
60344	Methyl hydrazine	10
624839	Methyl isocyanate	10
0	Nickel compounds	10
62759	N-Nitrosodimethylamine	100
684935	N-Nitroso-N-methylurea	1000
56382	Parathion	10
75445	Phosgene	10
7803512	Phosphine	10
7723140	Phosphorus	10
75558	1,2-Propylenimine	100
1746016	2,3,7,8-Tetrachlorodibenzo-p-dioxin	100,000
8001352	Toxaphene (chlorinated camphene)	100
75014	Vinyl chloride	10

The specific changes made to the methodology and the rationale for specific pollutants being added to or deleted from the list are described below.

2. Methodology for Selecting Pollutants for the High-Risk List

The methodology used to formulate the list of high-risk pollutants, the list itself, and the weighted offsetting scheme are a direct response to the

mandate in section 112(i)(5)(E) of the Act. The high-risk list and the weighted offsetting scheme may not be applicable to, or appropriate for, other sections in Title III of the Act. Other provisions of section 112, such as establishing lesser quantity emission rates under section 112(a) and identifying the relative hazards to human health from emissions of each of the listed hazardous air pollutants under 112(g) may also require the ranking of pollutants. The approach for identifying the high-risk pollutants may or may not be found to be appropriate for these or other provisions. The selection of today's approach for the purposes of section 112(i)(5)(E) is not intended to establish a precedent for other provisions or preclude the consideration of other alternative methodologies.

As presented in the preamble to the proposed rule, EPA used a number of criteria for selecting pollutants for the high-risk list. First, as specified by the CAA, chlorinated dioxins and furans (as listed in section 112(b)) were included on the high-risk list. Second, pollutants classified by EPA as Group A carcinogens (known human carcinogens) were judged to be of sufficient concern to be listed as high-risk. Third, as a way to systematically screen the remaining HAP's listed in section 112(b), EPA employed a three-tiered screening analysis for selecting high-risk pollutants.

In the first tier, health effects data were examined to rank pollutants based solely on health effects. The health

endpoints considered were carcinogenicity, reproductive and developmental toxicity, acute lethality, and systemic effects other than acute lethality (e.g., neurologic disorders). Consideration of health effects alone, however, was judged insufficient to address section 112(i)(5)(E) which describes high-risk pollutants as those for which high risks of adverse public health effects may be associated with exposure to small quantities. Accordingly, tier 2 of the analysis was exposure modeling using EPA's Human Exposure Model (HEM). The HEM provided an estimate of the ambient concentration 500 meters from a source emitting 10 tons per year at an average height of 10 meters under median meteorological conditions. As described in the preamble to the proposed rule, the ambient concentration predicted by the HEM was compared to selected risk levels to screen for pollutants likely to have an adverse effect at the exposure level that was modeled. For carcinogens, the modeled ambient concentration was compared to the concentration of each carcinogen that would result in an increase in cancer risk of one in ten thousand to the most exposed individual. For noncarcinogens, the modeled ambient concentration was compared to either (1) a level one order of magnitude greater than a verified inhalation reference concentration or oral reference dose, (2) a lowest observed effect level (LOEL) divided by an uncertainty factor of 100, or (3) the dose or concentration of a chemical that causes death in 50 percent of the exposed population (LD_{50} or LC_{50}) divided by an uncertainty factor of 1000.

Tier 3, which considered actual pollutant emissions as reported to the TRI, was intended to determine whether the pollutants were actually emitted at levels that could reasonably be expected to adversely affect public health. Pollutants with a low exposure potential were consequently eliminated from the high-risk list.

Several commenters stated that it was inappropriate to eliminate pollutants from the high-risk list based on emissions data. The commenters contended that use of the TRI is inappropriate because not all pollutants are reported, only large facilities in the manufacturing sector report to the inventory, and not all types of source categories are covered. The commenters felt that EPA should not eliminate substances because they are not currently in common use and that the tier 3 screen should be dropped from the analysis.

The EPA agrees with the commenters' concerns regarding use of the TRI and has consequently dropped tier 3 from the analysis. The EPA also agrees that chemicals not currently in common use should still be listed as high risk in case production of that chemical is resumed at a later date. The EPA now believes that tiers 1 and 2 adequately identify those pollutants that could reasonably be expected to adversely affect public health and thus limited the offsetting of these pollutants in the Early Reductions Program. The impact of dropping tier 3 is that the following pollutants have been added to the high-risk list: 2-acetylaminofluorene; 1,2 diphenyl hydrazine; toxaphene; nickel compounds; N-nitrosodimethylamine; ethylene imine (aziridine); dimethylcarbamoyl chloride; phosphorus and diazomethane.

Many commenters recommended changes to the parameters chosen for the tier 2 exposure analysis. Several commenters felt that the exposure assumptions were not conservative for several reasons including the meteorological data, the stack parameters, and the limitations of the HEM. One commenter stated that one year of meteorological data is not representative and that downwash was not considered. Two commenters suggested a shorter stack height of 3.5 meters and a 20 meter distance to the nearest residence. Another commenter recommended that the modeling use more realistic assumptions about the pollutants and emission sources. One commenter contended that the HEM is too simplistic because it does not consider actual exposure, short-term exposures or population activity patterns. Other commenters made suggestions which would make the analysis less conservative. Two commenters felt that the 500 meter distance to the nearest residence was too close. One of these commenters suggested a distance of 3000 meters and a 10 year population residence time (rather than the 70 year lifetime exposure associated with the cancer potency factor).

The second tier of the screening analysis to select the high-risk pollutants was a generic exposure modeling exercise. The EPA intended that the modeling results be used to determine which pollutants merited further analysis based on exposure potential. The EPA did not use the modeling results to estimate actual risk levels, but did use the modeling results to differentiate between pollutants. The EPA still considers the use of generic modeling parameters appropriate for this analysis because a wide range of

emission release and exposure scenarios across many varied source categories are anticipated under the Early Reductions Program.

The HEM was used to estimate a theoretical downwind concentration of a typical HAP. Because the pollutants are released from various types of sources with variable stack parameters (stack height, emission velocity, distance to nearest residence, etc.) there was no attempt made to model site-specific conditions. Meteorological data used were representative of between 2 and 10 years of data from the selected meteorological station. A 10 meter stack height was chosen to represent a chemical plant. For the proposed rule, the modeling parameters also assumed a 70-year continuous exposure and a 500 meter distance to the nearest residence. Upon re-evaluation, EPA has made changes to these two parameters.

First, the assumption that exposure to a pollutant occurs continuously over a 70-year period has been changed to 33 years for the purposes of this rulemaking. Thirty-three years is a duration representative of the 95th percentile for the number of years an individual would remain at the same residence, based on data on population mobility and mortality. The 33-year duration was selected for use in this analysis as representative of a reasonable worst case approach to assessing exposure duration. Second, EPA reconsidered the choice of 500 meters to the nearest residence and has revised the analysis using a 200 meter distance. The 200 meter distance to the nearest residence is the distance that has been most often used by EPA for analyses estimating exposure to emissions from point sources. This distance represents a reasonable worst case for point source and is judged to represent a reasonable worst case for facilities that are anticipated to participate in the Early Reductions Program. The net impact of these changes was the addition of hexachlorocyclopentadiene, phosphine, parathion, and manganese compounds to the list.

Four commenters disagreed with the one in ten thousand presumptive risk benchmark for carcinogens, stating that it was not conservative enough. One commenter recommended that EPA include every carcinogen with a potency factor greater than 1.35×10^{-8} ($\mu\text{g}/\text{m}^3$)⁻¹ based on modeling a 3.5 meter stack. Another commenter argued that Congress intended that sources with risk levels of one in one million be controlled. In contrast, one commenter recommended the benchmark be lowered to one in one thousand. This

commenter believes that the one in ten thousand risk benchmark is inconsistent with the "Savings Provision" in section 112(q)(1), where standards promulgated under section 112 in effect prior to the 1990 amendments are to remain in force unless revised by EPA.

The exposure modeling exercise conducted as part of tier 2 of the screening analysis was used as a tool to identify pollutants that could potentially cause a high risk to public health (under the exposure scenario that was modeled). The EPA has decided that for carcinogens a one in ten thousand presumptive risk level is appropriate for this analysis. This decision is based primarily on guidance concerning acceptable risk discussed in the benzene NESHAP promulgated on September 14, 1989 (54 FR 38044). In the preamble to the benzene decision, the use of the one in ten thousand benchmark is described—"EPA will consider the extent of the estimated risk were an individual exposed to the maximum level of pollutant for a lifetime. The EPA will generally presume that if the risk to that individual is no higher than approximately one in ten thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk, but does not constitute a rigid line for making that determination." In the case of the screening analysis for high-risk pollutants under the Early Reductions provisions, EPA believes the one in ten thousand presumptive risk level has been used appropriately. The commenters are reminded that the generic exposure analysis was not meant to estimate the actual risk from any one type of source category, but rather was used to differentiate between pollutants based on relative toxicities.

The EPA recognizes that other modeling assumptions could have been used that would have resulted in either more or fewer pollutants exceeding the presumptive risk level. However, EPA does not agree with the commenter's suggestion that every carcinogen with a potency factor greater than 1.35×10^{-8} ($\mu\text{g}/\text{m}^3$)⁻¹ should be considered high risk.

With respect to the comment that Congress intended that sources posing risks of one in one million be controlled, the commenter is referring to section 112(f)(A), the so-called "residual risk" provisions. In this provision it is stipulated that additional emission standards must be promulgated if a

source's emissions pose a risk greater than one in one million after application of control technology (as stipulated in section 112(d)). The commenter is reminded that the Early Reductions Program provides an extension of the compliance time for applying control technology that is stipulated by standards promulgated under section 112(d). After the compliance time extension, facilities participating in the Early Reductions Program must still apply the required technology if their emissions exceed specified levels. In addition, facilities that participate in the Early Reductions Program are not exempted from a residual risk test under section 112(f), so the commenter's concern that the intent of Congress is not being fulfilled is unwarranted.

With respect to the Savings Provision of section 112(q)(1) the commenter is reminded that today's rule is not an emission standard, but procedures for obtaining an Early Reductions compliance extension. The use of the presumptive risk benchmark of one in ten thousand in the screening analysis for selecting high-risk pollutants has no bearing on NESHAP that have already been promulgated.

Two commenters questioned the benchmarks chosen for health effects other than cancer. These commenters felt that neither the LOEL divided by a safety factor of 100 nor the LD₅₀ divided by a safety factor of 1000 were conservative enough. The commenters also thought that using a value one order of magnitude above the reference concentration was not conservative enough.

As stated in the preamble to the proposed rule, uncertainty factors were applied to the health effects benchmarks since the LOEL and LD₅₀ values represent levels at which health effects are known to occur. These uncertainty factors were meant to account for variables such as interspecies variations and sensitive subpopulations, but do not incorporate all the factors typically used in developing reference concentrations. The uncertainty factors used to develop an inhalation reference concentration are typically applied to a lowest observed adverse effect level (LOAEL) or no observed adverse effects level (NOAEL). The resulting reference concentration represents a level at which the potential for adverse public health effects is considered to be negligible. However, the purpose of this analysis was to identify pollutants whose emissions could potentially present a high risk, not a de minimis risk. Therefore, the uncertainty factors used in this analysis were not meant to account for all the factors typically used

in developing an inhalation reference concentration. For this analysis, EPA made a judgment that if a source's emissions were such that a LOEL or LD₅₀ could potentially be exceeded (after application of the uncertainty factors and under the modeling scenario used) then the pollutant could be considered high risk. In this application, EPA believes uncertainty factors of 100 and 1000 to be appropriate. Similarly, with respect to using a value one order of magnitude above the reference concentration, EPA believes this to be an appropriate estimate of a level at which health effects could potentially be significant enough to be regarded as high risk.

Two commenters strongly urged EPA to confine the selection of carcinogens for the high-risk list to consideration of carcinogenic potency and not make use of the weight-of-evidence classification. Three commenters objected to the addition of four Group A carcinogens to the list after the pollutants had been excluded by the 3-tiered process. On the other hand, two other commenters recommended that EPA prioritize the high-risk list using a qualitative rather than quantitative approach (i.e., use weight-of-evidence reviews for identifying substances rather than potency factors).

The EPA believes it appropriate for identification of high-risk pollutants to consider both the weight of evidence and carcinogenic potency of a pollutant. The EPA stands by the decision to list Group A carcinogens as high risk based on the fact that these are known human carcinogens. The EPA judged that emissions of known human carcinogens are of sufficient concern that use of offsetting reductions in other less hazardous pollutants under an Early Reduction demonstration should be limited. Three of the pollutants (benzidine, bis(chloromethyl) ether, and chloromethyl methyl ether) are extremely potent carcinogens and were excluded from the 3-tiered process at tier 3. This means that, according to the 1989 TRI, these pollutants were not emitted by any reporting facility in quantities sufficient to exceed the risk benchmark level proposed by EPA. In spite of this, EPA felt it prudent to list them as high risk in case a source's emissions changed in the future. As discussed above, since proposal of the high-risk list, EPA has decided to eliminate tier 3 from the screening analysis. As a result, even if EPA had decided not to use weight of evidence as a criterion, these carcinogens would still be listed as high-risk pollutants. Benzene was also included on the list even though the risk benchmark level

was not exceeded when a 10 tons per year emission rate was modeled. The rationale for this decision was that in addition to being a known human carcinogen, benzene is a very high volume chemical and emissions in excess of 10 tons per year are not uncommon. The EPA believes that offsetting emissions of this known human carcinogen with less hazardous pollutants should also be limited.

Two commenters suggested that EPA revise the selection criteria to include only known human carcinogens (Group A), probable human carcinogens (Group B1), and noncarcinogens for which chronic human health effects can be expected to occur at extremely low levels of exposure.

In selecting pollutants for the high-risk list, EPA considered weight-of-evidence, potency and exposure potential of the pollutant. As described above, a weight-of-evidence classification of Group A (known human carcinogen) was deemed sufficient to list a pollutant as high-risk. The EPA does not agree with the commenters suggestion that Group B2 and Group C carcinogens should not be considered for or included on the high-risk list. In order to be listed, however, carcinogens other than Group A had to pass tier 2 of the analysis which considered potency and exposure potential.

The EPA also disagrees with the commenters suggestion that only chronic human health effects should be considered. Section 112(b) of the CAA describes HAP's as those pollutants which present, or may present, a threat of adverse human health effects including substances which are carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic. Thus, EPA believed it appropriate to assess (and include on the high-risk list, where appropriate) pollutants that are acutely as well as chronically toxic.

3. Weighted Index for High-Risk Pollutants

In the proposed rule, EPA described an indexed offsetting system based on the toxicity of the high-risk pollutants relative to each other.

Several commenters believe that the weighted index system conflicts with the CAA because it allows offsetting of high-risk pollutants with non-high risk pollutants. The commenters state that high-risk pollutants should not be allowed to be offset by non-high risk pollutants, or only be allowed when high-risk pollutants are emitted in trace amounts. Other commenters agreed with

the weighting factor concept and the ability to offset high-risk pollutants.

In the final rule, a number of weighting factors have been adjusted as described below, but the weighting factor system as a whole is essentially unchanged. Contrary to several commenters contentions, the high-risk pollutant strategy does not conflict with section 112(i)(5)(E). That provision requires the Administrator to limit, by regulation, the use of offsetting reductions of other HAP's in counting towards the 90 (95) per cent reduction of high-risk pollutants. The statute does not say or even imply that the regulation must prohibit such offsetting reductions.

In response to the comment that these offsets should only be allowed when these pollutants are emitted in trace amounts, EPA notes that the weighting system effectively restricts the offsetting of emissions of the high-risk pollutants. Such a large reduction of a non-high risk pollutant is needed to offset a high-risk pollutant (up to 100,000 to 1) that only relatively trace amounts could be traded. Even in situations where the pollutant concentrations are relatively large (i.e., not trace amounts), it is appropriate to allow offsetting as long as the weighting factor system is followed. If one ton of a HAP with a weighting factor of 100 is offset with a 10 ton reduction in a pollutant with a weighting factor of 10, the offset generally should provide a similar degree of risk reduction. Consequently, EPA believes such offsets should not be prohibited. Note that these relative trades deal with decreases in the high-risk pollutants. It is not envisioned that any successful Early Reduction submittal will include any increase in high-risk pollutants other than incidental trace amounts.

Several commenters stated that trading among pollutants with different types of health effects is inappropriate. The commenters recommend using critical health effects and toxic potency information to place the listed pollutants into categories, with trading allowed within a category. Trading across categories would be allowed only for categories based on similar health effects. Weighting factors based on relative potencies would be used in such tradeoffs.

The development of the weighting system and the decision to allow trading between carcinogens and noncarcinogens is intended to provide flexibility to the participating facilities in achieving their emission reduction goals. As such, it is a policy decision and not one based purely on scientific grounds. If trading between pollutants

with different health endpoints was restricted, this could potentially exclude some facilities from participating in the Early Reductions Program. The EPA feels that such restrictions would not benefit the goals of the Program as a whole.

Several comment letters made reference to the development of weighting factors for the high-risk pollutants. One commenter recommended the weighting factors be based on weight of evidence classification. On the other hand, three commenters recommended the weighting factors be based only on potency as described by the cancer potency factor. Another commenter further suggested that the cancer potency factor be multiplied by one million to arrive at the weighting factor. Finally, one commenter suggested a combination approach where both weight-of-evidence and potency would be considered. In this approach, pollutants with the same weight-of-evidence classification and having potency factors within an order of magnitude would be grouped together.

The weighting factor system has been revised slightly since the high-risk list was proposed. In the final rule, carcinogens, with a Group C classification (possible human carcinogens) have been assigned a lower weight. Greater uncertainty exists regarding the evidence for a Group C classification than that existing for chemicals classified as Group A (known human carcinogen) or B (probably carcinogenic to humans). A Group C classification is defined by positive carcinogenicity in a single experiment, a tumor response of marginal statistical significance, or finding benign tumors only. A Group B classification, whereas, is defined by carcinogenicity in two or more animal species, strains, or experiments, either with or without limited human evidence. Group A is reserved for known human carcinogens. The greater uncertainty regarding a Group C classification is reflected in a lower weighting factor. As a result, two Group C carcinogens (1,1,2,2-tetrachloroethane and vinylidene chloride) have been assigned weighting factors of 1 rather than 10 as proposed. The EPA does not feel, however, that chemicals classified in Group B should necessarily be weighted lower than those classified as Group A. With respect to Group B chemicals, a sound foundation exists regarding carcinogenicity in animals, but the human data are either inconclusive or of limited value, most likely reflecting the difficulty of obtaining quality epidemiologic data. For this weighting

system then, chemicals classified as Group A or B are combined and ranked by potency.

For carcinogens, the actual weighting factors are based on the potency of the high-risk carcinogens relative to carcinogens not on the high-risk list. This approach is the same as was proposed. Multiplying the potency factors by one million as one commenter suggested to calculate weighting factors would result in the same relative ranking of the pollutants, but higher weighting factors. The EPA believes that basing the weighting factors on the differences between the potency of the high-risk carcinogens and the geometric mean potency of the group of carcinogens not on the high-risk list is more justifiable.

Three commenters questioned EPA's policy decision concerning the weighting factors for noncarcinogens. The commenters believe that EPA must assess many additional factors when ranking the hazards of noncarcinogens. These factors include the severity of effect, its reversibility, and chemical properties such as the half-life of volatile compounds in air, vapor pressure, persistence, and bioaccumulation potential.

In assigning weighting factors to the high-risk pollutants, EPA attempted to base the factors on the relative toxicity of the compounds. For the carcinogens, the cancer potency factor is a straightforward measure of relative toxicity and was used in conjunction with the weight of evidence classification to develop the weighting factors. For the noncarcinogens, however, there is not a comparable measure of toxicity that can be used consistently for pollutants with different health effects. In the absence of such a measure, EPA proposed to assign a weighting factor of 10 to the noncarcinogens on the high-risk list. Many of the carcinogens were also assigned a weighting factor of 10. The EPA chose a weighting factor of 10 for the noncarcinogens in recognition that noncancer health effects can be as seriously debilitating as cancer. Another alternative would have been to assign these pollutants a weighting factor of 1 because other indices were not available. The EPA rejected this option because only by assigning a weighting factor greater than 1 is offsetting limited between these noncarcinogens and other pollutants not on the high-risk list. In the final rule, three noncarcinogens were assigned weighting factors greater than 10. The rationale for increasing the weighting factor from 10 to 100 for mercury is based on consideration of persistence in the environment and

bioaccumulation, as discussed below. After a review of the scientific data, two other noncarcinogens (acrolein and 2-chloroacetophenone) have been assigned weighting factors of 100 rather than 10 in the final rule to provide an adequate margin of safety from adverse health effects. This decision is explained fully in a memorandum to the docket entitled "Need for Additional Weighting of Two Chemicals".

Four commenters believe EPA should establish more weighting factor categories to reflect more accurately the different toxicity levels of the various pollutants. On the other hand, two commenters believe more pollutants should be grouped together so that there is not such a wide range in weighting factors.

The EPA has reviewed the weighting factor categories and still finds four separate categories to be appropriate. As described in the comment above concerning weighting factors there were some adjustments made to the placement of certain pollutants. However, the general categories with weighting factors of 100,000; 1000; 100; and 10 are still believed to be appropriate. The difference between the most toxic carcinogen and the least toxic carcinogen with a weighting factor of 10 is about a factor of 35 (with the exception of one pollutant). Given the uncertainties inherent in the health data, EPA does not feel that this is enough of a difference to warrant another weighting factor category.

Another commenter suggested that the weighting factor could be customized for each facility by relating the weighting factor to the degree to which a reference concentration is exceeded. The commenter believed that this approach would emphasize reductions in cases where reference concentrations may be exceeded and assigns less weight to high-risk pollutants in cases where the reference concentrations are not likely to be exceeded.

There are several reasons why EPA prefers that weighting factors not be customized for each participating facility. The primary reason is that the weighting factors reflect the differences in the toxicity of the pollutants regardless of emission rates. For example, if facility X emits 50 tons of benzidine, a 1000 to 1 trade is necessary with a HAP not on the high-risk list. If facility Y emits 1 ton of benzidine, a 1000 to 1 offset is also required. The EPA believes this will emphasize reductions in the high-risk pollutants even if these emissions are small. In addition, participation in the Early Reductions Program is available to all

facilities throughout the Nation. The EPA prefers that for consistency in program implementation the weighting factors for the high-risk pollutants not be customized for each participating facility. In addition, such customizing can greatly complicate the application preparation and review process; facilities and reviewing agencies may not have the expertise or resources to either perform or review site-specific modeling analyses and determine appropriate weighting factors.

Four commenters discussed pollutants that persist in the environment and/or bioaccumulate. These commenters recommended that any pollutants identified as persistent or bioaccumulative be added to the list. The commenters further suggested that an additional weighting factor of 10 be applied to these pollutants. After consideration of public comments, EPA has decided to adjust the weighting factors for chlordane, heptachlor, hexachlorobenzene, mercury compounds, and toxaphene from 10 to 100 based on persistence in the environment and bioaccumulation. The weighting factors for these particular pollutants were increased based on persistence and bioaccumulation data compiled for EPA in support of the CAA Great Waters Study.

4. Additions/Deletions to the High-Risk List

In addition to the changes to the high-risk list described above, EPA added four pollutants to the list and deleted three pollutants on the basis of health effects data. Methyl hydrazine, 2-chloroacetophenone, and 1,2-dibromo-3-chloropropane were added based on newly available or revised RfCs. N-nitroso-N-methylurea was added because a unit risk estimate is available in a health assessment document. Benzotrichloride was deleted from the list because an inhalation potency factor was unavailable. Further review of the studies supporting the listing of chloroprene led to the determination that the primary study was not acceptable and, therefore, chloroprene was removed from the list. The RfC for 2,4-toluene diisocyanate is undergoing review based on new data and, therefore, 2,4-toluene diisocyanate was removed from the list.

Two commenters stated that when pollutants are added to the list, a source should not be exempt from further reducing those pollutants, but the source should be given up to three years to adjust its emissions to continue to qualify for the Early Reduction extension or else comply with the emissions standard under section

112(d). Other commenters believe the changes to the high-risk pollutant list should not affect the status of a previously submitted commitment or application.

The EPA has decided that sources with an approved enforceable commitment, or an approved permit specifying an alternative emission limit, will not be affected when a HAP is either added to the list in section 112(b), or is newly designated as a high-risk pollutant. The EPA expects to update the list of high-risk pollutants as the science requires. It is conceivable that a source would have to revise a post-reduction demonstration with each revision of the list. This requirement could add significantly to administrative burden for both the source and the reviewing agency. Given that the source will be in full compliance with the emission standards under section 112(d) at the end of the six year extension, EPA feels this additional administrative burden is unnecessary.

5. Comments on Specific High-Risk Pollutants

The EPA received one comment asking why lead was not listed as a high-risk pollutant.

Airborne lead emissions are currently regulated by a National Ambient Air Quality Standard (NAAQS). The EPA is currently reviewing the data the NAAQS is based on and expects to make a decision on revising the standard in the near future. Given this, and other policy considerations regarding identifying a criteria pollutant as high risk, at this time EPA believes it is appropriate to leave lead compounds off the high-risk list.

One commenter urged EPA to add radionuclides to the high-risk list.

The EPA did not add radionuclides to the high-risk list because radionuclide emissions are measured in terms of activity rather than mass and it would be extremely difficult to equate the two for the purpose of offsetting. The EPA recognizes however, that radionuclides could potentially be present in trace amounts from some combustion sources. To account for this, language has been added to the final rule that stipulates that if a radionuclide source is included in the emissions pool, EPA will not allow increases in radionuclide emissions under any post-reduction scenario.

Numerous commenters requested that specific pollutants be removed from the high-risk list. Most of the commenters took issue with the scientific basis of EPA potency factors or other specifics of the scientific studies that document the

health effects. As stated above, three chemicals were deleted from the list because of health effects data and two were assigned weighting factors of one because of their Group C cancer classification. All other requests to delete pollutants from the list were denied. The rationale supporting the specific determinations are addressed in the BID.

G. State Authority

A number of commenters recommended that States be delegated authority for implementing the Early Reductions Program even before States are given permitting authority under title V of the CAA.

The EPA specifically solicited comment on whether this Program should be delegated to the States. Based on the comments received, EPA is proceeding to establish the criteria for delegating the Early Reductions Program to those States that seek delegation in advance of having a title V operating permit program. Section 112(l) of the CAA authorizes the Administrator to approve a State program for the implementation and enforcement of the emission standards and other requirements of the section, including partial delegation of the Program. That is, EPA anticipates that it will, if a state so desires, delegate to a State the authority to develop and implement the Early Reductions Program. The EPA anticipates that it will publish delegation guidance in the near future that will be useful to the States in developing programs for submittal.

Of course, until such time as a State has an approved State program under title V, it cannot issue a title V permit. See CAA section 112(1)(9). Therefore, the Administrator cannot delegate his authority to issue a permit establishing an alternative emission limit under section 112(i)(5) until such time as the state has an approved title V permit program.

Various comments were received pertaining to a State's authority to impose stricter requirements for compliance extensions than those specified in the rule.

The CAA states in section 112(i)(5)(A) that "Nothing in this paragraph shall preclude a State from requiring reductions in excess of those specified in this subparagraph as a condition of granting the extension * * *. Although not specifically stated, it is implied that the excess reductions can only be required as a condition of the State granting the extension. The CAA, therefore, implies that when the State is the permitting authority, the State may require greater than 90 (95) percent

reduction as a condition for granting the extension. As long as EPA (administered through the Region) remains the permitting authority, the CAA specifies 90 (95) percent reduction.

Finally, two commenters contended that States should have the option of not allowing facilities in their States to participate in the Program or denying alternative emission limits.

The Early Reductions Program is a national program mandated by Congress through the CAA and as such, States do not have the authority to disallow participation. However, States do have the power to impose additional or stricter State standards or require greater than 90 (95) percent reduction as a condition of granting an Early Reductions compliance extension under their title V State permitting program.

H. Interface With Title V Permits

One commenter was concerned that the Early Reductions rule required compliance extensions to be in the form of a title V permit. Since there is a chance that the regulations for operating permits will not be finalized until after the first set of section 112(d) standards are proposed, the commenter believed that it may be too late to apply for a compliance extension for all sources covered by the section 112(d) standards.

The regulation allows sources covered by standards proposed prior to January 1, 1994, to submit an enforceable commitment prior to proposal of the standard. The source is then allowed until January 1, 1994, to achieve the reductions and may submit a permit application as late as December 1, 1993. Sources which have already achieved the required reduction prior to proposal of an applicable section 112(d) standard must submit a permit application containing the reduction demonstration prior to such proposal; or if a Federal or State permitting program is not yet in place, the permit application for the Early Reductions source may be submitted up to 120 days after the permitting authority has established a permitting program under title V. In the latter situation, even though the permit application would have to be submitted after proposal, the source owner or operator must still document that the required early reductions were achieved prior to proposal of the applicable section 112(d) standard. In the event that such documentation cannot be provided, the source's Early Reductions demonstration would be disallowed and the source would have to meet the section 112(d) standard.

It has become apparent recently that no comprehensive title V permitting mechanism, either a federal rule for

issuing title V permits or an approved State program, will be available in time to process permit applications for enforceable commitments which are due by December 1, 1993. In addition, it may be some time before any source achieving reductions prior to proposal of an early section 112(d) standard could submit a permit application. In both cases the owner or operator may not know if he would be granted a compliance extension in time enough to meet the section 112(d) standard if his Early Reductions demonstration were disapproved. Therefore, EPA is considering options to deal with this developing problem.

One option is for EPA to promulgate quickly a rule for interim federal issuance of title V specialty permits. The rule would apply only to Early Reductions permit applications that could not be processed due to lack of an applicable comprehensive title V program. Permits issued under the specialty program would encompass only the Early Reductions source at a facility and only the hazardous air pollutant emissions from that source. All other Act requirements applicable to the Early Reductions source would be handled through the comprehensive title V permitting process as it becomes available. A future Federal Register notice will describe EPA's proposed action on this matter.

Another commenter noted that there may be a gap between the time a permit application is approved and when a title V permit is issued. They suggested that alternative emission limitations be enforceable once permit applications are approved.

Permits do not have separate approval and issuance dates. When the proposed permit completes review, including federal oversight, the permit is considered valid at that time. Therefore, the date of approval and date of issuance are the same and there is no time gap.

One commenter suggested that EPA establish a policy for applications under review during the time that States receive final approval of a State title V program. The commenter felt that the reviewing agency should remain the same throughout the review and issuance of a permit.

The EPA generally agrees with the commenter that title V permit applications undergoing review by EPA for an Early Reductions demonstration and alternative emission limits should not have to be processed twice—once by EPA and then by the State. In most cases, this should not occur. However, there may be some situations where a State has received approval of its

comprehensive title V permitting program during the time that EPA is reviewing a permit application submitted by a source to EPA for an Early Reductions demonstration. The EPA will address this situation in the upcoming Federal Register proposal described above to deal with the permit mechanism for Early Reductions demonstrations.

Briefly, the EPA does not believe that permit issuance should be substantially delayed as a result of the transition to State responsibility for permitting. Owners or operators must know in a timely fashion whether their sources will be granted a compliance extension. If an extension denial occurs, the source will have to meet the applicable section 112(d) standard on schedule, and if substantial delays occur, it will mean less time for the source to prepare to meet the 112(d) standard.

The anticipated Early Reductions specialty permit rule will address when EPA will retain permit issuance even after a State receives approval for its comprehensive title V permit program, as well as when such review and specialty permit issuance will be transferred to the State after submittal to EPA by the source owner or operator. It is envisioned that in the event of such transfer, the State will adhere as closely as possible to the original review timetable established by EPA.

Several commenters expressed additional concerns with the timing of State title V programs. Commenters wanted assurances that any Early Reduction permit application approved by EPA (vs. the State) would be included in any future State title V operating permit without further negotiation.

Alternative emission limitations for Early Reductions sources remain in effect for the duration of the 6-year compliance extension. Because permits must be renewed after 5 years, the State would be the reviewing agency at that point. However, the alternative emission limitations, once granted, continue to be permit conditions until the compliance extension expires, in which case, applicable section 112(d) standards then take effect.

One commenter suggested that base-year review should be eliminated because it could potentially stress the reviewing capabilities of EPA and the States. In the opinion of the commenter, permit issuance was more important since the permit would enforce the early reductions.

Base year review will expedite the permit review and assist industry in making "acceptable" reductions. Early review of base year emissions is

essential before a source commits the resources to reduce emissions. This review will provide assurance of acceptable base year emissions prior to major expenditures.

Finally, one commenter felt that Early Reduction permits should not be revoked for any reason prior to the end of the 6-year extension, even pursuant to section 112(f) of the CAA.

Permits issued during the 6-year compliance extension may be revoked only in those circumstances that warrant permit revocation under the title V permit regulations. If the compliance extension were revoked, then the source would have to achieve timely compliance with any applicable section 112 standard. Section 112(i)(5) does not shield a source from standards issued under section 112(f).

I. Interface With Section 112(g) Modifications

One commenter requested clarification of the netting provisions of section 112(g) of the CAA, and how these provisions will be impacted by the Early Reductions Program.

The EPA recognizes that the availability of Early Reduction credits for use as offsets for emission increases under section 112(g) is an important issue. The EPA is currently developing regulations to implement section 112(g) of the CAA. The issue of offsetting emission increases with Early Reductions credits has not been resolved and will be addressed in the upcoming regulations governing section 112(g) modifications. However, EPA recognizes that there are disadvantages of allowing Early Reduction credits to be used to offset section 112(g) emission increases.

Section 112(i)(5) was designed to bring about a substantial reduction in air toxic emissions from sources prior to the actual issuance of standards governing such sources. In exchange, those sources would receive a limited compliance extension from the emission limitations established pursuant to section 112(d) of the CAA. Section 112(g) is a mechanism to allow owners or operators of facilities to make physical or operational changes to their facilities without triggering MACT requirements. A "major source" is considered not to have undergone a modification if any increase (greater than a de minimis increase) as a result of physical or operational changes is offset by an equal or greater decrease in the quantity of emissions of another hazardous air pollutant (or pollutants) from such source which is deemed more hazardous. The EPA believes that the intent of section 112(i)(5) would be

undermined by allowing the Early Reduction credits to be used under section 112(g).

This is best illustrated by example. If Company A submits an enforceable commitment to reduce its emissions by 90 percent at one-half of its facility (and that portion of the facility meets the definition of source in § 63.73) it will achieve those reductions (for example, from 100 tons/yr to 10 tons/yr) in exchange for an alternative emission limit for the first six years beyond the otherwise applicable compliance date. Later the company wants to undertake a physical change at the other half of the facility which would result in an increase in emissions of 90 tons/yr of a HAP. If, under section 112(g), the owner or operator is allowed to use as an offset credit those 90 tons/yr of reductions from the Early Reductions Program, the major source overall will emit the exact same level of HAP's as it did prior to making early reductions (i.e., 100 tons/yr), MACT requirements will be avoided on one half the facility, and the other half of the facility will have received a six year extension from an otherwise applicable section 112(d) standard.

J. Interface With Title I Provisions

One commenter suggested that facilities that reduce emissions for purposes of the Early Reductions Program should be able to use those reductions for offsetting and netting.

Most of the HAP's emitted by sources participating in the Early Reductions Program also are either volatile organic compounds (VOC) or particulate matter and, may therefore, be subject to other requirements under the CAA. For such situations, questions have surfaced over the interaction between the Early Reductions Program and the other CAA requirements. Specifically, a frequent question from interested companies concerns whether reductions made under the Early Reductions Program can be considered creditable reductions for purposes of New Source Review (NSR) permitting under parts C and D of title I of the CAA. The preamble to the proposed Early Reductions rule described the way Early Reductions would be treated in situations involving "offsets" under part D NSR requirements but did not discuss "netting" transactions. Today's preamble reiterates the proposal in the preamble discussion regarding use of Early Reductions as offsets and adds EPA's policy regarding netting transactions.

a. Offsets. Emission reductions of HAP's for the purpose of obtaining an alternative emission limitation under section 112(i)(5) of the CAA are not

creditable for the purpose of meeting an offset requirement under section 173(a)(1) of the CAA. A source in a nonattainment area (an area where a national ambient air quality standard is exceeded) or an ozone transport region may need to obtain offsets for emission increases from planned new construction or modification of existing facilities. The HAP reductions are not allowed as offsets in this instance because section 173(c)(2) of the CAA states that emission reductions otherwise required by this Act shall not be creditable as emissions reductions for purposes of any such offset requirement. A source successfully participating in the Early Reductions Program will be granted an alternative emissions limitation (for the duration of the compliance extension period) in lieu of a section 112(d) emission standard. Therefore, the reduction of HAP emissions under the Early Reductions Program is a substitute for the reduction of HAP emissions that would otherwise be required of the source under section 112(d).

However, a source owner or operator may use as offsets any reductions in HAP emissions in excess of those required to qualify for an extension under the Early Reductions Program or reductions in non-HAP emissions which are coincidentally obtained through use of the HAP reduction measures, if such reductions are not required by any other provision of the CAA and meet any other requirements for offsets under NSR rules. These reductions are allowed as offsets pursuant to section 173(c)(2) of the CAA which further states that incidental emission reductions which are not otherwise required by the Act shall be creditable as emission reductions for such purposes.

b. Netting. In general, an owner or operator considering a physical or operational change at a major stationary source (as defined in the NSR rules) will be subject to (1) the requirements of section 173(a) (e.g., offsets, application of LAER) in nonattainment areas or ozone transport regions or (2) the requirements for Prevention of Significant Deterioration (PSD) (e.g., application of BACT) in attainment or unclassifiable areas, unless the changes will not cause a "significant net emissions increase" in pollutants subject to NSR. To determine the net emissions increase for NSR purposes, the owner or operator is allowed to sum the emissions increase from the proposed change with any creditable increases and decreases elsewhere at the plant.

The New Source Review rules and EPA's "Emissions Trading Policy

Statement (ETPS)" (51 FR 43823, December 4, 1986) limit the creditability of some decreases in emissions for this "netting" procedure. For example, the NSR rules for nonattainment areas state that a decrease in emissions is creditable only to the extent that " * * * the reviewing authority has not relied on it in issuing any permit under regulations approved pursuant to 40 CFR part 51 subpart I or the State has not relied on it in demonstrating attainment or reasonable further progress; * * * " (40 CFR 51.165(a)(1)(vi)(E)). The PSD rules contain similar language. Essentially what this restriction does is prevent sources from obtaining two credits for one reduction, where the credits are related to the same air quality objective (which in this case is the attainment/maintenance of national ambient air quality standards). Thus, as an example, a source cannot use an emissions reduction to meet reasonable further progress requirements and as a reduction credit in netting calculations.

However, under the ETPS, HAP decreases credited under the Early Reductions Program also may be credited for purposes of determining the net emissions increase for a plant change proposed at a later time for new source review purposes, provided of course that the reduced HAP's also are pollutants subject to the NSR rules and that the decreases meet all other requirements for netting. In such situations, the HAP decreases produce benefits for two different air quality objectives and one credit can be given toward each; the HAP credit is associated with the air toxics reduction objectives of section 112 of the CAA and the NSR credit is associated with the attainment/maintenance of national ambient air quality standards and PSD. However, the amount of the HAP reduction creditable in these situations will be limited if the netting calculations involve HAP emissions increases. Specifically, the creditable HAP reductions from the Early Reductions Program will be reduced by the amount of any increase in HAP emissions involved in the netting calculations. If no HAP increases are involved, the entire HAP reduction is creditable.

The principle behind this policy limitation is similar to that behind the netting restriction in the NSR rule mentioned above, namely that a reduction should not receive two benefits or credits (double counting) for the same air pollution control objective. The objective of the Early Reductions Program under section 112 of the CAA is to achieve significant reductions of

HAP's at existing facilities. Sources that achieve such HAP reductions in accordance with the rules promulgated today receive credit for the reductions in the form of a six-year compliance extension from applicable section 112(d) standards. If the reductions also were allowed to be used as netting reduction credits for physical or operational changes involving increases in HAP's, then the reductions in effect would be promoting HAP increases elsewhere at the plant site by helping such facilities net out of NSR control requirements. Under such a scenario, an owner or operator could receive a six-year compliance extension to section 112(d) standards for some portion of the plant, net out of NSR control requirements, and have overall HAP emissions equal to preexisting levels. Clearly this is not a result consistent with the objectives of the CAA.

To illustrate the effect of this policy, consider a plant site in which a portion of the facility (e.g., a process unit) participates in the Early Reductions Program and achieves a 50 tons per year reduction of HAP's, which also are particulate matter. Later, the owner or operator proposes a physical or operational change at another section of the plant which would increase particulate emissions by 75 tons per year, and none of the emissions increase would be HAP's. In this case, the owner or operator can use all of the HAP reductions from the Early Reductions Program to net against the particulate emissions increase because no HAP increases are involved. However, if 30 tons per year of the proposed 75 ton increase are HAP's, then only 20 tons per year of the HAP reductions under the Early Reductions Program could be used as reduction credits in any netting calculations (20 tons per year is the amount by which the HAP reduction exceeds the proposed HAP increase). Finally, if 50 or more tons per year of the proposed 75 ton increase would be HAP emissions, then none of the HAP reductions from the Early Reductions Program could be used to net against the particulate emissions increase (because the HAP increase from the proposed modification is equal to or greater than the HAP reductions from the Early Reductions Program).

It should be noted that this netting policy for HAP reductions is applicable only for NSR programs. Under section 112(g) of the CAA, EPA must promulgate separate requirements for modification of HAP sources. The provisions to implement section 112(g) are under development but will not become effective in a State until the

State has obtained approval of a Title V permitting program.

Another commenter felt that a source that achieves a 90 (95) percent reduction from base year should be granted the same 6-year extension from complying with reasonably available control technology (RACT) requirements under Title I as received from section 112(d) standards under Title III.

Section 112(i)(5) of the CAA authorizes the Administrator (or a State operating pursuant to an authorized Title V permit program) to grant a 6-year extension from compliance with an emission standard promulgated under section 112(d) that would otherwise be applicable to that source, provided the source satisfies certain conditions. Nothing in section 112(i)(5) or any other provision of the CAA authorizes the Administrator to grant extension of any RACT requirement that might be required under other sections of the CAA. As a practical matter however, EPA anticipates that many of the methods or technologies adopted to reduce a source's HAP's by 90 (95) percent for purposes of obtaining a compliance extension from a section 112(d) standard may also constitute compliance with RACT requirements under other provisions of the CAA.

Although sources successfully participating in the Early Reductions Program will be granted an alternative emission limitation in lieu of meeting an applicable section 112(d) standard, the source still is responsible for complying with other applicable requirements of the CAA. For example, sources located in areas designated nonattainment for the criteria pollutant ozone are subject to other emission reduction requirements. State implementation plans (SIP's) for these nonattainment areas (plans for attaining the criteria pollutant ambient air quality standards) must contain requirements for application of RACT requirements for stationary sources of volatile organic compounds (VOC). The RACT is required for sources: (a) For which EPA has published, or will publish, a control techniques guideline document; and (b) that are "major" as defined in the CAA.

State implementation plans also must provide for other emission reductions sufficient to demonstrate attainment by specified deadlines and meet interim reasonable further progress requirements. States may obtain reductions from any VOC emission sources in the inventory, which means that they may eventually require additional emission reductions from sources participating in the Early Reductions Program. (It should be noted that VOC emission reductions resulting

from compliance with HAP rules, including those under the Early Reductions Program, are creditable toward the Program requirements to the extent that they were not required prior to enactment of the CAA Amendments of 1990 and are consistent with creditability requirements under the CAA.)

The interaction between the Early Reductions Program and other requirements for the attainment of national ambient air quality standards causes concern in that the prospect of later application of additional requirements to sources that make early reductions would effectively limit the attractiveness of, and therefore participation in, the Program. Therefore, with respect to the percentage reduction requirements, reasonable further progress and attainment demonstration requirements, EPA has established a policy to reduce the amount of uncertainty for sources that choose to participate in the Early Reductions Program. This guidance should further encourage possible applicants to participate in the Early Reductions Program. Briefly, the policy regarding RACT and reasonable further progress requirements for sources making early reductions provides that:

(1) The source must meet any applicable existing RACT requirements (including RACT which is required but has not been adopted by the State, i.e., RACT fixups);

(2) EPA encourages States to favorably consider the reductions made under the Early Reductions Program in its analysis of any future RACT requirements for the source; and

(3) EPA encourages States to seek any additional reductions (beyond those under the Early Reductions Program) needed to make reasonable further progress first from sources not participating in the Early Reductions Program.

The intent of the policy is to require compliance with existing RACT requirements, but potentially give sources some breathing room with respect to future RACT or reasonable further progress requirements, in recognition of the fact that substantial 90 (95) percent reductions already have been made at the source. This policy is appropriate because, in most cases, a 90 (95) percent reduction of HAP's from the sources will produce comparable reductions in criteria pollutants or criteria pollutant precursors (i.e., VOC). For example, nearly all HAP's emitted as gases also are VOC's.

However, it is possible that an Early Reduction demonstration will not produce a criteria pollutant reduction. A

creditable HAP emission reduction may be achieved by substituting a non-HAP compound for the HAP. If, for example, both compounds are VOC, then there is no VOC reduction although the HAP has been eliminated. In such cases it would not be appropriate to apply this policy.

K. Test Methods and Procedures

A variety of comments were received regarding Method 301. One commenter suggested that Method 301 should be made applicable to other waste media in addition to gaseous measurements (the language in the proposal package contained references to sampling trains, sampling probes, etc., specific to measurement of gases). The EPA concurs with this comment; an intent of the method and the rule is its applicability to all types of sources. Thus the language in Method 301 has been modified to be more generic as to source media. This modification does not change the requirements of the method nor does it affect the stringency or applicability of the method.

Three commenters suggested that EPA establish a de minimis concentration for all HAP's for Method 301. The de minimis concentration would be the lowest concentration for which the test methods would have to be validated.

It is beyond the scope of Method 301 to specify de minimis levels. Method 301 does provide specific procedure for the determination of the limit of quantitation. In addition, Method 301 requires that the data and the proposed method be validated for the concentration(s) of HAP's in the waste stream(s).

One commenter recommended that Method 301 contain a procedure for calculating the concentration range for which a method would be considered validated.

Method 301 advocates that the proposed test methodology be validated over the range of expected HAP concentrations, in the field or through laboratory testing utilizing the ruggedness test procedures. In addition, a procedure is offered for determining the limit of quantitation. Such procedures would establish the concentration range.

One commenter noted that Method 301 does not specify the process conditions under which the validation testing should be conducted.

The choice of operating conditions depends upon the end use(s) of the data. Considerations in structuring the validation test should include: Sample matrix complexity in regard to future applicability of the proposed method, sample analyte concentration(s) in the sample waste stream and of the

applicable emission standard, and representativeness of the process conditions in regard to establishing actual annual emissions.

Two commenters noted that the validation protocol in Method 301 will increase the cost of testing and the time required to test. In order to minimize the costs, they suggest that EPA not require pre-review of the validation report before the test method can be used.

The EPA agrees that the validation of data obtained by the proposed method can be conducted concurrently with other testing in order to combine the validation step with the source test. This is encouraged, where appropriate, and was an intent of Method 301. Note that the source owner or operator incurs some risk that the proposed method may not meet the Method 301 validation criteria and the emissions data may not be applicable for compliance determination. Well-substantiated validation reporting should keep this risk to a minimum.

Another commenter suggested that Method 301 should provide a less rigorous validation procedure for the early stages of method development so that these methods may be used to provide a data base for screening, ranking, and regional planning without the expectation of a high degree of knowledge about accuracy and precision.

The EPA agrees that an overall test method development program will be more extensive than a single application of Method 301. Method 301 is specifically a field validation protocol. Responsible method development and evaluation should provide an indication that the proposed method has a sufficient probability of performing within the criteria of Method 301 during field validating testing.

One commenter was concerned that Method 301 would adversely affect State toxic screening programs which have incorporated less precise emission measurement techniques.

Method 301 is applicable to source owners or operators wishing to comply with a Federal requirement using a test method which has not yet been validated. Because a source emission screening and ranking process for use in the development of a State toxics strategy is not subject to specific Federal requirements, Method 301 should not affect this type of program.

One commenter noted that Method 301 does not address the direct interface or dilution interface sampling options of Method 18.

Method 301 may be applied to the direct and dilution interface sampling

options of Method 18. However, the validation cannot be conducted without quadruplicate sampling and analytical systems, which EPA considered excessively burdensome. For the other sampling options of Method 18, such as container and absorption tube sampling, validation field testing should be conducted using Method 301.

One commenter felt that Method 301 requires an excessive number of samples for determining bias and precision. They suggested that reducing the number of test runs by half would only result in a difference of the t-statistic at an 80 percent confidence level by less than 11 percent, but cut the time, effort, and cost in half.

The decision level specified in the comment is incorrect and should be 0.05. The difference in the t-statistic resulting from reducing the number of samples by 50 percent is 17 rather than 11 percent. This difference is not acceptable to EPA.

One commenter raised questions about section 6.1.5 of the proposed method. The commenter noted that this section does not indicate the acceptance criteria for the correction factor calculated in Equation 301-5, and also contended that this correction factor may be inappropriate for methods which employ isotopic spiking (e.g., EPA Method 23 surrogate standards) where values are not corrected as long as the recovery is within 30 percent.

The acceptance criteria for the correction factor calculated in Equation 301-5 is specified in section 1.2.1 of the Method. Isotopic spiking with surrogate standards as specified in Method 23 is conducted as a quality assurance check of breakthrough of the analytes on the sorbent. The isotopic spiking specified in Method 301 is used to assess method bias. The two are not mutually exclusive. Where a significant bias is identified (section 6.1.4) using the spike, the correction factor (section 6.1.5) is calculated. The correction factor is evaluated by the criteria in section 1.2.1 and the data are either corrected or the data and procedure to obtain the data are rejected.

One commenter expressed concerns about the reasonableness of requiring reference materials at concentrations below a proposed method's detection limit or in concentrations in multiple ranges representative of several emission points at the same facility.

Validation of a proposed method requires that the method be capable of measuring in the applicable range of emission concentrations. A method with a detection limit above the emission concentration at a particular emission source could not be validated for that

source. Method 301 does provide for ruggedness testing which allows a proposed method to be validated for testing at multiple concentrations without requiring multiple field validation tests. Whether ruggedness testing or field validation is used to validate the method for the appropriate concentrations, it will be necessary to obtain reference materials in the applicable ranges.

One commenter was concerned that the limit for precision specified in Method 301 of 50 percent relative standard deviation was too high, even though 9 sampling runs are needed to show compliance. The commenter suggested that the relative standard deviation be reduced to 15 percent or less so that only three sampling periods are needed to show compliance.

The method criteria for precision and followup testing provide maximum flexibility in method development and application while achieving high quality results. They also serve indirectly as an incentive in method development; that is, the better the method precision, the less effort is required during followup testing using the validated method.

One commenter recommended that more explicit terminology be used in sections 6.2.1.3 and 6.2.2.3 of the rule pertaining to the F-test which tests the significance of the proposed method variance to that of the validated method.

The intent of the sections is to perform a comparison of the variances of the two methods. Method 301 has been revised to include both the F-test and simple comparison of variances, demonstrating that the variance of the proposed method is less than or equal to that of the validated method, as suggested by the commenter.

One commenter suggested that a hierarchy be established for identifying which validation procedures to use.

The EPA agrees that such guidance would be appropriate in Method 301 and has reworded sections 5.1 through 5.3 to define this hierarchy.

One commenter suggested that "documented" methods (section 12.1.2 of Method 301) such as National Institute of Occupational Safety and Health, American Society for Testing and Materials, and Occupational Safety and Health Administration methods should be considered validated methods.

The application for a waiver under section 12.2 should demonstrate the applicability of the "documented" method to the particular source to be measured. The validation procedure and documentation for that particular source would be reviewed with respect to Method 301 requirements.

Another commenter felt the Method 301 requirements in section 12.1.1 for extending applicability of a method to "similar" sources were burdensome. They suggested there be a more reasonable requirement than conducting a ruggedness test and applying to EPA for a waiver.

Section 12.1.1 states applicability to other sources may be demonstrated by conducting ruggedness testing. The EPA agrees with the commenter that ruggedness testing is not always necessary depending upon the similarity of the sample matrices. In addition, validation of the proposed method on a complex sample matrix may be sufficient to demonstrate that the method is applicable to a similar source with an emission matrix of less complexity. In every case, the requester must apply for a waiver to extend the applicability.

One commenter noted that Method 301 does not specify acceptable deviations in method procedures after validation.

Once validation of a method has been completed and the data used to meet a Federal or State requirement, modifications to the method can not be made without approval of the responsible agency or validation through application of Method 301. Any modification must be fully explained and documented with supporting data such as that from a ruggedness test. The primary consideration in acceptance of a modification will be its effect upon the results obtained by the previously validated method.

Finally, one State was concerned that the validation method at one source would be inappropriately interpreted as a validation for all applications.

The field validation procedure of Method 301 is appropriate for validating emissions data from the source and at the levels only for which the method was validated. Optional procedures are provided and must be applied to extend applicability of the methodology beyond the specific emission source and concentration levels at which the validation was conducted.

Various comments were received pertaining to other topics related to test methods and procedures. One commenter recommended that Method 25A be accepted for determining base year and post-reduction emissions. The commenter provided an example of where this method would be appropriate: When the gas stream is principally comprised of one HAP and the HAP contribution to the total hydrocarbon concentration can be documented. The commenter further suggested that continuous

measurements would be more appropriate for batch processes.

The EPA believes that application of Method 25A to a single HAP in a sample matrix containing no other hydrocarbons would prove acceptable, assuming the detector is calibrated using that HAP. Total emissions of the HAP would then be determined using the emission value integrated for the entire test run. Application of Method 25A to more complex gas streams would need to be examined on a case-by-case basis. Use of continuous mass spectrometric techniques where the HAP could be speciated may be more likely to succeed. Method 301 addresses composite sampling techniques and EPA believes that procedures similar to those specified for a composite sampling test method could be applied to the measurement of emissions from a batch process.

One commenter requested that the final rule include a definition of "particulate."

The definition of particulate matter is dependent upon the test method involved. The requirements of the applicable regulation, SIP, or Federal regulation should be reviewed first for applicable definition(s). The problem exists for emissions that can be in either a particulate or gaseous phase. If there is a question, the applicant should consult with EPA to arrive at a resolution.

One commenter raised an important consideration in preparing a field validation involving comparison of the proposed method against a validated method described in section 5.2 of appendix A of the proposed rule. The commenter stated that if emission concentrations are highly variable over time such as in the case with a batch process like coking operations, the method precision calculated using Equation 301-7 would be disproportionately influenced by large absolute differences.

If paired, rather than quadruplet samples are used for procedures under section 56.2, each test run of the validation testing should be conducted over the entire process cycle.

One commenter felt that the bias criterion for validation of the data obtained by a proposed method compared to a validated method is too restrictive.

For pollutants and sources for which validated method(s) are available, Method 301 requires alternative methods to have a similar precision and a reasonable bias (± 10) compared to the validated method(s). The EPA believes that these criteria are not too restrictive

and allow for innovative method development.

The EPA has made some minor changes to the proposed rule as a result of comments pertaining to test methods and procedures. One commenter suggested that revisions should be made in sections 6.1.2.4 and 6.2.2.4 to calculate the "standard deviation of the differences" rather than the "standard deviation of the mean of the differences." The EPA agrees with this suggestion and has made the appropriate changes in the rule.

Another commenter noted that section 6.3.2 did not specify calculation of the relative standard deviation for the spiked samples as was specified for the unspiked samples in section 6.3.6. It was not clear to the commenter which relative standard deviation is needed to meet the plus or minus 50 percent criterion in section 1.2.2.

Section 6.3.2 has been revised to parallel section 6.3.6. The method has also been revised to specify the 50 percent relative standard deviation criterion for both the spiked and unspiked samples.

One commenter suggested that section 8.2.4 specify that half the samples analyzed at the minimum and maximum storage times be from the validated method and half from the proposed method. It should also address procedures for samples which require extraction or digestion.

As a result of this comment, several wording changes have been made. Section 8.2.4 has been revised to specify that equal numbers of samples from the proposed and validated methods be analyzed. The procedures for samples requiring extraction or digestion parallel those described in section 8.2.2.

Finally, one commenter urged EPA to publish a guidance document outlining source testing methods.

The EPA has prepared an initial list of validated methods. This list may be obtained from the Emission Measurement Technical Information Center (EMTIC), U.S. Environmental Protection Agency (MD-19), Research Triangle Park, North Carolina 27711. Updates to the list of validated methods will be made available on a periodic basis. The EMTIC may be contacted at any time to review the current list at (919) 541-0200.

L. Other Changes to the Proposed Regulation

A number of commenters noted inconsistencies or ambiguities in the language used in the proposed regulation. Where appropriate, EPA has made changes to address or clarify these comments. One commenter suggested

that in § 63.72, the words "permitting authority" be used instead of "state acting pursuant to a permitting * * *." The wording in the proposed regulation implied that only the State had permitting authority.

The regulation has been changed to incorporate this comment. Section 63.72 of the regulation describes the general provisions of the Early Reductions Program. During the course of the Program, the authority to review and issue permits will shift from EPA to the States. The wording in the proposed regulation limited the provisions to States. The term "permitting authority" refers to States or EPA and is, therefore, the more appropriate term in this context.

Another commenter noted that the deadlines for submittal of late test data were different in §§ 63.75(d) and 63.77(f). They requested clarification of this inconsistency.

The test data referred to under § 63.75(d) supports base year data for enforceable commitments. Sources making enforceable commitments may need to act quickly to submit the commitment prior to the proposal of a section 112(d) standard. In this instance, sources will have very little time to obtain accurate test data. Therefore, EPA has granted a reasonable time period of 180 days after proposal of an applicable section 112(d) standard for sources to conduct necessary testing to support enforceable commitments.

The test data referred to under § 63.77(f) (now § 63.77(e)) supports post-reduction emissions for permit applications. In this case, EPA proposed allowing only 90 days for submission of test data. Since sources planning to submit a permit application will have sufficient lead time before applying, less additional time is needed than for submittal of supporting data for the enforceable commitment to produce necessary test data.

The EPA has modified the Early Reduction regulation to make consistent the deadlines for post-reduction emissions test data to support the reduction demonstration for enforceable commitments and permit applications. Section 63.77(f) of the proposed rule allowed sources with enforceable commitments 120 days (i.e., from December 1, 1993, until March 31, 1994) after the permit application deadline to submit test data but required other permit applicants to submit the same type data within 90 days. The 90-day deadline has now been changed to require test data within 120 days after the deadline for submittal of the permit application.

Two commenters noted that the proposed regulation used the term "post-control" when discussing emission reductions.

The EPA recognizes that there are many methods to reduce emissions other than applying a control device. Any emphasis on using a control device versus other methods of emission reduction was unintentional and, in fact, EPA encourages pollution prevention and recycling methods in preference to add-on controls. All references in the proposed regulation to "post-control" emissions have been replaced with "post-reduction" emissions.

The wording in the suggested commitment language in § 63.75(b) has been revised to be consistent with the requirement in § 63.75(a)(ii); that the base year emissions " * * * constitute the best available data for base year emissions * * * and are correct * * *." Language has also been added to clarify that the source owner or operator has not included in the base year emissions that exceed allowable emission levels specified by law, regulation or permit.

The wording in § 63.74(k) has been clarified to be consistent with the intent as described in the proposal preamble. Emissions in excess of allowable levels cannot be used to establish emissions, not "emission points." Emission points in violation of any rule, regulation, or law can be included in the source, but only allowable emissions from those points can be used to establish emissions.

The addresses in §§ 63.75 and 63.76 in the final rule to which enforceable commitments and base year reviews are sent has been revised by replacing the Office of General Counsel (LE-132A) with the Stationary Source Compliance Division (EN-341W).

VI. Administrative Requirements

A. Docket

The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file, since material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the statement of basis and purpose of the proposed and promulgated standards and EPA responses to significant comments, the contents of the docket, except for interagency review materials,

will serve as the record in case of judicial review (section 307(d)(7)(A)).

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060-0222. Public reporting burden for this collection of information is estimated to average 213 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch (PM-223Y); U.S. Environmental Protection Agency; 401 M St., SW.; Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

C. Executive Order 12291

Under Executive Order 12291, OMB is required to judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. The criteria set forth in Section 1 of the Order for determining whether a regulation is a major rule are as follows:

(1) Is likely to have an annual effect on the economy of \$100 million or more;

(2) Is likely to cause a major increase in costs or prices for consumers, individual industries, geographic regions, or Federal, State, or local governments; or

(3) Is likely to result in significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The EPA has determined that this regulation would result in none of the adverse economic effect set forth in section 1 of the Order as grounds for finding a regulation to be a "major rule." This is a voluntary program, open to sources that seek an alternative to meeting a section 112(d) standard. The program is attractive to sources because of the potential savings that can be realized in obtaining a compliance extension. Although EPA believes that significant savings will be realized by

industries that participate in this Program, it is not likely that savings will have an impact on the economy of \$100 million per year. The EPA estimates that 50 to 100 sources per year may participate in the Program, and thus each source would have to save over \$1 million to affect the economy by \$100 million per year. Based on the enforceable commitments received so far from the chemical industry, this does not seem to be the case. However, further quantification of the economic impact of this regulation is impossible without knowing what sources and how many will apply, how they will actually achieve the 90 (95) percent reductions, and what the otherwise applicable section 122(d) standards will be. Consequently, the EPA has concluded that this regulation is not a "major rule" under Executive Order 12291. The final rule was submitted to OMB for review as required by the Order.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires the identification of potentially adverse impacts of Federal regulations upon small business entities. The CAA specifically requires the completion of a Regulatory Flexibility Analysis in those instances where small business impacts are possible. Because these standards impose no adverse economic impacts, a Regulatory Flexibility Analysis has not been prepared.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 63

Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 29, 1992.

William K. Reilly,
Administrator.

Part 63 of 40 CFR chapter I is added to read as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

Subpart A—General Provisions [Reserved]

Subpart B—[Reserved]

Subpart C—List of Hazardous Air Pollutants, Petition Process, Lesser Quantity Designations, Source Category List [Reserved]

Subpart D—Regulations Governing Compliance Extensions for Early Reductions of Hazardous Air Pollutants

Sec.

- 63.70 Applicability.
- 63.71 Definitions.
- 63.72 General provisions for compliance extensions.
- 63.73 Source.
- 63.74 Demonstration of early reduction.
- 63.75 Enforceable commitments.
- 63.76 Review of base year emissions.
- 63.77 Application procedures.
- 63.78 Early reduction demonstration evaluation.
- 63.79 Approval of applications.
- 63.80 Enforcement.
- 63.81 Rule for special situations.

Appendix A to Part 63—Test Methods

Appendix B to Part 63—Sources Defined for Early Reduction Provisions Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—General Provisions [Reserved]

Subpart B—[Reserved]

Subpart C—List of Hazardous Air Pollutants, Petitions Process, Lesser Quantity Designations, Source Category List [Reserved]

Subpart D—Regulations Governing Compliance Extensions for Early Reductions of Hazardous Air Pollutants

§ 63.70 Applicability.

The provisions of this subpart apply to an owner or operator of an existing source who wishes to obtain a compliance extension from a standard issued under section 112(d) of the Act. The provisions of this subpart also apply to a State or local agency acting pursuant to a permit program approved under Title V of the Act. The Administrator will carry out the provisions of this subpart for any State that does not have an approved permit program.

§ 63.71 Definitions.

All terms used in this subpart not defined in this section are given the same meaning as in the Act.

Act means the Clean Air Act as amended.

Actual emissions means the actual rate of emissions of a pollutant, but does not include excess emissions from a malfunction, or startups and shutdowns associated with a malfunction. Actual emissions shall be calculated using the source's actual operating rates, and types of materials processed, stored, or combusted during the selected time period.

Artificially or substantially greater emissions means abnormally high emissions such as could be caused by equipment malfunctions, accidents, unusually high production or operating rates compared to historical rates, or other unusual circumstances.

EPA conditional method means any method of sampling and analyzing for air pollutants that has been validated by the Administrator but that has not been published as an EPA Reference Method.

EPA reference method means any method of sampling and analyzing for an air pollutant as described in appendix A of part 60 of this chapter, appendix B of part 61 of this chapter, or appendix A of part 63.

Equipment leaks means leaks from pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, agitators, accumulator vessels, and instrumentation systems in hazardous air pollutant service.

Existing source means any source as defined in § 63.72, the construction or reconstruction of which commenced prior to proposal of an applicable section 112(d) standard.

Hazardous air pollutant (HAP) means any air pollutant listed pursuant to section 112(b) of the Act.

High-risk pollutant means a hazardous air pollutant listed in Table 1 of § 63.74.

Malfunction means any sudden failure of air pollution control equipment or process equipment or of a process to operate in a normal or usual manner. Failures that are caused entirely or in part by poor maintenance, careless operation, or any other preventable upset condition or preventable equipment breakdown shall not be considered malfunctions.

Not feasible to prescribe or enforce a numerical emission limitation means a situation in which the Administrator or a State determines that a pollutant (or stream of pollutants) listed pursuant to section 112(b) of the Act cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant, or that any requirement for, or use of, such a conveyance would be inconsistent with any Federal law; or the application of measurement technology to a particular source is not

practicable due to technological or economic limitations.

Permitting authority means either a State agency with an approved permitting program under Title V of the Act or the Administrator in cases where the State does not have an approved permitting program.

Responsible official means one of the following:

(1) For a corporation, a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation; or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representative is approved in advance by the permitting authority.

(2) For a partnership or sole proprietorship, a general partner or the proprietor, respectively.

(3) For a municipality, State, Federal, or other public agency, either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., Regional Administrators of EPA).

Reviewing agency means a State agency with an approved permitting program under Title V of the Act. An EPA Regional Office is the reviewing agency where the State does not have such an approved permitting program.

State means a State or local air pollution control agency.

§ 63.72 General provisions for compliance extensions

(a) Except as provided in paragraph (f) of this section, a permitting authority acting pursuant to a permitting program approved under Title V of the Act shall by permit allow an existing source to meet an alternative emission limitation in lieu of an emission limitation promulgated under section 112(d) of the Act for a period of 6 years from the compliance date of the otherwise applicable standard provided the source owner or operator demonstrates:

(1) According to the requirements of § 63.74 that the source has achieved a reduction of 90 percent (95 percent or

more in the case of hazardous air pollutants which are particulates) in emissions of:

(i) Total hazardous air pollutants from the source;

(ii) Total hazardous air pollutants from the source as adjusted for high-risk pollutant weighting factors, if applicable.

(2) That such reduction was achieved before proposal of an applicable standard or, for sources eligible to qualify for an alternative emission limitation as specified in paragraph (c) of this section, before January 1, 1994.

(b) A source granted an alternative emission limitation shall comply with an applicable standard issued under section 112(d) of the Act immediately upon expiration of the six year compliance extension period specified in paragraph (a) of this section.

(c) An existing source that achieves the reduction specified in paragraph (a)(1) of this section after proposal of an applicable section 112(d) standard but before January 1, 1994, may qualify for an alternative emission limitation under paragraph (a) of this section if the source makes an enforceable commitment, prior to proposal of the applicable standard, to achieve such reduction. The enforceable commitment shall be made according to the procedures and requirements of § 63.75.

(d) For each permit issued to a source under paragraph (a) of this section, there shall be established as part of the permit an enforceable alternative emission limitation for hazardous air pollutants reflecting the reduction which qualified the source for the alternative emission limitation.

(e) An alternative emission limitation shall not be available with respect to standards or requirements promulgated to provide an ample margin of safety to protect public health pursuant to section 112(f) of the Act, and the Administrator will, for the purpose of determining whether a standard under section 112(f) of the Act is necessary, review emissions from sources granted an alternative emission limitation under this subpart at the same time that other sources in the category or subcategory are reviewed.

(f) Nothing in this subpart shall preclude a State from requiring hazardous air pollutant reductions in excess of 90 percent (95 percent in the case of particulate hazardous air pollutants) as a condition of such State granting an alternative emission limitation authorized in paragraph (a) of this section.

§ 63.73 Source.

(a) An alternative emission limitation may be granted under this subpart to an existing source. For the purposes of this subpart only, a source is defined as follows:

(1) A building structure, facility, or installation identified as a source by the EPA in appendix B of this part;

(2) All portions of an entire contiguous plant site under common ownership or control that emit hazardous air pollutants;

(3) Any portion of an entire contiguous plant site under common ownership or control that emits hazardous air pollutants and can be identified as a facility, building, structure, or installation for the purposes of establishing standards under section 112(d) of the Act; or

(4) Any individual emission point or combination of emission points within a contiguous plant site under common control, provided that emission reduction from such point or aggregation of points constitutes a significant reduction of hazardous air pollutant emissions of the entire contiguous plant site.

(b) For purposes of paragraph (a)(4) of this section, emissions reductions are considered significant if they are made from base year emissions of not less than:

(1) A total of 10 tons per year of hazardous air pollutants where the total emissions of hazardous air pollutants in the base year from the entire contiguous plant site is greater than 25 tons per; or

(2) A total of 5 tons per year of hazardous air pollutants where the total emissions of hazardous air pollutants in the base year from the entire contiguous plant site is less than or equal to 25 tons per year.

§ 63.74 Demonstration of early reduction.

(a) An owner or operator applying for an alternative emission limitation shall demonstrate achieving early reductions as required by § 63.72(a)(1) by following the procedures in this section.

(b) An owner or operator shall establish the source for the purposes of this subpart by documenting the following information:

(1) A description of the source including: a site plan of the entire contiguous plant site under common control which contains the source, markings on the site plan locating the parts of the site that constitute the source, and the activity at the source which causes hazardous air pollutant emissions;

(2) A complete list of all emission points of hazardous air pollutants in the source, including identification

numbers and short descriptive titles; and

(3) A statement showing that the source conforms to one of the allowable definition options from § 63.73. For a source conforming to the option in § 63.73(a)(4), the total base year emissions from the source, as determined pursuant to this section, shall be demonstrated to be at least:

(i) 5 tons per year, for cases in which total hazardous air pollutant emissions from the entire contiguous plant site under common control are 25 tons per year or less as calculated under paragraph (1) of this section; or

(ii) 10 tons per year in all other cases.

(c) An owner or operator shall establish base year emissions for the source by providing the following information:

(1) The base year chosen, where the base year shall be 1987 or later except that the base year may be 1985 or 1986 if the owner or operator of the source can demonstrate that emission data for the source for 1985 or 1986 was submitted to the Administrator pursuant to an information request issued under section 114 of the Act and was received by the Administrator prior to November 15, 1990;

(2) The best available data accounting for actual emissions, during the base year, of all hazardous air pollutants from each emission point listed in the source in paragraph (b)(2) of this section;

(3) The supporting basis for each emission number provided in paragraph (c)(2) of this section including:

(i) For test results submitted as the supporting basis, a description of the test protocol followed, any problems encountered during the testing, and a discussion of the validity of the method for measuring the subject emissions; and

(ii) For calculations based on emission factors, material balance, or engineering principles and submitted as the supporting basis, a step-by-step description of the calculations, including assumptions used and their bases, and a brief rationale for the validity of the calculation method used; and

(4) Evidence that the emissions provided under paragraph (c)(2) of this section are not artificially or substantially greater than emissions in other years prior to implementation of emission reduction measures.

(d) An owner or operator shall establish post-reduction emissions by providing the following information:

(1) For the emission points listed in the source in paragraph (b)(2) of this section, a description of all control measures employed to achieve the

emission reduction required by § 63.72(a)(1);

(2) The best available data on an annual basis accounting for actual emissions, after the base year and following employment of emission reduction measures, of all hazardous air pollutants from each emission point in the source listed in paragraph (b)(2) of this section;

(3) The supporting basis for each emission number provided in paragraph (d)(2) of this section including:

(i) For test results submitted as the supporting basis, a description of the test protocol followed, any problems encountered during the testing, and a discussion of the validity of the method for measuring the subject emissions; and

(ii) For calculations based on emission factors, material balance, or engineering principles and submitted as the supporting basis, a step-by-step description of the calculations, including assumptions used and their bases, and a brief rationale for the validity of the calculation method used;

(4) Evidence that all emission reductions used for the early reductions demonstration were achieved prior to proposal of an applicable standard issued under section 112(d) of the Act or, for sources subject to enforceable commitments, prior to January 1, 1994; and

(5) Evidence that there was no increase in radionuclide emissions from the source.

(e)(1) An owner or operator shall demonstrate that both total base year emissions and total base year emissions adjusted for high-risk pollutants, as applicable, have been reduced by at least 90 percent for gaseous hazardous air pollutants emitted and 95 percent for particulate hazardous air pollutants emitted by determining the following for gaseous and particulate emissions separately:

(i) Total base year emissions, calculated by summing all base year emission data from paragraph (c)(2) of this section;

(ii) Total post-reduction emissions, calculated by summing all post-reduction emission data from paragraph (d)(2) of this section;

(iii) (If applicable) Total base year emissions adjusted for high-risk pollutants, calculated by multiplying each emission number for a pollutant from paragraph (c)(2) of this section by the appropriate weighting factor for the pollutant from Table 1 in paragraph (f) of this section and then summing all weighted emission data;

(iv) (If applicable) Total post-reduction emissions adjusted for high-risk pollutants, calculated by

multiplying each emission number for a pollutant from paragraph (d)(2) of this section by the appropriate weighting factor for the pollutant from Table 1 and then summing all weighted emission data; and

(v) Percent reductions, calculated by dividing the difference between base year and post-reduction emissions by the base year emissions. Separate demonstrations are required for total gaseous and particulate emissions, and total gaseous and particulate emissions adjusted for high-risk pollutants.

(2) If any points in the source emit both particulate and gaseous pollutants, as an alternative to the demonstration required in paragraph (e)(1) of this section, an owner or operator may demonstrate:

(i) A weighted average percent reduction for all points emitting both particulate and gaseous pollutants where the weighted average percent reduction is determined by

$$\%_w = \frac{0.9(\sum M_g) + 0.95(\sum M_p)}{\sum M_g + \sum M_p} \times 100$$

where %_w=the required weighted percent reduction

$\sum M_g$ =the total mass rate (e.g., kg/yr) of all gaseous emissions

$\sum M_p$ =the total mass rate of all particulate emissions and,

(ii) The reductions required in paragraph (e)(1) of this section for all other points in the source.

(f) If lower rates or hours are used to achieve all or part of the emission reduction, any hazardous air pollutant emissions that occur from a compensating increase in rates or hours from the same activity elsewhere within the plant site which contains the source shall be counted in the post-reduction emissions from the source. If emission reductions are achieved by shutting down process equipment and the shutdown equipment is restarted or replaced anywhere within the plant site, any hazardous air pollutant emissions from the restarted or replacement equipment shall be counted in the post-reduction emissions for the source.

TABLE 1. LIST OF HIGH-RISK POLLUTANTS

CAS No.	Chemical	Weighting factor
53963	2-Acetylaminofluorene	100
107028	Acrolein	100
79061	Acrylamide	10
79107	Acrylic acid	10
107131	Acrylonitrile	10
0	Arsenic compounds	100
1332214	Asbestos	100
71432	Benzene	10
92875	Benzidine	1000

TABLE 1. LIST OF HIGH-RISK POLLUTANTS—Continued

CAS No.	Chemical	Weighting factor
0	Beryllium compounds	10
542881	Bis(chloromethyl) ether	1000
106990	1,3-Butadiene	10
0	Cadmium compounds	10
57749	Chlordane	100
532274	2-Chloroacetophenone	100
0	Chromium compounds	100
107302	Chloromethyl methyl ether	10
0	Coke oven emissions	10
334883	Diazomethane	10
132649	Dibenzofuran	10
96128	1,2-Dibromo-3-chloropropane	10
111444	Dichloroethyl ether (Bis(2-chloroethyl) ether)	10
79447	Dimethylcarbamoyl chloride	100
122667	1,2-Diphenylhydrazine	10
106934	Ethylene dibromide	10
151564	Ethyleneimine (Aziridine)	100
75218	Ethylene oxide	10
76448	Heptachlor	100
118741	Hexachlorobenzene	100
77474	Hexachlorocyclopentadiene	100
302012	Hydrazine	100
0	Manganese compounds	10
0	Mercury compounds	100
101688	Methylene diphenyl diisocyanate (MDI)	10
60344	Methyl hydrazine	10
624839	Methyl isocyanate	10
0	Nickel compounds	10
62759	N-Nitrosodimethylamine	100
684935	N-Nitroso-N-methylurea	1000
56382	Parathion	10
75445	Phosgene	10
7803512	Phosphine	10
7723140	Phosphorus	10
75558	1,2-Propylenimine	100
1746016	2,3,7,8-Tetrachlorodibenzo-p-dioxin	100,000
8001352	Toxaphene (chlorinated camphene)	100
75014	Vinyl chloride	10

(g) The best available data representing actual emissions for the purpose of establishing base year or post-reduction emissions under this section shall consist of documented results from source tests using an EPA Reference Method, EPA Conditional Method, or the owner's or operator's source test method which has been validated pursuant to Method 301 of appendix A of this part. However, if one of the following conditions exists, an owner or operator may submit, in lieu of results from source tests, calculations based on engineering principles, emission factors, or material balance data as actual emission data for establishing base year or post-reduction emissions:

(1) No applicable EPA Reference Method, EPA Conditional Method, or other source test method exists;

(2) It is not technologically or economically feasible to perform source tests;

(3) It can be demonstrated to the satisfaction of the reviewing agency that the calculations will provide emission estimates of accuracy comparable to that of any applicable source test method;

(4) For base year emission estimates only, the base year conditions no longer exist at an emission point in the source and emission data could not be produced for such an emission point, by performing source tests under currently existing conditions and converting the test results to reflect base year conditions, that is more accurate than an estimate produced by using engineering principles, emission factors, or a material balance; or

(5) The emissions from one or a set of emission points in the source are small compared to total source emissions and potential errors in establishing emissions from such points will not have a significant effect on the accuracy of total emissions established for the source.

(h) For base year or post-reduction emissions established under this section that are not supported by source test data, the source owner or operator shall include the reason source testing was not performed.

(i) In cases where emission control measures have been employed less than a year prior to demonstrating emission reductions under this section, an owner or operator shall extrapolate post-reduction emission rate data to an annual basis and shall describe the extrapolation method as part of the supporting basis required under paragraph (d) of this section.

(j) The EPA average emission factors for equipment leaks cannot be used under this subpart to establish base year emissions for equipment leak sources, unless the base year emission number calculated using the EPA average emission factors for equipment leaks also is used as the post-reduction emission number for equipment leaks from the source.

(k) A source owner or operator shall not establish base year or post-reduction emissions that include any emissions from the source exceeding allowable emission levels specified in any applicable law, regulation, or permit condition.

(l) For sources subject to paragraph (b)(3)(i) of this section, an owner or operator shall document total base year emissions from an entire contiguous plant site under common control by providing the information required pursuant to paragraphs (b)(2), (c)(2), and (e)(1)(i) of this section for all hazardous

air pollutants from all emission points in the contiguous plant site under common control.

(m) If a new pollutant is added to the list of hazardous air pollutants or high-risk pollutants, any source emitting such pollutant will not be required to revise an early reduction demonstration pursuant to this section if:

(1) Alternative emission limits have previously been specified by permit for the source as provided for in § 63.72(a); or

(2) The base year emissions submitted in an enforceable commitment have previously been approved by the reviewing agency.

§ 63.75 Enforceable commitments.

(a) To make an enforceable commitment an owner or operator shall submit a commitment to achieve the early reductions required under § 63.72(a)(1) to the appropriate EPA Regional Office and a copy of the commitment to the appropriate State, except that the commitment shall be submitted to the State and a copy to the EPA Regional Office if the State has an approved permitting program under Title V of the Act. A copy shall also be submitted to both the EPA Stationary Source Compliance Division (EN-341W), 401 M Street, SW., Washington, DC 20460 and the EPA Emission Standards Division (MD-13), Research Triangle Park, NC 27711; attention both to the Early Reductions Officer. The commitment shall contain:

(1) The name and address of the source;

(2) The name and telephone number of the source owner or operator or other responsible official who can be contacted concerning the commitment;

(3) An alternative mailing address if correspondence is to be directed to a location other than that given in paragraph (a)(1) of this section;

(4) All information specified in § 63.74(b), (c) and (e)(1)(i), which defines and describes the source and establishes the base year hazardous air pollutant emissions from the source;

(5) The general plan for achieving the required hazardous air pollutant emissions reductions at the source including descriptions of emission control equipment to be employed, process changes or modifications to be made, and any other emission reduction measures to be used; and

(6) A statement of commitment, signed by a responsible official of the source, containing the following:

(i) A statement providing the post-reduction emission levels for total hazardous air pollutants and high-risk pollutants, as applicable, from the

source on an annual basis which reflect a 90 percent (95 percent for particulate pollutants) reduction from base year emissions;

(ii) A statement certifying that the base year emission data submitted as part of the enforceable commitment constitute the best available data for base year emissions from the source, are correct to the best of the responsible official's knowledge, and are within allowable levels specified in any applicable law, regulation, or permit;

(iii) A statement that it is understood by the source owner or operator that submission of base year emissions constitutes a response to an EPA request under the authority of section 114 of the Act and that the commitment is subject to enforcement according to § 63.80; and

(iv) A statement committing the source owner or operator to achieving the emission levels, listed in paragraph (a)(6), (i) of this section, at the source before January 1, 1994.

(b) The following language may be used to satisfy the requirements of paragraphs (a)(6)(ii) through (a)(6)(iv) of this section:

I certify to the best of my knowledge that the base year emissions given above are correct and constitute the best available data for base year emissions from the source, and acknowledge that these estimates are being submitted in response to an EPA request under section 114 of the Act. I further certify that the base year emissions provided for all emission points in the source do not exceed allowable emission levels specified in any applicable law, regulation, or permit condition. I commit to achieve before January 1, 1994, the stated post-reduction emission level(s) at the source, which will provide the 90 (95) percent reduction required to qualify for the compliance extension, and acknowledge that this commitment is enforceable as specified in title 40, part 63, subpart D, of the Code of Federal Regulations.

(c) A commitment for a source shall be submitted prior to proposal of an applicable standard issued under section 112(d) of the Act. Commitments received after the proposal date shall be void.

(d) If test results for one or more emission points in a source are required to support base year emissions in an enforceable commitment but are not available prior to proposal of an applicable standard issued under section 112(d) of the Act, the test results may be submitted after the enforceable commitment is made but no later than 180 days after proposal of an applicable standard. In such cases, the enforceable commitment shall contain the best substitute emission data for the points in the source for which test results will be submitted later.

(e) An owner or operator may rescind such a commitment prior to December 1, 1993 without penalty and forfeit the opportunity to obtain a six year compliance extension under this subpart.

(Approved by the Office of Management and Budget under control number 2060-0222)

§ 63.76 Review of base year emissions.

(a) Pursuant to the procedures of this section, the appropriate reviewing agency shall review and approve or disapprove base year emission data submitted in an enforceable commitment under § 63.75 or in a request letter from an applicant that wishes to participate in the early reduction program but who is not required to submit an enforceable commitment. For review requests submitted to a State agency as the appropriate reviewing agency, a copy of the request also shall be submitted to the applicable EPA Regional Office. For review requests submitted to the EPA Regional Office as the appropriate reviewing agency, a copy of the request also shall be sent to the applicable State agency. Copies also shall be submitted to the EPA Stationary Source Compliance Division (EN-341W), 401 M Street, SW., Washington, DC 20460 and the EPA Emission Standards Division (MD-13), Research Triangle Park, NC 27711; to the attention of the Early Reductions Officer.

(b) Within 30 days of receipt of an enforceable commitment or base year emission data, the reviewing agency shall advise the applicant that:

(1) The base year emission data are complete as submitted; or

(2) The base year emission data are not complete and include a list of deficiencies that must be corrected before review can proceed.

(c) EPA will publish a notice in the Federal Register which contains a list, accumulated for the previous month, of the sources for which complete base year emission data have been submitted and which are undergoing review either in the EPA Regional Office or a State agency within the EPA region. The notice will contain the name and location of each source and a contract in the EPA Regional Office for additional information.

(d) Within 60 days of a determination that a base year emission data submission is complete, the reviewing agency shall evaluate the adequacy of the submission with respect to the requirements of § 63.74 (b) and (c) and either:

(1) Determine to approve the submission and publish a notice in a newspaper of general circulation in the

area where the source is located or in a State publication designed to give general public notice, providing the aggregate base year emission data for the source and the rationale for the proposed approval, noting the availability of the nonconfidential information contained in the submission for public inspection in at least one location in the community in which the source is located, providing for a public hearing upon request by an interested party, and establishing a 30 day public comment period that can be extended to 60 days upon request by an interested party; or

(2) Determine to disapprove the base year emission data and give notice to the applicant of the reasons for the disapproval. An applicant may correct disapproved base year data and submit revised data for review in accordance with this subsection, except that the review of a revision shall be accomplished within 30 days.

(e) If no adverse public comments are received by the reviewing agency on proposed base year data for a source, the data shall be considered approved at the close of the public comment period and a notice of the approval shall be sent to the applicant and published by the reviewing agency by advertisement in the area affected.

(f) If adverse comments are received and the reviewing agency agrees that corrections are needed, the reviewing agency shall give notice to the applicant of the disapproval and reasons for the disapproval. An applicant may correct disapproved base year emission data and submit revised emission data. If a revision is submitted by the applicant that, to the satisfaction of the reviewing agency, takes into account the adverse comments, the reviewing agency will publish by advertisement in the area affected a notice containing the approved base year emission data for the source and send notice of the approval to the applicant.

(g) If adverse comments are received and the reviewing agency determines that the comments do not warrant changes to the base year emission data, the reviewing agency will publish by advertisement in the area affected a notice containing the approved base year emission data for the source and the reasons for not accepting the adverse comments. A notice of the approval also shall be sent to the applicant.

(h) If an applicant submits revised emission data under paragraph (d)(2) or (i) of this section for a source subject to an enforceable commitment, the applicant also shall submit an amended enforceable commitment which takes

into account the revised base year emissions.

(i) If revised base year emission data are not submitted or notice of intent to submit revised data is not provided to the permitting authority by an applicant within 90 days of receiving adverse comments or a notice of disapproved base year emission data for a source that is subject to an enforceable commitment, the enforceable commitment shall be considered withdrawn and a notice to that effect shall be sent by the reviewing agency to the applicant.

§ 63.77 Application procedures.

(a) To apply for an alternative emission limitation under § 63.72, an owner or operator of the source shall file a permit application with the appropriate permitting authority.

(b) The permit application shall contain a demonstration of early reduction for the source as prescribed in § 63.74 and the additional information required for a complete permit application as specified by the State's permitting program approved under title V of the Act.

(c) Permit applications under this section for sources not subject to enforceable commitments shall be submitted by the later of the following dates:

(1) The date of proposal of an otherwise applicable standard issued under section 112(d) of the Act; or
(2) 120 days after approval of a State permit program under title V of the Act.

(d) Permit applications for sources subject to enforceable commitments pursuant to § 63.75 shall be submitted no later than December 1, 1993.

(e) If a source test is the supporting basis for establishing post-reduction emissions for one or more emission points in the source but the test results are not available by the deadline for submittal of a permit application according to paragraph (c) of this section, the owner or operator shall provide the supporting basis no later than 120 days after the applicable deadline for submittal of the permit application or no later than March 31, 1994 for sources subject to an enforceable commitment.

(f) Review and disposition of permit applications submitted under this section will be accomplished according to regulations in 40 CFR part 70.

§ 63.78 Early reduction demonstration evaluation.

(a) The permitting authority will evaluate an early reduction demonstration submitted by the source owner or operator in a permit

application with respect to the requirements of § 63.74.

(b) An application for a compliance extension may be denied if, in the judgement of the permitting authority, the owner or operator has failed to demonstrate that the requirements of § 63.74 have been met. Specific reasons for denial include, but are not limited to:

- (1) The information supplied by the owner or operator is incomplete;
- (2) The required 90 percent reduction (95 percent in cases where the hazardous air pollutant is particulate matter) has not been demonstrated;
- (3) The base year or post-reduction emissions are incorrect, based on methods or assumptions that are not valid, or not sufficiently reliable or well documented to determine with reasonable certainty that required reductions have been achieved; or
- (4) The emission of hazardous air pollutants or the performance of emission control measures is unreliable so as to preclude determination that the required reductions have been achieved or will continue to be achieved during the extension period.

§ 63.79 Approval of applications.

(a) If an early reduction demonstration is approved and other requirements for a complete permit application are met, the permitting authority shall establish by a permit issued pursuant to title V of the Act enforceable alternative emissions limitations for the source reflecting the reduction which qualified the source for the extension. However, if it is not feasible to prescribe a numerical emissions limitation for one or more emission points in the source, the permitting authority shall establish such other requirements, reflecting the reduction which qualified the source for an extension, in order to assure the source achieves the 90 percent or 95 percent reduction, as applicable.

(b) An alternative emissions limitation or other requirement prescribed pursuant to paragraph (a) of this section shall be effective and enforceable immediately upon issuance of the permit for the source and shall expire exactly six years after the compliance date of an otherwise applicable standard issued pursuant to section 112(d) of the Act.

§ 63.80 Enforcement.

(a) All base year or post-reduction emissions information described in § 63.74 and required to be submitted as part of a permit application under § 63.77 or an enforceable commitment under § 63.75 shall be considered to

have been requested by the Administrator under the authority of section 114 of the Act.

(b) Fraudulent statements contained in any base year or post-reduction emissions submitted to a State or EPA Regional Office under this subpart shall be considered violations of section 114 of the Act and of this subpart and, thus, actionable under section 113 of the Act and can be considered, in appropriate cases, violations of 18 U.S.C. 1001, the general false swearing provision of the United States Code.

(c) If a source subject to an enforceable commitment fails to achieve reductions before January 1, 1994, sufficient to qualify the source for an extension under this subpart, the source shall be considered to be in violation of the commitment and shall be subject to enforcement action under section 113 of the Act.

(d) If an early reduction demonstration in a permit application filed under § 63.77 is disapproved for a source not subject to an enforceable commitment, the owner or operator shall comply with an applicable standard issued under section 112(d) of the Act by the compliance date specified in such standard.

(e) If an early reduction demonstration in a permit application filed under § 63.77 is disapproved for a source that is subject to an enforceable commitment, the owner or operator shall comply with an applicable standard issued under section 112(d) of the Act by the compliance date specified in such standard and will be subject to enforcement action under section 113 of the Act.

(f) A violation of an alternative emission limitation or other requirement established by permit under § 63.79 (a) or (b) for the source is enforceable pursuant to the authority of section 113 of the Act notwithstanding any demonstration of continuing 90 percent (95 percent for hazardous air pollutants which are particulates) emission reduction over the entire source.

§ 63.81 Rules for special situations.

(a) If more than one standard issued under section 112(d) of the Act would be applicable to a source as defined under § 63.73, then the date of proposal referred to in §§ 63.72(a)(2), 63.72(c), 63.74(d)(4), 63.75(c), and 63.77(c) is the date the first applicable standard is proposed.

(b) Sources emitting radionuclides are not required to reduce radionuclides by 90 (95) percent. Radionuclides may not be increased from the source as a result of the early reductions demonstration.

Appendix A to Part 63—Test Methods Method 301—Field Validation of Pollutant Measurement Methods from Various Waste Media

1. Applicability and principle

1.1 Applicability. This method, as specified in the applicable subpart, is to be used whenever a source owner or operator (hereafter referred to as an "analyst") proposes a test method to meet a U.S. Environmental Protection Agency (EPA) requirement in the absence of a validated method. This Method includes procedures for determining and documenting the quality, i.e., systematic error (bias) and random error (precision), of the measured concentrations from an effected source. This method is applicable to various waste media (i.e., exhaust gas, wastewater, sludge, etc.).

1.1.1 If EPA currently recognizes an appropriate test method or considers the analyst's test method to be satisfactory for a particular source, the Administrator may waive the use of this protocol or may specify a less rigorous validation procedure. A list of validated methods may be obtained by contacting the Emission Measurement Technical Information Center (EMTIC), Mail Drop 19, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, (919) 541-0200. Procedures for obtaining a waiver are in Section 12.0.

1.1.2 This method includes optional procedures that may be used to expand the applicability of the proposed method. Section 7.0 involves ruggedness testing (Laboratory Evaluation), which demonstrates the sensitivity of the method to various parameters. Section 8.0 involves a procedure for including sample stability in bias and precision for assessing sample recovery and analysis times; Section 9.0 involves a procedure for the determination of the practical limit of quantitation for determining the lower limit of the method. These optional procedures are required for the waiver consideration outlined in Section 12.0.

1.2 Principle. The purpose of these procedures is to determine bias and precision of a test method at the level of the applicable standard. The procedures involve (a) introducing known concentrations of an analyte or comparing the test method against a validated test method to determine the method's bias and (b) collecting multiple or collocated simultaneous samples to determine the method's precision.

1.2.1 Bias. Bias is established by comparing the method's results against a reference value and may be eliminated by employing a correction factor established from the data obtained during the validation test. An offset bias may be handled accordingly. Methods that have bias correction factors outside 0.7 to 1.3 are unacceptable. Validated method to proposed method comparisons, section 6.2, requires a more restrictive test of central tendency and a lower correction factor allowance of 0.90 to 1.10.

1.2.2 Precision. At the minimum, paired sampling systems shall be used to establish precision. The precision of the method at the level of the standard shall not be greater than 50 percent relative standard deviation. For a validated method to proposed method

equivalency comparisons, section 6.2, the analyst must demonstrate that the precision of the proposed test method is as precise as the validated method for acceptance.

2. Definitions

2.1 Negative bias. Bias resulting when the measured result is less than the "true" value.

2.2 Paired sampling system. A sampling system capable of obtaining two replicate samples that were collected as closely as possible in sampling time and sampling location.

2.3 Positive bias. Bias resulting when the measured result is greater than the "true" value.

2.4 Proposed method. The sampling and analytical methodology selected for field validation using the method described herein.

2.5 Quadruplet sampling system. A sampling system capable of obtaining four replicate samples that were collected as closely as possible in sampling time and sampling location.

2.6 Surrogate compound. A compound that serves as a model for the types of compounds being analyzed (i.e., similar chemical structure, properties, behavior). The model can be distinguished by the method from the compounds being analyzed.

3. Reference Material

The reference materials shall be obtained or prepared at the level of the standard. Additional runs with higher and lower reference material concentrations may be made to expand the applicable range of the method, in accordance with the ruggedness test procedures.

3.1 Exhaust Gas Tests. The analyst shall obtain a known concentration of the reference material (i.e., analyte of concern) from an independent source such as a specialty gas manufacturer, specialty chemical company, or commercial laboratory. A list of vendors may be obtained from EMTIC (see Section 1.1.1). The analyst should obtain the manufacturer's stability data of the analyte concentration and recommendations for recertification.

3.2 Other Waste Media Tests. The analyst shall obtain pure liquid components of the reference materials (i.e., analytes of concern) from an independent manufacturer and dilute them in the same type matrix as the source waste. The pure reference materials shall be certified by the manufacturer as to purity and shelf life. The accuracy of all diluted reference material concentrations shall be verified by comparing their response to independently-prepared materials (independently prepared in this case means prepared from pure components by a different analyst).

3.3 Surrogate Reference Materials. The analyst may use surrogate compounds, e.g., for highly toxic or reactive organic compounds, provided the analyst can demonstrate to the Administrator's satisfaction that the surrogate compound behaves as the analyte. A surrogate may be an isotope or one that contains a unique element (e.g., chlorine) that is not present in the source or a derivation of the toxic or reactive compound, if the derivative formation is part of the method's procedure.

Laboratory experiments or literature data may be used to show behavioral acceptability.

3.4 Isotopically Labeled Materials.

Isotope mixtures may contain the isotope and the natural analyte. For best results, the isotope labeled analyte concentration should be more than five times the natural concentration of the analyte.

4. EPA Performance Audit Material

4.1 To assess the method bias independently, the analyst shall use (in addition to the reference material) an EPA performance audit material, if it is available. The analyst may contact EMTIC (see section 1.1.1) to receive a list of currently available EPA audit materials. If the analyte is listed, the analyst should request the audit material at least 30 days before the validation test. If an EPA audit material is not available, request documentation from the validation report reviewing authority that the audit material is currently not available from EPA. Include this documentation with the field validation report.

4.2 The analyst shall sample and analyze the performance audit sample three times according to the instructions provided with the audit sample. The analyst shall submit the three results with the field validation report. Although no acceptance criteria are set for these performance audit results, the analyst and reviewing authority may use them to assess the relative error of sample recovery, sample preparation, and analytical procedures and then consider the relative error in evaluating the measured emissions.

5. Procedure for Determination of Bias and Precision in the Field

The analyst shall select one of the sampling approaches below to determine the bias and precision of the data. After analyzing the samples, the analyst shall calculate the bias and precision according to the procedure described in section 6.0. When sampling a stationary source, follow the probe placement procedures in section 5.4.

5.1 *Isotopic Spiking.* This approach shall be used only for methods that require mass spectrometry (MS) analysis. Bias and precision are calculated by procedures described in section 6.1.

5.1.1 *Number of Samples and Sampling Runs.* Collect a total of 12 replicate samples by either obtaining six sets of paired samples or three sets of quadruplet samples.

5.1.2 *Spiking Procedure.* Spike all 12 samples with the reference material at the level of the standard. Follow the appropriate spiking procedures listed below for the applicable waste medium.

5.1.2.1 *Exhaust Gas Testing.* The spike shall be introduced as close to the tip of the sampling probe as possible.

5.1.2.1.1 *Gaseous Reference Material with Sorbent or Impinger Sampling Trains.* Sample the reference material (in the laboratory or in the field) at a concentration which is close to the allowable concentration standard for the time required by the method, and then sample the gas stream for an equal amount of time. The time for sampling both the reference material and gas stream should be equal; however, the time should be adjusted to avoid sorbent breakthrough.

5.1.2.1.2 *Gaseous Reference Material with Sample Container (Bag or Canister).* Spike the sample containers after completion of each test run with an amount equal to the allowable concentration standard of the emission point. The final concentration of the reference material shall approximate the level of the emission concentration in the stack. The volume amount of reference material shall be less than 10 percent of the sample volume.

5.1.2.1.3 *Liquid and Solid Reference Material with Sorbent or Impinger Trains.* Spike the trains with an amount equal to the allowable concentration standard before sampling the stack gas. The spiking should be done in the field; however, it may be done in the laboratory.

5.1.2.1.4 *Liquid and Solid Reference Material with Sample Container (Bag or Canister).* Spike the containers at the completion of each test run with an amount equal to the level of the emission standard.

5.1.2.2 *Other Waste Media.* Spike the 12 replicate samples with the reference material either before or directly after sampling in the field.

5.2 *Comparison Against a Validated Test Method.* Bias and precision are calculated using the procedures described in section 6.2. This approach shall be used when a validated method is available and an alternative method is being proposed.

5.2.1 *Number of Samples and Sampling Runs.* Collect nine sets of replicate samples using a paired sampling system (a total of 18 samples) or four sets of replicate samples using a quadruplet sampling system (a total of 16 samples). In each sample set, the validated test method shall be used to collect and analyze half of the samples.

5.2.2 *Performance Audit Exception.* Conduct the performance audit as required in section 4.0 for the validated test method. Conducting a performance audit on the test method being evaluated is recommended.

5.3 *Analyte Spiking.* This approach shall be used when sections 5.1 and 5.2 are not applicable. Bias and precision are calculated using the procedures described in Section 6.3.

5.3.1 *Number of Samples and Sampling Runs.* Collect a total of 24 samples using the quadruplet sampling system (a total of 6 sets of replicate samples).

5.3.2 In each quadruplet set, spike half of the samples (two out of the four) with the reference material according to the applicable procedure in section 5.1.2.1 or 5.1.2.2.

5.4 Probe Placement and Arrangement for Stationary Source Stack or Duct Sampling.

The probes shall be placed in the same horizontal plane. For paired sample probes the arrangement should be that the probe tip is 2.5 cm from the outside edge of the other with a pitot tube on the outside of each probe. Other paired arrangements for the pitot tube may be acceptable. For quadruplet sampling probes, the tips should be in a 6.0 cm x 6.0 cm square area measured from the center line of the opening of the probe tip with a single pitot tube in the center or two pitot tubes with their location on either side of the probe tip configuration. An alternative arrangement should be proposed whenever the cross-sectional area

of the probe tip configuration is approximately 5 percent of the stack or duct cross-sectional area.

6. Calculations

Data resulting from the procedures specified in section 5.0 shall be treated as follows to determine bias, correction factors, relative standard deviations, precision, and data acceptance.

6.1 *Isotopic Spiking.* Analyze the data for isotopic spiking tests as outlined in sections 6.1.1 through 6.1.6.

6.1.1 Calculate the numerical value of the bias using the results from the analysis of the isotopically spiked field samples and the calculated value of the isotopically labeled spike:

$$B = CS - S_m \quad \text{Eq. 301-1}$$

where:

B = Bias at the spike level.

S_m = Mean of the measured values of the isotopically spiked samples.

CS = Calculated value of the isotopically labeled spike.

6.1.2 Calculate the standard deviation of the S_i values as follows:

$$SD = \sqrt{\frac{\sum (S_i - S_m)^2}{(n-1)}}$$

Eq. 301-2

where:

S_i = Measured value of the isotopically labeled analyte in the ith field sample,
n = Number of isotopically spiked samples,
12.

6.1.3. Calculate the standard deviation of the mean (SDM) as follows:

$$SDM = \frac{SD}{\sqrt{n}}$$

Eq. 301-3

$$t = \frac{|B|}{SDM}$$

6.1.4 Test the bias for statistical significance by calculating the t-statistic, Eq. 301-4

and compare it with the critical value of the two-sided t-distribution at the 95-percent confidence level and n-1 degrees of freedom. This critical value is 2.201 for the eleven degrees of freedom when the procedure specified in section 5.1.2 is followed. If the calculated t-value is greater than the critical value the bias is statistically significant and the analyst should proceed to evaluate the correction factor.

6.1.5 *Calculation of a Correction Factor.* If the t-test does not show that the bias is statistically significant, use all analytical results without correction and proceed to the precision evaluation. If the method's bias is

statistically significant, calculate the correction factor, CF, using the following equation:

$$CF = \frac{1}{1 + \frac{B}{CS}}$$

Eq. 301-5

If the CF is outside the range of 0.70 to 1.30, the data and method are considered unacceptable. For correction factors within the range, multiply all analytical results by the CF to obtain the final values.

6.1.6 *Calculation of the Relative Standard Deviation (Precision)*. Calculate the relative standard deviation as follows:

$$RSD = \left(\frac{SD}{S_m} \right) \times 100$$

Eq. 301-6

where S_m is the measured mean of the isotopically labeled spiked samples.

6.2 *Comparison with Validated Method*. Analyze the data for comparison with a validated method as outlined in sections 6.2.1 or 6.2.2, as appropriate. Conduct these procedures in order to determine if a proposed method produces results equivalent to a validated method. Make all necessary bias corrections for the validated method, as appropriate. If the proposed method fails either test, the method results are unacceptable, and conclude that the proposed method is not as precise or accurate as the validated method. For highly variable sources, additional precision checks may be necessary. The analyst should consult with the Administrator if a highly variable source is suspected.

6.2.1 *Paired Sampling Systems*.

6.2.1.1. *Precision*. Determine the acceptance of the proposed method's variance with respect to the variability of the validated method results. If a significant difference is determined, the proposed method and the results are rejected. Proposed methods demonstrating F-values equal to or less than the critical value have acceptable precision.

6.2.1.2 Calculate the variance of the proposed method, S_p^2 , and the variance of the validated method, S_v^2 , using the following equation:

$$S_{(p \text{ or } v)}^2 = SD^2 \quad \text{Eq. 301-7}$$

where:

SD_v = Standard deviation provided with the validated method,

SD_p = Standard deviation of the proposed method calculated using Equation 301-9a.

6.2.1.3 *The F-test*. Determine if the variance of the proposed method is significantly different from that of the validated method by calculating the F-value using the following equation:

$$F = \frac{S_p^2}{S_v^2}$$

Eq. 301-8

Compare the experimental F value with the critical value of F. The critical value is 1.0 when the procedure specified in section 5.2.1 for paired trains is followed. If the calculated F is greater than the critical value, the difference in precision is significant and the data and proposed method are unacceptable.

6.2.1.4 *Bias Analysis*. Test the bias for statistical significance by calculating the t-statistic and determine if the mean of the differences between the proposed method and the validated method is significant at the 80-percent confidence level. This procedure requires the standard deviation of the validated method, SD_v , to be known. Employ the value furnished with the method. If the standard deviation of the validated method is not available, the paired replicate sampling procedure may not be used. Determine the mean of the paired sample differences, d_m , and the standard deviation, SD_d , of the differences, d_i 's, using Equation 301-2 where: d_i replaces S_i , d_m replaces S_m . Calculate the standard deviation of the proposed method, SD_p , as follows:

$$SD_p = SD_d - SD_v \quad \text{Eq. 301-9a}$$

(If $SD_v > SD_d$, let $SD = SD_d/1.414$.) Calculate the value of the t-statistic using the following equation:

$$t = \frac{d_m}{\left(\frac{SD_p}{\sqrt{n}} \right)}$$

Eq. 301-9

where n is the total number of paired samples. For the procedure in section 5.2.1, n equals nine. Compare the calculated t-statistic with the corresponding value from the table of the t-statistic. When nine runs are conducted, as specified in section 5.2.1, the critical value of the t-statistic is 1.397 for eight degrees of freedom. If the calculated t-value is greater than the critical value the bias is statistically significant and the analyst should proceed to evaluate the correction factor.

6.2.1.5 *Calculation of a Correction Factor*.

If the statistical test cited above does not show a significant bias with respect to the reference method, assume that the proposed method is unbiased and use all analytical results without correction. If the method's bias is statistically significant, calculate the correction factor, CF, as follows:

$$CF = \frac{1}{1 + \frac{d_m}{V_m}}$$

Eq. 301-10

where V_m is the mean of the validated method's values.

Multiply all analytical results by CF to obtain the final values. The method results, and the method, are unacceptable if the correction factor is outside the range of 0.9 to 1.10.

6.2.2 *Quadruplet Replicate Sampling Systems*.

6.2.2.1 *Precision*. Determine the acceptance of the proposed method's variance with respect to the variability of the validated method results. If a significant difference is determined the proposed method and the results are rejected.

6.2.2.2 Calculate the variance of the proposed method, S_p^2 , using the following equation:

$$S^2 = \frac{\sum d_i^2}{2n}$$

Eq. 301-11

where the d_i 's are the differences between the validated method values and the proposed method values.

6.2.2.3 *The F-test*. Determine if the variance of the proposed method is more variable than that of the validated method by calculating the F-value using Equation 301-8. Compare the experimental F value with the critical value of F. The critical value is 1.0 when the procedure specified in section 5.2.2 for quadruplet trains is followed. The calculated F should be less than or equal to the critical value. If the difference in precision is significant the results and the proposed method are unacceptable.

6.2.2.4 *Bias Analysis*. Test the bias for statistical significance at the 80 percent confidence level by calculating the t-statistic. Determine the bias (mean of the differences between the proposed method and the validated method, d_m) and the standard deviation, SD_d , of the differences. Calculate the standard deviation of the differences, SD_d , using Equation 301-2 and substituting d_i for S_i . The following equation is used to calculate d_i :

$$d_i = \frac{(V_{1i} + V_{2i})}{2} - \frac{(P_{1i} + P_{2i})}{2}$$

Eq. 301-12

and: V_{1i} = First measured value of the validated method in the i th test sample.
 P_{1i} = First measured value of the proposed method in the i th test sample.

Calculate the t-statistic using Equation 301-9 where n is the total number of test sample differences (d_i). For the procedure in section 5.2.2, n equals four. Compare the

calculated t-statistic with the corresponding value from the table of the t-statistic and determine if the mean is significant at the 80-percent confidence level. When four runs are conducted, as specified in section 5.2.2, the critical value of the t-statistic is 1.638 for three degrees of freedom. If the calculated t-value is greater than the critical value the bias is statistically significant and the analyst should proceed to evaluate the correction factor.

6.2.2.5 Correction Factor Calculation. If the method's bias is statistically significant, calculate the correction factor, CF, using Equation 301-10. Multiply all analytical results by CF to obtain the final values. The method results, and the method, are unacceptable if the correction factor is outside the range of 0.9 to 1.10.

6.3 Analyte Spiking. Analyze the data for analyte spike testing as outlined in Sections 6.3.1 through 6.3.3.

6.3.1 Precision.

6.3.1.1 Spiked Samples. Calculate the difference, d_i , between the pairs of the spiked proposed method measurements for each replicate sample set. Determine the standard deviation (SD_s) of the spiked values using the following equation:

$$SD_s = \sqrt{\frac{\sum d_i^2}{2n}}$$

Eq. 301-13

where: n = Number of runs.

Calculate the relative standard deviation of the proposed spiked method using Equation 301-6 where S_m is the measured mean of the analyte spiked samples. The proposed method is unacceptable if the RSD is greater than 50 percent.

6.3.1.2 Unspiked Samples. Calculate the standard deviation of the unspiked values using Equation 301-13 and the relative standard deviation of the proposed unspiked method using Equation 301-6 where S_m is the measured mean of the analyte spiked samples. The RSD must be less than 50 percent.

6.3.2 Bias. Calculate the numerical value of the bias using the results from the analysis of the spiked field samples, the unspiked field samples, and the calculated value of the spike:

$$B = S_m - M_m - CS$$

Eq. 301-14

where: B = Bias at the spike level.

S_m = Mean of the spiked samples.

M_m = Mean of the unspiked samples.

CS = Calculated value of the spiked level.

6.3.2.1 Calculate the standard deviation of the mean using the following equation where SD_s and SD_u are the standard deviations of the spiked and unspiked sample values respectively as calculated using Equation 301-13.

$$SD = \sqrt{SD_s^2 + SD_u^2}$$

Eq. 301-15

6.3.2.2 Test the bias for statistical significance by calculating the t-statistic using Equation 301-4 and comparing it with the critical value of the two-sided t-distribution at the 95-percent confidence level and $n-1$ degrees of freedom. This critical value is 2.201 for the eleven degrees of freedom.

6.3.3 Calculation of a Correction Factor.

If the t-test shows that the bias is not statistically significant, use all analytical results without correction. If the method's bias is statistically significant, calculate the correction factor using Equation 301-5. Multiply all analytical results by CF to obtain the final values.

7. Ruggedness Testing (Optional)

7.1 Laboratory Evaluation.

7.1.1 Ruggedness testing is a useful and cost-effective laboratory study to determine the sensitivity of a method to certain parameters such as sample collection rate, interferant concentration, collecting medium temperature, or sample recovery temperature. This Section generally discusses the principle of the ruggedness test. A more detailed description is presented in citation 10 of Section 13.0.

7.1.2 In a ruggedness test, several variables are changed simultaneously rather than one variable at a time. This reduces the number of experiments required to evaluate the effect of a variable. For example, the effect of seven variables can be determined in eight experiments rather than 128 (W.J. Youden, Statistical Manual of the Association of Official Analytical Chemists, Association of Official Analytical Chemists, Washington, DC, 1975, pp. 33-36).

7.1.3 Data from ruggedness tests are helpful in extending the applicability of a test method to different source concentrations or source categories.

8. Procedure for Including Sample Stability in Bias and Precision Evaluations

8.1 Sample Stability.

8.1.1 The test method being evaluated must include procedures for sample storage and the time within which the collected samples shall be analyzed.

8.1.2 This section identifies the procedures for including the effect of storage time in bias and precision evaluations. The evaluation may be deleted if the test method specifies a time for sample storage.

8.2 Stability Test Design. The following procedures shall be conducted to identify the effect of storage times on analyte samples.

Store the samples according to the procedure specified in the test method. When using the analyte spiking procedures (section 5.3), the study should include equal numbers of spiked and unspiked samples.

8.2.1 Stack Emission Testing.

8.2.1.1 For sample container (bag or canister) and impinger sampling systems, sections 5.1 and 5.3, analyze six of the samples at the minimum storage time. Then analyze the same six samples at the maximum storage time.

8.2.1.2 For sorbent and impinger sampling systems, sections 5.1 and 5.3, that require extraction or digestion, extract or digest six of the samples at the minimum

storage time and extract or digest six other samples at the maximum storage time. Analyze an aliquot of the first six extracts (digestates) at both the minimum and maximum storage times. This will provide some freedom to analyze extract storage impacts.

8.2.1.3 For sorbent sampling systems, sections 5.1 and 5.3, that require thermal desorption, analyze six samples at the minimum storage time. Analyze another set of six samples at the maximum storage time.

8.2.1.4 For systems set up in accordance with section 5.2, the number of samples analyzed at the minimum and maximum storage times shall be half those collected (8 or 9). The procedures for samples requiring extraction or digestion should parallel those in section 8.2.1.

8.2.2 Other Waste Media Testing.

Analyze half of the replicate samples at the minimum storage time and the other half at the maximum storage time in order to identify the effect of storage times on analyte samples.

9. Procedure for Determination of Practical Limit of Quantitation (Optional)

9.1 Practical Limit of Quantitation.

9.1.1 The practical limit of quantitation (PLQ) is the lowest level above which quantitative results may be obtained with an acceptable degree of confidence. For this protocol, the PLQ is defined as 10 times the standard deviation, s_0 , at the blank level. This PLQ corresponds to an uncertainty of ± 30 percent at the 99-percent confidence level.

9.1.2 The PLQ will be used to establish the lower limit of the test method.

9.2 Procedure I for Estimating s_0 . This procedure is acceptable if the estimated PLQ is no more than twice the calculated PLQ. If the PLQ is greater than twice the calculated PLQ use Procedure II.

9.2.1 Estimate the PLQ and prepare a test standard at this level. The test standard could consist of a dilution of the reference material described in section 3.0.

9.2.2 Using the normal sampling and analytical procedures for the method, sample and analyze this standard at least seven times in the laboratory.

9.2.3 Calculate the standard deviation, s_0 , of the measured values.

9.2.4 Calculate the PLQ as 10 times s_0 .

9.3 Procedure II for Estimating s_0 . This procedure is to be used if the estimated PLQ is more than twice the calculated PLQ.

9.3.1 Prepare two additional standards at concentration levels lower than the standard used in Procedure I.

9.3.2 Sample and analyze each of these standards at least seven times.

9.3.3 Calculate the standard deviation for each concentration level.

9.3.4 Plot the standard deviations of the three test standards as a function of the standard concentrations.

9.3.5 Draw a best-fit straight line through the data points and extrapolate to zero concentration. The standard deviation at zero concentration is s_0 .

9.3.6 Calculate the PLQ as 10 times s_0 .

10.0 Field Validation Report Requirements

The field validation report shall include a discussion of the regulatory objectives for the

testing which describe the reasons for the test, applicable emission limits, and a description of the source. In addition, validation results shall include:

10.1 Summary of the results and calculations shown in section 6.0.

10.2 Reference material certification and value(s).

10.3 Performance audit results or letter from the reviewing authority stating the audit material is currently not available.

10.4 Laboratory demonstration of the quality of the spiking system.

10.5 Discussion of laboratory evaluations.

10.6 Discussion of field sampling.

10.7 Discussion of sample preparations and analysis.

10.8 Storage times of samples (and extracts, if applicable).

10.9 Reasons for eliminating any results.

11. Followup Testing

The correction factor calculated in section 6.0 shall be used to adjust the sample concentrations in all followup tests conducted at the same source. These tests shall consist of at least three replicate samples, and the average shall be used to determine the pollutant concentration. The number of samples to be collected and analyzed shall be as follows, depending on the validated method precision level:

11.1 Validated relative standard deviation (RSD) ≤ 15 Percent. Three replicate samples.

11.2 Validated RSD ≤ 30 Percent. Six replicate samples.

11.3 Validated RSD ≤ 50 Percent. Nine replicate samples.

11.4 Equivalent method. Three replicate samples.

12. Procedure for Obtaining a Waiver

12.1 *Waivers.* These procedures may be waived or a less rigorous protocol may be granted for site-specific applications. The following are three example situations for which a waiver may be considered.

12.1.1 *"Similar" Sources.* If the test method has been validated previously at a "similar" source, the procedures may be waived provided the requester can demonstrate to the satisfaction of the Administrator that the sources are "similar." The methods's applicability to the "similar" source may be demonstrated by conducting a ruggedness test as described in section 6.0.

12.1.2 *"Documented" Methods.* In some cases, bias and precision may have been documented through laboratory tests or protocols different from this method. If the analyst can demonstrate to the satisfaction of the Administrator that the bias and precision apply to a particular application, the Administrator may waive these procedures or parts of the procedures.

12.1.3 *"Conditional" Test Methods.* When the method has been demonstrated to be valid at several sources, the analyst may seek a "conditional" method designation from the Administrator. "Conditional" method status provides an automatic waiver from the procedures provided the test method is used within the stated applicability.

12.2 *Application for Waiver.* In general, the requester shall provide a thorough

description of the test method, the intended application, and results of any validation or other supporting documents. Because of the many potential situations in which the Administrator may grant a waiver, it is neither possible nor desirable to prescribe the exact criteria for a waiver. At a minimum, the requester is responsible for providing the following.

12.2.1 A clearly written test method, preferably in the format of 40 CFR part 60, appendix A Test Methods. The method must include an applicability statement, concentration range, precision, bias (accuracy), and time in which samples must be analyzed.

12.2.2 Summaries (see section 10.0) of previous validation tests or other supporting documents. If a different procedure from that described in this method was used, the requester shall provide appropriate documents substantiating (to the satisfaction of the Administrator) the bias and precision values.

12.2.3 Results of testing conducted with respect to sections 7.0, 8.0, and 9.0.

12.2.3 Discussion of the applicability statement and arguments for approval of the waiver. This discussion should address as applicable the following: Applicable regulation, emission standards, effluent characteristics, and process operations.

12.3 *Requests for Waiver.* Each request shall be in writing and signed by the analyst. Submit requests to the Director, OAQPS, Technical Support Division, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

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APPENDIX B TO PART 63—SOURCES DEFINED FOR EARLY REDUCTION PROVISIONS

Source	Location of definition
1. Organic Process Equipment in Volatile Hazardous Air Pollutant Service at Chemical Plants and Other Designated Facilities.	56 FR 9315, March 8, 1991, Announcement of Negotiated Rule-making
a. All valves in gas or light liquid service within a process unit	
b. All pumps in light liquid service within a process unit	
c. All connectors in gas or light liquid service within a process unit	
d. Each compressor	
e. Each product accumulator vessel	
f. Each agitator	
g. Each pressure relief device	
Each open-ended valve or line	
i. Each sampling connection system	
j. Each instrumentation system	
k. Each pump, valve, or connector in heavy liquid service	
l. Each closed vent system and control device	

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Part III

Department of Labor

Employment and Training Administration

20 CFR Part 626, et al.

Job Training Partnership Act; Final Rule

DEPARTMENT OF LABOR**Employment and Training Administration**

20 CFR Parts 626, 627, 628, 629, 630, 631, 637

RIN 1205-AA-95

Job Training Partnership Act**AGENCY:** Employment and Training Administration, Labor.**ACTION:** Interim final rule.

SUMMARY: The Employment and Training Administration (ETA) of the Department of Labor amends the Job Training Partnership Act (JTPA) regulations to implement the Job Training Reform Amendments of 1992. As a result of these interim final regulations, the Department intends for the direction and focus of the JTPA training and employment programs to be on improving the targeting of JTPA services to those facing serious barriers to employment, enhancing the quality of services provided and program outcomes, strengthening fiscal and program accountability and the linkage between the services provided and local labor market needs, and fostering a comprehensive and coherent system of human resource services.

EFFECTIVE DATES: The effective date for this interim final rule is December 18, 1992 through June 1, 1993. The Department will issue a final rule on or before the last effective date of this interim rule and after it has reviewed public comments.

Comments: Written comments are invited on this interim final rule. Such comments will be considered at any time up to the publication of the final rule. Whenever possible, commenters are requested to specifically identify the topic or section(s) of the rule that are subject to comment. To be most useful in the development of the final rule, however, comments in response to this notice should be received on or before February 12, 1993.

ADDRESSES: Written comments shall be mailed to the Assistant Secretary for Employment and Training, Department of Labor, room N-4703, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Mr. Hugh Davies, Acting Director, Office of Employment and Training Programs. Commenters wishing acknowledgment of receipt of their comments shall submit them by certified mail, return receipt requested.

Comments received will be available for public inspection during normal business hours at the Office of Employment and Training Programs,

U.S. Department of Labor, 200 Constitution Avenue NW., room N-4469, Washington, DC 20210. Persons who need assistance to review the comments will be provided with appropriate aids such as readers or print magnifiers. To schedule an appointment, call (202) 219-6825 (VOICE) or (202) 326-2577 (TDD).

Copies of this notice of interim final rulemaking are available in the following formats: Electronic file on computer disk; and audio tape. They may be obtained at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Hugh Davies, Acting Director, Office of Employment and Training Programs. Telephone: (202) 219-5580 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The JTPA was enacted in 1982 principally to establish a new program and delivery system for training and related assistance for economically disadvantaged youth and adults leading to permanent, private sector employment. Since the original enactment, the essential structure and design of programs and activities under titles I and II of JTPA have remained substantially the same. These programs have an impressive record of placing participants in jobs.

Over the past few years, the JTPA program has been the subject of extensive review and discussions. This process was largely initiated with an examination of the JTPA and its future by a JTPA Advisory Committee to the Secretary of Labor, has included a multi-year national impact study, and extensive deliberations by the Congress. Throughout this review process there have been constructive comments and suggestions from a wide variety of parties, including business leaders, States, service delivery areas (SDA's), labor organizations, community-based organizations (CBO's), the Department of Labor Office of the Inspector General (OIG), the General Accounting Office, and others with an interest in improving JTPA. Important topics of interest included how to identify and to enroll those most in need of JTPA services, an emphasis on ways in which the program can maximize the delivery and effectiveness of training resources, and the broad areas of program administration improvements and program and fiscal integrity.

The culmination of this activity was the enactment of the Job Training Reform Amendments of 1992 on September 7, 1992, Public Law 102-367 (hereinafter the "Job Training Amendments of 1992", or the "Amendments"). Through these

changes, the direction of JTPA will be focused on the provision of quality training and assistance to the most needy by a well-administered and fiscally sound program. With cooperation among the Federal, State, and local government levels, the partners in the private sector, education, labor, and community agencies, the JTPA system will be better able to respond to the nation's changing workforce needs.

Background

On October 13, 1982, the President signed into law the Job Training Partnership Act, Public Law 97-300 (JTPA or the Act).

The stated purpose of the Act was to establish programs to prepare youth and unskilled adults for entry into the labor force and to afford job training to those economically disadvantaged individuals and others facing serious barriers to employment who are in special need of such training to obtain productive employment.

Title I of the Act sets forth general requirements for programs, as well as some requirements for State and local operation of programs. Title II provides requirements for State and local operation of adult and youth programs for the economically disadvantaged. Title III of the Act provides for operation of State and substate programs of employment and training assistance for dislocated workers. Title IV provides requirements for special programs for targeted groups, such as Native Americans, migrant and seasonal farmworkers and veterans, as well as for the Job Corps and other specialized programs. Title V provides incentives to States to reduce welfare dependency and increase self sufficiency for absent parents of children receiving aid to families with dependent children and blind or disabled individuals receiving supplemental security income under Title XVI of the Social Security Act.

Prior Actions

The Department is conducting the development of the final rule in an open and public manner. Since the enactment of the Amendments, Department officials have responded to numerous invitations to discuss the Amendments with organizations interested in the Amendments and proposed regulatory action. Additionally, a group of technical experts has offered suggestions to the Department on the proposed areas for regulatory action.

On September 10, 1992, the Department published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register inviting

comments from interested parties regarding proposed or recommended regulatory actions to be taken by the Department.

A total of 162 letters were received by the end of the ANPR comment period. A total of 277 have been received to date and the Department continues to receive comments. In general, the comments received after the official comment period are consistent with those discussed in the text below. Sources were as follows: State JTPA Liaisons and officials (48); private contractors (44); service delivery areas (27); private industry councils (30); public interest groups (20); community-based organizations (13); State education agencies (10); Federal agencies (4); State job training coordinating councils (2); unions (3); service providers (3); private citizens (8); Congress (4); and others (3). Additionally, 54 comments were received from JTPA Section 401 and 402 organizations (Indians and Native Americans and migrant and seasonal farmworkers).

The Department fully considered these comments and addresses the issues they raised in the following discussion.

Approach to Rulemaking

It is the Department's intent in developing these regulations to continue to provide substantial responsibility and discretion to States and local areas in developing policy and in implementing procedures for JTPA programs. This State responsibility is key to the overall success of JTPA. Thus, in many instances in these interim final regulations, responsibility for certain decisions is vested in the State, and through the State, in the SDA's. For example, where definitions of terms are not included, it is intended that the State or SDA administrative entity will define such terms. The Department intends to limit regulations only to those areas in which they are specifically required by the Act or identified by the Department or the public as necessary to provide guidance and clarification, or essential to further the purposes of the Act. Additionally, the Department fully intends to provide strong oversight and monitoring of JTPA programs, in conjunction with strengthened State and local oversight and monitoring. It is through the monitoring of the implementation of the Amendments and these regulations, rather than through promulgation of prescriptive regulations, that the Department, working with the States and service delivery and substate areas, will ensure effective program operations.

The Department has sought to strike a balance in these interim final regulations in terms of depth and breadth. Of all consultations and comments the Department has received, about half express interest in having the Department be more detailed in the regulations, and the other half prefer that the Department provide minimal guidance. The Department intends that the regulations be sufficiently clear so that all parties with an interest in JTPA understand both the requirements and the areas of flexibility provided under in the program.

This interim final rule is not a stand-alone document; the companion document is the JTPA, as amended. In several instances, however, portions of the Act are repeated to make the interim final rule user-friendly and to facilitate its use as a reference tool.

In addition to the 1992 JTPA Amendments, Section 4467 of the National Defense Authorization Act for Fiscal Year 1993 (Defense Authorization Act) amends certain provisions of title III of JTPA. The interim final regulations in 20 CFR part 631 provide for limited modifications to existing title III regulations as required by these amendments.

It is the Department's plan to separately issue reporting instructions and instructions for establishing and adjusting title II performance standards. Both sets of instructions will be published as notices for comment in the *Federal Register*. Copies will be made available to States by issuance of Training and Employment Information Notices (TEINS).

The Department also plans to separately issue proposed revisions to the regulations for title IV, part A, the Employment and Training Programs for Native Americans and Migrant and Seasonal Farmworkers, and for title IV, part B, the Job Corps. When it does, the contents of the regulations as reflected herein may change.

The Department plans to issue Solicitations for Grant Applications (SGAs) for the Youth Fair Chance, Replication, and MicroEnterprise grants authorized by the Amendments at title IV, parts D, H, and I, respectively. The SGAs will elaborate on the requirements of these programs.

The Department of Labor is issuing interim final regulations with a request for comments to implement provisions of the Job Training Reform Amendments of 1992, which amends portions of the Job Training Partnership Act (JTPA). These interim final regulations comply with the statutory provision that final regulations be issued not later than December 18, 1992. At the same time

they provide the opportunity for comment. Modification of the JTPA regulations is necessary to incorporate the revisions contained in the amended legislation. It is clearly the intent of Congress that these amendments be implemented with the JTPA Program Year that begins on July 1, 1993. Planning and implementation actions which must be undertaken prior to the publication of final regulations shall be consistent with these interim final regulations which provide a legal basis for such actions.

The Department understands that States and SDA's must begin planning as soon as possible to meet the statutory effective date of July 1, 1993, and expects that these interim final regulations will be used for planning. In drafting these interim final regulations, the Department has carefully considered the ANPR comments and has extensively consulted both within and outside of the Department. The Department is providing a full and open comment process on these interim final regulations and will respond to comments and make revisions, as appropriate, in the final rule.

The Department intends to fully consider any comments received on this interim final rule and to issue a final rule in a timely fashion on or before June 1, 1993, the effective date for this interim final rule.

Framework for Implementation of the Amendments

As discussed in the ANPR, the Department believes that certain principles are central to the JTPA and to the implementation of the Amendments. The following principles are central to the Department's efforts to oversee and guide the implementation process, including the development of these interim final and subsequent final regulations.

- An enhanced role for the private sector is key to an effective JTPA program. Building on their significant contributions to date, the Department wants to ensure that private sector leaders participate in JTPA private industry councils (PIC's)—particularly in the design and operation of JTPA programs. This includes participation in setting high standards for the content and acquisition of skills through training and linking training with job opportunities in the local and national labor market. The Department also wishes to ensure that the PIC's are full partners in the JTPA public-private planning and delivery system.

- Training services provided by JTPA should be of the highest quality and responsive to the needs of the

individual participants and the labor market. This is a cornerstone of the Amendments, and is consistent with the findings and recommendations of the JTPA Advisory Committee, the Secretary's Commission on Achieving Necessary Skills (SCANS), and the concepts embodied in the President's Job Training 2000 proposal. In issuing regulations, the Department wants to establish a framework under which the processes used to assess the skill levels and service needs of individuals and under which participants are assigned to and receive training services—especially services required by the Act—will be most effective and efficient. At the same time, the Department recognizes that the JTPA system, within the framework of the Act and regulations, must be flexible and able to design and to deliver programs to meet local job training needs.

- The JTPA performance standards based on program outcomes will be the basic measure of the accomplishments of the JTPA system. In setting performance standards, the Department will encourage interventions, program strategies, and arrangements that provide appropriate services to participants, enhance opportunities for long-term employment, and increase participant earnings potential. The Department will also pursue cost-effective reporting methods that quantify the results of these efforts.

- JTPA programs must meet the highest possible standards for the use of public funds. Substantial attention was given in the Amendments to strengthening program management, procurement, and fiscal and accountability standards for the JTPA system. The Department intends to advance fully these goals and to ensure the implementation of the requirements contained in the Amendments relating to these areas.

- JTPA and other human resource programs must have a workable system of relationships to jointly serve their participants. There are a number of educational and training programs that provide services to disadvantaged individuals in addition to the JTPA program. It is unlikely that any single program will have the capacity to meet all the training, educational, and service needs of a participant. The Department is proposing regulations that foster the development of joint relationships among programs in order to provide high quality comprehensive services to individuals and to increase the capability to JTPA programs in conjunction with other human resource programs to maximize quality services to individuals.

Format of these Interim Final Regulations

The structure, organization, and numbering of the JTPA regulations have been revised to accommodate the Amendments. Throughout this document, JTPA or the Act refers to the Job Training Partnership Act, as amended (29 U.S.C. 1501 *et seq.*); Department or DOL refers to the U.S. Department of Labor; and Secretary refers to the Secretary of the U.S. Department of Labor or the Secretary's designated representative(s). As used in these interim final regulations, the term "title" refers to titles of the Job Training Partnership Act unless the text specifically refers to another statute. The terms "section", "part", and "subpart" refer to sections, parts, and subparts of these interim final regulations unless the text specifically refers to another document.

Program Coordination

Several States have urged ETA to consider whether certain regulatory provisions would inhibit coordination, and whether the Secretary should establish a process to waive such regulatory provisions. The Department believes it must adhere to certain criteria in establishing regulatory provisions, including adhering to the statute, promoting coordination, targeting JTPA services to the hard to serve, and promoting basic and occupational skills training. The Department requests comments to identify particular provisions of the rules which might discourage coordination and actions the Department might take in this regard including the establishment of a waiver procedure.

As specified at Part 626—Introduction to the Regulations Under the Job Training Partnership Act, part 627 applies to all programs under titles I, II, and III of the Act, except where noted, and part 628 generally applies to title II programs. Parts 629 and 630 are reserved for future use. Part 631 continues to apply to title III programs and part 637 has been revised for the Title V Jobs for Employable Dependent Individuals (JEDI) program. Therefore, various sections that previously appeared in parts 627, 628, 629, and 630 have been shifted to parts 627 and 628.

A new § 626.3 has been added to specify the purpose of these interim final regulations and to identify the entities to which these regulations apply.

Definitions

Comments on the ANPR regarding definition of terms were directed to

clarifying ambiguities and the need for common definitions applying across JTPA titles and other Federal programs.

In response to these comments, and in addition to new and revised definitions contained in section 4 of the Act, § 626.5 contains definitions of terms used in these regulations as well as the Act. Definitions have been provided for terms such as: Accrued expenditures, awarding agency, capacity building, commercial organizations, commercially available off-the-shelf training package, contractor, family, family income, funding period, Governor, grant, grantee, individual service strategy, obligations, program year, recipient, service provider, State, stand-in costs, subgrant, subgrantee, subrecipient, technical assistance, and vendor.

Commenters requested that the Department clarify what "appropriate grade level" means for purposes of the requirement of section 263(b). The Department has chosen not to define this term because it is properly a matter for the Governor to determine as part of State and local educational policy.

The definition of offender is found in the Act, and is broader than the definition used for reporting. For reporting purposes, offender has been redefined to exclude those arrested or convicted of misdemeanors in order to better represent a true "barrier to employment" for purposes of defining a hard-to-serve group and adjusting performance standards. This is intended to reflect a concern that, for performance standard adjustment purposes, the term connotes a more serious barrier to labor market participation. The Department has chosen to retain the statutory definition for the purpose of identifying hard-to-serve individuals. This is being done in order to include individuals who may not meet the reporting definition such as youthful offenders who may, for instance, be in a pre-trial intervention program and therefore are not felons. The Department seeks comments on whether this approach will cause a problem in the administration and operation of JTPA programs and alternative approaches that may be adopted.

Prior to the JTPA Amendments of 1992, the term "family" was not defined in the statute. The definition of "family" has been the subject of much recent discussion, in particular as that term related to establishing "family-of-one" criteria for the purposes of income eligibility determinations for receipt of JTPA services. The Department issued a policy interpretation on the matter to all Governors via Training and Employment Guidance Letter (TEGL)

No. 5-89 (April 5, 1989) and TEGL No. 5-89, Change 1 (September 5, 1990). The Department's interpretation established a "basic" definition of the term "family", while maintaining the considerable latitude of the Governor to interpret "family" consistent with the "basic" definition, under the provisions of § 627.1. In light of the Department's interpretation, the various States reviewed their policies and, where necessary, revised their policies to conform to the Department's interpretation. With the inclusion of a statutory definition of "family" in the JTPA Amendments of 1992, the Department reviewed its guidance to the States in the development of the interim final rule. We believe that the Department's interpretation is not inconsistent with the statutory definition. With minor exceptions, we do not anticipate that the statutory definition will require any significant revision of current State policies. The interim final rule indicates that the Governor may make interpretations in the context of the definition of "family" concerning how "dependent children" are defined for JTPA programs. The interim final rule also defines the term "living in a single residence" with other family members to differentiate between temporary, voluntary residence elsewhere (which is included), and as opposed to involuntary, temporary residence elsewhere (which is excluded).

In specifying that these regulations flow through to JTPA subrecipients, and in redefining the term "subrecipient" in § 626.5, among other things it is the Department's intent to make clear that the term "subrecipient" as used in these regulations does not apply to entities such as vendors or individuals enrolled in JTPA programs. The Department intends to apply the standard Federal Government-wide distinctions between subrecipients and vendors that already exist in the audit requirements of Office of Management and Budget (OMB) Circulars A-128 and A-133, as well as the distinctions and definitions of the OMB Circular A-102 Common Rule and other Federal Government-wide requirements applicable to grant programs (see 29 CFR parts 93, 96, 97 and 98). Requirements applicable to vendors are those requirements and conditions contained in the individual contract, purchase order, or other payment arrangements.

In a May, 1992 document titled "Questions and Answers on OMB Circular A-133," developed by the President's Council on Integrity and Efficiency and distributed by the Employment and Training

Administration (ETA) to State JTPA Liaisons on July 27, 1992, as an attachment to Training and Employment Information Notice No. 2-92, the distinction between subrecipients and vendors is described. That document provides, in part, the following:

A subrecipient is an entity that receives Federal assistance passed through from a prime recipient or another subrecipient to carry out or administer a program. Distinguishing characteristics of a subrecipient include items such as:

- Determining eligibility for assistance;
- Performance measured against meeting the objectives of the program;
- Responsibility for programmatic decisionmaking;
- Responsibility for applicable program compliance requirements; and
- Use of the funds passed through to carry out a program of the subentity as compared to providing goods or services for a program of the prime recipient.

A vendor is an entity responsible for providing generally required goods or services related to the administrative support of the Federal award. These goods or services may be for the recipient's or subrecipient's own use or for the use of participants in the program. Distinguishing characteristics of a vendor include items such as:

- Providing the goods and services within normal business operations;
- Providing similar goods or services to many different purchasers;
- Operating in a competitive environment; and
- Program compliance requirements do not pertain to the goods or services provided.

Similar guidance was also published by OMB in the *Federal Register* on November 13, 1987, "Questions and Answers on OMB Circular A-128," questions 21 and 22.

In making this distinction between a subrecipient and a vendor, the Department has a concern that some JTPA entities may attempt to use the "vendor" label inappropriately to avoid certain JTPA requirements including audits, cost classification, procurement and cost limitations. States, SDA's, and substate grantees (SSG's) are encouraged to review carefully these distinctions, to ensure that such distinctions are clear from an operational standpoint, and ensure the proper application of these terms.

The major changes in Part 627—General Provisions Governing Programs Under the Act are as follows.

Governor/Secretary Agreement

Language has been included in § 627.200 to require the publication of rules, guidelines, interpretations, and definitions adopted by the Governor.

Public Service Employment Prohibition

Section 627.205 remains unchanged except for extending the prohibition to include title II-C funds.

Nondiscrimination and Equal Opportunity

The Job Training Amendments of 1992 amended section 167 of the Act to require the Secretary to issue final regulations which would clarify the application of the nondiscrimination and equal opportunity provisions of the JTPA and provide uniform procedures for implementing these provisions. On October 19, 1992, the Directorate of Civil Rights, the DOL agency responsible for enforcing the various Federal nondiscrimination and equal opportunity statutes applicable to federally assisted programs, issued a notice of proposed rulemaking to implement the nondiscrimination and equal opportunity requirements of the JTPA (29 CFR part 34). Throughout these interim final JTPA regulations, all of the Department's nondiscrimination and equal opportunity regulations (29 CFR parts 31, 32, and proposed 34) are cited since they are all applicable to JTPA federally assisted programs. In order to eliminate the burden of complying with overlapping regulatory requirements, the proposed 29 CFR part 34 would provide that compliance by JTPA recipients with part 34 would constitute compliance with the Department's title VI regulations (29 CFR part 31) and with specified portions of the Department's section 504 federally assisted program regulations. (29 CFR part 32, subparts A, C, and E).

Relocation

Section 141(c) of the Act was substantially revised to prohibit the use of JTPA funds to induce or to encourage the relocation of a company when such relocation results in the loss of employment of any employee of the company at the original site. This subsection also prohibits certain assistance to any relocating company for the first 120 days after the company commences operations at the new or expanded location, if the relocation results in an employee's job loss at the original site. If the Secretary finds that the State, SDA, or SSG has violated either provision, fines are to be levied equal to double the amount expended. If the violator demonstrates that it neither knew nor reasonably could have

known (after an inquiry undertaken with due diligence) that funds it provided were expended in violation of these provisions, only the amount expended is to be repaid.

The comments received on these provisions expressed concern in several areas, including how SDA's may be certain whether a company is relocating. One scenario was cited where a company opens in a new area under a different name with plans to close the original facility after a year, when the second location is fully operational. Another situation was raised where a company is expanding a location at the expense of another.

Section 627.215(d) sets forth a requirement to document a pre-award review which is intended to address the concerns discussed above. The review is to be conducted and documented by the SDA or SSG jointly with the establishment seeking JTPA assistance. This review should include information such as the company official providing the information, other company names, and whether the company is relocating, or expanding, from another area with a resulting loss in employment. In addition, the SDA or SSG should include contract provisions specifically reflecting the statutory prohibition. Although other commenters requested that the terms "encourage" and "induce" be clarified so as not to impact on job development activities, the Department believes that these terms are addressed sufficiently under the prohibition on economic development activities at § 627.225(a), and that the use of pre-award review questions will assist in establishing whether a company's plans to relocate will mean a loss of employment at another location.

Guidance on the Issue of Duplicate and Overlapping Payments Among Federal, State, and Local Programs, Including Pell Grants

Section 627.220 clarifies the interpretation of sections 141(b) and 107(b) of the Act. This section also provides guidance for coordination with title IV of the Higher Education Act, and with the new coordination provisions at sections 205 and 265 of the Act, as amended, which require SDA's to coordinate with other programs to enhance the provision of services.

Several commenters noted that the purpose of the linkages and coordination requirements was to preclude duplicate or overlapping payments among Federal, State, and local programs to participants and training institutions and to ensure that

the best mix of programs and funds is available to the JTPA participant.

In response to these comments, § 627.220 assigns responsibility to the SDA's to establish coordination procedures, including provisions for the school's financial aid officer to share information on financial resources for participants with the SDA's, and contractual safeguards to prevent duplication or overlap of services and funding among the programs. The SDA is also to provide to an educational institution's financial aid officer the names of JTPA participants who are to attend the educational institution and for whom JTPA payments will be made.

JTPA program operators should be aware that the use of certain contracting methods, particularly contracts for classroom sized projects and fixed unit performance-based contracts, affect how educational institutions are permitted to calculate the Cost of Attendance (COA) for Pell Grants. An institution can include a tuition and fee charge for calculating the Pell Grant COA only when contracts or agreements specify the tuition and fees which the SDA will pay for each student (i.e., individual referrals). Agreements which do not allow tuition and fees to be included in the Pell COA are:

(A) Blanket agreements which do not specify an individual amount to be paid by the SDA for tuition and fees but may include a number of students to be trained and an amount of compensation to be paid to the school.

(B) Performance-based contracts in which some portion of the tuition payment is contingent upon criteria such as the student's completion of the training, placement in a job, or retention in a job.

Section 627.220 also describes the importance of a coordinated approach in developing the Individual Service Strategy (ISS) so that the financial needs and resources of the participant are adequately addressed. The participant's ISS should ensure the optimum mix and coordination of Federal, State, and local programs and funding resources for the participant. The SDA's assessment of the participant's financial capability for participating in a program, as well as coordination and effective use of information and services among programs, is essential to effective program administration and prudent use of funds.

For purposes of coordinating financial resources, it is suggested, where appropriate, that Pell Grant eligibility be established during the objective assessment process, to the extent practicable, rather than after obligation of JTPA funds. These interim final

regulations do not specify the portion of the participant's Pell Grant that should defray tuition costs as opposed to other educational expenses.

Employment Generating, Economic Development, and Other Activities

Section 141(q) of the Act, as amended, prohibits employment generating activities (EGA) with JTPA funds (including both grants and program income). Included in the prohibition are economic development activities, revolving loan funds, capitalization of businesses, contract bidding resource centers, and similar activities. However, as several commenters pointed out, JTPA's role in assisting participants is intimately tied to economic development, including economic development agency representation on the PIC. JTPA programs provide trained workers to new and expanding businesses and, in this capacity, a partnership with local economic development efforts is helpful.

Section 627.225(b) indicates that SDA staff may work with economic development agencies and participate on economic development boards and commissions to provide information about JTPA. Such participation may also assist SDA staff make informed decisions about community job training needs and the future direction of local JTPA training. In addition, the prohibition on EGA should not be taken to prohibit ordinary employer outreach and job development activities.

Displacement

The provisions in the regulations have not been substantially changed from the prior § 629.4 and closely reflect the provisions of section 143(b) of the Act.

On-the-Job Training (OJT)

Over 30 comments were received on OJT. Comments focused on extraordinary costs, reverse referrals, and temporary employment. (Youth OJT is discussed in part 628.)

Section 141(g) of the Act was amended to add new requirements for the provisions of on-the-job training (OJT) under the Act. These new regulations are applicable to all programs conducted under JTPA.

OJT is an important training activity in JTPA. Employers provide necessary training for regular jobs through a "hire first, train later" strategy, with participants who successfully complete OJT retained in permanent employment.

Several issues and questions arising from DOL (ETA and the OIG) and the GAO oversight activities are addressed, including practices such as reverse

referrals, temporary employment, and extraordinary training costs.

Each OJT contract is to specify the type and duration of training to be developed and other services to be provided in order to ensure that proposed costs are reasonable.

OJT is a training option meant to be conducted in the highest skill occupations appropriate for the eligible participant. It is not subsidized employment for low-skill occupations which need very little training time. OJT is only appropriate for the length of time necessary to be trained in the specific job. The regulations limit the use of JTPA funds for OJT to not more than 6 months. However, the period of reimbursement may be longer than 6 months for participants with special needs, provided the total training hours reimbursed are less than 500 hours.

Each training opportunity should be structured to meet the specific training needs of a participant. The duration should reflect both training needs that must be met for the job and the experience and the background of the participant. OJT agreements are to specify training content.

Employers who exhibit a pattern of failing to provide participants with continued long-term employment (minimum of 6 months), or who provide wages and benefits not at the same level as other employees similarly employed, both during the OJT period and upon completion, will be ineligible for additional OJT contracts. For example, an employer which has entered into 2 OJT contracts, trains 8 participants under the first and 4 under the second, and then terminates, without cause, 5 at the conclusion of the first contract and another 2 at the conclusion of the second, may be determined to exhibit a pattern of failing to provide continued long-term employment. In addition, an employer which is an OJT contractor and has entered into 3 OJT contracts and trained 15 participants at a starting wage of \$6.50 an hour and, subsequent to the conclusion of the OJT contracts, reduces, without cause, the salaries of the all but 3 of the former JTPA participants to \$5.50 an hour, may be determined to exhibit a pattern of failing to provide continued employment with wages at the same level as similarly situated employees. Again, these cases are only intended as examples, and not intended to set a standard. The Governor will be expected to set standards.

The Department is developing a technical assistance guide to provide additional guidance on OJT, including such areas as appropriate occupational skill levels for OJT agreements,

occupations, ratio of trainees to total staff and to supervisory staff. Guidance will also be provided on how to use available reference materials including, but not limited to, the "Dictionary of Occupational Titles" (DOT) codes and participant histories in determining training lengths.

It is expected that the amended legislation, these interim final regulations, technical assistance, and Department of Labor monitoring will help to eliminate the problems that were identified in OJT during the recent oversight and monitoring activities.

The term "reverse referrals" describes situations where employers refer individuals whom they have already decided to hire to the SDA. The SDA, in turn, refers the individuals back to the employers to receive OJT with the employers receiving payments from JTPA.

"Temporary employment" occurs when the OJT participant is actually employed by a temporary agency and not the worksite employer where on-site training is received. Some worksite employers use the temporary agency for all new employees for a probationary or try-out period.

"Extraordinary training costs" are those costs incurred by the employer as a result of hiring OJT participants which are over and above the costs normally incurred in hiring and training employees without the assistance of JTPA. Extraordinary costs represent the additional burden borne by employers in training JTPA participants, and the lower initial productivity of such participants.

The major comments were on the following areas:

Length of training. Some commenters requested clarification on the 6-month and 499-hour limitations on OJT. Some recommended that the Specific Vocational Preparation (SVP) be used instead of DOT codes. One mentioned that OJT duration for high-tech occupations cannot be limited to 6 months.

Section 627.240(b)(2) encourages OJT for higher-skill occupations requiring long-term training as appropriate for the participant, but clarifies that JTPA funds may only be used to reimburse employers for 6 months. However, the period of reimbursement may be longer than 6 months for participants with special needs (such as the disabled) who participate on a less-than-full-time basis, provided the total OJT training hours reimbursed are less than 500 hours. When other training, such as classroom training, is linked with OJT, the time in such related training is not included within the 6-month limitation

unless the participant receives a wage from the employer for such time and the employer is reimbursed a portion of that wage as OJT. Further, the use of allowable recognized reference materials to determine the length of training for an occupation is not limited to DOT codes. The SVP and other recognized sources are acceptable.

Over-regulation/extraordinary costs. The preponderance of comments on OJT urged DOL not to provide excessive regulations or documentation requirements on OJT. They stated that over-regulation would discourage employer participation in JTPA, thereby diminishing OJT as a training option. A few mentioned that this was particularly true for small employers. Many of the above comments on over-regulation were specific to concerns about excessive recordkeeping requirements on employers in tracking extraordinary costs.

The interim final regulations at § 627.240(c)(2) clarify that extraordinary costs do not have to be separately documented. However, it should be noted that, consistent with § 627.240(d), OJT contracts are to include documentation of the type and duration of training services that will be provided. Further, employers are required to maintain acceptable time and attendance, payroll, and other records to support amounts reimbursed under OJT contracts.

Reverse referrals. Several commenters stated that reverse referrals were good for outreach, certification, recruitment, and short-term supportive services where necessary.

Section 627.240(f) requires that referrals from employers may be accepted for OJT only if the participant's assessment and ISS document such OJT as an appropriate training activity. The participant must be a part of the JTPA system before receiving OJT, classroom training, supportive services or any other authorized activity or service based on the ISS.

Temporary employment. For the most part, commenters felt that temporary employment was a positive program aspect; only one said to disallow it.

Since OJT is designed to provide long-term, permanent employment, the interim final regulations at § 627.240(i) only allow temporary employment agencies to serve as the employer of record for purposes of providing OJT to participants when the participants are treated as all other agency employees. The employer providing the on-site training is required to have a contractual relationship with the JTPA program. A "temporary employer" as an

intermediary runs counter to the goal of OJT resulting in long-term, permanent employment with the employer providing the training.

Work Experience

Three commenters called for regulatory guidance on the use of work experience. One commenter asked that work experience be defined and two requested that the conditions under which work experience is suitable be specified. One also requested that limits be set on the length of work experience participation. Section 627.245 generally limits participation in adult work experience activities to no longer than 6 months or 499 hours, if working part time. This activity is to be justified in the ISS, based on the participant's needs. Section 627.245 also defines work experience and provides guidance on individuals for whom work experience is suitable.

Needs-Based Payments

The Amendments emphasize targeting services to the hard to serve. Further, the Amendments recognize the need to provide appropriate supportive services to allow participants to stay in a JTPA program longer. The Amendments also provide for several types of payments, all of which are to be charged to the training-related and supportive services category. Commenters requested that clarification be provided on the requirements and the mechanisms for payments to participants.

Section 627.305 provides clarification on the use of needs-based payments, which are allowable under title II. A commenter suggested allowing needs-based payments to be determined based upon a group characteristic, such as welfare recipient. This, however, would be inconsistent with the section 204(c)(3) of the Act which uses the language "necessary for participation," which can only be determined at the local level by evaluating the needs and circumstances of individual participants. This determination should be based upon the results of the objective assessment and documented in the ISS.

Incentive payments and bonuses to participants based on attendance and performance in a program are allowable only in the year-round youth program. The formula or procedure for such a payment is to be included in the SDA job training plan. Payments are to be reasonable and commensurate with the behavior being rewarded. One commenter requested that payments be viewed as training and, as such, be charged to training. However, consistent with the treatment of other payments,

incentive payments are to be charged to the training-related and supportive services category.

To allow for longer term participation, § 627.305(d) provides for wages to be paid for certain title II activities, such as work experience and limited internships. Section 627.305(e) provides for the payment of such wages for participation in other activities, such as classroom training, if the concurrent wage earning activity is for more than 50 percent of the training time.

The Department wants to encourage JTPA programs which provide a combination of work and learning. The statute provides that the work experience activity may not be conducted on a stand-alone basis so it will be conducted in conjunction with some other training activity. Combining a wage-equivalent payment with classroom training is intended to create an incentive for completion of the classroom training activity. The regulation requires that work experience and classroom training be linked as contextual learning as a condition to making such wage payments for adults.

Supportive Services

Supportive services are often critical for serving those most in need. The use of supportive services is encouraged to enable the hard-to-serve population to participate in longer-term interventions. The provision of supportive services must be determined on an individual basis. Comments were received on the need to have supportive services available to eligible applicants. The Department agrees that limited supportive services may be provided to eligible applicants, before they are enrolled as participants, to permit participation in assessment activities.

Section 627.310(a) sets forth the parameters for the provision of supportive services. Section 627.310(a)(3) provides that supportive services may include limited financial assistance. This activity allows for a payment to cover a financial need of a participant that, if unmet, would prevent that participant from attending his or her JTPA training. Financial assistance is to be provided to pay for specific, necessary services at the SDA's discretion, upon description in the Job Training Plan of the procedures for providing such assistance and approval by the Governor. The amount provided to meet a particular need may be predetermined by a formula or procedure; however, any determination of need for the financial assistance must be made by evaluating the needs and circumstances of the individual

participant as part of the objective assessment, and development of the ISS.

Grant Agreement and Funding

Section 627.405 establishes a new annual grant agreement process to facilitate the obligation, accounting, and closeout of JTPA funds by year of appropriation.

Reallotment and Reallocation

Section 627.410 has been established to implement the new section 109 of the Act, which requires the Governor to reallocate, among SDA's in the State, unobligated funds in excess of 15 percent of any SDA's program year title II allocation. Section 109(b) of the Act provides that the Secretary is to reallocate, to the eligible States, unobligated funds in excess of 15 percent of any State's program year allocation.

Several comments were received on reallocation/reallotment. Most frequently, commenters requested that the term obligated be clearly defined and that the circumstances under which reallocation/reallotment can occur be identified. Two commenters asked that the Governor be allowed to be more restrictive, for example, basing reallocation(s) on expenditures, not obligations. One commenter requested the opposite, i.e., that the regulations clearly omit the use of expenditures for reallocation purposes.

Section 627.410 reflects the mandate of section 109 of the Act. It does not establish additional requirements beyond those established in the Act. The term "obligations" is defined in § 626.5, using the standard Federal grant definition of the term. It should be understood that the Secretary will reallocate funds under title II based on the State's obligation of funds and the Governor will reallocate funds based on each SDA's obligation of funds.

Several commenters also questioned whether the Department was going to provide further interpretation of section 109(a)(3) of the Act concerning SDA's that have the highest rates of unemployment for an extended period of time and the highest poverty rates. Comments were split on whether the Department should expand on this criterion or leave it to each Governor. The Department elects not to elaborate further and will leave the interpretation of this section to each Governor, provided such interpretations are objective and applied consistently.

Insurance

Section 627.415 provides a cross reference to the property management section (§ 627.465) and does not provide cost classification guidance, since such

guidance is contained in the cost classification section (§ 627.440).

Procurement

Section 164 of the Act requires the Secretary to establish minimum procurement requirements in regulations, which are to be followed by Governors in prescribing and implementing procurement standards. These standards are to maximize competition, ensure fiscal accountability, and prevent fraud and abuse in JTPA programs. The Amendments require the Secretary to consult with the Inspector General of the Department of Labor and take into consideration relevant aspects of the OMB Circulars in establishing minimum procurement requirements. In response to this mandate, all but 1 of the 9 procurement requirements in the Amendments have been amplified, based on OMB Circular language. (The one exception is the requirement that State or local government transactions be conducted on a cost reimbursable basis.) To facilitate the reader's use of these regulations, parts of these Circulars have been paraphrased extensively within these interim final regulations. In accordance with § 627.420(a), the Governor/State is required to establish specific standards and implementing procedures based on the minimum requirements set forth in the regulation.

Procurements are to be conducted in a manner providing full and open competition, and the use of sole source procurements is to be minimized to the extent practicable. In support of these two requirements, § 627.420(d), based on the OMB Circulars, details the methods of procurement that subrecipients are to use. It is noted that OJT can be sole sourced. JTPA procurements are not to permit either excess program income or excess profit. If profit or program income is included in the price, States and subrecipients are to negotiate the profit or program income as a separate element of the price for each contract in which there is no price competition. The regulations list the conditions that are to be taken into consideration in establishing a fair and reasonable profit or program income. The OIG has recommended that certain clauses be included in JTPA procurements. As a result, requirements have been established for the inclusion of specific clauses in State and subrecipient procurements. The clauses listed are based on OIG recommendations and the OMB Circulars. JTPA contracts are to include a clause that establishes payment conditions and delivery terms. States

and subrecipients are encouraged to establish payment conditions that call for the withholding of final payment until all delivery conditions are met. For example, in the case of an OJT contract, it would be reasonable to withhold the final OJT payment until the participant has been retained on the job for a specified period of time after the completion of training. Other requirements are that States and subrecipients establish dispute/protest procedures and retain records of procurements for prescribed periods.

A total of 39 comments were received on procurement issues. Fifteen commenters requested that the regulations not be overly prescriptive. Three requested that the regulations not require separate State systems. Two asked that the OMB Circulars not be adopted in their entirety.

In response to comments, the interim final regulations allow the Governor to establish policies that identify specific types of entities, such as school systems, to which subrecipients may make sole source awards. These regulations will not require separate State JTPA procurement systems to be implemented. Many States are operating their procurement systems in accordance with the OMB Circulars. Although the interim final regulations are based only on portions of the OMB Circulars, these requirements are with most existing State systems.

Section 627.420(c) specifies restrictions on conflict of interest and specifically addresses PIC conflict of interest at paragraph (c)(4). The Act and these regulations very specifically address conflict of interest, including conflict of interest for PIC members; but, these restrictions do not preclude representatives of businesses in the community from being members of the PIC or from employing JTPA participants. The Act requires that business representatives be included on PIC's and anticipates that they be actively involved in the program. That same principle applies to representatives from other organizations involved in job training in the community. Similarly, community based organizations, education agencies, or other service deliverers are expected to be represented on the PIC, and this representation does not disqualify these organizations from participating in the JTPA program as long as appropriate disclosure and recusal rules are followed.

Selection of SDA Grant Recipients and Service Providers

A total of 47 comments were received on this issue. The majority of these

comments concerned the desire that competition and an "even playing field" govern the selection of service providers. Nine commenters requested guidance on determining demonstrated effectiveness. Some commenters were concerned that as a result of the Amendments more SDA's/SSG's would be providing JTPA services in-house, rather than contracting-out for them. These commenters, for the most part, requested that an SDA/SSG not be permitted to select itself as a service provider unless it meets the Act's procurement requirements applicable to other service providers. Section 627.422 reflects the requirement at section 107 of the Act that the Secretary establish guidelines on the selection of service providers, based on demonstrated performance. Some of the "demonstrated performance" measures contained in the Act and listed in the interim final regulation include: Likelihood of meeting performance goals, cost, quality of training, and characteristics of participants. The Department of Education is currently developing standards under the Higher Education Act (HEA) which will consider the effectiveness of educational institutions participating under the HEA. The process is not sufficiently developed to be of immediate assistance to the JTPA system at this time, but the Department of Labor may consider use of such standards at a later date in connection with the selection of service providers.

Additionally, the selection of service providers is to be made to the extent practicable on a competitive basis; include a determination of the ability of the service provider to meet program design specifications; and include documentation of compliance with procurement standards established by the Governor. Several of these listed measures are similar to the responsibility measures contained in the "Federal Acquisition Regulation" (FAR). This section is applicable to both the selection of contractors and grantees. This new section is based on the Act and the FAR.

Section 627.422(a), implementing section 107(e)(2) of the Act, requires the Governor to establish standards in making determinations of demonstrated performance, in accordance with the requirements of §§ 627.420 (Procurement) and 627.422 of the regulations and section 164(a)(3) of the Act. Section 627.422(b), implementing section 107(e) of the Act requires States and subrecipients to select service providers on a competitive basis, which addresses commenters' concerns over selecting service providers

competitively. The determinations of demonstrated performance required by this section take various issues and sources into consideration. Of the matters listed in § 627.422(d), four have a basis in the FAR. These are: The requirement of having adequate financial resources; the requirement to be able to meet program design specification at a reasonable cost (also based on section 107 of the Act); the requirement of having the necessary organization, experience, accounting and operational controls (also based on section 104 of the Act); and the requirement of having the technical skills to perform the work. The remainder of this new section lists other service provider requirements that are found throughout the Act.

Regarding selection of CBO's as service providers, the interim final regulations require that consideration is to be given to CBO's that are recognized in the community in which they are to provide services. The Act and the regulations require that appropriate education agencies are to be provided the opportunity to provide educational services, unless it is demonstrated that alternative agencies of organizations would be more effective. Regarding the selection of institutions/organizations to provide training, States and subrecipients are to take into consideration such performance measures as retention in training, training completion, and job placement. Regarding the impact on new CBO's and other new organizations, the requirements for demonstrated past performance do not require that this past performance be JTPA-specific. CBO's and organizations with experience in other training or education venues exclusively should not be eliminated from consideration. Regardless of the types of organizations that are being considered for selection as service providers, the Department expects the selection process to be accomplished in an unbiased manner, and in compliance with the Act and the regulations. All organizations under consideration are to be afforded a "level playing field" in the selection process.

Another issue related to service provider selection concerned SDA's/SSG's providing services themselves. Section 627.422(c) requires SDA's/SSG's to apply to themselves the same criteria which are applied to other service providers, and to document this process in writing.

Funding Restrictions for "High-risk" Recipients and Subrecipients

Section 627.423 establishes the authority and the opportunity for any

entity that makes awards or subawards to impose certain funding restrictions on recipients or subrecipients that are responsible entities but have a history of performance problems or system deficiencies. Such funding restrictions are not viewed by the Department of Labor as sanctions but rather as a mechanism to improve performance and/or increase accountability and fiscal integrity, without unduly interrupting the flow of funds.

Prohibition of Subawards to Debarred and Suspended Parties

Section 627.424 applies the Federal government-wide requirements on awards to debarred or suspended parties contained in Executive Orders 12549 and 12689 and implemented for all Department of Labor grant programs in regulations codified at 29 CFR part 98. These requirements were previously issued to JTPA Liaisons in a Grant Officer Notice dated April 30, 1992. As provided in 29 CFR part 98, certifications are not required for the State "pass-through" of JTPA funds to SDA's/SSG's since these are considered "mandatory awards" and are, therefore, exempt from the 29 CFR part 98 requirements. However, any other subaward (contract or subgrant) over \$25,000, such as an SDA contract or subgrant with a service provider, must meet the "lower-tier" certification. These "lower-tier" certifications are to remain with the respective awarding agency.

Standards for Financial Management and Participant Data Systems

Section 164(a)(1) of the Act requires that all financial transactions be conducted and records maintained in accordance with generally accepted accounting principles applicable in each State.

Generally accepted accounting principles (GAAP) are accounting rules and procedures established by authoritative bodies or conventions that have evolved through custom and common usage. The application of GAAP results in uniform standards and guidelines for financial accounting and reporting; however, the principles vary depending on the type of entity, e.g., State or local government, not-for-profit entity, or educational institution. Some of the additional requirements necessary for a financial management system to be in compliance with GAAP that may affect JTPA recipients and subrecipients include accrual or modified accrual accounting, financial statement presentation, full financial disclosure, budgetary control and reporting, and accounting for and/or reporting of

contingencies, fixed assets, pension funds, and long-term liabilities.

The Department does not view the inclusion of the GAAP requirement as a new JTPA requirement for most of the entities that have previously administered JTPA or other Federal grant funds. The audit requirements that have previously been applicable to JTPA funds, and continue to be applicable, have required, as specified in the "Standards for Audit of Governmental Organizations, Programs, Activities, and Functions" (GAO Yellow Book), a determination of "whether the financial statements of an audited entity present fairly the financial position and the results of financial operations in accordance with generally accepted accounting principles" as part of the audit scope.

Section 627.425 is a redesignation of § 629.35 in the present regulations. Section 627.425(a)(2) has been added to clearly specify the right of a higher tier organization to monitor the financial management systems of an entity awarded a JTPA grant, subgrant, or contract. This right also extends to Department of Labor monitoring activities.

Section 627.425(b) has been revised to reflect the statutory GAAP provision and was further revised to clarify that responsibility for the adequacy of financial management systems of JTPA subrecipients is the responsibility of each subrecipient as well as the responsibility of the State. Additionally, this section specifies that JTPA-related funds, including program income and potential stand-in costs, must also be traceable in the recipient's or subrecipient's financial system.

Section 627.425(c) has been revised to include a requirement that titles II-A, II-C and III records be maintained of applicants for whom an eligibility determination has been made, as well as records of participants.

Finally, the provisions regarding retention of records that previously appeared in paragraphs (e) through (g) of § 629.35 have been redesignated as a new § 627.460 (Retention and access requirements for records) for clarity.

Any additional requirements to be issued by the Department which are covered by the Paperwork Reduction Act (PRA) will not be issued without appropriate notice and comment pursuant to PRA.

Grant Payments

Section 162 of the Act contains a new subsection (f) that provides that when contracting with nonprofit organizations of demonstrated effectiveness, the Secretary, States, SDA's, and SSG's may

advance payments provided that such payments are based on the financial need of such organization and are not in excess of 20 percent of the total contract amount.

Section 627.430 has been expanded, both due to changes necessitated by the Cash Management Improvement Act (CMIA) and its implementing regulations promulgated by the Department of the Treasury and to improve the fiscal integrity of the JTPA program by establishing additional requirements on JTPA cash management.

This section sets standards as to when advances to subrecipients and contractors are appropriate and when the reimbursement method is appropriate. It also makes provision for using the working capital advance payment method and permits such working capital advances of up to 20 percent, consistent with section 162(f) of the Act. This section also requires that cash on hand attributable to JTPA be disbursed before requesting additional cash payments.

While § 627.430 requires compliance with the Treasury Department CMIA regulations at 31 CFR part 205, including effective cash management, this section authorizes an exception to the Treasury Department regulations as they pertain to interest earned by JTPA subrecipients on advances of Federal funds. As provided at section 141(m) of the Act, interest earned on JTPA funds is program income and may be used for program purposes.

For States, as defined at 31 CFR 205.3, the Treasury Department CMIA regulations require selection of either a funding technique that results in no interest earnings on Federal funds or a funding technique that results in an interest liability to the Federal Government. States, including subrecipients that are State entities, that select the latter may use interest earned on JTPA funds to offset any interest liability of the State.

This section also encourages the use of minority-owned banks.

Cost Principles and Allowable Costs

Section 164(a)(2) of the Act, as amended, requires the Secretary to prescribe regulations establishing uniform cost principles substantially equivalent to those generally applicable to recipients of Federal grant funds. In addition, sections 164(a)(1) and 165(f)(1) of the Act require application of GAAP in the accounting and reporting of JTPA costs.

Most commenters discussed the degree to which the OMB Circulars containing cost principles should be

adopted as opposed to leaving flexibility with the States to establish requirements in this area. Practically all commenters indicated that uniform cost standards were required to some extent.

Section 627.435(a) has been revised to require that costs to be charged to the JTPA program be consistent with GAAP rather than the previous consistency standard of "like circumstances in nonfederally sponsored activities".

Paragraphs (a) through (h) of § 627.435 establish JTPA cost principles and provide guidance on the allowability and nonallowability of certain items of cost. New guidance is provided on applicable credits, lobbying costs, back pay, clarification of legal expenses, and new prohibitions on contingency reserves and bad debts expense as allowable JTPA costs.

Paragraph (i) contains a listing of selected items of costs for which the Governor will be required to prescribe treatment. This approach contains two significant differences with the Federal cost principles: (1) There is no requirement for recipients to submit Indirect Cost Rate Proposals to the cognizant Federal agency and obtain Federal approval, and (2) Attachment B of A-87 details specific treatment for selected items of cost while the interim final regulation lists items of cost and requires the Governor to determine specific treatment for each item. The Department believes this approach, along with the other provisions in this section discussed above, is consistent with the requirement at section 164(a)(2) of the Act to establish uniform cost principles substantially equivalent to the principles generally applicable to recipients of Federal grant funds, while also maintaining the role and responsibility of the Governor in the administration of JTPA programs. This approach assures that the same items of costs will be treated by all States, while permitting some flexibility for individual State discretion and decisions on individual items, tailored in part, to the JTPA program.

Classification of Costs

Section 108 of the Act requires that funds expended under the Act be charged to the appropriate cost category. The exceptions to this requirement are commercially available training packages purchased competitively for off-the-shelf prices and tuition costs. Section 108(b) also revises the three cost categories from those previously used by JTPA and requires the Secretary to define the cost categories.

Numerous comments were received on this subject, including comments on the potential for community-based and

other organizations to incur higher administrative costs as a result of the extensive time and resources required to serve people with "multiple barriers" to employment and on the possible inability of private-for-profit (commercial) entities to continue to play a role in JTPA because of cost allocation constraints. Specific cost items that received the most comments were indirect or overhead costs; classification of profits or fees; cost of initial intake, eligibility determination, or pre-enrollment assessment; and costs of management information system (MIS) functions. Several commenters encouraged the application of charges by function rather than position, particularly in charging the costs of positions such as a project director who is also directly involved in the delivery of services to participants. Other commenters requested definition of the phrase "commercially available training packages purchased competitively for off-the-shelf prices." Comments were also received on fixed-unit price, performance-based contracts and whether they could continue to be charged 100 percent to the direct training category; continuation of administrative cost pooling; and the need for broad definitions of training and training-related costs coupled with a narrow definition of administrative costs.

Most commenters requested as much delineation as possible regarding what items are to be charged to each cost category. All commenters cautioned against defining administrative costs in a manner that would cause effective service providers to leave the JTPA system.

Section 627.440 has been substantially revised to conform to the requirement, at section 108(b)(3) of the Act, that the Secretary define the three title II cost categories of administration, training-related and supportive services, and direct training services. The Secretary's definitions of these categories are contained in § 627.440(d). In addition, § 627.440 (b) and (c) specify all of the title II cost categories (or cost objectives) applicable to the JTPA program.

Section 627.440(a) requires costs to be charged to the benefitting cost category (or objective) to the extent that benefits are received by such cost category or objective.

Provisions covering JTPA administrative cost pools have been moved from the cost limitation section to § 627.440(f) as it is principally a cost classification subject, rather than a cost limitation subject. The language has been changed to state that, for JTPA

reporting purposes, costs must be allocated to the benefitting programs based on the benefits received by each program. The Department recognizes that this language represents a departure from previously established policy on the manner in which pooled administrative costs are to be reported. Commenters are requested to identify the impact, if any, of the revised requirement to allocate pooled administrative costs solely on the basis of "benefits received".

Four commenters raised the question of consolidating the II-A and II-C adult and youth State set-asides, for ease of accounting and reporting. Section 627.440(b) provides that these funds may be combined.

Several commenters raised questions about the applicability of cost categories and cost limitations to incentive funds received by an SDA. Section 627.440(c)(2) specifies that the cost categories and cost limitations are not applicable to such funds. Incentive funds must, of course, be used for JTPA title II-A or II-C purposes.

In defining the cost categories in paragraph (d), it is impossible to specify treatment of every conceivable item of cost. The Department has attempted to provide specificity for most items of cost and to apply a basic principle of cost being charged to a cost category in accordance with the benefits received by that category. Within the direct training services category, the Department's definition is linked to the concept of benefits received by or directly benefitting program participants. Major highlights of these definitions are as follows:

- Numerous commenters requested that the classification of costs be tied to functions rather than positions. The Department's definitions are principally written against the items of cost and the function of various positions. Paragraph (e)(1) also provides that the cost of positions or other costs involving multiple functions may be allocated to the benefitting cost categories. It is expected that actual time distribution will be the basis for such allocations of staff costs.
- Numerous commenters raised questions about both costs of tuition and commercially available, off-the-shelf training packages, since both of these items are specified in section 141(d) of the Act. The Department's definition of a commercially available, off-the-shelf training package is included in § 626.5. The Department is not further delineating the term tuition, since it is specifically defined in the

Act. However, it is expected that both of these cost items will frequently be for the purchase of such items from vendors and, therefore, are 100 percent chargeable to the category benefitting. The inclusion of tuition and off-the-shelf training packages in the statute makes it clear that subrecipients, as part of the procurement process, cannot require such vendors to break out the individual cost components of their services. In addition, the term "instructional materials * * * used by or for participants" has also been included in the list of cost items within the direct training services category.

- In those instances in which the terms of a subrecipient's award are for the delivery of an off-the-shelf training package consistent with the provisions of paragraph (e)(3). The Department is specifically interested in comments on this approach.
- Many comments were received on the classification of the costs of outreach, intake, eligibility determination and related activities. Paragraph (d)(3) specifically includes these costs in the training-related and supportive services category. The intent of this provision is to allow costs incurred on behalf of an individual prior to becoming (or not becoming) a participant to be charged to the training-related and supportive services category. The costs of objective assessment and related functions, after an applicant becomes a participant, are to be charged to the direct training services cost category.
- In response to comments concerning indirect or overhead costs, this subject is addressed in paragraph (e)(2). It provides that indirect or overhead costs normally are to be charged to administration, except where costs can be identified directly with another cost category. This approach is narrower than that requested by most commenters, but the Department believes that the test of benefits received directly by participants should be met for costs to be charged to direct training services.
- Finally, in response to numerous comments on the classification of profits and fees, paragraph (e)(4) provides that, to the extent allowable in accordance with the Governor's allowable cost guidelines, they may be allocated to all three cost categories based on

the proportionate share of actual costs attributable to each category. Such earnings by subrecipients other than commercial organizations become program income, as provided by section 141(m) of the Act.

Limitations on Certain Costs

Section 108 of the Act requires that at least 50 percent of the funds received by an SDA under title II-A and C must be expended for direct training services and establishes a revised limit of 20 percent of funds that may be expended for administration. The third cost category has been revised to include the cost of training-related services as well as supportive services.

In response to a large number of comments received on this subject, paragraph (d) of this section recognizes the provisions made in section 141(d)(3) for excluding administrative costs incurred by community-based organizations and private non-profit service providers from the SDA's administrative cost limitation under certain criteria and conditions specified in the Amendments. Paragraph (d) provides clarity to those criteria and conditions and provides an example of their application. Specifically, 627.445(d) of the regulations addresses provisions in section 141(d)(3)(C) of the Act which provide for certain situations under which funds expended by a CBO or non-profit organization for the costs of administration may be the basis for increasing the administration cost limit applicable to the SDA from 20 percent to up to a maximum of 25 percent. Those situations require that such funds be expended under an agreement under which not less than 90 percent of the funds provided to the service provider are to be expended for the cost or direct training and training-related and supportive services. Further, the expenditures are to be charged to the appropriate cost category, and the SDA is to be in compliance with the direct training cost limitation requirement of 50% under section 108(b)(4)(B) of the Act for the program year, as adjusted consistent with section 141(d)(3) of the Act. These provisions are limited to situations in which the SDA provides funds to a CBO or other non-profit organization, therefore, the administrative entity of an SDA may not include itself under these provisions.

Most of the comments discussed above under cost classification were also applicable to cost limitations as well. Comments were also received on the time period and process for determining compliance with the cost limitations.

Section 627.445 describes cost limitations contained in various sections of the Amendments and clarifies cost limitations applicable to State-administered activities. Paragraph (a) specifies that, for State-administered activities, cost limitations are applicable to (1) II-A funds allotted for section 204(d) activities (older individuals), and (2) the combined total of II-A and II-C funds allotted to carry out activities pursuant to section 123(d)(2)(B) of the Act education services (80 percent of the 8 percent). For cost limitations applicable to funds allocated to SDA's, paragraph (b) provides that the total funds allocated to an SDA include or exclude, as applicable, any transfers of funds made in accordance with sections 206, 256, or 266 of the Act, and funds reallocated by the Governor under the authority of section 109(a) of the Act.

Paragraph (c)(2) provides that States and SDA's have the 3-year period of fund availability, specified at section 161(b) of the Act, to comply with the cost limitations. This provision, coupled with the statutory changes on cost limitations, replaces the policy guidance issued by ETA in 1984 and 1985 on the subject of cost limitations. In addition, while this provision provides that compliance is not finally determined until the end of the third year of availability, States are required to review compliance on a regular basis and implement corrective action before the time limitation expires.

Program Income

Section 141(m) of the Act provides new treatment for the use of program income as well as a description of what constitutes program income, including interest earned on funds received under the Act.

Most comments were directed at the need for the establishment of clear requirements concerning the use and treatment of program income, including the applicability of the cost categories and the cost limitations.

Section 627.450 has significantly expanded the current 20 CFR 629.32, both to implement the new provisions of section 141(m) of the Act and to improve the fiscal integrity of the JTPA program. The section now contains a definition of what is and what is not program income for JTPA purposes, establishes requirements for its use that are consistent with section 141(m) of the Act, and establishes timeframes for the treatment and use of program income. It also provides for the State to determine the disposition of program income not used in accordance with this section or remit it to the Department. Section 627.450(c) specifies that the cost

categories and the administrative cost limitations are applicable to program income.

Reports Required

Section 165(f) of the Act requires financial reporting on a quarterly basis and costs to be reported by year of appropriation. Section 627.455 has been revised to include these requirements. In addition, this section now also specifies that:

- (1) States may impose different reporting requirements on subrecipients as long as the State can meet the Secretary's reporting requirements;
- (2) The Secretary may provide computer printouts to recipients to expedite or contribute to the accuracy of reporting;

(3) The Secretary may accept required information from States in electronically reported format or computer printouts instead of prescribed forms;

(4) States will report program expenditures on an accrual basis; and

(5) A final financial report is required 90 days after the expiration of a funding period.

Retention and Access Requirements for Records

Section 165(e) of the Act requires each Governor to ensure that requirements are established for retention of all records pertinent to all grants awarded, and all contracts and agreements entered into under the Act, for 2 years following the date on which the annual expenditure report containing the final expenditures charged to a program year's allotment is submitted to the Secretary. Records for nonexpendable property are to be retained for a period of 3 years after final disposition of the property.

Section 627.460(a) provides that the State, in establishing record retention requirements for records of subrecipients, may set a starting date for record retention of either the date of (1) the State's submission to the Secretary of the final expenditure report for a program year's allotment, or (2) the subrecipient's submission of a similar final report to the subrecipient's awarding agency. If the former is used, the retention period is 2 years after the report submission. If the latter is used, the retention period is 3 years after submission. It is expected that either approach will result in most JTPA records being maintained for the same total period of time. The latter approach will enable subrecipients to control the starting date of the retention period for their own records, and to maintain and to dispose of JTPA records in the same timeframes that apply to other records

of the subrecipient covered by applicable OMB Circulars.

Property Management Standards

Section 141(r) of the Act provides that the Federal requirements governing the title, use, and disposition of real property, equipment, and supplies purchased with JTPA funds will be the Federal requirements generally applicable to Federal grants to States and local governments.

Seventeen comments discussed the provisions of the OMB Circulars in this area, the need for rules to address property that becomes obsolete, depreciation and replacement of property (trade-in), and questions of prior approval.

Section 627.465 reflects the new requirements of section 141(r) of the Act. The Federal requirements generally applicable to Federal grants to States and local governments are codified for Department of Labor grant programs at 29 CFR part 97. Therefore, the provisions of those regulations applicable to property requirements have been incorporated into this section for governmental recipients and subrecipients.

Since the Federal requirements generally applicable to Federal grants to States and local governments provide that subrecipients that are institutions of higher education, hospitals, and other nonprofit organizations will follow the Federal agency regulations that implement OMB Circular A-110, those requirements are incorporated into this section. It is anticipated that this approach will provide administrative relief for such subrecipients since it will prevent an organization administering other Federal grants or subgrants from having to follow two different sets of requirements. In addition, the Federal requirements applicable to intangible personal property have been incorporated into this section.

There are no Federal requirements generally applicable to commercial subrecipients; therefore, § 627.465 provides specific JTPA requirements for these organizations.

It is recognized that these statutory changes in property requirements for the JTPA program may cause some transition issues. To avoid future questions about property acquired prior to the effective date of these changes, the regulations specifically provide that the new rules would apply only to property acquired after July 1, 1993.

In response to comments concerning prior approval requirements, the Department is not imposing any specific prior approval requirements other than on subrecipients that are commercial

organizations. However, in § 627.435, Cost Principles and Allowable Costs, Governors are required to treat this issue in the State's allowable cost guidelines. For commercial subrecipients, the prior approval of the entity that will hold title to the property is required, since this will enable the governmental or non-profit entity that will hold title to be a part of the decision-making process to acquire the property.

Performance Standards

Section 627.470 provides for the establishment of performance standards for older worker programs under section 204(d) of the Act, in addition to adult and youth programs under title II-A and II-C and dislocated workers under title III. These standards for both adults and youth may include standards for employment competencies which are to be based on such factors as entry-level skills and other hiring requirements. The interim final regulations make clear that the Governor is responsible for establishing an incentive awards policy that rewards performance in title II programs, with the exception of the older worker program, and for providing technical assistance to SDA's which fail to meet, as specified by the Secretary, performance standards for a given program year. The regulation also incorporates the requirement in section 106(j) of the Act, for the imposition of a reorganization plan on SDA's failing for 2 consecutive years to meet more than half of the performance standards, with the exception of the older worker programs. The Governor is to notify the Secretary and the SDA of the continued failure and impose a reorganization plan within 90 days of the end of the second program year. If the reorganization plan is not imposed within the 90 days, then the Secretary will develop and impose it. The Secretary will give the Governor and the SDA 30 days in which to comment to the Secretary on the proposed reorganization plan prior to its imposition. Further, the Secretary will recapture or withhold up to one-fifth of the State's administration set-aside to provide technical assistance to an SDA where the Secretary has imposed the reorganization plan or where the Governor has not provided appropriate technical assistance.

Oversight and Monitoring

The Department believes that effective monitoring and oversight of JTPA program operators at the Federal, State, and local levels is essential, not only to the maintenance of program integrity, but also to ongoing program evaluation and planning. The Department intends that there be expanded oversight and

monitoring activities to ensure the requirements of the Amendments and these regulations are accomplished. Section 627.475 summarizes the roles of each administrative level in a comprehensive monitoring and oversight system.

The Governor is to develop a State monitoring plan which requires that each SDA and SSG be monitored at least once a year. The plan must also require the collection and the review of sufficient information to enable the Governor to determine whether substate entities have demonstrated substantial compliance with the oversight requirement to permit a waiver of the imposition of sanctions authorized under section 164(e) of the Act, or if a job training plan should be disapproved pursuant to section 105 of the Act.

Based on instructions issued by the Governor, the SDA's/SSG's will be required to develop a substate monitoring plan which is to be part of the job training plan. At a minimum, the Governor's instructions are to address the scope and frequency of the monitoring as well as any policy guidance and emphasis provided by the Secretary.

In addition, the Governor is to establish general standards for PIC oversight responsibilities in relation to SDA/SSG performance. These standards are to be included in the GCSSP. Section 103(b)(2) of the Act authorizes the PIC to provide oversight of programs conducted under the job training plan. In strengthening the role of the PIC as the local decisionmaking body, it is important that it gather sufficient information to evaluate and to review the results of its decisions and their implementation.

As a consequence of this additional emphasis on the Federal, State, PIC, and SDA/SSG monitoring role, each administrative level will be expected to take a greater measure of accountability for program operations through appropriate followup action. The outcomes of the monitoring at any level could result in the provision of additional guidance and technical assistance, recommendations regarding continuance of particular training or service strategies or programs, more effective future program planning, and the identification of models of exemplary performance for replication or areas of concern requiring more intensive monitoring attention.

Audits

With the exception of paragraph (a)(3), the changes in § 627.480 from the present regulations are not substantive,

but are intended solely to more clearly delineate existing requirements.

Paragraph (a) of § 627.480 reflects the audit requirements that apply to the different types of entities which operate JTPA programs. To ensure appropriate coverage of JTPA programs that are operated by subrecipients which are commercial organizations, § 627.480(a)(3) has been added, specifying audit requirements for such organizations.

Audit Resolution

Section 627.481 sets forth the actual procedures followed by the ETA Grant Officer to resolve audits with recipients. This section differentiates between audits of direct recipients and those procedures applicable to audits of subrecipients. This section addresses the requests of several commenters that the Department more clearly describe its audit resolution process.

Closeout

Sections 627.485, 627.490, and 627.495 replace the previous closeout section that was reserved at § 629.45. Section 627.485 establishes a requirement and a process to close each annual grant award after the 3-year time limitation for expenditure of JTPA has expired. It also establishes a deadline for the State's submission of any revised expenditure reports and a provision for the Secretary to extend the deadline based on a written request from a State, with justification. Sections 627.490 and 627.495 establish post-closeout rights and responsibilities of the Secretary and the State.

Grievances and Sanctions

The regulatory provisions formerly found at 20 CFR part 629, Subpart D—"Grievances, Investigations, and Hearings" have been revised, redesignated, and reordered in these interim final regulations in a new part 627, subparts E, F, G, and H. The interim final regulations more clearly define the various JTPA grievance procedures which are required to be established by section 144 of the Act. The procedures which apply to a particular grievance process level have been consolidated into discrete subparts. In addition, the "Sanctions for violations of the Act" provisions formerly at 20 CFR 629.44 of the regulations have been moved into this part as a separate subpart.

The proposed provisions of the new part 627, subpart E set forth the grievance procedures required at the State and local levels, including State review, that were generally found at 20 CFR 629.52.

The proposed new part 627, subpart F sets forth the provisions which apply to the handling of administrative and civil complaints at the Federal level that were generally set forth at 20 CFR 629.52(d) and 629.54. In addition, § 627.603 of the interim final regulations implements the provisions of section 144 of the Act relating to the Federal handling of labor standards violations under section 143 of the Act. Section 627.604 sets forth the provisions which apply to the alternative procedure (binding arbitration) for handling section 143 labor standards violations provided for at section 144 of the Act.

The proposed new part 627, subpart G consolidates the sanction provisions for violations of the Act into a more logical order, with separate sections addressing: sanctions and corrective actions (§ 627.702), the process for waiver of State liability (§ 627.704), the approval process for contemplated corrective actions (§ 627.706), and the provisions applicable to the use of "offset" for debts established against the State (§ 627.708).

The proposed new part 627, subpart H sets forth the provisions that apply to hearings before the Office of Administrative Law Judges (OALJ) formerly at 20 CFR 629.57 and includes the alternative dispute resolution provisions that appeared at 20 CFR 629.56. The jurisdiction of the OALJ has been expanded, by a conforming amendment to section 186(a) of the Act, to include labor standard violations under section 143 of the Act, and violations of the relocation provisions at section 141(c) of the Act.

Timeframes Regarding Grievances, Complaints and Appeals

There are a number of provisions concerning Federal, State and local timeframes for grievances, complaints, appeals and other matters. There are only a few instances where the timeframes are statutory. The Department has set timeframes, but we would like commenters to provide input on any areas of concern in meeting the timeframes provided in the regulations.

Transition Provisions

In order to assure an orderly transition from the existing JTPA programs to the program requirements mandated by the Amendments, the Department requested comments on "transition" in ANPR. Fifteen comments were received, generally falling into 1 or more of 5 topics.

Several commenters expressed concern about program operation. These issues include a need to "grandparent" participants and current allocated funds

in order to achieve an orderly transition to the requirements of the Amendments. Guidance on eligibility, in-school/out-of-school ratios, the reallocation process, tracking of transferred funds, current fixed-unit priced contracts, and the operation of the 1993 Summer Youth Employment and Training Program (SYETP) under current regulations were other issues included in the comments.

The Department agrees that participants enrolled in, and funds obligated for, the title II-A program on or before June 30, 1993, may continue to be used under the provisions of the Act that were in place prior to the enactment of the Amendments. Participants enrolled and funds obligated on or after July 1, 1993, will be administered pursuant to the provisions of the Amendments. The Department intends that the 1993 SYETP be operated under the current regulations. Specific guidance on titles II and III program operations will be issued in field issuances concurrent with the publication of the final rule for the Amendments or as soon thereafter as possible.

Several comments focused on the need to enhance existing data collection systems in order to track the program experience of participants, as required by the Amendments. The Department agrees and intends that currently available 6 percent funds allotted for Program Year (PY) 1992 and prior years be used for this transitional purpose. States and SDAs may use available 6 percent funds in connection with updating their MIS systems during the period of fund availability.

Another topic addressed by commenters was the need for guidance regarding for the transfer of funds between titles II-A and II-C, and from title II-B to title II-C programs. The Department intends that this transfer be accomplished as specified in sections 206, 256 and 266 of the Act. Reporting requirements and instructions are being developed which will be published in field issuances at a future date.

Commenters indicated that guidance is needed on the PY 1993 planning process. Of specific concern are the Department's expectations regarding modifications to the GCSSP and job training plans. The Department will provide specific guidance for the PY 1993 planning process through field issuances published in January 1993.

Finally, commenters requested one or more transition periods to implement changes in phases beyond July 1, 1993. The Department expects that the requirements of the Amendments and these regulations will be fully implemented by July 1, 1993, except as

otherwise provided for in the Amendments. The Department is aware that some difficulties may arise in the initial period related to the appropriate implementation of certain requirements related to program design. Therefore, in determining compliance with the program design requirements of these regulations during PY 1993, the Department will take into consideration whether the States and SDA's have made a good faith effort to properly implement these new regulatory requirements.

PART 628—PROGRAMS UNDER TITLE II OF THE JOB TRAINING PARTNERSHIP ACT

Nontraditional Employment for Women (NEW) Act (Pub. L. 102-235)

NEW's purposes are to provide a wider range of training opportunities for women under existing JTPA programs; to provide incentives for the establishment of programs that train, place, and retain women in nontraditional fields; and to facilitate coordination of JTPA and vocational education resources available for training and placing women in nontraditional employment. Further, the NEW Act is consistent with the overall goal of JTPA programs to increase participants' employment, earnings, educational and occupational skills.

"Nontraditional employment" is defined as occupations or fields or work where women comprise less than 25 percent of the individuals employed in such occupation or field of work. Although nontraditional occupations are usually thought of only as construction or skilled trades, these occupations encompass a much broader spectrum of jobs in technical and other fields.

Nontraditional occupations have the potential for greatly improving the economic status of women, particularly when they are growth occupations with increased wage potential.

Nontraditional training for women also provides benefits for the States and the SDA's. The Department believes that this kind of training expands the occupational mix available to all clients, and can enhance coordination with other education and training programs as well as with labor and apprenticeship programs. It helps advance efforts by the States and/or SDA's to be a valuable source of trained individuals for employers and unions. Through the implementation of NEW, it is the Department's intent that changes will occur throughout the job training system so that training in nontraditional

occupations becomes institutionalized in each State.

The GCSSP and the job training plan prepared by each SDA were required to include goals, actions, and accomplishments for the training and placement of women in nontraditional employment for the 2-year period beginning July 1, 1992 and beyond. NEW does not establish specific numerical goals by SDA or State. However, since the number of women currently trained in nontraditional occupations nationwide is estimated at 9 percent, States and SDA's may wish to use this figure as a baseline until they can collect data specific to that State.

The Department expects that the GCSSP and the SDA's plan will reflect specific measurable activities to train and to place women in nontraditional employment and apprenticeships, as required by the statute. As mentioned earlier, SDA's may wish to consider using the national figure of 9 percent as a baseline until geographic-specific data becomes available. Sections 104(b) (6) and (13), 121(b)(3) and 122(b)(5)-(7) of the Act require the States and SDA's to set goals and report on program accomplishments. The Department intends to look closely at these activities to ensure compliance with requirements of NEW.

Further, the Department expects that each State's and SDA's plans and activities will reflect the development of outreach and promotional materials and/or activities aimed at making women aware of the programs and the services available through JTPA, particularly of nontraditional training and placement opportunities. Examples of outreach materials include, but are not limited to, nontraditional career information modules, video and print materials on nontraditional career options (for counselors), recruitment brochures targeted at both the client and the employer, and dissemination of preexisting resource materials and/or model curricula. States may also wish to undertake statewide public education campaigns, similar to those conducted for literacy programs, on nontraditional training and employment opportunities.

The Department expects statewide dissemination of model programs/approaches to serve as a method of encouraging the replication and institutionalization of nontraditional training in the State. The Department encourages the States to disseminate to SDA's and service providers the SJTCC's summary report on promising programs funded by JTPA or the Carl Perkins Vocational Education and Applied Technology Act.

Specific changes in Part 628—Programs under Title II of the Job Training Partnership Act are as follows.

State Planning

Minor changes have been made in § 628.200, which addresses the GCSSP. This section now outlines, in broad terms, the areas which are to be addressed in the plan, and provides the Secretary with 45 days to review the plan.

State Human Resource Investment Council

Section 628.215 provides for the voluntary establishment of a State Human Resource Investment Council (HRIC). The HRIC is responsible for advising the Governor on: Coordination of Federal human resource programs; ways to meet the human investment needs in the State while maximizing the use of Federal funds and avoiding duplication of services; and development and implementation of State and local standards and performance measures. States have the option of constituting the HRIC to carry out the duties and functions of existing State Councils established under applicable Federal law, such as the State Job Training Coordinating Council (SJTCC) and State Council on Vocational Education (SCOVE). If States exercise this option, one Council is to be established, replacing all other State Councils. The HRIC may utilize funds available for other State Councils and administrative funds otherwise available under applicable Federal human resource programs. To achieve the economy and efficiency of the single Council contemplated by these provisions, however, States must conform the HRIC to meet all of the new requirements, assuming all duties and responsibilities of the former Councils.

The interim final regulations emphasize the following areas of concern that were raised by commenters: The HRIC must carry out the responsibilities of the Councils it replaces; the Governor, the head of each agency, and the SCOVE must approve the establishment of the HRIC; and the HRIC and its staff must reflect the necessary expertise to carry out the responsibilities of each of the former Councils.

Education Coordination and Grants

Section 628.315 clarifies the Governor's responsibilities in the selection of the State education agency to be the recipient of funds under section 123 of the Act. The section makes clear that the organizational entity operating JTPA at the State level

may not be considered as an education agency for the purpose of receiving section 123 funding, nor can agencies which do not have education as a primary purpose, such as corrections departments.

Allowable activities under this section are specifically directed to support school-to-work programs, literacy and lifelong learning opportunities, and statewide coordinated education and training services to train, place and retain women in nontraditional employment. The intent is that these broad categories will accommodate a wide variety of coordinated education programs, and may include youth apprenticeship programs.

Not less than 80 percent of the funds provided under this section must be used to carry out projects in these areas. Not more than 20 percent of the funds may be used either to facilitate coordination of education and training services for those projects, or to support activities of a State Council that meet one of two criteria. One criteria is that the State council is a HRIC, constituted under title VII of the Act, which includes all seven of the applicable programs listed in section 701(b)(2). The other criteria is that the State Council carries out functions similar to a HRIC and was established prior to July 1, 1992.

Section 628.315 clarifies the circumstances under which the Governor may administer programs pursuant to section 123(e) of the Act. The section also provides guidance on the plan jointly developed by the Governor and the education agency(ies), and the agreements which must be entered into, pursuant to section 123(b) of the Act, to administer the projects through which section 123 funds are expended.

The section clarifies allowable activities and expenditure requirements. It also specifies that federal funds other than those appropriated under JTPA may be used for the match requirement. Undertaking to meet the matching fund requirements through using services provided under other federal job training sources may provide opportunities for constructive coordination arrangements.

Capacity Building and Technical Assistance

The JTPA has been amended to include capacity building and technical assistance as priorities at the national, State and local levels. Section 453 of the Act calls for the creation of a national Capacity Building and Information and Dissemination Network and a

Replication Grant Program. State and local priorities are established through sections 202(c)(3)(A) and 262(c)(3)(A) of the Act which make available up to 33 percent of the 5 percent incentive funds for capacity building and technical assistance activities. Section 121(a)(3) of the Act, as amended, requires that capacity building and technical assistance plans be included in the GCSSP. Greater emphasis is placed on general technical assistance activities for the development and training of State, SDA, and service provider staff.

The Department received comments supporting the use of incentive funds reserved for capacity building for development of computer-based information networks. Commenters also requested that capacity building be given a comprehensive definition, be made a priority in the JTPA system, and that regulations preserve State flexibility in designing and implementing capacity building and technical assistance strategies. Other comments stressed the importance of ensuring that activities using capacity building funds reach and be developed in consultation with SDA's, CBO's, and local service providers. Some commenters expressed concern that the nonduplication provision in section 202(c)(3)(B) could seriously hamper State and local flexibility in developing products and delivering training.

In response to these comments and earlier recommendations from the JTPA Advisory Committee and JTPA system representatives, the Department has developed interim final regulations that emphasize the need for State and local capacity building efforts, provide guidance on the Governor's responsibility concerning use of the funds, and encourage the coordination of capacity building and technical assistance efforts throughout the entire JTPA system. While the State's prerogative to establish priorities is retained, Governors are strongly encouraged to use funds for the development of staff capabilities at all levels, and particularly for front-line staff, through a comprehensive capacity building and technical assistance strategy.

State and local capacity building efforts are to be coordinated and integrated with the national Capacity Building Information Dissemination Network, pursuant to sections 202(c)(3)(B) and 262(c)(3)(B) of the Act. In order to maximize funds available, the Network will build, to the extent possible, on what already exists in the system. Through its clearinghouse, it will make information accessible to the JTPA system on current and planned

Network products so that duplication of effort may be avoided as States and SDAs plan their capacity building agendas. States and SDAs are to retain the flexibility to tailor Network products to their own needs and/or to produce and train on similar or related products when local circumstances so dictate.

Section 626.5 provides definitions of capacity building and technical assistance. The definition of capacity building is applicable at the Federal, State, and local levels. Section 628.325(c) establishes State responsibilities and provides for the use of up to 33 percent of the 5 percent incentive funds for capacity building and technical assistance. This section also provides guidance on the use of funds, cost sharing approaches, and SDA use of awarded incentive grants. Section 628.325(c)(2)(iii) provides for the purchase of hardware and/or software if directly related to capacity building and technical assistance activities of the national Capacity Building and Information and Dissemination Network.

Section 628.205 sets forth requirements that capacity building and technical assistance plans be included in the GCSSP. The interim final regulations recognize that a "customer-driven" approach offers the best opportunity for a meaningful capacity building effort. Accordingly, Governors are encouraged to share capacity building and technical assistance plans in advance with SDA's and to include SDA's and local service providers in the development of such plans.

Guidance concerning SDA capacity building responsibilities can be found in § 628.420, the Job training plan.

SDA Designation Process

Section 628.405 clarifies the SDA designation process. SDA designations are to occur every 2 years, consistent with the preparation of the 2-year GCSSP and the SDA job training plan.

In section 101(a)(4)(A) of the Act, Congress established the population threshold of 200,000 for determining the minimum area of a mandatory SDA, which is required to be designated by the Governor. The Department believes that normally this threshold is the minimum necessary to constitute an SDA that can adequately implement the administrative and management requirements set forth for in the Amendments and these regulations.

In past decisions, the Department has deferred to the Governor in the designation of SDA's, particularly with respect to the criteria for what constitutes a substantial part of a labor market, as long as the Governor's

criteria were consistently applied and were not inconsistent with the Act. The regulations clarify that when there are competing requests for designation under section 101(a)(4)(A) of the Act the Governor is to designate the entity which has a population closest to 200,000, unless such designation would bring the population of the competing entity to less than 200,000 in which case the Governor has the discretion to choose which request to honor.

At present, the number of SDA's has risen to over 640 and almost one-third of the SDA's have been designated on a discretionary basis by the Governor under the provisions of section 101(a)(4)(B) of the Act and serve populations of less than 200,000. In order to promote the designation of the most effective delivery system, the regulations require the Governor to establish standards by which to evaluate a proposed discretionary SDA prior to granting designation status which, at a minimum, is to include the criteria set forth in § 628.405. It is the Department's intent that the Governor apply these standards to determine whether to waive the 200,000 population criterion for an SDA. Finally, the regulations require, for SDA's designated pursuant to sections 101(a)(4)(A)(ii) or (B) of the Act, that the Governor is to define "substantial part" and "substantial portion", but that these may not be less than 10 percent of a labor market area.

Some commenters requested that DOL not regulate any further in this area. It appears that these comments were addressing unknown actions that the Department might take, and whether these actions would affect existing designations. The interim final regulation closely tracks the law with regard to SDA designation. The regulation requires the Governor to establish policies which, in most cases, will already exist. The transition provisions clarify the Governor's discretion to not apply the new regulatory provisions to the Governor's current discretionary SDA designations made prior to July 1, 1992.

Representation of Private Industry Councils

Many commenters addressed the statutory provision at section 102(a)(2) of the Act requiring that representatives from organized labor and CBO's constitute no less than 15 percent of the PIC membership. One commenter suggested that the regulations establish minimum requirements for the solicitation and appointment of labor representatives by requiring that the local elected official contact the principal officer of the local AFL-CIO

central body in his/her jurisdiction in writing to solicit nominations providing a period of 60 days for response. The commenter also suggested that, where the local AFL-CIO body is unable to nominate a sufficient number of labor representatives, the chief elected official be required to contact the principal officer of the State AFL-CIO in writing to solicit nominations with a 60 day period for response. As provided in the Act, the Department intends that chief elected officials access local and State labor federations to provide nominations for the appointment of the labor representatives to the PIC. For this reason, a description of the nomination process is specifically included in the PIC certification by the Governor. One commenter suggested that regulations should provide that individual workers can be appointed only in cases where the local and State AFL-CIO bodies fail to provide a "sufficient number" of individuals to meet the labor representation requirements. The regulations reflect the statutory provisions in this area.

In developing and nominating that 15 percent component of the PIC, local elected officials may wish to consider the diversity of the population being served. If there is to be systemic change in the job training delivery system, sensitivity to the diverse populations being served should be exhibited by the PIC in its composition. Such changes would provide greater public awareness of the PIC and its role in the delivery of services in the community.

Role of the Private Industry Council

A number of comments were received concerning the need for strengthened PIC capacity and role. These comments were about equally divided between those who recommended giving more direction to PIC's and those who considered the existing law and regulations to provide sufficient guidance. Several comments were received from CBO's and labor unions, which urged increased representation and responsibilities on the PIC's for their constituencies. There were several commenters who recommended the periodic revalidation of the agreement between the PIC and the local elected official(s).

Section 628.410 describes the role of the PIC and establishes ongoing procedures to further the public-private partnership by providing for strengthened PIC capacity. To this end, the Department reviewed the findings of its study of exemplary PIC's and identified several key features that have been incorporated in these interim final regulations to foster more effective PIC's

and establish some minimum standards for review of PIC's. These key features included an effective well-planned organizational structure; a membership of high-ranking individuals from businesses and other community agencies who represent a balance among important interests in the community; a positive, harmonious relationship with the chief elected official that is formalized with an agreement; and an active role in monitoring or directly operating programs.

The regulations establish that the PIC is to be recertified biennially 1 year prior to the submittal of the job training plan. This certification by the Governor is to encompass three areas—certification of the membership, review and validation of the PIC/chief elected official agreement, and approval of an organizational plan that describes how the PIC governs itself. The organizational plan is to include a mission statement, committee structure, staffing, budget, policies such as meetings schedule, policies governing conflict of interest, and nomination procedures. The biennial certification schedule being set at the midpoint of the 2-year operational period ensures adequate time for the Governor to address any certification concerns without interrupting the development of the job training plan. In addition, § 628.410 lists the roles assigned to the PIC by statute. It is not intended that this listing limit the role of the PIC but rather that it emphasizes the major role to be played in the program from initial program planning and direction to monitoring and evaluating the implementation of that plan.

The Governor is expected to issue procedures and guidelines for this recertification process. This process affords the Governor a continuing role in ensuring an effective local policy decisionmaking body. The Amendments revise the nominations and recommendations processes for selecting PIC members to represent education and labor. In the recertification instructions, the Governor may require assurance that the nomination and recommendation processes have been duly followed. The Governor shall also monitor compliance with this assurance. In addition, the Governor is expected to provide a procedure for modification of the PIC operating plan.

Conflict of interest restrictions for PIC members is discussed in § 627.420, Procurement.

Job Training Plan

Section 628.420 includes not only the specific items which are statutorily

required in the plan, but also to provide guidance on program emphases in accordance with instructions or policies issued by the Secretary. This ensures that the job training plan will address at the local level other national and State concerns important to the program that are not specifically in the statute. The Governor's role is strengthened by language requiring issuance of instructions to the SDA's for use in preparation of the job training plan. The SDA shall be monitored by the Governor on the basis of its implementation of this plan.

Linkages

Sections 205 and 265 of the Act require that SDA's operating adult and year-round youth programs establish appropriate linkages with other Federal human resource programs. Other linkages may also be established with appropriate State and local educational, social service, and public housing agencies, and with CBO's, business and labor organizations, volunteer groups and others to avoid duplication and to enhance the delivery of services. In addition, youth programs are required to establish linkages with appropriate educational agencies which include formal agreements for procedures for referring and serving in-school youth, methods of assessment, notification when students drop out of school, and arrangements with educational agencies for services for in-school and out-of-school youth. These provisions are reflected in § 628.545.

General Program Design Requirements

The Amendments mandate significant changes in the front-end operations for most SDA's. The statute will cause major alterations in the intake structure and will necessitate revisions in the appraisal of each participant's capabilities, needs, and occupational goals. In these interim final regulations, the Department has provided necessary direction based on the Amendments and has clarified and highlighted significant changes from the present statute.

Eligibility Determination and Intake

Two major criteria must be considered in the process of determining which applicants are eligible for JTPA program services. As set forth in § 628.505, the first criterion is age. The second is economic disadvantage. The standard for determining economic disadvantage will be the annual Department of Health and Human Services poverty guidelines. The use of these guidelines provides a standardized income determination across federally funded programs. It

should be noted that these guidelines do include Social Security and Supplemental Security Income in the determination.

The Congressional intent in this area and the approach in the regulations was to minimize the amount of documentation necessary to establish an individual's eligibility for services, while maintaining the necessary safeguards to prevent misuse of program funds.

Fifteen comments were received on eligibility and targeting issues. Most encouraged a streamlining of the eligibility documentation process, including self-attestation. Several questioned what documentation would be required for barriers and requested guidance. Several indicated concern over burdensome paperwork requirements for referral of applicants to other than title II programs. The Secretary intends to issue an eligibility documentation TAG to be used by SDA's in the eligibility determination process. The procedures set forth in this TAG, if followed by the SDA's, will protect them from audit exceptions based on inadequate documentation. The Department solicits comments on whether the provisions of the regulations should be expanded in the area of eligibility and whether the issuance of the TAG on eligibility documentation without additional regulatory guidance is adequate. In addition, the Department will welcome comments on the contents of the TAG when it is issued.

Section 628.510 describes the changes surrounding targeting and referral requirements. During the intake process, personal data on individuals are collected and a preliminary determination regarding suitability for title II services is made. In order to focus program services on harder to serve individuals, not less than 65 percent of participants must have one or more barriers to employment as specified at the amended section 203(b) of the Act. The States and/or SDA's will establish procedures to ensure compliance with the targeting requirements and determining actions to address noncompliance with the requirements.

Objective Assessment

It is the Department's intention that the objective assessment be a smooth, client-centered and flexible process.

Fourteen comments were received on the assessment process. All supported the concept and the intent for individualized program services. Three indicated concern over the presumed lack of testing and evaluation credentials possessed by existing JTPA

staff who would be administering the objective assessment. Two indicated that the content of assessment and the development of service strategies should be left to local discretion. However, as many requested guidance in the development of assessment and service strategies. While the Department expects that States and SDA's will retain authority for program design, technical assistance will be provided on assessment and development of the ISS. Most of the specific comments on assessment addressed concern over the determination of how much assessment could be provided at the intake/eligibility stage prior to enrollment of an eligible applicant and to which cost category this would be charged. Costs incurred on behalf of an applicant, including intake, eligibility determination, and assessment necessary to facilitate the eligibility determination, should be charged to the training-related services cost category. Once an applicant is determined to be eligible and the decision made to enroll the applicant, (making the applicant a participant), the objective assessment can be administered and is to be charged to the direct training services category. While the regulations afford an opportunity to charge preliminary assessment functions to the training-related cost category, the Department expects that the entire process to be sensitive to the client and not be unduly disjointed as a result of charging assessment functions to two cost categories.

One commenter requested that the Department define "Generally accepted standardized test". The Department believes that the criteria for what constitutes an acceptable test can be found in the testing measurements literature and is most appropriately disseminated through technical assistance rather than regulations.

Section 628.515 sets forth the requirements of the objective assessment. The objective assessment is to be a client-centered, diagnostic approach to evaluation of the needs of participants without regard to services or training programs already available in an SDA. The phrase "without regard to" is intended to expand the scope of the assessment and services to the participant beyond those only available through the SDA. It is an independent, comprehensive evaluation of an individual designed to identify information vital to the design of a service strategy culminating in gainful employment. The objective assessment is an ongoing process and should not be viewed as a one-time event. It should be a multi-faceted approach which

includes a full array of options including items such as structured interviews, paper and pencil tests, performance tests, behavioral observations, interest inventories, career guidance instruments, aptitude tests, and basic skills tests. From these options, and others, assessment staff may select the most appropriate tools for each participant to measure skills, abilities, aptitudes, and interests, and to counsel participants on how their assessment results relate to local labor market demands. SDA's are strongly encouraged to select appropriate measures prudently and to select only those tools which will provide necessary information for the reasonable development of a service strategy leading to a realistic employment goal. The objective assessment and process should be sensitive to the testing and evaluation environment and the comfort and confidence level of the participant. The temptation to over-test or over-evaluate, providing excess information for which there is no immediate application, does not serve the client's best interest, is detrimental to the client/counselor relationship, and costly to the SDA.

The objective assessment, as an ongoing process, is to be revisited regularly and amended, as appropriate, when additional needs are identified or goals achieved.

Assessments recently conducted by other human service programs or schools are viewed as viable options and may be used, where appropriate, rather than requiring the client to undergo additional assessments and duplicating information already obtained.

Individual Service Strategy

Seven comments were received on the development of the ISS. All requested clarification on the specific level of services that SDA's would be required to provide to participants as identified by the objective assessment and documented in the ISS. Each expressed concern not only over the expense of the requirement to provide all services indicated by the assessment, but also over the concern that many services are simply not available in some communities, at any cost.

Section 628.520 establishes the requirements of the ISS, or employability development plan. The ISS is an individual plan that is developed based on information provided by the objective assessment. It is to outline the appropriate mix and sequence of services and justify the decisions for each; indicate any need for supportive services; and develop the

individual continuum of services that will lead to an employment goal. Decisions made in this document are to be made in partnership with the participant and are to be determined in conformance with applicable Civil Rights provisions.

The ISS, to be effective, must be regularly reviewed and adjusted to reflect the progress and to meet the continuing needs of each participant. The ISS will serve as the basis for the entire case management strategy. Case management is an allowable direct training activity and the Department encourages its use as an effective strategy for providing quality services for the participant.

Section 628.520(d) recognizes that every SDA will not be able to provide the full array of services indicated by the objective assessment and documented in the ISS. In arranging for the mix and sequence of appropriate services, it is fully expected that SDA's will refer participants to other programs for certain specified activities. In those cases where services required are indicated on the ISS and not available from any source in the SDA, such information is to be documented in the ISS and an alternative plan developed which may include referral to another program. SDA's are expected to make every reasonable effort to make the recommended training or services available to each participant; however, consistent with § 628.525, it is understood that the ISS does not give legal or entitlement rights to participants for services. JTPA is not an entitlement program and available resources are limited. In some cases, such as cases when an applicant would require excessive supportive service costs for medical and mental health needs, there might be reasons for which an SDA might elect not to enroll an otherwise eligible applicant. The Department does not intend this limitation to relieve the SDA from otherwise providing necessary supportive services such as child care.

Consistent with § 628.520(e), service providers and contractors may conduct objective assessment and develop the ISS; however, SDA's must recognize that the amendments anticipate longer term interventions for participants who are the hardest to serve and, therefore, must ensure that the development of the ISS and the services provided are client-focused, reflecting the most appropriate mix and sequence of services culminating with a realistic employment goal.

The ISS is the framework to record and document decisions about and for individual participants. It is the

instrument to justify decisions concerning the appropriate mix and sequence of services, including referral to other programs, development of work experience or OJT assignments, or referral out of title II.

Referrals of Participants to Other Programs

The regulations at § 628.530 specify the requirements for referral of eligible applicants for whom available title II services are not deemed suitable to appropriate human service programs in the community. A significant change in this section allows the SDA to assess eligible applicants before they are enrolled as participants. The purpose of this pre-participation assessment is to enable SDA's to make more precise judgments as to the suitability of the applicant for participation in JTPA and/or additional services. In these cases, the assessment activities may be charged to the training-related activities cost category.

The responsibility of the SDA at this point in the intake process is to assure that eligible applicants not suitable for title II participation are "provided information on the full array of applicable or appropriate services that are available * * *" (section 204(a)(2)(A) of the Act) and make necessary arrangements for individuals to make contact with those services.

In the case of service providers who discover that an eligible individual does not meet program enrollment requirements, § 628.510(e) requires that service providers refer such individuals back to the SDA for further assessment and referral.

Job Search Limitations

Section 628.535 of the interim final regulations codifies the languages contained in the Act at section 204(c)(2)(B) of the Act, as amended, which limits the provision of stand-alone job search assistance, job search skills training, and job club activities to participants. As part of the Amendment's focus to provide more long-term and higher quality services, such activities are allowable using title II funding only when the job search activities are combined with additional services designed to increase the educational level or occupational skills of participants.

Title II funding of job search training without the additional services described above is permissible only when the following two conditions are both fulfilled:

(1) The objective assessment and ISS of a participant do not indicate the need for additional services, and

(2) There are no job search assistance activities, including job search skills training, and job clubs, available or accessible to the participant through the Employment Service or other public agencies. These interim final regulations deem the services normally available and provided by the Employment Service within the commuting area to meet the job search availability criteria. Therefore, the SDA must document the lack of availability of job search assistance, job search skills training, or job clubs before funds are expended for those purposes. The Department may revisit this approach when performance standards for the employment service are issued.

Title II-A—The Adult Program

Most of the general requirements of title II-A appear in subpart E of the interim final regulations. There are a few specific requirements of title II-A which appear in subpart F. These include sections on eligibility; requirements to assist hard-to-serve individuals; types of training services, counseling and supportive services; and linkages and coordination.

Services to Older Individuals

The State setaside program for older workers was incorporated into section 204(d) of the Amendments. Requirements for the older workers program are set forth in § 628.320 of the regulations. The Governor continues to be responsible for carrying out these programs pursuant to agreements with public agencies, PICs, SDAs, non-profits or private businesses. The Amendments add requirement that, in entering into these agreements, the Governor is to give priority to agencies and organizations which have a record of demonstrated effectiveness in serving older individuals. The Governor is also responsible for ensuring that the program provides services throughout the State on an equitable basis, taking into account the relative share of the eligible older individuals residing in each SDA and their participation in the labor force.

The Amendments also revise the eligibility criteria by allowing up to 10% of the participants to be older individuals who are not economically disadvantaged if such individuals face serious barriers to employment and meet the income eligibility requirements under title V of the Older Americans Act of 1965. Finally, the Amendments provide that, with limited exceptions, the general title II-A requirements are to apply to the older worker program, including requirements for the objective assessment, ISS, the conditions on

services, the cost limitations, and performance standards. The exceptions include the provisions relating to referrals, targeting, reallotment, the job training plan, and performance standards incentive payments and sanctions.

Summer Youth Employment and Training Program

Eleven commenters raised issues related to the SYETP authorized under title II-B. Commenters requested flexibility in the scope of the objective assessment required for summer program participants; requested guidance pertaining to the determination and documentation of eligibility under the National School Lunch Act; cited the 15-percent limitation on administrative costs as the basis for requesting that summer program activities be defined as direct training to the maximum extent possible; asked for a transition provision allowing the 1993 summer program to operate under current requirements; and raised questions concerning the option to transfer 10 percent of summer program funding to the year-round youth program authorized under title II, part C of the Act. An additional commenter viewed separate eligibility requirements for title II parts B and C as being at cross purposes with the statutory provision authorizing concurrent enrollment in the two programs.

Subpart G sets forth the basic requirements for the SDA's operation of the SYETP. While subpart G references the objective assessment and service strategy requirements included in subpart E of the interim final regulations, it is recognized that the achievement objectives and resulting service strategies for youth differ from what might be expected in the adult program and that the corresponding assessment processes would vary accordingly. The interim final regulations clarify that SDA's are not responsible for verifying eligibility determinations made under the National School Lunch Act beyond establishing that such determinations have been made by duly authorized persons. With regard to the 15-percent limitation on administrative costs, that limitation is statutory; further, the classification of administrative and non-administrative costs for the summer youth program must be consistent with the cost classification provisions of part 627. Finally, issues pertaining to concurrent enrollment will be addressed in guidance to be provided by the Secretary as required by the Act.

Year Round Youth Program

The new title II-C program authorizes a variety of activities that may be used to address the needs of in-school and out-of-school youth. This program was developed in response to concerns about the lack of workforce skills in today's youth, both in- and out-of-school. A priority has been placed on youth currently out of any formalized school system, including dropouts. These youth are considered the most disadvantaged and the most difficult to reach and to serve.

Section 628.800 sets forth the program's primary objective of increasing the long-term employability of eligible youth. The regulations establish program design elements, such as objective assessment and other requirements for the SDA's.

At § 628.803 the eligibility criteria are set forth. These include requirements for out-of-school youth and in-school youth. Eligibility may be verified through the local education agency or an assurance that the student is eligible to participate in the free lunch program. The interim final regulations require that at least 65 percent of the in-school and the out-of-school youth are to have at least one additional barrier to employment listed in sections 263(b) and (d) of the Act, respectively. The SDA may identify one additional barrier not listed in the Act. These interim final regulations also require that non-economically disadvantaged individuals (up to 10 percent) served by the title II-C program still must face one or more barriers to employment. Further, non-disadvantaged students may participate if they are enrolled in a schoolwide project for low income schools.

There are two factors the SDA's must consider for the purposes of title II-C eligibility. The first is that at least 50 percent of the total title II-C participants in each SDA are to be out-of-school. The second is that in-school participants who are served under a schoolwide project are *not* to be counted in determining the ratio of in-school to out-of-school youth.

Section 628.804 sets forth authorized services in title II-C. It should be noted that the OJT requirements are in addition to those in part 627, subpart E. Among these is a provision mandating that the participant's wage equals or exceeds the average wage at placement in the preceding program year in the SDA for participants under title II-A. A school dropout under the age of 18 is required to attend a school, course or program. The provision of preemployment and work maturity skills training is to be accompanied by

either work experience or other additional services designed to increase the basic skills of the participant. Activities including work experience, job search assistance and job club activities must be accompanied by additional services designed to increase the basic skills of the youth. There are also provisions for the year-round operation of the program, and coordination with local educational agencies, service providers, and other programs. Schools operating on a 9-month schedule are not prohibited from providing title II-C program services.

PART 631—PROGRAMS UNDER TITLE III OF THE JOB TRAINING PARTNERSHIP ACT

In addition to the Job Training Amendments of 1992, amendments to title III were included in the Defense Authorization Act for Fiscal Year 1993. The proposed modifications to the regulations for part 631, Programs under Title III of the Job Training Partnership Act, are being driven by the changes to the legislative provisions made in the amendments. The significant modifications to the current regulations for the title III program are:

(1) The regulations at § 631.2 add an additional definition for "substantial layoff (for rapid response assistance)" which establishes a minimum threshold for the provision of rapid response assistance, as required by section 314(b)(4). This minimum threshold cannot be waived, but a new provision at § 631.30(b)(6) provides the Governor with alternatives for complying with the threshold and providing rapid response assistance in exceptional circumstances.

(2) Broader eligibility criteria are established in § 631.3(b) for the receipt of selected readjustment and retraining services in instances where an employer makes a public announcement of a plant closure, pursuant to section 314(h). The statutory provision that funding for these basic readjustment services, to the extent practicable, is to come from the Governor's reserve funds is reflected at § 631.41(g).

(3) Section 314(f)(2) of the Act defines the eligibility of individuals participating in title III programs to receive unemployment compensation benefits consistent with State policies under the Approved Training Rule to be "participating in training (except on-the-job training)." The language in the regulations at § 631.4 has been revised from participation in "any of the programs" to "any retraining activity, except on-the-job training." Because title III participants who are otherwise eligible for unemployment

compensation benefits and are not in training are generally seeking and available for work, this change is not expected to have a significant impact.

(4) The basis for computing the cost limitations which apply to expenditures of title III funds has been changed from annual expenditures to program year allocation (for substates), or reserved by the Governor from the program year allotment (for States). This change in § 631.14 reflects the amendments to section 315, and recognizes that grantees are permitted to have up to three years in which to spend allotted funds, subject to minimum annual expenditure rates.

(5) A provision has been added to § 631.14(i) to clarify that funds allocated to a substate grantee from the Governor's reserve funds to provide additional basic readjustment or retraining assistance shall be included in the substate grantee's formula allocation for purposes of applying the cost limits, reflecting the provision in section 302(c)(1)(E).

(6) A new provision has been added at § 631.14(h) to allow neighboring substate grantees to combine funds to serve dislocated workers from two or more substate areas, as authorized in section 315(d). To qualify for this provision, consistent with the congressional intent that this provision apply to neighboring substate grantees, the substate grantees must be contiguous or be part of the same labor market area.

(7) A new provision is added at § 631.15 requiring the State to provide a breakout of all administrative expenditures by the dislocated worker unit (DWU), pursuant to section 311(b)(11).

(8) A new provision is added at § 631.17 clarifying the Secretary's authority to oversee the State's provision of rapid response assistance and require corrective action as necessary, as provided for in section 314(b)(3).

(9) An amended provision in section 314(e)(1) regarding eligibility for needs-related payments requires that a participant be unemployed, and this has been incorporated in § 631.20(c).

(10) A provision at § 631.30(a)(8) requires the State to immediately notify the substate grantee of current or projected layoffs and closures in the local area for the purpose of continuing and expanding upon the services initiated by the rapid response team, as required in section 311(b)(3)(D).

(11) Section 311(b)(12) stipulates that accountability for rapid response assistance resides in the DWU, although the DWU may contract with other

entities for the provision of these services. This is reflected in the provisions at § 631.30(b).

(12) A provision has been added to § 631.32(b)(2) to clarify that Governors must give consideration to each of the substate allocation formula factors required by section 302(d) of the Act unless the factor is not relevant to economic dislocation conditions in the State.

(13) Pursuant to section 315, § 631.62 stipulates that the cost limitations under part A of title III will apply to projects operated under part B of title III, except when waived or altered by the application guidelines, or by the Grant Officer in the terms of the grant.

(14) A provision is added at § 631.63 enumerating the Federal Reporting requirements for recipients of title III discretionary grants, consistent with section 322(a)(4).

(15) A provision is added at § 631.64 clarifying the administrative requirements under title I of the Act which apply for grantees other than States, including procedures for grievances and procurement.

(16) A new subpart I, to be administered as part of the title III National Reserve Grants program, provides for Disaster Relief Employment Assistance, as authorized by amendments to title IV of the Act.

In addition, technical changes have been made so that the regulations in this part conform to related provisions in the other parts.

Promulgation of rules for the Clean Air Employment Transition Assistance (CAETA) program, and for the Defense Conversion Adjustment (DCA) program are being deferred until finalization of these regulations. Commenters may want to provide comments through this review process on the impact of these regulations on the regulation or operation of the CAETA and DCA programs. See *Federal Register* at 57 FR 4808 (February 7, 1992) for the Clean Air Employment Transition Assistance program; and 57 FR 30536 (July 9, 1992) for the Defense Conversion Adjustment program.

PART 637—JOBS FOR EMPLOYABLE DEPENDENT INDIVIDUALS (JEDI)

The Incentive Bonus Program established under title V by the enactment of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988 on November 7, 1988, was substantially changed with the enactment of the Amendments. As a result, the regulations at part 637 have been revised. Among the significant changes in the Program, which are

reflected in the revised regulations, are the new target groups, which are absent parents of children receiving AFDC and recipients of supplementary security income, the simplified eligibility criteria for receipt of bonuses, the simplified application requirements, the simplified review and approval process for applications, the reduction in the administrative monies available to States, the elimination of startup grants, and the elimination of the trigger for the appropriation of funds.

Two States commented on the revised JEDI program. One State requested that recordkeeping requirements be kept to a minimum and the other commenter requested guidance on how to implement this Program without any funds being appropriated by Congress. Regarding the first comment, the Amendments provide that the States are required to have documentation sufficient to support their applications for incentive bonuses. The regulations do not prescribe additional recordkeeping requirements. Regarding the implementation of the Program, there is currently no appropriation for title V and no funds are assured for future fiscal years. Each State will have to make a determination as to whether or not to begin tracking the data necessary for incentive bonus applications without having title V funds to offset these additional costs.

Regulatory Impact

The interim final rule implements Public Law 102-367, 106 Stat. 1021 (September 7, 1992) and the Defense Authorization Act for Fiscal Year 1993, Public Law 102-484, makes technical changes, and clarifies existing regulations to reflect continuing policies. While the programs are modified pursuant to the statutory amendments, the delivery system for the JTPA programs under the interim final rule remains essentially the same as in existing regulations. It does not have the financial or other impact to make it a major rule and, therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291, 3 CFR, 1981 Comp., p. 127, 5 U.S.C. 601 note.

The Department of Labor has certified to the Chief Counsel for Advocacy, Small Business Administration, that, pursuant to the Regulatory Flexibility Act at 5 U.S.C. 605(b), the interim final rule would not have a significant economic impact on a substantial number of small entities. No significant economic impact would be imposed on such entities by the interim final rule.

As discussed above, the Job Training Reform Amendments of 1992 mandate

that these regulations be in effect by December 18, 1992. Modification of the JTPA regulations is necessary to incorporate the statutory amendments. It is clearly the intent of Congress that the statutory and regulatory amendments be implemented for the JTPA Program Year beginning on July 1, 1993. Planning and implementation actions must be undertaken as soon as these regulations are published, to adequately implement the programs on a timely basis. Therefore, the Department of Labor has found good cause, pursuant to 5 U.S.C. 553(b)(B), to publish the interim final regulations without a prior proposed rule, since such a proposed rule is impracticable and contrary to the public interest. For similar grounds, the Department has found that good cause exists, pursuant to 5 U.S.C. 553(d)(3), to make these interim final regulations effective on the date mandated by statute, December 18, 1992. Comments are requested and the final rule is expected to be published on or before June 1, 1993, the expiration date of this interim final rule.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act, information collection requirements which would be imposed as a result of the interim final rule are being submitted separately to the Office of Management and Budget.

Catalog of Federal Domestic Assistance Number

These programs are listed in the Catalog of Federal Domestic Assistance at No. 17-246, "Employment and Training Assistance—Dislocated Workers" (JTPA Title III Programs); and No. 17-250, "Job Training Partnership Act (JTPA)" (JTPA titles I, II, and V Programs).

List of Subjects in 20 CFR Parts 626 through 631 and 637

Grant programs, Labor, Manpower training programs, Dislocated worker programs.

Interim Final Rule

Accordingly, chapter V of title 20, Code of Federal Regulations, is amended, as follows:

1. Part 626 is revised to read as follows:

PART 626—INTRODUCTION TO THE REGULATIONS UNDER THE JOB TRAINING PARTNERSHIP ACT

Sec.

- 626.1 Scope and purpose of the Job Training Partnership Act.
- 626.2 Format of the Job Training Partnership Act regulations.

Sec.

- 626.3 Purpose, scope, and applicability of the Job Training Partnership Act regulations.
 - 626.4 Table of contents for the Job Training Partnership Act regulations.
 - 626.5 Definitions.
- Authority: 29 U.S.C. 1579(a); sec. 6305(f), Pub. L. 100-418, 102 Stat. 1107; 29 U.S.C. 1791(e).

§ 626.1 Scope and purpose of the Job Training Partnership Act.

It is the purpose of the Job Training Partnership Act (JTPA or the Act) to establish programs to prepare youth and adults facing serious barriers to employment for participation in the labor force by providing job training and other services that will result in increased employment and earnings, increased educational and occupational skills, and decreased welfare dependency, thereby improving the quality of the work force and enhancing the productivity and competitiveness of the Nation (section 2).

§ 626.2 Format of the Job Training Partnership Act regulations.

(a) Regulations promulgated by the Department of Labor to implement the provisions of the Act are set forth in parts 626 through 638 of title 20, chapter V, of the Code of Federal Regulations, with the exception of the veterans' employment program's chapter IX regulations of the Office of the Assistant Secretary for Veterans' Employment and Training, which are set forth at part 1005 of title 20.

(b) Nondiscrimination and equal opportunity requirements and procedures, including complaint processing and compliance reviews, will be governed by the provisions of 29 CFR parts 31, 32 and 34 and will be administered by the Department of Labor (Department or DOL) Directorate of Civil Rights.

(c) General authority for the JTPA regulations is found at section 169 of the Act. Specific statutory authorities other than section 169 are noted throughout the JTPA regulations.

§ 626.3 Purpose, scope, and applicability of the Job Training Partnership Act regulations.

(a) Parts 626 through 638 of this chapter and part 1005 of chapter IX (Veterans' employment programs under title IV, part C of the Job Training Partnership Act) establish the Federal programmatic and administrative requirements for JTPA grants awarded by the Department of Labor to eligible grant recipients.

(b) Parts 626 through 638 of this chapter and part 1005 of chapter IX

apply to recipients and subrecipients of JTPA funds.

§ 626.4 Table of contents for the Job Training Partnership Act regulations.

The table of contents for the regulations under the Job Training Partnership Act, 20 CFR parts 626-638 and 1005, is as follows:

PART 626—INTRODUCTION TO THE REGULATIONS UNDER THE JOB TRAINING PARTNERSHIP ACT

Sec.

- 626.1 Scope and purpose of the Job Training Partnership Act.
- 626.2 Format of the Job Training Partnership Act regulations.
- 626.3 Purpose, scope and applicability of the Job Training Partnership Act regulations.
- 626.4 Table of contents for the Job Training Partnership Act regulations.
- 626.5 Definitions.

PART 627—GENERAL PROVISIONS GOVERNING PROGRAMS UNDER THE ACT

Subpart A—Scope and Purpose

- 627.100 Scope and Purpose of Part 627.

Subpart B—Program Requirements

- 627.200 Governor/Secretary agreement.
- 627.205 Public service employment prohibition.
- 627.210 Nondiscrimination and nonsectarian activities.
- 627.215 Relocation.
- 627.220 Coordination with programs under title IV of the Higher Education Act including the Pell grant program.
- 627.225 Employment generating activities.
- 627.230 Displacement.
- 627.235 General program requirements.
- 627.240 On-the-job training.
- 627.245 Work experience.
- 627.250 Interstate agreements.

Subpart C—Payments, Benefits and Working Conditions

- 627.300 Scope and purpose.
- 627.305 Payments.
- 627.310 Benefits and working conditions.

Subpart D—Administrative Standards

- 627.400 Scope and purpose.
- 627.405 Grant agreement and funding.
- 627.410 Reallotment and reallocation.
- 627.415 Insurance.
- 627.420 Procurement.
- 627.422 Selection of service providers.
- 627.423 Funding restrictions for "high-risk" recipients and subrecipients.
- 627.424 Prohibition of subawards to debarred and suspended parties.
- 627.425 Standards for financial management and participant data systems.
- 627.430 Grant payments.
- 627.435 Cost principles and allowable costs.
- 627.440 Classification of costs.
- 627.445 Limitations on certain costs.
- 627.450 Program income.
- 627.455 Reports required.
- 627.460 Requirements for records.

- 627.463 Public access to records.
- 627.465 Property management standards.
- 627.470 Performance standards.
- 627.471 Reorganization plan appeals.
- 627.475 Oversight and monitoring.
- 627.480 Audits.
- 627.481 Audit resolution.
- 627.485 Closeout.
- 627.490 Later disallowances and adjustments.
- 627.495 Collection of amounts due.

Subpart E—Grievances Procedures at the State and Local Level

- 627.500 Scope and purpose.
- 627.501 State grievance and hearing procedures for non-criminal complaints at the recipient level.
- 627.502 Grievance and hearing procedures for non-criminal complaints at the SDA, and SSG levels.
- 627.503 Recipient-level review.
- 627.504 Non-criminal grievance procedure at employer level.

Subpart F—Federal Handling of Non-criminal Complaints and Other Allegations

- 627.600 Scope and purpose.
- 627.601 Complaints and allegations at the Federal Level.
- 627.602 Resolution of investigative findings.
- 627.603 Special handling of labor standards violations under section 143 of the Act.
- 627.604 Alternative procedure for handling labor standards violations under section 143—Binding arbitration.
- 627.605 Special Federal review of local level complaints without decision.
- 627.606 Grant officer resolution.

Subpart G—Sanctions for Violations of the Act

- 627.700 Scope and purpose.
- 627.702 Sanctions and corrective actions.
- 627.703 Failure to comply with procurement provisions.
- 627.704 Process for waiver of State liability.
- 627.706 Process for advance approval of a recipient's contemplated corrective actions.
- 627.708 Offset process.

Subpart H—Hearings by the Office of Administrative Law Judges

- 627.800 Scope and purpose.
- 627.801 Procedures for filing request for hearing.
- 627.802 Rules of procedure.
- 627.803 Relief.
- 627.804 Timing of decisions.
- 627.805 Alternative dispute resolution.
- 627.806 Other authority.

Subpart I—Transition Provisions

- 627.900 Scope and purpose.
- 627.901 Transition period.
- 627.902 Governor's actions.
- 627.903 Actions which are at the discretion of the Governor.
- 627.904 Transition and implementation.
- 627.905 Guidance on contracts and other agreements.
- 627.906 Determinations on State and SDA implementation.

PART 628—PROGRAMS UNDER TITLE II OF THE JOB TRAINING PARTNERSHIP ACT

Subpart A—Scope and Purpose

- 628.100 Scope and purpose of part 628.

Subpart B—State Planning

- 628.200 Scope and purpose.
- 628.205 Governor's coordination and special services plan.
- 628.210 State Job Training Coordinating Council.
- 628.215 State Human Resource Investment Council.

Subpart C—State Programs

- 628.300 Scope and purpose.
- 628.305 State distribution of funds.
- 628.310 Administration.
- 628.315 Education coordination and grants.
- 628.320 Services for older individuals.
- 628.325 Incentive grants, capacity building and technical assistance.

Subpart D—Local Service Delivery System

- 628.400 Scope and purpose.
- 628.405 Service delivery areas.
- 628.410 Private Industry Council.
- 628.415 Selection of SDA grant recipient and administrative entity.
- 628.420 Job training plan.
- 628.425 Review and approval.
- 628.426 Disapproval of the plan.
- 628.430 State SDA submission.

Subpart E—Program Design Requirements for Programs Under Title II of the Job Training Partnership Act

- 628.500 Scope and purpose.
- 628.505 Eligibility.
- 628.510 Intake, referrals, and targeting.
- 628.515 Objective assessment.
- 628.520 Individual service strategy.
- 628.525 Limitations.
- 628.530 Referrals of participants to non-title II programs.
- 628.535 Limitations on job search assistance.
- 628.540 Volunteer program.
- 628.545 Linkages and coordination.
- 628.550 Transfer of funds.

Subpart F—The Adult Program

- 628.600 Scope and purpose.
- 628.605 Eligibility.
- 628.610 Authorized services.

Subpart G—The Summer Youth Employment and Training Program

- 628.700 Scope and purpose.
- 628.701 Program goals and objectives.
- 628.702 Eligibility.
- 628.705 SYETP authorized services.
- 628.710 Period of program operation.

Subpart H—Youth Training Program

- 628.800 Scope and purpose.
- 628.803 Eligibility.
- 628.804 Authorized services.

PART 629—[RESERVED]

PART 630—[RESERVED]

PART 631—PROGRAMS UNDER TITLE III OF THE JOB TRAINING PARTNERSHIP ACT

Subpart A—General Provisions

- 631.1 Scope and purpose.
- 631.2 Definitions.
- 631.3 Participant eligibility.
- 631.4 Approved training rule.

Subpart B—Additional Title III Administrative Standards and Procedures

- 631.11 Allotment and obligation of funds by the Secretary.
- 631.12 Reallocation of funds by the Secretary.
- 631.13 Classification of costs at State and substate levels.
- 631.14 Limitations on certain costs.
- 631.15 Federal reporting requirements.
- 631.16 Complaints, investigations, and penalties.
- 631.17 Federal monitoring and oversight.
- 631.18 Federal by-pass authority.
- 631.19 Appeals.

Subpart C—Needs-Related Payments

- 631.20 Needs-related payments.

Subpart D—State Administration

- 631.30 Designation or creation and functions of a State dislocated worker unit or office and rapid response assistance.
- 631.31 Monitoring and oversight.
- 631.32 Allocation of funds by the Governor.
- 631.33 State procedures for identifying funds subject to mandatory federal reallocation.
- 631.34 Designation of substate areas.
- 631.35 Designation of substate grantees.
- 631.36 Biennial State plan.
- 631.37 Coordination activities.
- 631.38 State by-pass authority.

Subpart E—State Programs

- 631.40 State program operational plan.
- 631.41 Allowable State activities.

Subpart F—Substate Programs

- 631.50 Substate plan.
- 631.51 Allowable substate program activities.
- 631.52 Selection of service providers.
- 631.53 Certificate of continuing eligibility.

Subpart G—Federal Delivery of Dislocated Worker Services

- 631.60 General.
- 631.61 Application for funding and selection criteria.

Subpart H—Transition Provisions

- 631.70 Special provisions for program startup.

PART 632—INDIAN AND NATIVE AMERICAN EMPLOYMENT AND TRAINING PROGRAMS

Subpart A—Introduction

- 632.1 [Reserved]
- 632.2 Scope and purpose.
- 632.3 Format for these regulations.
- 632.4 Definitions.

Subpart B—Designation Procedures for the Native American Grantees

- 632.10 Eligibility requirements for designation as a Native American grantee.
- 632.11 Designation of Native American grantees.
- 632.12 Alternative arrangements for the provision of services, nondesignation.
- 632.13 Review of denial of designation as a Native American grantee, or rejection of a comprehensive annual plan.

Subpart C—Program Planning, Application and Modification Procedures

- 632.17 Planning process.
- 632.18 Regional and national planning meetings.
- 632.19 Grant application content.
- 632.20 Submission of grant applications.
- 632.21 Application disapproval.
- 632.22 Modification of a Comprehensive Annual Plan (CAP) and/or Master Plan.
- 632.23 Termination and corrective action of a CAP and/or Master Plan.

Subpart D—Administrative Standards and Procedures

- 632.31 General.
- 632.32 Financial management systems.
- 632.33 Audits.
- 632.34 Program income.
- 632.35 Native American grantee contracts and subgrants.
- 632.36 Procurement standards.
- 632.37 Allowable costs.
- 632.38 Classification of costs.
- 632.39 Administrative cost plan.
- 632.40 Administrative staff and personnel standards.
- 632.41 Reporting requirements.
- 632.42 Grant closeout procedures.
- 632.43 Reallocation of funds.
- 632.44 Sanctions for violation of the Act.

Subpart E—Program Design and Management

- 632.75 General responsibilities of Native American grantees.
- 632.76 Program management systems.
- 632.77 Participant eligibility determination.
- 632.78 Training activities.
- 632.79 Employment activities.
- 632.80 Other activities.
- 632.81 Payments to participants.
- 632.82 Benefits and working conditions for participants.
- 632.83 FICA.
- 632.84 Non-Federal status of participants.
- 632.85 Participant limitations.
- 632.86 Nondiscrimination and nonsectarian activities.
- 632.87 Equitable provisions of services to the eligible population and significant segments.
- 632.88 General responsibilities of the Department.
- 632.89 Performance standards.

Subpart F—Prevention of Fraud and Program Abuse

- 632.115 General.
- 632.116 Conflict of interest.
- 632.117 Kickbacks.
- 632.118 Nepotism.
- 632.119 Political patronage.

- 632.120 Political activities.
- 632.121 Lobbying activities.
- 632.122 Unionization and antiunionization activities; work stoppages.
- 632.123 Maintenance of effort.
- 632.124 Theft or embezzlement from employment and training funds; improper inducement; obstruction of investigations and other criminal provisions.
- 632.125 Responsibilities of Native American grantees, subgrantees and contractors for preventing fraud and program abuse and for general program management.

Subpart G—[Reserved]**Subpart H—Job Training Partnership Act Programs Under Title IV, Section 401**

- 632.170 Eligibility for funds.
- 632.171 Allocation of funds.
- 632.172 Eligibility for participation in Title IV, Section 401.
- 632.173 Allowable program activities.
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- 632.250 General.
- 632.251 Eligibility for funds.
- 632.252 Allocation of funds.
- 632.253 Special operating provision.
- 632.254 Program startup.
- 632.255 Program planning.
- 632.256 Submission of applications.
- 632.257 Eligibility for participation.
- 632.258 Allowable activities.
- 632.259 Vocational exploration program.
- 632.260 Worksite standards.
- 632.261 Reporting requirements.
- 632.262 Termination date for the summer program.
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PART 633—MIGRANT AND SEASONAL FARMWORKER PROGRAMS**Subpart A—Introductory Provisions**

- 633.102 Scope and purpose of Title IV, Section 402 programs.
- 633.103 Format for these regulations.
- 633.104 Definitions.
- 633.105 Allocation of funds.
- 633.106 Eligibility for allocable funds.
- 633.107 Eligibility for participation in Section 402 programs.

Subpart B—Grant Planning and Application Procedures

- 633.201 Grant planning and application procedures in general.
- 633.202 Announcement of State planning estimates and invitation to submit a grant application.
- 633.203 Review of funding request.
- 633.204 Responsibility review.
- 633.205 Notification of selection.

Subpart C—Program Design and Administrative Procedures

- 633.301 General responsibilities.
- 633.302 Training activities and services.
- 633.303 Allowable costs.
- 633.304 Section 402 cost allocation.
- 633.305 General benefits and working conditions for program participants.
- 633.306 Retirement benefits.

- 633.307 Packages of benefits.
- 633.308 Non-Federal status of participants.
- 633.309 Recordkeeping requirements.
- 633.310 Bonding.
- 633.311 Management information systems.
- 633.312 Grantee contracts and subgrants.
- 633.313 Administrative staff and personnel standards.
- 633.314 Reports required.
- 633.315 Replacement, corrective action, termination.
- 633.316 Closeout procedures.
- 633.317 Reallocation of funds.
- 633.318 Nondiscrimination and nonsectarian activities.
- 633.319 Lobbying, political activities and unionization.
- 633.320 Nepotism.
- 633.321 Performance standards for Section 402 programs.
- 633.322 Sanctions for violation of the Act.

PART 634—LABOR MARKET INFORMATION PROGRAMS UNDER TITLE IV, PART E OF THE JOB TRAINING PARTNERSHIP ACT**Comprehensive Labor Market Information System**

- 634.1 General.
- 634.2 Availability of funds.
- 634.3 Eligible recipients.
- 634.4 Statistical standards.
- 634.5 Federal oversight.

PART 635—[RESERVED]**PART 636—COMPLAINTS, INVESTIGATIONS AND HEARINGS**

- 636.1 Scope and purpose.
- 636.2 Protection of informants.
- 636.3 Complaint and hearing procedures at the grantee level.
- 636.4 Grievance procedures at the employer level.
- 636.5 Exhaustion of grantee level procedure.
- 636.6 Complaints and investigations at the Federal level.
- 636.7 Subpoenas.
- 636.8 Initial and final determination; request for hearing at the Federal level.
- 636.9 Opportunity for informal review.
- 636.10 Hearings before the Office of Administrative Law Judges.
- 636.11 Final action.

PART 637—PROGRAMS UNDER TITLE V OF THE JOB TRAINING PARTNERSHIP ACT**Subpart A—General Provisions**

- 637.1 Scope and purpose.
- 637.2 Definitions.

Subpart B—Program Planning and Operation

- 637.10 Allotments to States.
- 637.11 Notice of intent to participate.
- 637.12 Incentive bonus program applications.
- 637.13 Review, verification and approval of applications for incentive bonus payments.
- 637.14 Eligibility criteria for individuals eligible to be counted in determining incentive bonuses.
- 637.15 Determination of incentive bonus.
- 637.16 Use of incentive bonuses.

**Subpart C—Additional Title V
Administrative Standards and Procedures**

- 637.20 Management systems, reporting and recordkeeping.
- 637.21 Federal monitoring and oversight.
- 637.22 Audits.

Subpart D—Data Collection [Reserved]

**PART 638—JOB CORPS PROGRAM UNDER
TITLE IV—B OF THE JOB TRAINING
PARTNERSHIP ACT**

Subpart A—Purpose and Scope

- 638.100 General.

Subpart B—Definitions

- 638.200 Definitions.

**Subpart C—Funding, Site Selection and
Facilities Management**

- 638.300 Eligibility for funds and eligible deliverers.
- 638.301 Funding procedures.
- 638.302 Center performance measurement.
- 638.303 Site selection and facilities management.
- 638.304 Historical preservation.
- 638.305 Capital improvements.
- 638.306 Protection and maintenance of contract center facilities owned or leased by Job Corps.
- 638.307 Facilities surveys.

**Subpart D—Enrollment, Transfers,
Terminations, and Placements in the Job
Corps**

- 638.400 Eligibility for participation.
- 638.401 Outreach and screening of participants.
- 638.402 Enrollment by readmission.
- 638.403 Selective service.
- 638.404 Transfers.
- 638.405 Extensions of enrollment.
- 638.406 Federal status of students.
- 638.407 Terminations.
- 638.408 Transportation.
- 638.409 Placement and job development.

Subpart E—Center Operations

- 638.500 Orientation program.
- 638.501 Student handbook.
- 638.502 Job Corps basic education program.
- 638.503 Vocational training.
- 638.504 Occupational exploration programs.
- 638.505 Scheduling of training.
- 638.506 Purchase of vocational supplies and equipment.
- 638.507 Work experience.
- 638.508 Sale of services or objects.
- 638.509 Leisure-time employment.
- 638.510 Health care and services.
- 638.511 Drug use and abuse.
- 638.512 Sexual behavior and harassment.
- 638.513 Death.
- 638.514 Residential support services.
- 638.515 Recreation/avocational program.
- 638.516 Laundry, mail, and telephone service.
- 638.517 Counseling.
- 638.518 Intergroup relations program.
- 638.519 Incentives system.
- 638.520 Student government and leadership program.
- 638.521 Student welfare associations.
- 638.522 Evaluation of student progress.

- 638.523 Food service.
- 638.524 Allowances and allotments.
- 638.525 Clothing.
- 638.526 Tort and other claims.
- 638.527 Federal employees' compensation.
- 638.528 Social Security.
- 638.529 Income taxes.
- 638.530 Emergency use of personnel, equipment, and facilities.
- 638.531 Limitations on the use of students in emergency projects.
- 638.532 Annual leave.
- 638.533 Other student absences.
- 638.534 Legal services to corpsmembers.
- 638.535 Voting rights.
- 638.536 Religious rights.
- 638.537 Disclosure of information.
- 638.538 Disciplinary procedures and appeals.
- 638.539 Complaints and disputes.
- 638.540 Cooperation with agencies and institutions.
- 638.541 Job Corps training opportunities.
- 638.542 Child care services.
- 638.543 Community relations program.

**Subpart F—Applied Vocational Skills
Training (VST)**

- 638.600 Applied vocational skills training (VST) through work Projects
- 638.601 Applied VST budgeting.

**Subpart G—Experimental, Research, and
Demonstration Projects**

- 638.110 Experimental, research, and demonstration projects.

Subpart H—Administrative Provisions

- 638.800 Program management.
- 638.801 Staff training.
- 638.802 Student records management.
- 638.803 Safety.
- 638.804 Environmental health.
- 638.805 Security and law enforcement.
- 638.806 Property management and procurement.
- 638.807 Imprest and petty cash funds.
- 638.808 Center financial management and reporting.
- 638.809 Audit.
- 638.810 Reporting requirements.
- 638.811 Review and evaluation.
- 638.812 State and local taxation of Job Corps deliverers.
- 638.813 Nondiscrimination, nonsectarian activities.
- 638.814 Lobbying; political activities; unionization.
- 638.815 Charging fees.

**PART 1005—VETERANS' EMPLOYMENT
PROGRAMS UNDER THE TITLE IV, PART C
OF THE JOB TRAINING PARTNERSHIP ACT**

Subpart A—General Provisions

- 1005.1 Scope and purpose.
- 1005.2 Program administration.
- 1005.3 Participant eligibility.

Subpart B—Program Funding

- 1005.11 Availability of funds.
- 1005.12 Eligibility for funds.
- 1005.13 Application for funding.
- 1005.14 Review of application for funding.
- 1005.15 Approval of funding requests.

**Subpart C—Program Design and
Management**

- 1005.21 General.
- 1005.22 Allowable activities.
- 1005.23 Program management and performance standards.
- 1005.24 Recordkeeping and reporting requirements.
- 1005.25 Monitoring and oversight.
- 1005.26 Grievance procedures.

§ 626.5 Definitions.

In addition to the definitions contained in section 4 of the Act, the following definitions of terms used in the Act or parts 626–631 of this chapter apply as appropriate to programs under titles I, II, and III of the Act:

Accrued expenditures means charges made to the JTPA program. Expenditures are the sum of actual cash disbursements, the amount of indirect expense incurred, and the net increase (or decrease) in the amounts owed by the recipient for the goods and other property received, for services performed by employees, contractors, subgrantees, subcontractors, and other payees, and other amounts becoming owed under programs for which no current services or performance are required, such as annuities, insurance claims, and other benefit payments.

Act means the Job Training Partnership Act.

ALJ means an administrative law judge in the Office of Administrative Law Judges of the U.S. Department of Labor.

Awarding agency means:

- (1) With respect to a grant, the Department of Labor; and
- (2) With respect to a subgrant or contract, the party that awarded the subgrant or contract.

Capacity building means the systematic improvement of job functions, skills, knowledge, and expertise of the personnel who staff employment and training and other closely related human service systems. Capacity building is designed to enhance the effectiveness, to strengthen the caliber of client services provided under the Act and other Federal, State, and local employment and training programs, and improve coordination among them. Capacity building includes curricula development, appropriate training, technical assistance, staff development, and other related activities.

Chief elected official (CEO) means the official or officials, or their representatives, or the jurisdiction or jurisdictions which requested designation by the Governor as a service delivery area.

Commercial organizations means private for-profit entities.

Commercially available or off-the-shelf training package means a training package sold or traded unmodified, in substantial quantities to the general public in the course of normal business operations, at prices based on established catalog or market prices. To be considered as "sold to the general public", the package must be regularly sold in sufficient quantities to constitute a real commercial market, to buyers which may include JTPA programs but must include other than JTPA programs. The package must include performance criteria.

Contractor means the organization, entity, or individual that is awarded a procurement contract under the recipient's or subrecipient's procurement standards and procedures.

Cost means accrued expenditure.

Department means the U.S.

Department of Labor.

DOL means the U.S. Department of Labor.

ETA means the Employment and Training Administration of the U.S. Department of Labor.

Family is defined at section 4(34) of the Act. An "individual with a disability" may, for the purposes of income eligibility determination, be considered to be an unrelated individual who is a family unit of one. The Governor may provide interpretations of the term "family" related to how "dependent children" are defined for programs within a State, consistent with the Act, and all applicable rules and regulations, and State or local law. Such interpretations by the Governor may address the treatment of certain individuals who may need to be viewed discretely in the income eligibility determination process, such as runaways, emancipated youth, and court adjudicated youth separated from the family.

The phrase "living in a single residence" with other family members includes temporary, voluntary residence elsewhere (e.g. attending school or college, or visiting relatives). It does not include involuntary temporary residence elsewhere (e.g. incarceration, or placement as a result of a court order).

Family income means "income" as defined by the Department of Health and Human Services in connection with the annual poverty guidelines. Such income shall not include unemployment compensation, child support and public assistance, as provided for at section 4(8) of the Act.

Funding period means the period of time when JTPA funds are available for expenditure. Unless a shorter period of time is specified in a title III

discretionary award, the JTPA funding period is the 3-year period specified in JTPA section 161(b); the program year in which Federal funds are obligated to the recipient, and the two succeeding program years.

Governor means, in addition to the definition at section 4(9) of the Act, the recipient of JTPA funds awarded to the State under titles I through III.

Grant means an award of JTPA financial assistance by the U.S. Department of Labor to an eligible JTPA recipient. (Also, see §§ 627.405 and 627.430 of these regulations).

Grantee means the recipient.

Individual service strategy (ISS) is defined in § 628.520 of these regulations.

Job search assistance (also including **job search skills training and job club activities**) means the provision of instruction and support to a participant to give the participant skills in acquiring full-time employment. The services provided may include, but are not limited to, resume writing, interviewing skills, labor market guidance, telephone techniques, information on job openings, and job acquisition strategies, as well as the provision of office space and supplies for the job search.

Job Training Partnership Act means Public Law (Pub. L.) 97-300, as amended, 29 U.S.C. 1501 et seq.

JTPA means the Job Training Partnership Act.

Nontraditional employment, as applied to women, means occupations or fields of work where women comprise less than 25 percent of the individuals employed in such occupation or field of work. (Pub. L. 102-235, Nontraditional Employment for Women Act).

OALJ means the Office of Administrative Law Judges of the U.S. Department of Labor.

Obligations means the amounts of orders placed, contracts and subgrants awarded, goods and services received, and similar transactions during a funding period that will require payment by the recipient or subrecipient during the same or a future period.

OIG means the Office of the Inspector General of the U.S. Department of Labor.

PIC means a private industry council.

Participant is defined in section 4(37) of the Act.

Program year means the 12-month period beginning July 1 of the indicated year.

Recipient means the entity to which a JTPA grant is awarded directly from the Department of Labor to carry out the JTPA program. The recipient is the entire legal entity that received the

award and is legally responsible for carrying out the JTPA program, even if only a particular component of the entity is designated in the grant award document. For JTPA grants under titles I, II and III, except for certain discretionary grants awarded under title III, part B, the State is the recipient.

SDA means a service delivery area designated by the Governor pursuant to section 101(a)(4) of the Act. As used in these regulations, SDA may also refer to the entity which administers the JTPA program within the designated area.

SDA grant recipient means the entity that receives JTPA funds for a service delivery area directly from the recipient.

Secretary means the Secretary of Labor.

Section, as used in this chapter, means a section of the Act unless the text specifically indicates otherwise.

Service provider means any subrecipient, including a service delivery area or substate grantee, that is responsible for the delivery of training and/or supportive services directly to JTPA participants. Awards to service providers may be made by subgrant, contract, subcontract, or other legal agreement.

Stand-in costs means costs paid from non-Federal sources which a recipient proposes to substitute for Federal costs which have been disallowed as a result of an audit or other review. In order to be considered as valid substitutions, the costs (1) must have been reported by the grantee as uncharged program costs under the same title and in the same year in which the disallowed costs were incurred and (2) must have been incurred in compliance with laws, regulations, and contractual provisions governing JTPA.

State is defined at section 4(22) of the Act. For cash payment purposes, the definition of "State" contained in the Department of Treasury regulations at 31 CFR 205.3 shall apply to JTPA programs.

State council means the State Job Training Coordinating Council (SJTCC) or, in a State with a Human Resource Investment Council (SHRIC) pursuant to § 628.315 of the chapter, the SHRIC.

Subgrant means an award of JTPA financial assistance in the form of money, or property in lieu of money, made under a grant by a recipient to an eligible subrecipient. It also means a subgrant award of JTPA financial assistance by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement purchases from vendors nor does it include any

form of assistance received by program participants.

Subgrantee mean a subrecipient.

Subrecipient means the legal entity to which a subgrant is awarded and which is accountable to the recipient (or higher tier subrecipient) for the use of the funds provided. For JTPA purposes, distinguishing characteristics of a subrecipient include items such as determining eligibility of applicants, enrollment of participants, performance measured against meeting the objectives of the program, responsibility for programmatic decisionmaking, responsibility for compliance with program requirements, and use of the funds awarded to carry out a JTPA program or project, as compared to providing goods or services for a JTPA program or project (vendor). Depending on local circumstances, the PIC, local elected official, or administrative entity may be a subrecipient. SDA grant recipients and JTPA title III substate grantees are particular types of subrecipients.

Substate grantee (SSG) means that agency or organization selected to administer programs pursuant to section 312(b) of the Act. The substate grantee is the entity that receives JTPA title III funds for a substate area directly from the Governor.

Technical assistance is a facet of capacity building which includes information sharing, dissemination and training on program models and job functions; peer-to-peer networking and problem solving; guides; and interactive communication technologies.

Title, as used in this chapter, means a title of the Act, unless the text of the regulation specifically indicates otherwise.

Vendor means an entity responsible for providing generally required goods or services to be used in the JTPA program. These goods or services may be for the recipient's or subrecipient's own use or for the use of participants in the program. Distinguishing characteristics of a vendor include items such as: Providing the goods and services within normal business operations; providing similar goods or services to many different purchasers, including purchasers outside the JTPA program; and operating in a competitive environment. A vendor is not a subrecipient and does not exhibit the distinguishing characteristics attributable to a subrecipient as defined above. Any entity directly involved in the delivery of program services not available to the general public, with the exception of an employer providing on-the-job-training, shall be considered a subrecipient rather than a vendor.

Wagner-Peyser Act means 29 U.S.C. 49 et seq.

2. Part 627 is revised to read as follows:

PART 627—GENERAL PROVISIONS GOVERNING PROGRAMS UNDER TITLES I, II, AND III OF THE ACT

Subpart A—Scope and purpose

627.100 Scope and Purpose of Part 627.

Subpart B—Program Requirements

627.200 Governor/Secretary agreement.

627.205 Public service employment prohibition.

627.210 Nondiscrimination and nonsectarian activities.

627.215 Relocation.

627.220 Coordination with programs under title IV of the Higher Education Act including the Pell grant program.

627.225 Employment generating activities.

627.230 Displacement.

627.235 General program requirements.

627.240 On-the-job training.

627.245 Work experience.

627.250 Interstate agreements.

Subpart C—Payments, Benefits and Working Conditions

627.300 Scope and purpose.

627.305 Payments.

627.310 Benefits and working conditions.

Subpart D—Administrative Standards

627.400 Scope and purpose.

627.405 Grant agreement and funding.

627.410 Reallotment and reallocation.

627.415 Insurance.

627.420 Procurement.

627.422 Selection of service providers.

627.423 Funding restrictions for "high-risk" recipients and subrecipients.

627.424 Prohibition of subawards to debarred and suspended parties.

627.425 Standards for financial management and participant data systems.

627.430 Grant payments.

627.435 Cost principles and allowable costs.

627.440 Classification of costs.

627.445 Limitations on certain costs.

627.450 Program income.

627.455 Reports required.

627.460 Requirements for records.

627.463 Public access to records.

627.465 Property management standards.

627.470 Performance standards.

627.471 Reorganization plan appeals.

627.475 Oversight and monitoring.

627.480 Audits.

627.481 Audit resolution.

627.485 Closeout.

627.490 Later disallowances and adjustments after closeout.

627.495 Collection of amounts due.

Subpart E—Grievances Procedures at the State and Local Level

627.500 Scope and purpose.

627.501 State grievance and hearing procedures for non-criminal complaints at the recipient level.

627.502 Grievance and hearing procedures for non-criminal complaints at the SDA and SSG levels.

627.503 Recipient-level review.

627.504 Non-criminal grievance procedure at employer level.

Subpart F—Federal Handling of Non-criminal Complaints and Other Allegations

627.600 Scope and purpose.

627.601 Complaints and allegations at the Federal level.

627.602 Resolution of investigative findings.

627.603 Special handling of labor standards violations under section 143 of the Act.

627.604 Alternative procedure for handling labor standards violations under section 143—Binding arbitration.

627.605 Special Federal review of SDA- and SSG-level complaints without decision.

627.606 Grant officer resolution.

Subpart G—Sanctions for Violations of the Act

627.700 Scope and purpose.

627.702 Sanctions and corrective actions.

627.703 Failure to comply with procurement provisions.

627.704 Process for waiver of State liability.

627.706 Process for advance approval of a recipient's contemplated corrective actions.

627.708 Offset process.

Subpart H—Hearings by the Office of Administrative Law Judges

627.800 Scope and purpose.

627.801 Procedures for filing request for hearing.

627.802 Rules of procedure.

627.803 Relief.

627.804 Timing of decisions.

627.805 Alternative dispute resolution.

627.806 Other authority.

Subpart I—Transition Provisions

627.900 Scope and purpose.

627.901 Transition period.

627.902 Governor's actions.

627.903 Actions which are at the discretion of the Governor.

627.904 Transition and implementation.

627.905 Guidance on contracts and other agreements.

627.906 Determinations on state and SDA implementation.

Authority: 29 U.S.C. 1579(a); Sec. 6305(f), Pub. L. 100-418, 102 Stat. 1107; 29 U.S.C. 1791(e).

Subpart A—Scope and Purpose

§ 627.100 Scope and purpose of part 627

(a) This part sets forth requirements for implementation of programs under titles I, II, and III of the Job Training Partnership Act.

(b) Subpart B provides general program requirements which apply to all programs under the titles I, II, and III of the Act, except as provided elsewhere in the Act or this chapter. These requirements include the Governor/Secretary agreement, the

nondiscrimination and nonsectarian activity provisions, coordination provisions with Higher Education Act programs, and the prohibitions on public service employment, relocation assistance, displacement, and employment generating activities. This subpart also sets forth comprehensive rules for on-the-job training for JTPA participants as well as for work experience.

(c) Subpart C sets forth requirements for allowable payments to JTPA participants.

(d) Subpart D establishes the administrative and financial standards and requirements that apply to funds received under the Act.

(e) Subpart E establishes the procedures which apply to the handling of non-criminal complaints under the Act at the Governor, the SDA, and title III SSG levels.

(f) Subpart F establishes the procedures which apply to the filing, handling, and review of complaints at the Federal level.

(g) Subpart G sets forth the provisions which apply to the sanctions and corrective actions that may be imposed by the Secretary for violations of the Act, regulations, or grant terms and conditions.

(h) Subpart H sets forth procedures which apply to hearing by the Office of the Administrative Law Judges.

Subpart B—Program Requirements

§ 627.200 Governor/Secretary agreement.

(a)(1) To establish a continuing relationship under the Act, the Governor and the Secretary shall enter into a Governor/Secretary agreement. The agreement shall consist of a statement assuring that the State shall comply with (i) the Job Training Partnership Act and all applicable rules and regulations and (ii) the Wagner-Peyser Act and all applicable rules and regulations. The agreement shall specify that guidelines, interpretations, and definitions adopted and published by the Governor shall, to the extent that they are consistent with the Act and applicable rules and regulations, be accepted by the Secretary.

(2) Either the Governor or the Secretary may seek a modification, revision, or termination of the agreement at any time, to be effective at the end of a program year.

(b) Except as provided at part B of title III of the Act and part 631, subpart G, of this chapter, the State shall be the grant recipient of JTPA funds awarded under titles I, II, and III.

§ 627.205 Public service employment prohibition.

No funds available under titles I, II—A, II—C, or III—A of the Act may be used for public service employment (sections 141(p) and 314(d)(2)).

§ 627.210 Nondiscrimination and nonsectarian activities.

(a)(1) Recipients, SDA grant recipients, title III substate grantees, and other subrecipients shall comply with the nondiscrimination provisions of section 167 of the Act.

(2) Nondiscrimination and equal opportunity requirements and procedures, including complaint processing and compliance reviews, are governed by the provisions of 29 CFR parts 31, 32, and 34 and are administered and enforced by the DOL Directorate of Civil Rights.

(3) Funds may be used to meet a recipient's or subrecipient's obligation to provide physical and programmatic accessibility and reasonable accommodation as required by section 504 of the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act of 1990.

(b) The employment or training of participants in sectarian activities is prohibited.

§ 627.215 Relocation.

(a) No funds provided under the Act shall be used, or proposed for use, to encourage or to induce the relocation of an establishment, or part thereof, that results in the loss of employment for any employee of such establishment at the original location.

(b) For 120 days after the commencement or the expansion of commercial operations of a relocating establishment, no funds provided under this Act shall be used for customized or skill training, on-the-job training, or company-specific assessments of job applicants or employees, for any relocating establishment or part thereof at a new, or expanded location, if the relocation of such establishment or part thereof results in a loss of employment for any employee of such establishment at the original location.

(c) For the purposes of this section, *relocating establishment* means a business entity, including a successor in interest, which is moving any operations from a facility in one labor market area within the United States and its territories to a new or expanding facility in another labor market area.

(d) Pre-award review. To verify that an establishment which is new or expanding is not, in fact, relocating employment from another area, a standardized pre-award review shall be

completed and documented jointly by the service delivery area or substate grantee with the establishment as a prerequisite to JTPA assistance.

(e) Violations and sanctions. The Secretary will promptly review and take appropriate action with regard to alleged violations of the provisions of paragraphs (a) and (b) of this section. Procedures for the investigation and resolution of violations are provided for under subpart F of this part. Sanctions and remedies are provided for under subpart G of this part.

§ 627.220 Coordination with programs under Title IV of the Higher Education Act including the Pell grant program.

(a) When financial assistance programs under title IV of the Higher Education Act (HEA) (the Pell Grant program, the Supplemental Education Opportunity Grant program, the Work-study program, the Perkins loan program, the Family Education Loan program—including Stafford, PLUS and Supplemental Loans for Students programs—and the Direct Loan Demonstration program), which provide student financial aid programs for postsecondary education, are available to JTPA participants, SDA's and title III SSG's shall establish coordination procedures and contractual safeguards to ensure that JTPA funds are in addition to funds otherwise available in the area (sections 141(b), 107(b), 205(b), and 265(b)).

(b)(1) To avoid the possibility of doubling billing and duplication of Federal funds, contracts with title IV-eligible educational institutions shall clearly identify available JTPA and HEA title IV funds, and stipulate that the educational institution's financial aid officer shall inform the SDA's/SSG's of the amounts and disposition of HEA title IV awards and other types of financial aid to each JTPA participant (section 141(b)).

(2) The participant awarded a Pell Grant shall be party to an agreement with the SDA/SSG and the educational institution which indicates the portion of the HEA grant to be applied to the cost of tuition, fees and books. This information shall be verified in program monitoring procedures.

(3) For JTPA contracts where Pell Grants are involved, SDA's/SSG's shall document in the ISS its determination with the educational institution of the participant's training-related financial assistance needs and the proper mix of JTPA and Pell Grant funds, since a Pell Grant may be used for applicable living expenses as well as for tuition, fees, and books. The SDA shall provide to the educational institution's financial aid

officer the names of JTPA participants who are to attend such institution and for whom JTPA payments will be made (sections 141(b) and 107(b)).

(c) In completing the objective assessment and developing the Individual Service Strategy for a title II participant, the SDA shall ensure, to the extent practicable, that available Federal, State, and local resources are coordinated sufficiently to meet the training and education-related costs of services, so that the participant can afford to complete the agreed-upon program successfully (sections 141(b), 107(b), 205(b), and 265(b)).

§ 627.225 Employment generating activities.

(a) No funds available under the Act shall be used for employment generating activities, economic development activities, investment in revolving loan funds, capitalization of businesses, investment in contract bidding resource centers, or similar activities. No funds under titles I, II or III of the Act shall be used for foreign travel.

(b) JTPA funds may be used for normal employer outreach and job development activities including, but not limited to: contacts with potential employers for the purpose of placement of JTPA participants; participation in business associations (such as chambers of commerce); JTPA staff participation on economic development boards and commissions, and work with economic development agencies, to provide information about JTPA and to assist in making informed decisions about community job training needs; subscriptions to relevant publications; general dissemination of information on JTPA programs and activities; labor market surveys; and development of on-the-job training (OJT), as defined in § 627.240; and other allowable JTPA activities in the private sector.

§ 627.230 Displacement.

(a) No currently employed worker shall be displaced by any participant (including partial displacement such as a reduction in the hours of non-overtime work, wages, or employment benefits).

(b) No participant shall be employed or job opening filled:

(1) When any other individual is on layoff from the same or any substantially equivalent job, or

(2) When the employer has terminated any regular employee without cause or otherwise reduced its workforce with the intention of filling the vacancy so created by hiring a participant whose wages are subsidized under the Act.

(c) Violations and sanctions. The Secretary will promptly review and take

appropriate action with regard to alleged violations of the provisions of paragraphs (a) and (b) of this section. Procedures for the investigation and resolution of violations are provided for under subpart F of this part. Sanctions and remedies are provided for under subpart G of this part.

§ 627.235 General program requirements.

(a) The requirements set forth in sections 141, 142 and 143 of the Act apply to all programs under titles I, II, and III of the Act, except as provided elsewhere in the Act.

(b) Recipients shall ensure that an individual enrolled in a JTPA program meets the requirements of section 167(a)(5) of the Act, section 3 of the Military Selective Service Act (50 U.S.C. app. 453) and other requirements applicable to programs funded under the specific section or title of the Act under which the participant is enrolling (section 604).

(c) Recipients shall ensure that individuals are enrolled within 45 days of the date of application or a new application shall be taken, except that eligible summer program applicants under title II-B may be enrolled within 45 days into a summer youth enrollee pool, and no subsequent application need be taken prior to participation during the period of that summer program. In addition, the 45-day enrollment requirement shall not apply for individuals who have a valid certificate of continuing eligibility under the title III program, as described in § 631.3 and § 631.53 of this chapter.

(d) Programs operated under titles I, II, and III of the Act are not subject to the provisions of 29 CFR part 97, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments", except as otherwise explicitly provided in this chapter.

(e) If a recipient or SDA imposes a requirement relating to the administration and operation of programs funded by the Act, the recipient or SDA shall identify the requirement as a State- or SDA-imposed requirement (section 124).

§ 627.240 On-the-job training.

(a) General. "On-the-job training (OJT)" means training in the private or public sector given to a participant who, after objective assessment, has been referred to and hired by the employer. OJT which occurs while the participant is engaged in productive work which provides knowledge and skills essential to the full and adequate performance of the job. This does not preclude a participant who has been trained by one

employer from ultimately being placed in a comparable, training-related position with another employer. OJT may be sequenced with or accompanied by other types of training such as classroom training or literacy training.

(b) Duration of OJT. (1) OJT authorized for a participant shall be limited to a period not in excess of that generally required for the acquisition of skills needed for the position within a particular occupation, but in no event may reimbursement exceed the later of 6 months or 499 hours, including time spent in related classroom training during which wages are paid by the employer. In determining the period generally needed for the acquisition of necessary skills, consideration shall be given to recognized reference materials, including, but not limited to the "Dictionary of Occupational Titles", employer training plans and content, and the participant's education, prior work experience, and ISS.

(2) OJT is encouraged in higher skill occupations appropriate to the participant's needs and occupational interests and training plans may be developed which reflect the customary duration of training specified in recognized reference materials; but the maximum period for which JTPA funds may be used to reimburse an employer for OJT shall be as specified in paragraph (b)(1) of this section.

(3) Recipients and SDA's/SSG's shall develop policies and procedures for determining training duration. These policies and procedures shall specify the guidelines and reference materials to be used and shall indicate how the specific training content, the participant's prior work experience, and the participant's ISS will be factored into the determination of training length.

(4) The ISS developed for each OJT participant shall document how the training length was determined and shall include a justification in each case where the length of training exceeds that provided for in a recognized reference material adopted by the recipient.

(c) Employer payments. (1) Payments for OJT shall not exceed the average of 50 percent of the total wages paid by the employer to each participant during the period of training.

(2) Payments to employers for OJT are deemed to be in compensation for the extraordinary cost associated with training participants and in compensation for the costs associated with the lower productivity of such participants. Employers are not required to maintain separate records to

document the extraordinary costs actually incurred.

(d) OJT contracts. (1) OJT contracts shall specify the types and duration of OJT and other services to be provided in sufficient detail, as specified in paragraph (d)(2) of this section, to allow for a fair analysis of the reasonableness of proposed costs and otherwise to comply with the applicable requirements of section 164 of the Act.

(2) Each contract with an OJT employer, at a minimum, shall specify the number of participants to be trained, participant wage rates, and the method and maximum amount of reimbursement; and shall provide a job description and brief training outline, including training hours by skill area or task. OJT employers shall maintain adequate time and attendance, payroll and other records to support amounts reimbursed under OJT contracts.

(3) Each contract with an OJT employer that is written by a brokering contractor (not written directly by the SDA/SSG or recipient) shall specify and clearly differentiate the services to be provided by the brokering contractor, the OJT employer, and other agencies and subcontractors, if any, including services provided with or without cost.

(4) OJT employers may also be reimbursed for the actual costs incurred in providing classroom training and training-related and supportive services to JTPA participants, including reimbursement for the cost of participant wages paid by the employer for time spent in such activities during working hours. Any such additional reimbursements shall be only for training and for support over and above that provided to regular employees, and must be documented by the employer.

(e) Labor standards. OJT participants shall be compensated by the employer at the same rates, including periodic increases not related to individual performance, as similarly situated employees or trainees, but in no event less than the highest of the minimum wage prescribed under the Fair Labor Standards Act of 1938, as amended, or applicable State or local minimum wage laws.

(f) Suitability of participants. (1) Only those participants who have been assessed and for whom OJT has been documented as an appropriate activity in the participant's ISS shall be referred to an employer for participation in OJT.

(2) An individual referred to the JTPA program by an employer may be enrolled in an OJT program with such employer only upon completion of an objective assessment and individual service strategy in which OJT with such employer has been determined to be an

appropriate activity and the employer has not already hired such individual.

(3) Employment of an OJT participant with the participant's previous employer in the same, a similar, or an upgraded job is not permitted.

(g) Employer eligibility. (1) An OJT contract shall not be entered into with an employer who had two or more previous OJT contracts and exhibited a pattern of failing to provide OJT participants continued long-term employment as regular employees with wages and working conditions at the same level and to the same extent as similarly situated employees.

(2) Governors shall issue procedures and criteria to implement the requirement in paragraph (g)(1) of this section, and which shall specify the duration of the period of loss of eligibility. Such procedures may provide that situations in which OJT participants quit voluntarily or are terminated for cause or are released due to unforeseeable changes in business conditions will not necessarily result in termination of employer eligibility.

(h) Youth training program. OJT conducted under title II-C shall meet the requirements of subpart H of part 628 of this chapter (§ 628.804), as well as the requirements of this section. Where OJT is provided to youth concurrently enrolled under titles II-B and II-C, the source of funding for the OJT shall determine which requirements apply.

(i) A temporary employment agency may serve as the employer of record for purposes of providing OJT to a participant in employment only when such participants are treated as all other agency employees and not when such agency provides probationary seasonal, temporary, or intermittent employment.

(j) Monitoring. (1) Each contract with an OJT employer, whether awarded by the recipient, subrecipient, brokering contractor, or subcontractor, shall be periodically monitored on-site sufficiently to assure the validity and propriety of amounts claimed for reimbursement, that they are substantiated by payroll and time and attendance records, and that training is being provided as specified in the contract.

(2)(i) Brokering contractors shall conduct on-site monitoring of the OJT employers and other subcontractors to verify compliance with subcontract terms before making payments.

(ii) Nothing in this paragraph (j) shall relieve recipients and SDA's from responsibility for monitoring expenditures under the Act.

§ 627.245 Work experience.

(a) General. "Work experience" means a short-term or part-time work assignment with a public or private nonprofit employing agency for a participant who needs assistance in becoming accustomed to basic work requirements. It is prohibited in the private for-profit sector except for limited internships and entry employment experience programs, as provided in section 264(c)(1) (F) and (H).

(b) Suitability. Work experience is designed to promote the development of good work habits and basic work skills for individuals who have never worked or who have been out of the labor force for an extended period of time including, but not limited to, students, summer youth, school dropouts, individuals with disabilities, and older workers.

(c) Duration of work experience. Participation in work experience shall be for a reasonable length of time, based on the needs of the participant, which shall be documented in the participant's ISS. Generally, work experience for adults may not exceed the later of 6 months or 499 hours if working part time. The ISS shall include a justification in each case where work experience is authorized in excess of these limits for adults.

(d) Combination with other services. Work experience conducted under titles II-A and II-C shall be accompanied, either concurrently or sequentially, by other services designed to increase the basic education and/or occupational skills of the participant, as documented in the ISS.

(e) Work experience is not an allowable activity under title III of the Act.

§ 627.250 Interstate agreements.

The Secretary hereby grants authority to the several States to enter into interstate agreements and compacts in accordance with section 127 of the Act and, as specified in § 627.420(g), Procurement, of these regulations.

Subpart C—Payments, Benefits, and Working Conditions

§ 627.300 Scope and purpose.

This subpart sets forth requirements for allowable payments to JTPA participants. These include needs-based payments under title II, incentive and bonus payments, wages, wages for combined activities, and needs-related payments under title III. This subpart also sets forth rules for benefits and working conditions for JTPA participants. These include

requirements for supportive services, workers' compensation coverage or medical and accident insurance where there is no State workers' compensation law, working conditions which are detrimental to the participant's health and safety, and child labor laws.

§ 627.305 Payments.

(a)(1) General. Allowable types of payments to participants are needs-based payments for participants in programs under titles I and II as described in this section, incentive and bonus payments for participants in title II-C programs, wages, wages for combined activities in title II programs, and needs-related payments for participants in title III programs as described in section 631 of this chapter. These payments may be made in accordance with paragraphs (b) through (f) of this section.

(2) A participant shall receive no payments for training activities in which the participant fails to participate without good cause (section 142 (a)(1)).

(b) Needs-based payments. (1) In accordance with a locally developed formula or procedure, needs-based payments may be provided to individual participants where such payments are necessary to enable the individual to participate in training programs under this part. Such formula or procedure shall be included in the job training plan.

(2) Documentation supporting the locally developed formula or procedure shall be maintained in accordance with instructions from the Governor.

(3) The formula or procedure shall provide for the maintenance of an individual record of the determination of the need for, and the amount of, each participant's needs-based payments.

(4) An SDA shall be able to demonstrate that the formula or procedure has been utilized on an individual basis to determine the amount of needs-based payments approved for each participant.

(5) The individual determination of a participant's needs-based payment and the amount of such payment shall be based upon the results of the objective assessment and recorded in the ISS.

(c) Incentive and bonus payments. (1) Participants in programs funded under title II-C may receive incentive and bonus payments based on attendance and/or performance and in accordance with a locally developed formula or procedure. The formula or procedure shall include a specification of the requirements for the receipt of such payments and the level of payments and shall be described in the job training plan approved by the Governor.

(2) Documentation supporting the locally developed formula or procedure shall be maintained in accordance with instructions from the Governor.

(3) The formula or procedure shall provide for the maintenance of an individual record of the determination of the need for, and the amount of, any participant's incentive and bonus payments.

(4) SDA's must be able to demonstrate that the described formula or procedure has been applied on an individual basis to determine the bonus or incentive payment.

(d) Wages. Individuals participating in programs under title II of the Act in work experience, in limited internships in the private sector, in entry employment experience programs or in other activities which would result in an employee-employer relationship if wages were paid by the employer, may be paid wages. Any wage payments shall be at the same rates as similarly situated employees or trainees, but in no event less than the higher of the minimum wage prescribed under the Fair Labor Standards Act of 1938, as amended, or applicable State or local minimum wage laws. The SDA is responsible for meeting applicable Internal Revenue Service requirements.

(e) Wages for combined activities. (1) For title II programs, participants in one of the activities described in paragraph (d) of this section for which wages are payable for more than 50 percent of the participant's scheduled time including classroom training, may also be paid wages for hours of participation in classroom training.

(2) In order to pay wages in combined activities for adults as described in paragraph (e)(1) of this section, the classroom training must have a work-based context and be linked to any occupational skills training provided in the work experience component.

(f) Summer payments. Summer participants may receive wages or wage equivalent payments for participation in activities under title II-B.

(g) Needs-related payments. The requirements pertaining to needs-related payments provided for under section 315(b) of the Act, are described in part 631 of this chapter.

§ 627.310 Benefits and working conditions.

(a) Supportive services. (1) Supportive services may be provided in-kind, through cash assistance, or by arrangement with another human service agency when necessary to enable an individual eligible for training under a JTPA-assisted program, but who cannot afford to pay for such services,

to participate in such JTPA-assisted program (section 4).

(2) Necessary supportive services shall be specified in a participant's ISS under title II, or a participant's individual readjustment plan under title III.

(3) Financial assistance shall only be used to pay for specific necessary services and shall be limited to discrete payments which are necessary for participation in a program funded under this Act.

(i) Provision of such financial assistance shall be based on an SDA/SSG procedure which shall be described in the job training plan.

(ii) Documentation supporting the procedure shall be maintained in accordance with instructions from the Governor.

(iii) The individual determination of financial assistance and the amount of such assistance shall be based upon the results of the objective assessment and documented in the participant's ISS.

(b) Where a participant is not covered under a State's workers' compensation law, the participant shall be provided with adequate on-site medical and accident insurance for work-related activities. For work-related activities, income maintenance coverage is not required for the participant (section 143(a)(3)).

(c) Where a participant is engaged in activities not covered under the Occupational Safety and Health Act of 1970, as amended, the participant shall not be required or permitted to work, be trained, or receive services in buildings or surroundings or under working conditions which are unsanitary, hazardous, or dangerous to the participant's health or safety. A participant employed or trained for inherently dangerous occupations, e.g., fire or police jobs, shall be assigned to work in accordance with reasonable safety practices (section 143(a)(2)).

(d) In the development and conduct of programs funded under the Act, SDA's and SSG's shall ensure compliance with applicable child labor laws. (29 CFR part 570)

Subpart D—Administrative Standards

§ 627.400 Scope and purpose.

This subpart establishes the administrative and financial standards and requirements that apply to funds received under the Act.

§ 627.405 Grant agreement and funding.

(a)(1) Pursuant to § 627.200 of this part and the Governor/Secretary agreement, each program year there will be executed a grant agreement signed by

the Governor or the Governor's designated representative and the Secretary or the Secretary's designated representative (Grant Officer).

(2) The grant agreement described in paragraph (a)(1) of this section shall be the basis for Federal obligation of funds for the program year for programs authorized by titles I, II, and III, including any title III discretionary projects awarded to the State, and such other funds as the Secretary may award under the grant.

(b) Funding. The Secretary shall allot funds to the States in accordance with sections 162, 202, 252, 262, and 302 of the Act. The Secretary shall obligate such allotments through Notices of Obligation.

(c) Pursuant to instructions issued by the Secretary, additional funds may be awarded to States for the purpose of carrying out the administrative activities described in section 202(c)(1)(A) when a State receives an amount under such section that is less than \$500,000 (section 453(d)).

(d) Termination. Each grant shall terminate when the period of availability for expenditure (funding period), as specified in section 161(b) of the Act, has expired and shall be closed in accordance with § 627.485, of this part, Closeout.

§ 627.410 Reallocation and reallocation.

(a) The Governor shall reallocate title II-A and II-C funds among service delivery areas within the State in accordance with the provisions of section 109(a) of the Act. The amounts to be reallocated, if any, shall be based on SDA obligations of the funds allocated separately to each SDA for title II-A or II-C programs.

(b) The Secretary shall reallocate title II-A and II-C funds among the States in accordance with the provisions of section 109(b) of the Act. The amounts to be reallocated, if any, shall be based on State obligations of the funds allotted separately to each State for title II-A or II-C programs, excluding funds allotted under section 202(c)(1)(D) and the State's obligation of such funds.

(c) Title III funds shall be reallocated by the Secretary in accordance with section 303 of the Act.

§ 627.415 Insurance.

(a) General. Each recipient and subrecipient shall follow its normal insurance procedures except as otherwise indicated in this section and § 627.465 of this part, Property Management Standards.

(b) DOL assumes no liability with respect to bodily injury, illness, or any other damages or losses, or with respect

to any claims arising out of any activity under a JTPA grant or agreement whether concerning persons or property in the recipient's or any subrecipient's organization or any third party.

(c) Consistent with § 627.310(b) of this part, Benefits and working conditions, recipients and subrecipients shall secure insurance coverage for injuries suffered by participants who are not covered by existing workers' compensation. Contributions to a reserve for a self-insurance program, to the extent that the type and extent of coverage and the rates and premiums would have been allowed had insurance been purchased to cover the risks, are allowable (section 143(a)(3)).

§ 627.420 Procurement.

(a) General. (1) The Governor, in accordance with the minimum requirements established in this section, shall prescribe and implement procurement standards to ensure fiscal accountability and prevent waste, fraud, and abuse in programs administered under this Act.

(2) When procuring property and services, a State shall follow the same policies and procedures it uses for procurements from its non-Federal funds, provided that the State's procurement procedures also comply with the minimum requirements of this section.

(3) Each subrecipient shall use its own procurement procedures which reflect applicable State and local laws and regulations, provided that the subrecipient's procurement procedures also comply with the requirements of this section and the standards established by the Governor, pursuant to paragraph (a)(1) of this section.

(4) States and subrecipients shall not use funds provided under JTPA to duplicate facilities or services available in the area (with or without reimbursement) from Federal, State, or local sources, unless it is demonstrated that the JTPA-funded alternative services or facilities would be more effective or more likely to achieve performance goals (sections 107(b) and 141(h)).

(b) Competition. (1) Each State and subrecipient shall conduct procurements in a manner which provides full and open competition. Some of the situations considered to be restrictive of competition include, but are not limited to:

(i) Placing unreasonable requirements on firms or organizations in order for them to qualify to do business;

(ii) Requiring unnecessary experience and excessive bonding;

(iii) Noncompetitive pricing practices between firms or organizations or between affiliated companies or organizations;

(iv) Noncompetitive awards to consultants that are on retainer contracts;

(v) Organizational conflicts of interest;

(vi) Specifying only a "brand name" product instead of allowing "an equal" product to be offered and describing the performance of other relevant requirements of the procurement;

(vii) Overly restrictive specifications; and

(viii) Any arbitrary action in the procurement process.

(2) Each State and subrecipient shall have written procedures for procurement transactions. These procedures shall ensure that all solicitations:

(i) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description shall not, in competitive procurements, contain features which unduly restrict competition; and

(ii) Identify all requirements which the offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(3) Each State and subrecipient shall ensure that all prequalified lists of persons, firms, or other organizations which are used in acquiring goods and services are current and include sufficient numbers of qualified sources to ensure maximum open and free competition.

(c) Conflict of interest. (1) Each recipient and subrecipient shall maintain a written code of standards of conduct governing the performance of persons engaged in the award and administration of JTPA contracts and subgrants.

(2) Each recipient and subrecipient shall ensure that no individual in a decisionmaking capacity including PIC members (whether compensated or not) shall engage in any activity, including participation in the selection, award, or administration of a subgrant or contract supported by JTPA funds if a conflict of interest, real or apparent, would be involved. Such a conflict would arise when:

(i) The individual,
(ii) Any member of the individual's immediate family,
(iii) The individual's partner, or
(iv) An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm or organization selected for award.
(3) The officers, employees, or agents of the agency making the award will

neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, potential contractors, or parties to subagreements. States and subrecipients may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value.

(4) PIC conflict of interest: (i) A PIC member shall not cast a vote on, nor participate in, any decisionmaking capacity on the provision of services by such member (or any organization which that member directly represents), nor on any matter which would provide any direct financial benefit to that member.

(ii) Neither membership on the PIC nor the receipt of JTPA funds to provide training and related services shall be construed, by themselves, to violate provisions of section 141(f) of the Act or § 627.420 of this chapter.

(5) To the extent permitted by State or local law or regulation, such standards of conduct will provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the awarding agency's officers, employees, or agents, or by contractors or their agents.

(d) Methods of procurement. Each State and subrecipient shall use one of the following methods of procurement, as appropriate for each procurement action: (1) *Small purchase procedures*—simple and informal procurement methods for securing services, supplies, or other property that do not cost more than \$25,000 in the aggregate. The Governor shall establish standards for small purchase procedures which insure that price or rate quotations will be documented from an adequate number of qualified sources.

(2) *Sealed bids (formal advertising)*—bids are publicly solicited procurement for which a firm-fixed-price contract (lump sum or unit price) or other fixed-price arrangement is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is the lowest in price. The Governor shall establish standards for sealed bids which include a requirement that invitations for bids be publicly advertised, and bids shall be solicited from an adequate number of organizations.

(3) *Competitive proposals*—normally conducted with more than one source submitting an offer, and either a fixed-price or cost-reimbursement type contract is awarded. The Governor shall establish standards for competitive proposals which include requirements for the establishment of a documented methodology for technical evaluations

and award to responsible offeror whose proposals are most advantageous to the program with price, technical, and other factors considered.

(4) *Noncompetitive proposals (sole source)*—procurement through solicitation of a proposal from only one source, the funding of an unsolicited proposal, or, after solicitation of a number of sources, when competition is determined inadequate. Each State and subrecipient shall minimize the use of sole source procurements to the extent practicable, but in every case, the use of sole source procurements shall be justified and documented. Procurement by noncompetitive proposals may be used only when the award of a contract is infeasible under small purchase procedures, sealed bids, or competitive proposals and one of the following circumstances applies:

- (i) The item or service is available only from a single source;
- (ii) The public exigency or emergency need for the item or service does not permit a delay resulting from competitive solicitation;
- (iii) The awarding agency authorizes noncompetitive proposals;
- (iv) After solicitation of a number of sources, competition is determined inadequate;
- (v) On-the-job training (OJT) contracts, except OJT brokering contracts which shall be selected competitively; or
- (vi) Enrollment of individual participants in classroom training.

(e) Cost or price analysis. (1) Each recipient, in accordance with the minimum requirements established in this section, shall establish standards on the performance of cost or price analysis.

(2) Each recipient and subrecipient shall perform a cost or price analysis in connection with every procurement action, including contract modifications. The method and degree of analysis depends on the facts surrounding the particular procurement and pricing situation, but at a minimum, the awarding agency shall make independent estimates before receiving bids or proposals. A cost analysis is necessary when the offeror is required to submit the elements of the estimated cost, when adequate price competition is lacking, and for sole source procurements, including contract modifications or change orders, unless price reasonableness can be established on the basis of a catalog or market price of a commercial product sold in substantial quantities to the general public or based on prices set by law or regulation. The offeror shall certify that to the best of its knowledge and belief,

the cost data are accurate, complete, and current at the time of agreement on price. Contracts or modifications negotiated in reliance on such data should provide the awarding agency a right to a price adjustment to exclude any significant sum by which the price was increased because the contractor had submitted data that were not accurate, complete, or current as certified. A price analysis shall be used in all other instances to determine the reasonableness of the proposed contract price.

(3) JTPA procurements shall not permit excess program income (for nonprofit and governmental entities) or excess profit (for private for-profit entities). If profit or program income is included in the price, the awarding agency shall negotiate profit or program income as a separate element of the price for each contract in which there is no price competition and in all cases where cost analysis is performed. To establish a fair and reasonable profit or program income, consideration shall be given to:

- (i) The complexity of the work to be performed;
- (ii) The risk borne by the contractor;
- (iii) The contractor's investment;
- (iv) The amount of subcontracting;
- (v) The quality of the contractor's record of past performance;
- (vi) Industry profit rates in the surrounding geographical area for similar work; and
- (vii) Market conditions in the surrounding geographical area.

(4) Each recipient and subrecipient may charge to the grant or subgrant only those contractor costs which are consistent with the allowable cost provisions of § 627.435 of this part, including the guidelines issued by the Governor, as required at § 627.435(c) of this part.

(5) The cost plus a percentage of cost method of contracting shall not be used.

(f) Oversight. (1) Each recipient and subrecipient shall conduct and document oversight to ensure compliance with the procurement standards, in accordance with the requirements of § 627.475 of this part, Oversight and monitoring.

(2) Each recipient and subrecipient shall maintain a contract administration system which ensures that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

(g) Transactions between units of government. Procurement transactions between units of State or local governments, and any other entities organized principally as the administrative entity for service

delivery areas or substate areas, shall be conducted on a cost reimbursable basis.

(h) Contract provisions. Each recipient and subrecipient procurement shall:

(1) Clearly specify deliverables and the basis for payment; and

(2) Contain clauses that provide for:

(i) Compliance with the JTPA regulations (subrecipient contracts only);

(ii) For contracts other than small purchases, administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, which shall provide for such sanctions and penalties as may be appropriate;

(iii) Notice of JTPA requirements pertaining to patent rights;

(iv) Notice of JTPA requirements pertaining to copyrights and rights in data;

(v) For all contracts in excess of \$10,000, termination for cause and for convenience by the awarding agency, including the manner by which the termination will be effected and the basis for settlement;

(vi) Access by the recipient, the subrecipient, the Department of Labor, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records (including computer records) of the contractor or subcontractor which are directly pertinent to charges to the program, in order to conduct audits and examinations, and make excerpts, transcripts, and photocopies; this right also includes timely and reasonable access to contractor's and subcontractor's personnel for the purpose of interviews and discussions related to such documents (vendor contracts);

(vii) Notice of awarding agency requirements and regulations pertaining to reporting;

(viii) Audit rights and requirements;

(ix) Payment conditions and delivery terms;

(x) Process and authority for contract changes; and

(xi) Provision against assignment.

(xii) The assurance of nondiscrimination and equal opportunity as found in 29 CFR 34.20, Assurance required; duration of obligation; covenants.

(3) The Governor may establish additional clauses, as deemed appropriate, for State and subrecipient procurements.

(i) Disputes. (1) The Governor shall insure that the recipient and each subrecipient have protest procedures to handle and resolve disputes relating to

their procurements. A protester shall exhaust all administrative remedies with the subrecipient before pursuing a protest at a higher level.

(2) Violations of law will be referred to the Department of Labor Office of the Inspector General and other appropriate local and State authorities having proper jurisdiction.

(j) Each recipient and subrecipient shall maintain records sufficient to detail the significant history of a procurement. These records shall include, but are not necessarily limited to, the following: Rationale for the method of procurement, the selection of contract type, contractor selection or rejection, and the basis for the contract type.

§ 627.422 Selection of service providers.

(a) Service providers selected under titles I, II, and III of the Act shall be selected in accordance with the provisions of section 107 of the Act, except that section 107(d) shall not apply to training under title III.

(b) Consistent with the requirements of this section, the Governor shall establish standards to be followed by in making determinations of demonstrated performance, prior to the award of all subgrants, contracts, and subcontracts under titles I, II, and III of the Act. These standards shall comply with the requirements of this section, § 627.420, of this part, Procurement, and section 164(a)(3) of the Act. The standards shall require that determinations of demonstrated performance will be in writing, and completed prior to the award of a grant, subgrant, contract or subcontract.

(c) Each recipient and subrecipient, to the extent practicable, shall select service providers on a competitive basis, in accordance with the standards established in § 627.420(b) of this part, Procurement. When a State, SDA, SSG, or administrative entity determines that services will be provided by its own staff, a determination shall be made of the demonstrated performance of the staff to operate the program. This determination shall be in writing and take into consideration the matters listed in paragraph (d) of this section.

(d) Awards are to be made to organizations possessing the demonstrated ability to perform successfully under the terms and conditions of a proposed subgrant or contract. Such determinations shall be in writing, and take into consideration such matters as whether the organization has:

(1) Adequate financial resources or the ability to obtain them;

(2) The ability to meet the program design specifications at a reasonable cost, as well as the ability to meet performance goals;

(3) A satisfactory record of past performance (in job training, basic skills training, or related activities), including demonstrated quality of training; reasonable drop-out rates from past programs; the ability to provide or arrange for appropriate supportive services as specified in the ISS, including child care; retention in employment; and earning rates of participants;

(4) For title II programs, the ability to provide services that can lead to the achievement of competency standards for participants with identified deficiencies;

(5) A satisfactory record of integrity, business ethics, and fiscal accountability;

(6) The necessary organization, experience, accounting and operational controls; and

(7) The technical skills to perform the work.

(e) In selecting service providers to deliver services in an SDA, proper consideration shall be given to community-based organizations (section 107(a)). These community-based organizations shall be organizations, including women's organizations with knowledge about or experience in nontraditional training for women, which are recognized in the community in which they are to provide services.

(f) Appropriate education agencies in the service delivery area/substate area shall be provided the opportunity to provide educational services, unless the administrative entity demonstrates that alternative agency(ies) or organization(s) would be more effective or would have greater potential to enhance the participants' continued educational and career growth. (section 107(c)).

(g) In determining demonstrated performance of institutions/organizations which provide training, such performance measures as retention in training, training completion, job placement, and rates of licensure shall be taken into consideration.

(h) Amounts for service providers. Each SDA/SSG shall ensure that, for all services provided to participants through contracts, grants, or other agreements with a service provider, such contract, grant, or agreement shall include appropriate amounts necessary for administration and supportive services. (section 108(b)(5)).

(i) Service providers under agreements to conduct projects under section 123(a)(2) shall be selected in

accordance with the requirements of this section.

(j) The requirements of section 204(d)(2)(B) shall be followed in entering into agreements to provide services for older individuals funded under title II, part A.

(k) Additional requirements for selection of service providers by substate grantees are described at section 313(b)(6) of the Act and § 631.52 of this chapter.

§ 627.423 Funding restrictions for "high-risk" recipients and subrecipients.

(a) A recipient or subrecipient may be considered "high-risk" if an awarding agency determines that the recipient or subrecipient is otherwise responsible but:

- (1) Has a history of unsatisfactory performance;
- (2) Is not financially stable;
- (3) Has a management system which does not meet the management standards set forth in this part; or
- (4) Has not conformed to terms and conditions of a previously awarded grant or subgrant.

(b) If the awarding agency determines that a grant or subgrant will be made to a "high-risk" recipient or subrecipient, then special funding restrictions that address the "high-risk" status may be included in the grant or subgrant. Funding restrictions may include but are not limited to:

- (1) Payment on a reimbursement basis;
- (2) Requiring additional and/or more detailed financial or performance reports;
- (3) Additional monitoring;
- (4) Requiring the recipient or subrecipient to obtain specific technical or management assistance; and/or
- (5) Establishing additional prior approvals.

(c) If an awarding agency decides to impose such funding restrictions, the awarding official will notify the recipient or subrecipient as early as possible, in writing, of:

- (1) The nature of the funding restrictions;
- (2) The reason(s) for imposing them;
- (3) The corrective actions which must be taken before they will be removed and the time allowed for completing the corrective actions; and
- (4) The method of requesting reconsideration of the restrictions imposed.

§ 627.424 Prohibition of subawards to debarred and suspended parties.

(a) No recipient or subrecipient shall make any subgrants or permit any contract or subcontract at any tier to any

party which is debarred or suspended or is otherwise excluded from or ineligible for participation in Federal assistance programs in accordance with the Department of Labor regulations at 29 CFR part 98.

(b) Recipients and subrecipients shall comply with the applicable requirements of the Department of Labor regulations at 29 CFR part 98.

§ 627.425 Standards for financial management and participant data systems.

(a)(1) *General.* The financial management system and the participant data system of each recipient and subrecipient shall provide federally required records and reports that are uniform in definition, accessible to authorized Federal and State staff, and verifiable for monitoring, reporting, audit, program management, and evaluation purposes (sections 165(a) (1) and (2), and 182).

(2) An awarding agency may review the adequacy of the financial management system and participant data system of any recipient/subrecipient as part of a preaward review or at any time subsequent to award.

(b) *Financial systems.* Recipients and subrecipients shall ensure that their own financial systems as well as those of their subrecipients provide fiscal control and accounting procedures that are:

- (1) In accordance with generally accepted accounting principles, financial systems shall include:
 - (i) Information pertaining to subgrant and contract awards, obligations, unobligated balances, assets, expenditures, and income;
 - (ii) Effective internal controls to safeguard assets and assure their proper use;
 - (iii) A comparison of actual expenditures with budgeted amounts for each subgrant and contract;
 - (iv) Source documentation to support accounting records; and
 - (v) Proper charging of costs and cost allocation; and
- (2) Be sufficient to:
 - (i) Permit preparation of required reports;
 - (ii) Permit the tracing of funds to a level of expenditure adequate to establish that funds have not been used in violation of the applicable restrictions on the use of such funds;
 - (iii) As required by section 165(g), permit the tracing of program income, potential stand-in costs and other funds that are allowable except for funding limitations as defined in § 627.480(g) of this part, Audits; and

(iv) Demonstrate compliance with the matching requirement of section 123(b)(2).

(c) *Applicant and participant data systems.* Each recipient and subrecipient shall ensure that records are maintained:

- (1) Of each applicant for whom an application has been completed and a formal determination of eligibility or ineligibility made;
- (2) Of each participant's enrollment in a JTPA-funded program in sufficient detail to demonstrate compliance with the relevant eligibility criteria attending a particular activity and with the restrictions on the provision and duration of services and specific activities imposed by the Act; and
- (3) Of such participant information as may be necessary to develop and measure the achievement of performance standards established by the Secretary.

§ 627.430 Grant payments.

(a) Except as provided in paragraph (h)(2) of this section, JTPA grant payments shall be made to the Governor in accordance with the Cash Management Improvement Act of 1990 (31 U.S.C. 6501 et seq.), Department of Treasury regulations at 31 CFR part 205, and the State Agreement entered into with the Department of the Treasury.

(b) *Basic standards.* (1) Except as provided in paragraphs (d) and (e) of this section, each recipient and subrecipient shall be paid in advance, provided it maintains or demonstrates the willingness and ability to maintain procedures that are in accordance with Department of Treasury regulations at 31 CFR part 205.

(2) For payments to contractors under a grant or subgrant, reimbursement is the preferred method. However, the awarding agency may provide advances to contractors after determining that:

- (i) Reimbursement is not feasible because the contractor lacks sufficient working capital;
- (ii) The contractor meets the standards of this section and 31 CFR part 205 governing advances to subrecipients; and
- (iii) Advance payment is in the best interest of the awarding agency.

(c) *Advance Payments.* To the maximum extent feasible, each subrecipient shall be provided advance payments via electronic funds transfer, following the procedures of the awarding agency.

(d) *Reimbursement.* (1) Reimbursement is the preferred method when the requirements in paragraph (b)(1) of this section are not met.

(i) Each recipient shall submit requests for reimbursement in

accordance with the provisions at 31 CFR part 205.

(ii) Each subrecipient shall submit requests for reimbursement as authorized by the awarding agency.

(2) Each subrecipient shall be paid as promptly as possible after receipt of a proper request for reimbursement.

(e) *Working capital advance payments.* If a subrecipient or contractor cannot meet the criteria for advance payments described in paragraph (b)(1) of this section, and the awarding agency has determined that reimbursement is not feasible because the subrecipient or contractor lacks sufficient working capital, the awarding agency may provide cash on a working capital advance payment basis. Under this procedure, the awarding agency shall advance cash to the subrecipient or contractor to cover its estimated disbursement needs for an initial period, generally geared to the subrecipient's or contractor's disbursing cycle and in no event may such an advance exceed 20 percent of the award amount. Thereafter, the awarding agency shall reimburse the subrecipient or contractor for its actual cash disbursements. The working capital advance method of payment shall not be used by recipients or subrecipients if the reason for using such method is the unwillingness or inability of the recipient or subrecipient to provide timely advances to the subrecipient to meet the subrecipient's actual cash disbursements.

(f) *Effect of program income, refunds, and audit recoveries on payment.* Each recipient and subrecipient shall disburse program income, rebates, refunds, contract settlements, audit recoveries, and interest earned on such funds before requesting additional cash payments.

(g) *Cash depositories.* (1) Consistent with the national goal of expanding the opportunities for minority business enterprises, each recipient and subrecipient is encouraged to use minority-owned banks (a bank which is owned at least 50 percent by minority group members). Additional information may be obtained from the Minority Business Development Agency, Department of Commerce, Washington, DC 20230.

(2) A recipient or subrecipient shall not be required to maintain a separate bank account but shall separately account for Federal funds on deposit.

(h) *Interest earned on advances.* (1) An interest liability shall accrue on advance payments between Federal agencies and State governments as provided by the Cash Management Improvement Act (31 U.S.C. 6501 et

seq.) and implementing regulations at 31 CFR part 205.

(2) Each subrecipient other than a State entity shall account for interest earned on advances of Federal funds as program income, as provided at § 627.450 of this part, Program income.

§ 627.435 Cost principles and allowable costs.

(a) General: To be allowable, a cost shall be necessary and reasonable for the proper and efficient administration of the program, be allocable to the program, and, except as provided herein, not be a general expense required to carry out the overall responsibilities of the Governor or a governmental subrecipient. Costs charged to the program shall be accorded consistent treatment through application of generally accepted accounting principles appropriate to the JTPA program, as determined by the Governor.

(b) Whether a cost is charged as a direct cost or as an indirect cost shall be determined in accordance with the descriptions of direct and indirect costs contained in the OMB Circulars identified in DOL's regulations at 29 CFR 97.22(b).

(c) Costs of another Federal grant, JTPA program, or cost category may not be shifted to a JTPA grant, subgrant, program, or cost category to overcome fund deficiencies, avoid restrictions imposed by law or grant agreements, or for other reasons.

(d) Applicable credits such as rebates, discounts, refunds, and overpayment adjustments, as well as interest earned on any of them, shall be credited as a reduction of costs if received during the same funding period that the cost was initially charged. Credits received after the funding period shall be returned to the Department as provided for at § 627.490(b).

(e) The following costs are not allowable charges to the JTPA program:

(1) Costs of fines and penalties resulting from violations of, or failure to comply with, Federal, State, or local laws and regulations;

(2) Back pay, unless it represents additional pay for JTPA services performed for which the individual was underpaid;

(3) Entertainment costs;

(4) Bad debts expense;

(5) Insurance policies offering protection against debts established by the Federal Government;

(6) Contributions to a contingency reserve or any similar provision for unforeseen events;

(7) Costs prohibited by 29 CFR part 93 (Lobbying Restrictions) or costs of any

salaries or expenses related to any activity designed to influence legislation or appropriations pending before the Congress of the United States; and

(8) Costs of activities prohibited in § 627.205, Public service employment prohibition; § 627.210, Nondiscrimination and nonsectarian activities; § 627.215, Relocation; § 627.225, Employment generating activities; and § 627.230, Displacement, of this part.

(f)(1) The cost of legal expenses required in the administration of grant programs is allowable. Legal expenses includes the expenses incurred by the JTPA system in the establishment and maintenance of a grievance system, including the costs of hearings and appeals, and related expenses such as lawyers' fees. Legal expenses do not include costs resulting from, and after, the grievance process such as fines and penalties, which are not allowable, and settlement costs, which may or may not be allowable.

(2) Legal services furnished by the chief legal officer of a State or local government or staff solely for the purpose of discharging general responsibilities as a legal officer are unallowable.

(3) Legal expenses for the prosecution of claims against the Federal Government, including appeals to an Administrative Law Judge, are unallowable.

(g) Costs of travel and incidental expenses incurred by volunteers are allowable provided such costs are incurred for activities that are generally consistent with section 204(c)(6) of the Act.

(h) Construction costs are not allowable costs except for funds used to:

(1) Purchase equipment, materials, and supplies for use by participants while on the job and for use in the training of such participants (examples of such equipment, materials, and supplies are handtools, workclothes, and other low cost items); and

(2) Cover costs of a training program in a construction occupation, including costs such as instructors' salaries, training tools, books, and needs-based payments, or other financial assistance to participants.

(i) The Governor shall prescribe and implement guidelines on allowable costs for SDA, SSG, and statewide programs that are consistent with the cost principles and allowable costs provisions of paragraphs (a) through (h) of this section and that include, at a minimum, provisions that specify the extent to which the following cost items are allowable or unallowable JTPA costs and, if allowable, guidelines on

conditions and amounts, documentation requirements, and any prior approval requirements applicable to such cost items:

- (1) Compensation for personal services of staff, including wages, salaries, supplementary compensation, and fringe benefits;
- (2) Costs incurred by the SJTCC, HRIC, PIC's, and other advisory councils or committees;
- (3) Advertising costs;
- (4) Depreciation and/or use allowances;
- (5) Printing and reproduction costs;
- (6) Interest expense;
- (7) Expenditures for transportation and travel;
- (8) Payments to OJT employers, training institutions, and other vendors;
- (9) Fees or profits;
- (10) Insurance costs, including insurance coverage for injuries suffered by participants who are not covered by existing workers' compensation, and personal liability insurance for PIC members;
- (11) Participant supportive services including needs-based payments and, for youth enrolled in title II-C, cash incentives and bonuses, except that needs-based payments shall be determined in accordance with a locally developed formula or procedure;
- (12) Acquisitions of capital assets;
- (13) Building space costs, including rent, repairs, and alterations;
- (14) Pre-agreement costs;
- (15) Fund-raising activities;
- (16) Professional services, including organizational management studies conducted by outside individuals or firms; and
- (17) Taxes.

§ 627.440 Classification of costs.

(a) Allowable costs for programs under title II and title III shall be charged (allocated) to a particular cost objective/category to the extent that benefits are received by such cost objective/category. The classification of costs for programs under title III of the Act are set forth at § 631.13 of this chapter, Classification of costs at State and substate levels.

(b) For State-administered programs under Title II, the State is required to plan, control, and charge expenditures against the following cost objectives/categories:

- (1) Titles II-A and II-C (combined)—capacity building technical assistance (sections 202(c)(1)(B) and 262(c)(1)(B) of the Act to carry out activities pursuant to sections 202(c)(3)(A) and 262(c)(3)(A) of the Act);
- (2) Titles II-A and II-C (combined)—8 percent coordination (sections

202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(A) of the Act);

(3) Titles II-A and II-C (combined)—8 percent services/direct training (sections 202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(B) of the Act);

(4) Titles II-A and II-C (combined)—8 percent services/training-related and supportive services (sections 202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(B) of the Act);

(5) Titles II-A and II-C (combined)—8 percent services/administration (sections 202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(B) of the Act);

(6) Titles II-A and II-C (combined)—8 percent services to disadvantaged (section 202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(C) of the Act);

(7) Title II-A—older individuals/direct training (section 202(c)(1)(D) of the Act to carry out activities pursuant to section 204(d) of the Act);

(8) Title II-A—older individuals/training-related and supportive services (section 202(c)(1)(D) of the Act to carry out activities pursuant to section 204(d) of the Act);

(9) Title II-A—older individuals/administration (section 202(c)(1)(D) of the Act to carry out activities pursuant to section 204(d) of the Act); and

(10) Titles II-A and II-C (combined)—administration (sections 202(c)(1)(A) and 262(c)(1)(A) of the Act).

(c)(1) SDA grant recipients and their subrecipients shall plan, control, and charge expenditures, excluding incentive funds received pursuant to sections 202(c)(1)(B) and 262(c)(1)(B) of the Act, against the following cost objectives/categories:

- (i) Title II-A direct training services;
- (ii) Title II-C direct training services;
- (iii) Title II-A training-related and supportive services;
- (iv) Title II-C training-related and supportive services;
- (v) Title II-B training and supportive services;
- (vi) Title II-A administration;
- (vii) Title II-B administration; and
- (viii) Title II-C administration.

(2) Incentive funds received pursuant to sections 202(c)(1)(B) and 262(c)(1)(B) of the Act, may be combined and accounted for in total, without regard to cost categories or cost limitations.

(d) States and subrecipients shall use the following definitions in assigning costs to the cost categories contained in paragraphs (b) and (c) of this section:

(1) *Direct training services—title II-A.* Costs for direct training services that

may be charged to the title II-A program are:

(i) The personnel and non-personnel costs directly related to providing those services to participants specified in section 204(b)(1) of the Act and which can be specifically identified with one or more of those services. Generally, such costs are limited to:

(A) Salaries, fringe benefits, equipment, supplies, space, staff training, transportation, and other related costs of personnel directly engaged in providing training; and

(B) Salaries, fringe benefits, and related non-personnel costs of program component supervisors and/or coordinators as well as clerical staff, provided such staff work exclusively on activities or functions specified in section 204(b)(1) of the Act or actual allocations of time and related costs are made;

(ii) Books, instructional materials, and other teaching aids used by or for participants;

(iii) Equipment and materials used in providing training to participants;

(iv) Classroom space and utility costs;

(v) Costs of insurance coverage of participants as specified at § 627.415 of this part, Insurance; and

(vi) Payments to vendors for goods or services procured for the use of benefit of program participants for direct training services, including:

(A) Payments for commercially available training packages purchased competitively pursuant to section 141(d)(3) of the Act;

(B) Tuition charges and entrance fees of an educational institution, as specified at section 141(d)(3)(B) of the Act, when such tuition charges or entrance fees are not more than the educational institution's catalogue price, necessary to receive specific training, charged to the general public to receive the same training, and are for training of participants; and

(C) Payments to OJT employers, but not brokering contractors. Costs incurred under brokering arrangements shall be allocated to all of the benefitting cost categories.

(2) *Direct training services—title II-C.* Costs for direct training services that may be charged to the title II-C program are the costs identified in paragraph (d)(1) of this section as well as costs directly related to providing those services to participants specified in section 264(c)(1) of the Act and which can be specifically identified with one or more of those services.

(3) *Training-related and supportive services—title II-A.* Costs for training-related and supportive services that may be charged to the title II-A program are:

(i) The personnel and non-personnel costs directly related to providing outreach, intake, and eligibility determination as well as those services to participants specified in section 204(b)(2) of the Act and which can be specifically identified with one or more of those services. Generally, such costs are limited to:

(A) Salaries, fringe benefits, equipment, supplies, space, staff training, transportation, and other related costs of personnel directly engaged in providing training-related and/or supportive services; and
(B) Salaries, fringe benefits, and related non-personnel costs of program component supervisors and/or coordinators as well as clerical staff, provided such staff work exclusively on activities or functions specified in section 204(b)(2) of the Act or actual allocations of time and related costs are made.

(ii) Needs-based payments and other financial assistance to eligible applicants and participants.

(4) *Training-related and supportive services—title II-C.* Costs for training-related and supportive services that may be charged to the title II-C program are the costs identified in paragraph (d)(3) of this section as well as costs directly related to providing those services to participants specified in section 264(c)(2) of the Act and which can be specifically identified with one or more of those services.

(5) *Administration.* The costs of administration are that portion of necessary and allowable costs associated with the overall management and administration of the JTPA program and which are not directly related to the provision of services to participants or otherwise allocable to the program cost objectives/categories in paragraphs (b)(1)–(8) or (c)(1)–(5) of this section. These costs can be both personnel and non-personnel and both direct and indirect. Costs of administration shall include:

(i) Except as provided in paragraph (e)(1) of this section, costs of salaries, wages, and related costs of the recipient's or subrecipient's staff or PIC staff engaged in:

(A) Overall program management, program coordination, and general administrative functions, including the salaries and related costs of the executive director, JTPA director, project director, personnel officer, fiscal officer/bookkeeper, purchasing officer, secretary, payroll/insurance/property clerk and other costs associated with carrying out administrative functions;

(B) Preparing program plans, budgets, schedules, and amendments thereto;

(C) Monitoring of programs, projects, subrecipients, and related systems and processes;

(D) Procurement activities, including the award of specific subgrants, contracts, and purchase orders;

(E) Providing State or local officials and the general public with information about the program (public relations);

(F) Developing systems and procedures, including management information systems, for assuring compliance with program requirements;

(G) Preparing reports and other documents related to the program requirements;

(H) Coordinating the resolution of audit findings;

(I) Evaluating program results against stated objectives; and

(J) Performing administrative services including such services as general legal services, accounting services, audit services; and managing purchasing, property, payroll, and personnel;

(ii) Costs for goods and services required for administration of the program, including such goods and services as rental or purchase of equipment, insurance, utilities, office supplies, postage, and rental and maintenance of office space;

(iii) The costs of organization-wide management functions; and

(iv) Travel costs incurred for official business in carrying out program management or administrative activities, including travel costs incurred by PIC members.

(e) *Other cost classification guidance.*

(1) Personnel and related non-personnel costs of the recipient's or subrecipient's staff, including project directors, that perform services or activities that benefit two or more of the cost objectives/categories identified in this section may be allocated to the benefitting cost objectives/categories based on documented distributions of actual time worked and related costs.

(2) Indirect or overhead costs normally shall be charged to administration, except that specific costs charged to an overhead or indirect cost pool that can be identified directly with a JTPA cost objective/category other than administration may be charged to the JTPA cost objective/category directly benefitted. Documentation of such charges shall be maintained.

(3) Where an award to a subrecipient is for a "commercially available or off-the-shelf training package", as defined at § 626.5 of this chapter, the subrecipient may charge all costs of such package to the direct training services cost category.

(4) Profits, fees, and other revenues earned by a subrecipient that are in excess of actual costs incurred, to the extent allowable and consistent with the guidelines on allowable costs prescribed by the Governor in accordance with § 627.435(i). Cost principles and allowable costs, may be allocated to all three cost categories based on the proportionate share of actual costs incurred attributable to each category.

(f) *Administrative cost pool.* Joint JTPA administrative costs that are charged initially to an administrative cost pool must be allocated, for JTPA Federal reporting purposes, to the benefitting JTPA programs based on the benefits received by each program.

§ 627.445 Limitations on certain costs.

(a) *State-administered programs—(1) Services for older individuals.* Of the funds allocated for any program year for section 202(c)(1)(D) of the Act to carry out activities pursuant to section 204(d) of the Act—

(i) Not less than 50 percent shall be expended for the cost of direct training services; and

(ii) Not more than 20 percent shall be expended for the cost of administration.

(2) *State education services.* Of the funds allocated for any program year for sections 202(c)(1)(C) and 262(c)(1)(C) of the Act to carry out activities pursuant to section 123(d)(2)(B) of the Act—

(i) Not less than 50 percent shall be expended for the cost of direct training services; and

(ii) Not more than 20 percent shall be expended for the cost of administration.

(3) The limitations specified in paragraph (a)(2) of this section shall apply to the combined total of funds allocated for sections 202(c)(1)(C) and for section 262(c)(1)(C) of the Act.

(b) *SDA allocations.* (1) In applying the title II-A and II-C cost limitations specified in section 108(b)(4) of the Act, the funds allocated to a service delivery area shall be net of any:

(i) Transfers made in accordance with sections 206, 256, and 266 of the Act; and

(ii) Reallocations made by the Governor in accordance with section 109(a) of the Act.

(2) The limitations specified in paragraph (b)(1) of this section shall apply separately to the funds allocated for title II-A and title II-C programs.

(3) The title II-B administrative cost limitation of 15 percent shall be 15 percent of the funds allocated for any program year to a service delivery area, excluding any funds transferred to title II-C in accordance with section 256 of the Act. (section 253(a)(3)).

(c)(1) The State shall establish a system to regularly assess compliance

with the cost limitations including periodic review and corrective action, as necessary.

(2) States and service delivery areas shall have the 3-year period of fund availability to comply with the cost limitations in section 108 of the Act and paragraphs (a) and (b) of this section. (section 161(b)).

(d) Administrative costs incurred by a community-based organization or private non-profit service provider shall not be included in the limitation described in section 108(b)(4)(A) of the Act if:

(1) Such costs are incurred under an agreement that meets the requirements of section 141(d)(3)(C) (i) and (ii) of the Act;

(2) The total administrative expenditures of the service delivery area, including the administrative expenditures of such community-based organizations and private non-profit service providers, do not exceed 25 percent of the funds allocated to the service delivery area for the program year of allocation; and

(3) The total direct training expenditures of the service delivery area, including the direct training expenditures of such community-based organizations and private non-profit service providers, is equal to or exceeds 50 percent of the funds allocated to the service delivery area for the program year less one-half of the percentage by which the total administrative expenditures of the service delivery area exceeds 20 percent; for example, if the total administrative expenditures of the service delivery area is 24 percent then the total direct training expenditures of the service delivery area must be at least 48 percent.

(e) The provisions of this section do not apply to any title III programs.

(f) The provisions of this section do not apply to any designated SDA which served as a concentrated employment program grantee for a rural area under the Comprehensive Employment and Training Act (section 108(d)).

§ 627.450 Program income.

(a) *Definition of program income.* (1) Program income means income received by the recipient or subrecipient directly generated by a grant or subgrant supported activity, or earned only as a result of the grant or subgrant. Program income includes:

(i) Income from fees for services performed and from conferences;

(ii) Income from the use or rental of real or personal property acquired with grant or subgrant funds;

(iii) Income from the sale of commodities or items fabricated under a grant or subgrant;

(iv) Revenues earned by a governmental or private non-profit service provider under either a fixed-price or reimbursable award that are in excess of the actual costs incurred in providing the services; and

(v) Except for States, as defined in the Department of Treasury's Cash Management Improvement Act regulation at 31 CFR 205.3, interest income earned on advances of subgrant funds.

(2) Program income does not include:

(i) Rebates, credits, discounts, refunds, etc., or interest earned on any of them, which shall be credited in accordance with § 627.435(d), Cost principles and allowable costs;

(ii) Taxes, special assessments, levies, fines, and other such governmental revenues raised by a recipient or subrecipient; or

(iii) Income from royalties and license fees for copyrighted material, patents, patent applications, trademarks, and inventions developed by a recipient or subrecipient.

(3) *Property.* Proceeds from the sale of property shall be handled in accordance with the requirements of § 627.465, of this part, Property management standards.

(b) *Cost of generating program income.* Costs incidental to the generation of program income may be deducted, if not already charged to the grant, from gross income to determine program income.

(c) *Use of program income.* (1) A recipient or subrecipient may retain any program income earned by the recipient or subrecipient only if such income is added to the funds committed to the particular JTPA grant or subgrant under which it was earned and such income is used for JTPA purposes and under the terms and conditions applicable to the use of the grant funds. The classification of costs in § 627.440 and the administrative cost limitation in § 627.445 shall apply to such funds.

(2) Program income generated under title II may also be used to satisfy the matching requirement of section 123(b) of the Act.

(3) Program income shall be used prior to the submission of the final report for the funding period of the program year to which the earnings are attributable.

(4) If the subrecipient that earned program income cannot use such income for JTPA purposes, the recipient may permit another entity to use the program income for JTPA purposes.

(5) Program income not used in accordance with the requirements of this section shall be returned to the Department of Labor.

(d) *Program and other income after the funding period.* Rental income and user fees on real and personal property acquired with JTPA funds shall continue to be JTPA program income in subsequent funding periods. There are no Federal requirements governing the disposition of all other income that is earned after the end of the funding period.

§ 627.455 Reports required.

(a) *General.* The Governor shall report to the Secretary pursuant to instructions issued by the Secretary. Reports shall be submitted no more frequently than quarterly in accordance with section 165(f) of the Act, and within 45 calendar days after the end of the report period. Additional reporting requirements for title III are set forth at § 631.15 of this chapter.

(b) A recipient may impose different forms or formats, shorter due dates, and more frequent reporting requirements on subrecipients, however, the recipient is required to meet the reporting requirements imposed on it by the Secretary.

(c) The Secretary may provide computer outputs to recipients to expedite or contribute to the accuracy of reporting. The Secretary may accept the required information from recipients in electronically reported format or computer printouts instead of prescribed forms.

(d) *Financial reports:* (1) Financial reports for programs under titles I, II, and III shall be submitted to the Secretary by each State quarterly and by program year of appropriation.

(2) Each recipient shall report program outlays on an accrual basis. If the recipient's accounting records are not normally kept on the accrual basis, the recipient shall develop such accrual information through an analysis of the documentation on hand.

(3) A final financial report is required 90 days after the expiration of a funding period (see § 627.485 of this part, Closeout).

§ 627.460 Requirements for records.

(a) Records, including the records identified in section 165(g) of the Act, shall be retained in accordance with section 165(e) of the Act. In establishing the time period of record retention requirements for records of subrecipients, the State may either:

(1) Impose the time limitation requirement of section 165(e) of the Act; or

(2) Require that subrecipient records for each funding period be retained for 3 years after the subrecipient submits to the awarding agency its final expenditure report for that funding period.

(b) The Governor shall ensure that the records under this section shall be retained beyond the prescribed period, if any litigation or audit is begun or if a claim is instituted involving the grant or agreement covered by the records. In these instances, the Governor shall ensure that the records shall be retained until the litigation, audit, or claim has been finally resolved.

(c) In the event of the termination of the relationship with a subrecipient, the Governor or SDA grant recipient or title III SSG shall be responsible for the maintenance and retention of the records of any subrecipient unable to retain them.

(d) Substitution of microfilm: Copies made by microfilming, photocopying, or similar methods may be substituted for the original records.

(e) Federal and awarding agencies' access to records—(1) *Records of recipients and subrecipients.* The awarding agency, the Department of Labor (including the Department of Labor's Office of the Inspector General), and the Comptroller General of the United States, or any of their authorized representatives, have the right of timely and reasonable access to any books, documents, papers, computer records, or other records of recipients and subrecipients that are pertinent to the grant, in order to conduct audits and examinations, and to make excerpts, transcripts, and photocopies of such documents. This right also includes timely and reasonable access to recipient and subrecipient personnel for the purpose of interview and discussion related to such documents.

(2) *Expiration of right of access.* The right of access in this section is not limited to the required retention period but shall last as long as the records are retained.

§ 627.463 Public access to records.

(a) *Access—(1) Public access.* Except as provided in paragraph (b) of this section, records maintained by recipients or subrecipients pursuant to section 165(a) of the Act shall be made available to the public upon request, notwithstanding the provisions of State or local law.

(2) *Freedom of Information Act (FOIA).* Records maintained by recipients or subrecipients are not subject to the Freedom of Information Act (5 U.S.C. 552).

(b) *Exceptions.* A record maintained by a recipient or subrecipient pursuant to section 165(a) of the Act shall not be made available to the public, notwithstanding the provisions of State or local law, where such record is:

(1) Information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; or

(2) A trade secret, or commercial or financial information, obtained from a person and privileged or confidential.

(c) *Fees.* For processing of a request for a record under paragraph (a)(1) of this section, a recipient or subrecipient may charge a fee to the extent sufficient to recover the cost applicable to processing such request. (section 165(a)(4)).

§ 627.465 Property management standards.

(a) *States and governmental subrecipients.* Real property, equipment, supplies, and intangible property acquired or produced after July 1, 1993, by States and governmental subrecipients with JTPA funds shall be governed by the definitions and property requirements in the DOL regulations at 29 CFR part 97.

(b) *Nongovernmental subrecipients.* Except as provided in paragraph (c) of this section, real and personal property, including intangible property, acquired or produced after July 1, 1993, by nongovernmental subrecipients with JTPA funds shall be governed by the definitions and property management standards of OMB Circular A-110, as codified by administrative regulations of the Department of Labor.

(c) *Special provisions for property acquired under subgrants to commercial organizations—(1) Scope.* This paragraph (c) applies to real and personal property other than supplies that are acquired or produced after July 1, 1993, under a JTPA subgrant to a commercial organization.

(2) *Property acquired by commercial subrecipients.* Title to property acquired or produced by a subrecipient that is a commercial organization shall vest in the awarding agency, provided such agency is a governmental entity or nongovernmental organization that is not a commercial organization. Property so acquired or produced shall be considered to be acquired or produced by the awarding agency and paragraph (a) or (b) of this section, as appropriate shall apply to that property. If the awarding agency is also a commercial organization, title shall vest in the higher level, non commercial awarding agency that made the subaward to the commercial subrecipient.

(3) *Approval for acquisition.* A subrecipient that is a commercial organization shall not acquire property subject to this section without the prior approval of the awarding agency.

(d) *Notification to the Secretary of real property acquisitions.* Recipients shall notify the Secretary immediately upon acquisition of real property with JTPA funds, including acquisitions by subrecipients. Such notification shall include the location of the real property and the Federal share percentage.

§ 627.470 Performance standards.

(a) *General:* The Secretary shall prescribe performance standards for adult programs under title II-A, for youth programs under title II-C, for dislocated worker programs under title III, and for older worker programs under section 204(d) of the Act. Any performance standards developed for employment competencies shall be based on such factors as entry level skills and other hiring requirements.

(b) Pursuant to instructions and timelines issued by the Secretary, the Governor shall:

(1) Collect the data necessary to set performance standards pursuant to section 106 of the Act; and

(2) Maintain records and submit reports required by sections 106(j)(3), 165(a)(3), (c)(1), and (d) and 121(b)(6) of the Act.

(c) *Title II performance standards:* (1) The Governor shall establish SDA performance standards for title II within the parameters set by the Secretary pursuant to sections 106(b) and (d) of the Act and apply the standards in accordance with section 202(c)(1)(E) of the Act.

(2) The Governor shall establish incentive award policies pursuant to section 106(b)(7) of the Act, except for programs operated under section 204(d) of the Act.

(3) The Governor shall provide technical assistance to SDA's failing to meet performance standards established by the Secretary for a given program year. (section 106a(j)(2)).

(4)(i) If an SDA fails to meet a prescribed number of the Secretary's performance standards for 2 consecutive years, the Governor shall notify the Secretary and the service delivery area of the continued failure, and impose a reorganization plan (section 106(j)(4)).

(ii) The number of standards deemed to constitute failure shall be specified by the Secretary biennially and shall be based on an appropriate proportion of the total number of standards established by the Secretary for that performance cycle.

(iii) A reorganization plan shall not be imposed for a failure to meet performance standards other than those established by the Secretary.

(e)(1) If the Governor does not impose a required reorganization plan, required by paragraph (c)(4) of this section, within 90 days of the end of the second program year in which an SDA has failed to meet its performance standards, the Secretary shall develop and impose such a plan (section 106(j)(5)).

(2) Before imposing a reorganization plan, the Secretary shall notify the Governor and SDA in writing of the intent to impose the plan and provide both parties the opportunity to submit comments within 30 days of receipt of the Secretary's notice.

(d) An SDA subject to a reorganization plan under paragraph (c)(4) or (d) of this section may, within 30 days of receiving notice of such action, appeal to the Secretary to revise or rescind the reorganization plan under the procedures set forth at § 627.471 of this subpart, Reorganization plan appeals (section 106(j)(6)(A)).

(f) Secretarial action to recapture or withhold funds: (1) The Secretary shall recapture or withhold an amount not to exceed one-fifth of the State administration set-aside allocated under sections 202(c)(1)(A) and 262(c)(1)(A) of the Act when:

(i) the Governor has failed to impose a reorganization plan under paragraph (c)(4) of this section, for the purposes of providing technical assistance under a reorganization plan imposed by the Secretary (section 106(j)(5)(B)); or

(ii) the Secretary determines in an appeal provided for at paragraph (e) of this section, and set forth at § 627.471 of this subpart, that the Governor has not provided appropriate technical assistance as required at section 106(j)(2), for the purposes of providing such assistance (section 106(j)(6)(B)).

(2)(i) A Governor of a State that is subject to recapture or withholding under paragraph (f)(1) of this section may, within 30 days of receipt of such notice, appeal such recapture or withholding to the Secretary.

(ii) The Secretary may consider any comments submitted by the Governor, and shall make a decision within 45 days after the appeal is received.

(g) Title III performance standards: (1) The Governor shall establish SSG performance standards for programs under title III within the parameters set annually by the Secretary pursuant to section 106(c) and (d) of the Act.

(2) Any performance standard for programs under title III shall make appropriate allowances for the

difference in cost resulting from serving workers receiving needs-related payments authorized under § 631.20 of this chapter (section 106(c)(2)).

(3) The Secretary annually shall certify compliance, if the program is in compliance, with the title III performance standards established pursuant to paragraph (a) of section 322(a)(4).

(4) The Governor shall not establish standards for the operation of programs under title III that are inconsistent with the performance standards established by the Secretary under provisions of section 106(c) of the Act (Section 311(b)(8)).

(5) When an SSG fails to meet performance standards for 2 consecutive years, the Governor may institute procedures pursuant to the Governor's by-pass authority in accordance with § 631.38(b) of this chapter or require redesignation of the substate grantee in accordance with § 631.35 of this chapter, as appropriate.

§ 627.471 Reorganization plan appeals.

(a) A reorganization plan imposed by the Governor, as provided for at § 627.470(c)(4) of this part, or by the Secretary, as provided for at § 627.470(d) of this part, may be appealed directly to the Secretary without prior exhaustion of local remedies.

(b)(1) Appeals shall be submitted to the Secretary, U.S. Department of Labor, Washington, DC 20210, Attention: ASET. A copy of the appeal shall be provided simultaneously to the Governor.

(2) The Secretary shall not accept an appeal dated later than 30 days after receipt of written notification from the Governor or the Secretary.

(3) The appealing party shall explain why it believes the decision to impose the reorganization plan is contrary to the provisions of section 106 of the Act.

(4) The Secretary shall accept the appeal and make a decision only with regard to determining whether or not the decision to impose the reorganization plan is inconsistent with section 106 of the Act. The Secretary may consider any comments submitted by the Governor or the SDA, as appropriate. The Secretary shall make a final decision within 60 days after this appeal is received. (section 106(j)).

§ 627.475 Oversight and monitoring.

(a) The Secretary may monitor all recipients and subrecipients of financial assistance pursuant to section 163 of the Act.

(b) The Governor is responsible for oversight of all SDA and SSG activities

and State-supported programs. The Governor shall develop and make available for review a State monitoring plan. The plan shall specify the mechanism which:

(1) Ensures that established policies to achieve program quality and outcomes meet the objectives of the Act and regulations promulgated thereunder;

(2) Enables the Governor to determine if SDA's and SSG's have demonstrated substantial compliance with the requirements for oversight;

(3) Determines that a Job Training Plan shall be disapproved if the plan does not meet the criteria contained in section 105(b)(1) of the Act;

(4) Regularly examines expenditures against the cost categories and cost limitations specified in the Act and these regulations;

(5) Ensures that SDA's and SSG's are monitored onsite regularly, but not less than once annually; and

(6) Provides for corrective action to be imposed if items in paragraphs (b) (1)-(4) of this section are not met.

(c) The Governor shall issue instructions to SDA's and title III SSG's on the development of a substate monitoring plan. The instructions for development of the monitoring plan, at a minimum, shall address the monitoring scope and frequency, and the Secretary's emphasis and direction. The substate monitoring plan shall be part of the job training plan.

(d) The Governor shall establish general standards for PIC oversight responsibilities. The required PIC standards shall be included in the Governor's Coordination and Special Services Plan (GCSSP).

(e)(1) The PIC, pursuant to standards established by the Governor, shall establish specific policies for monitoring and oversight of SDA performance which shall be described in the job training plan.

(2) The PIC may exercise independent oversight over activities under the job training plan which shall not be circumscribed by agreements with the appropriate chief elected official(s) of the SDA.

(f) The PIC and chief elected official(s) may conduct such oversight as they, individually or jointly, deem necessary or delegate oversight responsibilities to an appropriate entity pursuant to their mutual agreement.

§ 627.480 Audits.

(a) *Non-Federal Audits*—(1) *Governments*. Each recipient and governmental subrecipient is responsible for complying with the Single Audit Act of 1984 (31 U.S.C. 7501-7) and 29 CFR part 96, the

Department of Labor regulations which implement Office of Management and Budget (OMB) Circular A-128, "Audits of State and Local Governments".

(2) *Non-governmental subrecipients.* Each non-governmental subrecipient shall comply with OMB Circular A-133, "Audits of Institutions of Higher Education and Other Nonprofit Institutions", as implemented by the Department of Labor regulations at 29 CFR part 96. The provisions of this paragraph (a)(2) do not apply to any non-governmental subrecipient that is:

(i) A commercial organization; or
(ii) A hospital or an institution of higher education for which State or local governments choose to apply OMB Circular A-128.

(3) *Commercial organizations.* A commercial organization which is a subrecipient and which receives \$25,000 or more a year in Federal financial assistance to operate a JTPA program shall have either:

(i) A program specific annual independent financial and compliance audit conducted and prepared in accordance with generally accepted government auditing standards; or
(ii) An organization-wide audit that includes coverage of the JTPA program within its scope.

(b) *Federal audits.* The notice of audits conducted or arranged by the Office of Inspector General or the Comptroller General shall be provided in advance as required by section 165(b) of the Act.

(c) *Audit reports.* (1) Audit reports of recipient-level entities and other organizations which receive JTPA funds directly from the U.S. Department of Labor shall be submitted to the Office of the Inspector General.

(2) Audit reports of other organizations than those described in paragraph (c)(1) of this section shall be submitted to the entity which provided the JTPA funds.

(d) Each entity that receives JTPA program funds and awards a portion of those funds to one or more subrecipients shall:

(1) Ensure that each subrecipient complies with the applicable audit requirements;

(2) Resolve all audit findings that impact the JTPA program with its subrecipient and ensure that corrective action for all such findings (including debt collection action for disallowed costs) is instituted within 6 months after receipt of the audit report; and

(3) Maintain an audit resolution file documenting the disposition of reported questioned costs and corrective actions taken for all findings; the ETA Grant Officer may request that an audit

resolution report, as specified in paragraph (e)(2) of this section, be submitted for such audits or may have the audit resolution reviewed through the compliance review process.

(e)(1) Audits of recipient-level entities and other organizations which receive JTPA funds directly from DOL and all audits conducted by or under contract for the Office of Inspector General shall be issued by the OIG to the Employment and Training Administration after acceptance by OIG.

(2) After receipt of the audit report, the ETA Grant Officer shall request that the State submit an audit resolution report documenting the disposition of the reported questioned costs, i.e., whether allowed or disallowed, the basis for allowing questioned costs, the method of repayment planned or required, and corrective actions, including debt collection efforts, taken or planned.

(f) If the recipient intends to request a waiver of liability under section 164(e)(2) of the Act for misexpenditures by a subrecipient, such requests shall be accompanied by the audit resolution report along with supporting documentation.

(g) If the recipient intends to propose the use of "stand-in" costs as substitutes for otherwise unallowable costs, the proposal shall be included with the audit resolution report. To be considered, the proposed "stand-in" costs shall have been reported as uncharged JTPA program costs, included within the scope of the audit, and accounted for in the auditee's financial system as required by § 627.425, of this part, Standards for financial management and participant data systems. To be accepted, stand-in costs shall be from the same title, cost category, and funding period as the costs which they are proposed to replace.

(h) After receiving the audit resolution report, the ETA Grant Officer shall review the report, the recipient's disposition, and any liability waiver request. If the Grant Officer agrees with all aspects of the recipient's disposition of the audit, the Grant Officer shall so notify the recipient. If the Grant Officer disagrees with the recipient's conclusion on specific points in the audit, the Grant Officer shall resolve the audit through the initial and final determination process described in § 627.606 of this part.

§ 627.481 Audit resolution.

(a) *Federal audit resolution.* When the OIG issues an audit report to the Employment and Training Administration for resolution, the ETA

Grant Officer shall provide a copy of the report to the recipient (if it does not already have the report), along with a request that the recipient submit its audit resolution report as specified in § 627.480(e)(2), of this part, unless the Grant Officer chooses to proceed directly against the recipient pursuant to § 627.601.

(1) For audits of recipient-level entities and other organizations which receive JTPA funds directly from DOL, the Grant Officer shall request that the audit resolution report be submitted within 60 days from the date that the audit report is issued by the OIG.

(2) For audits of subrecipient organizations, the Grant Officer shall provide the recipient with a 180-day period within which to resolve the audit with its subrecipient(s), and shall request that the audit resolution report be submitted at the end of that 180-day period.

(b) After receiving the audit resolution report, the ETA Grant Officer shall review the report, the recipient's disposition, any liability waiver request, and any proposed "stand-in" costs. If the Grant Officer agrees with all aspects of the recipient's disposition of the audit, the Grant Officer shall so notify the recipient, constituting final agency action on the audit. If the Grant Officer disagrees with the recipient's conclusion on specific points in the audit, or if the recipient fails to submit its audit resolution report, the Grant Officer shall resolve the audit through the initial and final determination process described in § 627.606 of this part. Normally, the Grant Officer's notification of agreement (a concurrence letter) or disagreement (an initial determination) with the recipient's audit resolution report will be provided within 180 days of the Grant Officer's receipt of the report.

(c) *Non-Federal audit resolution.* (1) To ensure timely and appropriate resolution for audits of all subrecipients, including SDA grant recipients and title III SSG's, and to ensure recipient-wide consistency, the Governor shall prescribe standards for audit resolution and debt collection policies and procedures that shall be included in each job training plan in accordance with section 104(b)(12) of the Act.

(2) The Governor shall prescribe an appeals procedure for audit resolution disputes which, at a minimum, provides for:

- (i) The period of time, not less than 15 days nor more than 30 days, after the issuance of the final determination in which an appeal may be filed;
- (ii) The rules of procedure;
- (iii) Timely submission of evidence;

- (iv) The timing of decisions; and
- (v) Further appeal rights, if any.

§ 627.485 Closeout.

(a) *General.* The Grant Officer shall close out each annual JTPA grant agreement within a timely period after the funding period covered by the award has expired.

(b) Revisions to the reported expenditures for a program year of funds may be made until 90 days after the time limitation for expenditure of JTPA funds, as set forth in section 161(b) of the Act, has expired. The Grant Officer may extend this deadline if the recipient submits a written request with justification. After that time, the Grant Officer shall consider all reports received as final and no additional revisions may be made.

(c) When closing out a JTPA grant, the Grant Officer shall notify the recipient, by certified mail, that, since the time limitation for expenditure of funds covered by the grant award has expired, it is the Department of Labor's intent to close the annual grant as follows:

(1) *Cost adjustment.* Based on receipt of reports in paragraph (b) of this section, the Grant Officer shall make upward or downward adjustments to the allowable costs; and

(2) *Cash adjustment.* DOL shall make prompt payment to the recipient for allowable reimbursable costs; the recipient shall promptly refund to DOL any balance of cash advanced that is in excess of allowable costs for the grant award being closed.

(d) The recipient shall have an additional 60 days after the date of the notice described in paragraph (c) of this section in which to provide the Grant Officer with information as to the reason(s) why closeout should not occur.

(e) At the end of the 60-day period described in paragraph (d) of this section, the Grant Officer shall notify the recipient that closeout has occurred, unless information provided by the recipient, pursuant to paragraph (d) of this section, indicates otherwise.

§ 627.490 Later disallowances and adjustments after closeout.

The closeout of a grant does not affect:

- (a) The Grant Officer's right to disallow costs and recover funds on the basis of a later audit or other review;
- (b) The recipient's obligation to return any funds due as a result of later refunds, corrections, subrecipient audit disallowances, or other transactions;
- (c) Records retention requirements in § 627.460 of this part, Requirements for records, and § 627.463 of this part, Public access to records;

(d) Property management requirements in § 627.465 of this part, Property management standards; and

(e) Audit and audit resolution requirements in § 627.480 of this part, Audits and § 627.481 of this part, Audit resolution.

§ 627.495 Collection of amounts due.

(a) Any funds paid to a recipient in excess of the amount to which the recipient is finally determined to be entitled under the terms of the grant constitute a debt to the Federal Government. If not paid within a reasonable period after demand, the Secretary may take any actions permitted by law to recover the funds.

(b) The Secretary shall charge interest on an overdue debt in accordance with the Federal Claims Collection Standards (4 CFR ch. II).

Subpart E—Grievances Procedures at the State and Local Level**§ 627.500 Scope and purpose.**

(a) *General.* This subpart establishes the procedures which apply to the handling of non-criminal complaints under the Act at the Governor, the SDA, and the SSG levels. Nothing contained in this subpart shall be deemed to prejudice the separate exercise of other legal rights in pursuit of remedies and sanctions available outside the Act. Complaints of discrimination pursuant to section 167(a) of the Act shall be handled under 29 CFR parts 31, 32 and 34.

(b) *Handling of criminal complaints and reports of fraud, waste, and abuse.* All information and complaints involving fraud, waste, abuse or criminal activity shall be reported directly and immediately to the DOL Office of the Inspector General.

(c) *Non-JTPA remedies.* Whenever any person, organization, or agency believes that a recipient, an SDA, an SSG, or other subrecipient has engaged in conduct that violates the Act and that such conduct also violates a Federal statute other than JTPA, or a State or local law, that person, organization, or agency may, with respect to the non-JTPA cause of action, institute a civil action or pursue other remedies authorized under other Federal, State or local law against the recipient, the SDA, the SSG, or other subrecipient, without first exhausting the remedies in this subpart. Nothing in the Act or this chapter shall:

- (1) Allow any person or organization to file a suit which alleges a violation of JTPA or regulations promulgated thereunder without first exhausting the

administrative remedies described in this subpart; or

- (2) Be construed to create a private right of action with respect to alleged violations of JTPA or the regulations promulgated thereunder.

§ 627.501 State grievance and hearing procedures for non-criminal complaints at the recipient level.

(a)(1) Each recipient shall maintain a recipient-level grievance procedure and shall ensure the establishment of procedures at the SDA level and the SSG level for resolving any complaint alleging a violation of the Act, regulations promulgated thereunder, grants, or other agreements under the Act. The procedures shall include procedures for the handling of complaints and grievances arising in connection with JTPA programs operated by each SDA, SSG, and subrecipient under the Act (section 144(a)).

(2) The procedures described in paragraph (a)(1) of this section shall also provide for resolution of complaints arising from actions taken by the recipient with respect to investigations or monitoring reports.

(b) The recipient's grievance hearing procedure shall require written notice to interested parties of the date, time, and place of the hearing; an opportunity to present evidence; and a written decision. For matters under paragraph (a)(2) of this section, the notice of hearing shall indicate the nature of the violation(s) which the hearing covers.

§ 627.502 Grievance and hearing procedures for non-criminal complaints at the SDA and SSG levels.

(a) Each SDA and SSG, pursuant to guidelines established by the recipient, shall establish procedures for resolving complaints and grievances arising in connection with JTPA programs operated by the SDA, the SSG, and other subrecipients under the Act. The procedures also shall provide for resolution of complaints arising from actions taken by the SDA or the SSG with respect to investigations or monitoring reports of their subgrantees, contractors, and other subrecipients. (section 144(a)).

(b) Each SDA and SSG grievance hearing procedure shall include written notice of the date, time, and place of the hearing; an opportunity to present evidence; a written decision; and a notice of appeal rights.

(c) The SDA and SSG procedures shall provide for a decision within 60 days of the filing of the complaint.

§ 627.503 Recipient-level review.

(a) If a complainant does not receive a decision at the SDA or the SSG level within 60 days of filing the complaint or receives a decision unsatisfactory to the complainant, the complainant shall have the right to request a review of the complaint by the recipient. The recipient shall issue a decision within 30 days of receipt of the complaint.

(b) The recipient shall also provide for an independent review of a complaint initially filed at the recipient level on which a decision was not issued within 60 days of receipt of a complaint or on which the complainant has received an adverse decision. A decision shall be made within 30 days of receipt by the recipient.

(c) A request for review under the provisions of paragraph (a) or (b) of this section shall be filed within 10 days of receipt of the adverse decision or, if no timely decision is rendered, within 15 days from the date on which the complainant should have received a timely decision.

(d) With the exception of complaints alleging violations of the labor standards at section 143 of the Act, the recipient's decision is final unless the Secretary exercises the authority for Federal-level review in accordance with the provisions at § 627.601, of this part, Complaints and grievances at the Federal level. Complaints alleging violations of section 143 of the Act shall be handled under the procedures set forth at § 627.603, of this part, Special handling of labor standards violations under section 143.

§ 627.504 Non-criminal grievance procedure at employer level.

(a) Recipients, SDA's, SSG's, and other subrecipients shall assure that other employers, including private-for-profit employers of participants under the Act, have a grievance procedure relating to the terms and conditions of employment available to their participants (section 144(b)).

(b) Employers under paragraph (a) of this section may operate their own grievance system or may utilize the grievance system established by the recipient, the SDA, or the SSG under this subpart. Employers shall inform participants of the grievance procedures they are to follow when the participant begins employment.

(c) An employer grievance system shall provide for, upon request by the complainant, a review of an employer's decision by the SDA, or the SSG and the recipient if necessary, in accordance with § 627.501 and § 627.502 of this part.

Subpart F—Federal handling of non-criminal complaints and other allegations.**§ 627.600 Scope and purpose.**

This subpart establishes the procedures which apply to the filing, handling, and reviewing of complaints at the Federal level. Nothing in the Act or this chapter shall allow any person or organization to join or sue the Secretary with respect to the Secretary's responsibilities under JTPA except after exhausting the remedies in subpart E of this part and this subpart F. Complaints of discrimination pursuant to section 167(a) of the Act shall be handled under 29 CFR parts 31, 32 and 34.

§ 627.601 Complaints and allegations at the Federal level.

(a) The types of complaints and allegations that may be received at the Federal level for review include:

(1) Complaints for which the recipient has failed to issue a timely decision as required by § 627.503 of this part;

(2) Alleged violations of the Act and/or the regulations promulgated thereunder resulting from Federal, State, and/or SDA and SSG monitoring and oversight reviews;

(3) Alleged violations of the labor standards provisions at section 143 of the Act;

(4) Alleged violations of the relocation provisions in section 141(c) of the Act; and

(5) Other allegations of violations of the Act or the regulations promulgated thereunder.

(b) Upon receipt of a complaint or allegation alleging any of the violations listed in paragraph (a) of this section, the Secretary may:

(1) Direct the recipient to handle a complaint through local grievance procedures established under § 627.502 of this part; or

(2) Investigate and determine whether the recipient or subrecipient(s) are in compliance with the Act and regulations promulgated thereunder (section 163 (b) and (c)).

(3) Allegations of violations of sections 141(c) or 143 of the Act and § 627.503 of this part shall be handled under paragraph (b)(2) of this section.

§ 627.602 Resolution of investigative findings.

(a)(1) As a result of an investigation or monitoring by the Department, or of the actions specified in paragraph (c) of § 627.601 of this part, the Grant Officer shall notify the recipient of the findings of the investigation and shall give the recipient a period of time, not to exceed 60 days, depending on the nature of the

findings, to comment and to take appropriate corrective actions.

(2) The Grant Officer shall review the complete file of the investigation and the recipient's actions. The Grant Officer's review shall take into account the sanction provisions of subpart G of this part. If the Grant Officer agrees with the recipient's handling of the situation, the Grant Officer shall so notify the recipient. This notification shall constitute final agency action.

(3) If the Grant Officer disagrees with the recipient's handling of the matter, the Grant Officer shall proceed pursuant to § 627.606 of this part, Grant Officer resolution.

(b) [Reserved].

§ 627.603 Special handling of labor standards violations under Section 143 of the Act.

(a) A complaint alleging JTPA section 143 violations may be submitted to the Secretary by either party to the complaint when:

(1) The complainant has exhausted the grievance procedures set forth at subpart E of this part, or

(2) The 60-day time period specified for reaching a decision under a procedure set forth at subpart E of this part has elapsed without a decision. (section 144 (a) and (d)(1)).

(b)(1) The Secretary shall investigate the allegations contained in a complaint alleging violations of JTPA section 143, make a determination whether a violation has occurred, and issue a decision within 120 days of receipt by the Secretary of the complaint. (section 144 (c) and (d)).

(2) If the results of the Secretary's investigation indicate that a decision by a recipient under a procedure set forth at subpart E of this part requires modification or reversal, or that the 60-day time period for decision under section 144(a) has elapsed, the Secretary shall modify, reverse, or issue such decision.

(3) If the Secretary modifies or reverses a decision made under a procedure set forth at subpart E of this part, or issues a decision where the 60-day time period has elapsed without a decision, the Secretary shall offer an opportunity for a hearing, in accordance with the procedures under section 168 of the Act and subpart H of this part (sections 144(d)(2) and 166(a)).

(4) If the Secretary upholds a recipient's decision, the determination is the final decision of the Secretary. (section 144(d)(3)). This decision is not appealable to the Office of Administrative Law Judges.

(c) Except as provided in paragraph (d) of this section, remedies available

under this section to a grievant for violations of section 143 of the Act shall be limited to:

(1) Suspension or termination of payments under the Act;

(2) Prohibition of placement of a participant, for an appropriate period of time, in a program under the Act with an employer that has violated section 143 of the Act, as determined under section 144 (d) or (e) of the Act; and/or

(3) Appropriate equitable relief (other than back pay). (section 144(f)(1)).

(d) Available remedies for violations of sections 143 (a)(4), (b)(1), (b)(3), and (d) of the Act include the remedies listed in subsection (c) of this section, and may include the following:

(1) Reinstatement of the grievant to the position held prior to displacement;

(2) Payment of lost wages and benefits; and/or

(3) Reestablishment of other relevant terms, conditions, and privileges of employment.

(e) Nothing in this section shall be construed to prohibit a grievant from pursuing a remedy authorized under another Federal, State, or local law for a violation of section 143 of the Act. (section 144(g)).

§ 627.604 Alternative procedure for handling labor standards violations under section 143 of the Act—binding arbitration.

(a) A person alleging a violation of section 143 of the Act, as an alternative to processing the grievance under a procedure described at section 144 of the Act, may submit the grievance to a binding arbitration procedure, if a collective bargaining agreement covering the parties to the grievance so provides (section 144(e)(1)).

(b) A person electing to have her/his complaint on JTPA section 143 labor standard violations processed under binding arbitration provisions—

(1) Shall choose binding arbitration before, and in lieu of, initiating a complaint under other grievance procedure established pursuant to section 144 of the Act, and

(2) May not elect binding arbitration for a complaint that previously has been or is subject to any other grievance procedure established under the Act.

(c) Binding arbitration decisions under the provisions of section 144(e) of the Act are not reviewable by the Secretary.

(d) The remedies available to a grievant under binding arbitration are limited to those set forth at section 144(f)(1)(C) and (f)(2) of the Act (section 144(e)(2)).

(e) Nothing in this section shall be construed to prohibit a grievant from pursuing a remedy authorized under

another Federal, State, or local law for a violation of section 143 of the Act (section 144(g)).

§ 627.605 Special Federal review of SDA- and SSG-level complaints without decision.

(a) Should the recipient fail to provide a decision as required in § 627.503 of this part, the complainant may then request from the Secretary a determination whether reasonable cause exists to believe that the Act or regulations promulgated thereunder have been violated.

(b) The Secretary shall act within 90 days of receipt of a request made pursuant to paragraph (a) of this section. Where there is reasonable cause to believe the Act or regulations promulgated thereunder have been violated, the Secretary shall direct the recipient to issue a decision adjudicating the dispute pursuant to recipient and local procedures. The Secretary's action does not constitute final agency action and is not appealable under the Act (sections 166(a) and 144(c)). If the recipient does not comply with the Secretary's order within 60 days, the Secretary may impose a sanction upon the recipient for failing to issue a decision.

(c) A request pursuant to paragraph (a) of this section shall be filed no later than 15 days from the date on which the complainant should have received a decision as required in § 627.503 of this part. The complaint shall contain the following:

(1) The full name, telephone number (if any), and address (if any) of the person making the complaint;

(2) The full name and address of the respondent against whom the complaint is made;

(3) A clear and concise statement of the facts, including pertinent dates, constituting the alleged violation;

(4) The provisions of the Act, regulations promulgated thereunder, grant, or other agreement under the Act believed to have been violated;

(5) A statement disclosing whether proceedings involving the subject of the request have been commenced or concluded before any Federal, State, or local authority, and, if so, the date of such commencement or conclusion, the name and address of the authority, and the style of the case; and

(6) A statement of the date the complaint was filed with the recipient, the date on which the recipient should have issued a decision, and an attestation that no decision was issued.

(d)(1) A request pursuant to paragraph (a) of this section will be considered to have been filed when the Secretary receives from the complainant a written

statement sufficiently precise to evaluate the complaint and the grievance procedure used by the recipient, the SDA, or the SSG.

(2) When an imprecise request is received within the 15-day period prescribed in paragraph (a) of this section, the Secretary may extend the period for submission.

§ 627.606 Grant Officer resolution.

(a) When the Grant Officer is dissatisfied with the State's disposition of an audit, as specified in § 627.481 of this part, or other resolution of violations (including those arising out of incident reports or compliance reviews), with the recipient's response to findings resulting from investigations pursuant to § 627.503 of this part, or if the recipient fails to comply with the Secretary's decision pursuant to § 627.605(b) of this part, the initial and final determination process shall be used to resolve the matter.

(b) Initial determination. The Grant Officer shall make an initial determination on the findings for both those matters where there is agreement and those where there is disagreement with the recipient's resolution, including the allowability of questioned costs or activities. Such initial determination shall be based upon the requirements of the Act, regulations promulgated thereunder, grants, contracts, or other agreements under the Act.

(c) Information resolution. The Grant Officer shall not revoke a recipient's grant in whole or in part, nor institute corrective actions or sanctions, without first providing the recipient with an opportunity to present documentation or arguments to resolve informally those matters in controversy contained in the initial determination. The initial determination shall provide for an informal resolution period which shall be at least 60 days from issuance of the initial determination. If the matters are resolved informally, the Grant Officer shall issue a final determination pursuant to paragraph (d) of this section which notifies the parties in writing of the nature of the resolution and may close the file.

(d) Grant Officer's final determination. (1) If the matter is not fully resolved informally, the Grant Officer shall provide each party with a written final determination by certified mail, return receipt requested. For audits of recipient-level entities and other recipients which receive JTPA funds directly from DOL, ordinarily the final determination will be issued not later than 180 days from the date that the OIG issues the final approved audit

report to the Employment and Training Administration. For audits of subrecipients conducted by the OIG, ordinarily the final determination will be issued not later than 360 days from the date the OIG issues the final approved audit report to ETA.

(2) A final determination under this paragraph (d) shall:

- (i) Indicate that efforts to informally resolve matters contained in the initial determination have been unsuccessful;
- (ii) List those matters upon which the parties continue to disagree;
- (iii) List any modifications to the factual findings and conclusions set forth in the initial determination;
- (iv) Establish a debt, if appropriate;
- (v) Require corrective action when needed;
- (vi) Determine liability, method of restitution of funds and sanctions; and
- (vii) Offer an opportunity for a hearing in accordance with subpart G of this part.

(3) Unless a hearing is requested, a final determination under this paragraph (d) constitutes final agency action and is not subject to further review.

(d) Nothing in this section shall preclude the Grant Officer from issuing an initial determination and/or final determination directly to a subrecipient, in accordance with section 164(e)(3) of the Act. In such a case, the Grant Officer shall inform the recipient of such action.

Subpart G—Sanctions for Violations of the Act.

§ 627.700 Purpose and scope.

This subpart describes the sanctions and appropriate corrective actions that may be imposed by the Secretary for violations of the Act, regulations promulgated thereunder, or grant terms and conditions. (Sections 106(j)(5), 164 (b), (d), (e), (f), (g), and (h)).

§ 627.702 Sanctions and corrective actions.

(a) Except for actions under sections 106(j), 164 (b) and (f), and 167 of the Act and the funding restrictions specified at § 627.423 of this part, Funding restrictions for "high-risk" recipients and subrecipients, the Grant Officer shall utilize initial and final determination procedures outlined in § 627.606, Grant Officer resolution, of this part to impose a sanction or corrective action.

(b) To impose a sanction or corrective action regarding a violation of section 167 of the Act, the Department shall utilize the procedures of 29 CFR part 31, 32 and 34.

(c) To impose a sanction or corrective action for failure to meet performance standards, where the recipient has not acted as required at section 106(j)(4), the Grant Officer shall utilize the procedures set forth at section 106(j)(5) of the Act.

(d) To impose a sanction or corrective action for non-compliance with the procurement standards provisions set forth at section 164(a) of the Act and § 627.420 of this part, where the recipient has not acted, the Grant Officer may utilize the procedures set forth at section 164(b) of the Act.

(e) The recipient shall be held responsible for all funds under the grant(s) to the recipient. The recipient shall hold subrecipients, including SDA's and SSG's, responsible for JTPA funds received through the grant, and may ultimately hold the units of local government which constitute the SDA or the SSG responsible for such funds.

(f) Nothing in this section shall preclude the Grant Officer from imposing a sanction directly against a subrecipient, as authorized in section 164(e)(3) of the Act. In such a case, the Grant Officer shall inform the recipient of such action.

§ 627.703 Failure to comply with procurement provisions.

(a) If, as part of the recipient's annual on-site monitoring of its SDA's/SSG's, the recipient determines that an SDA/SSG is not in compliance with the procurement requirements established in accordance with the provisions at section 164(a)(3) of the Act and § 627.420 of this part, Procurement, and § 627.422 of this part, Selection of service providers, the recipient shall:

- (1) Require corrective action to secure prompt compliance; and
- (2) Impose the sanctions provided for under the provisions at section 164(b) if the recipient finds that the SDA/SSG has failed to take timely corrective action under paragraph (a)(1) of this section (section 164(a) (4) and (5)).

(b) An action by the recipient to impose a sanction against either an SDA or SSG, in accordance with this section, may be appealed to the Secretary under the same terms and conditions as the disapproval of the respective plan, or plan modification, as set forth at § 628.425(e), Review and approval (section 164(b)(2)).

(c) If, upon a determination under paragraph (a)(2) of this section to impose a sanction under section 164(b) of the Act, the recipient fails to promptly take the actions required under paragraph (a)(2) of this section, the Secretary shall take such actions

against the recipient or the SDA/SSG as appropriate (section 164(b)(3)).

§ 627.704 Process for waiver of State liability.

(a) A recipient may request a waiver of liability as described in section 164(e)(2) of the Act. Any such request shall be made no later than the informal resolution period described in § 627.606(b) of this part.

(b) A waiver of the recipient's liability can only be considered by the Grant Officer when:

- (1) The misexpenditure was not a violation of section 164(e)(1) of the Act, or did not constitute fraud;
- (2) The misexpenditure of JTPA funds occurred at a subrecipient level;
- (3) The recipient has issued a final determination which disallows the misexpenditure, the recipient's appeal process has been exhausted, and a debt has been established; and
- (4) The recipient requests such a waiver and provides documentation to demonstrate that it has substantially complied with the requirements of section 164(e)(2) (A), (B), (C), and (D) of the Act.

(c) The recipient shall not be released from liability for misspent funds under the determination required by section 164(e) of the Act unless the Grant Officer determines that further collection action, either by the recipient or subrecipient, would be inappropriate or would prove futile.

§ 627.706 Process for advance approval of a recipient's contemplated corrective actions.

(a) The recipient may request advance approval from the Grant Officer for contemplated corrective actions, including debt collection actions, which the recipient plans to initiate or to forego. The recipient's request shall include a description and assessment of all actions taken by the subrecipient to collect the misspent funds.

(b) Based on the recipient's request, the Grant Officer may determine that the recipient may forego certain collection actions against a subrecipient where:

- (1) The subrecipient was not at fault with respect to the liability criteria set forth in section 164(e)(2) (A), (B), (C), and (D) of the Act;
- (2) The misexpenditure of funds was not made by that subrecipient but by an entity that received JTPA funds from that subrecipient;
- (3) A final determination which disallows the misexpenditure and establishes a debt has been issued at the appropriate level;
- (4) Final action within the recipient's appeal system has been completed; and

(5) Further debt collection action by that subrecipient or the recipient would be either inappropriate or futile.

§ 627.708 Offset process.

(a) In accordance with section 164(d) of the Act, the primary sanction for misexpenditure of JTPA funds is repayment.

(b) A recipient may request that a debt, or a portion thereof, be offset against amounts chargeable by the recipient as administrative costs under the current or a future JTPA entitlement.

(1) For title II grants, any offset shall be applied against the recipient-level 5 percent administrative cost set-aside only and may not be distributed by the recipient among its subrecipients.

(2) For title III grants, any such offset must be applied against that portion of funds reserved by the recipient for recipient-level administration only and may not be distributed by the recipient among its subrecipients.

(c) The Grant Officer may approve an offset request, under section 164(d) of the Act, if the misexpenditures were not in violation of section 164(e)(1) of the Act.

(d) If offset is granted, the debt shall not be fully satisfied until the Grant Officer reduces amounts allotted to the State by the amount of the misexpenditure.

(e) The recipient shall not have the authority to reduce allocations to an SDA or SSG for misexpenditure of JTPA funds under section 164(d) of the Act.

Subpart H—Hearings by the Office of Administrative Law Judges

§ 627.800 Scope and purpose.

(a) The jurisdiction of the Office of the Administrative Law Judges (OALJ) extends only to those complainants identified in sections 141(c), 144(d), 164(f), and 166(a) of the Act.

(b) Actions arising under section 167 of the Act shall be handled under 29 CFR part 34.

(c) All other disputes arising under the Act shall be adjudicated under the appropriate recipient or subrecipient grievance procedures or other applicable law.

§ 627.801 Procedures for filing request for hearing.

(a) Within 21 days of receipt of a final determination imposing a sanction or corrective action, or denying financial assistance, the applicant, the recipient, the SDA, the SSG, or other subrecipient of funds against which the Grant Officer has imposed a sanction or corrective action may transmit by certified mail, return receipt requested, a request for hearing to the Chief Administrative Law

Judge, U.S. Department of Labor, 800 K Street, NW., suite 400, Washington, DC 20001, with one copy to the departmental official who issued the determination.

(b) The 21-day filing requirement in paragraph (a) of this section is jurisdictional. Failure to timely request a hearing acts as a waiver of the right to hearing.

(c) A request for a hearing under this section shall state specifically those issues of the final determination upon which review is requested. Those provisions of the final determination not specified for review, or the entire final determination when no hearing has been requested within the 21 days, shall be considered resolved and not subject to further review. Only alleged violations of the Act, regulations promulgated thereunder, grant or other agreement under the Act fairly raised in the determination, and the request for hearing are subject to review.

(d) The procedures in this subpart apply in the case of a complainant who has not had a dispute adjudicated under the alternative dispute resolution process set forth in § 627.805 of this part within the 60 days, except that the request for hearing before the OALJ must be filed within 15 days of the conclusion of the 60-day period. In addition to including the final determination upon which review is requested, the complainant shall include a copy of any Stipulation of Facts and a brief summary of proceedings.

§ 627.802 Rules of procedure.

(a) The rules of practice and procedure promulgated by the OALJ at subpart A of 29 CFR part 18, shall govern the conduct of hearings under this section, except that a request for hearing under this section shall not be considered a complaint to which the filing of an answer by DOL or a DOL agency or official is required. Technical rules of evidence shall not apply to hearings conducted pursuant to this part, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to cross-examination, shall apply.

(b) Prehearing procedures. In all cases, the ALJ should encourage the use of prehearing procedures to simplify and to clarify facts and issues.

(c) Subpoenas. Subpoenas necessary to secure the attendance of witnesses and the production of documents or things at hearings shall be obtained from the ALJ and shall be issued pursuant to the authority contained in section

163(b) of the Act, incorporating 15 U.S.C. 49.

(d) Timely submission of evidence. The ALJ shall not permit the introduction at the hearing of any documentation if such documentation has not been made available for review by the other parties to the proceeding either at the time ordered for any prehearing conference, or, in the absence of such an order, at least 3 weeks prior to the hearing date.

(e) Burden of production. The Grant Officer shall have the burden of production to support her or his decision. To this end, the Grant Officer shall prepare and file an administrative file in support of the decision which shall be made part of the record. Thereafter, the party or parties seeking to overturn the Grant Officer's decision shall have the burden of persuasion.

§ 627.803 Relief.

In ordering relief, the ALJ shall have the full authority of the Secretary under section 164 of the Act.

§ 627.804 Timing of decisions.

The ALJ should render a written decision not later than 90 days after the closing of the record.

§ 627.805 Alternative dispute resolution.

(a) Parties to a complaint under § 627.801 of this part, Procedures for filing a request for hearing, may choose to waive their rights to an administrative hearing before the OALJ by choosing to transfer the settlement of their dispute to an individual acceptable to all parties for the purpose of conducting an informal review of the stipulated facts and rendering a decision in accordance with applicable law. A written decision will be issued within 60 days after the matter is submitted for informal review.

(b) The waiver of the right to request a hearing before the OALJ will automatically be revoked if a settlement has not been reached or a decision has not been issued within the 60 days provided paragraph (a) of this section.

(c) The decision rendered under this informal review process shall be treated as a final decision of an Administrative Law Judge pursuant to section 166(b) of the Act.

§ 627.806 Other authority.

Nothing contained in this subpart shall be deemed to prejudice the separate exercise of other legal rights in pursuant to remedies and sanctions available outside the Act.

Subpart I—Transition Provisions**§ 627.900 Scope and purchase.**

In order to provide for the orderly transition to and implementation of the provisions of this chapter, the following conditions apply to the use of JTPA title II and title III funds allotted by formula to the State. These regulations identify issues which require action by the Governor, and those which are operational during the transition period.

§ 627.901 Transition period.

The transition period will be through program year PY 1992 ending June 30, 1993 unless otherwise stated. The intent of the transition period is to complete, to the extent possible, activity begun on or before June 30, 1993 under current policy and regulations and to ensure that all requirements mandated by the 1992 JTPA amendments have been implemented.

§ 627.902 Governor's actions.

The following are actions that must be accomplished by the Governor prior to June 30, 1993:

- (a) Review current policies, practices, procedures, and delivery systems to ensure that they conform to the requirements of the amendments;
- (b) Modify the Governor's coordination and special services plan in accordance with instructions issued by the Secretary;
- (c) Modify job training plans as necessary;
- (d) Execute a new Governor/Secretary agreement and a new grant agreement;
- (e) Issue procurement standards that comply with the Act and these regulations as described in § 627.420 of this part, Procurement;
- (f) Issue instructions necessary to implement program year 1993 cost categories pursuant to § 627.440 of this part, Classification of costs;
- (g) Issue instructions necessary for SDAs to report program expenditures by year of appropriation pursuant to § 627.455 of this part, Reports required;
- (h) Certify private industry councils pursuant to § 628.410 of this chapter, Private Industry Council;
- (i) Resolve outstanding grievances, investigations, and hearings in effect on June 30, 1993 under the regulations published September 22, 1989 at 20 CFR 629.51;
- (j) Issue instructions necessary for service delivery areas to operate the 1993 summer program in accordance with regulations found at subpart G of part 628 of this chapter, The Summer Youth Employment and Training Program.

§ 627.903 Actions which are at the discretion of the Governor.

- (a) Establish a State Human Resource Investment Council (SHRIC);
- (b) Issue instructions to "grandparent" participants in JTPA programs as of June 30, 1993 for purposes of completing training;
- (c) Issue instructions for use of current 6 percent performance standards incentive funds to further develop and implement data collection and management information systems to track the program experience of participants. PY 1993 and subsequent performance standards incentive funds may not be used for this purpose;
- (d) Of the title II and title III unobligated balance of funds available as of June 30, 1993, any amount may be reprogrammed into PY 1993 activity. The Department believes these amounts will be minimal and not represent a significant proportion of the funds available. Such reprogrammed funds will be subject to requirements contained in JTPA regulations effective July 1, 1993.

§ 627.904 Transition and implementation.

- (a) *Review.* The Governor shall conduct a comprehensive review of the current policies, procedures, and delivery systems relating to programs authorized under the Job Training Partnership Act for the purpose of ensuring the effective implementation of the amendments. Such a review shall include consideration of the appropriateness of current SDA designations, the representation on current State and local councils, the adequacy of current administrative systems, the effectiveness of current outreach, service delivery, and coordination activities, and other relevant matters.
- (b) *Governor's Coordination and Special Services Plan (GCSSP).* The GCSSP will require modification to assure conformance to the requirements of the amendments. The plan is to be modified pursuant to instructions issued by the Secretary and shall be submitted to the Secretary for review by May 15, 1993.
- (c) *Job training plans.* Service delivery area job training plans will require modification to comply with § 628.420 of this chapter, Job training plan.
- (d) *Governor/Secretary agreement and grant agreement.* A new Governor/Secretary agreement is required to assure that the State shall comply with JTPA as amended, and the applicable rules and regulations; the Wagner-Peyser Act, as amended, and the applicable rules and regulations. A new grant agreement is needed to provide

the basis for Federal obligation of funds for programs authorized by titles I, II and III, and such other funds as the Secretary may award under the grant.

(e) *Procurement standards.* In order to ensure fiscal accountability and prevent waste, fraud, and abuse in programs administered under JTPA, as amended, the Governor shall prescribe and implement procurement standards according to § 627.420 of this part, Procurement. All procurements initiated on or after July 1, 1993 shall be governed by and follow the requirements in § 627.420 of this part.

(f) *Participants.* In order to have the least possible disruption to program participants, during PY 1993, Governors have the flexibility to "grandparent" participants already enrolled in JTPA programs up to an including June 30, 1993 under existing rules and regulations, but not to beyond June 30, 1994. All participants in programs on June 30, 1993, will be eligible for transfer to programs operated under the new provisions at any time beginning on July 1, 1993. "Hard to serve" barriers to participation, assessment and Individual Service Strategy provisions of the amendments will not apply to participants enrolled prior to July 1, 1993.

(g) *Cost categories.* Cost categories and limitations applicable to PY 1992 and earlier funds will be subject to existing regulations either until the funds have been exhausted or program activity has been completed. Any prior year carry over funds reprogrammed into PY 1993 will be subject to the reporting requirements and cost limitations associated with PY 1993 funds.

(h) *Financial reporting.* Notwithstanding reprogramming, expenditures must be recorded separately by year of appropriation.

(i) *Private Industry Council.* The private industry councils shall be certified pursuant to § 627.410 of this part, Private Industry Council.

(j) *Grievances, Investigations, and Hearings.* Generally, all grievances, investigations and hearings pending on or before June 30, 1993 should be resolved and settled under then-existing rules and procedures. The Department believes the interests of all parties are best served by adhering to the current regulation at 20 CFR part 629 subpart D. Grievances, investigations, and hearings occurring on or after July 1, 1993 will be governed by the procedures described in subparts E, F, and H of this part.

(k) *Summer Program.* The Title II-B Summer Youth Employment Program for 1993 shall be governed by the Act

and regulations in effect prior to the Amendments (prior to September 7, 1992).

(1) *SDA designation.* At the Governor's discretion, SDA's designated prior to July 1, 1992 need not be subject to the provisions of § 628.405, Service delivery areas.

§ 627.905 Guidance on contracts and other agreements.

The Department does not intend for contracts, agreements, inter-agency agreements, retainers, and other like arrangements to be negotiated and/or entered into for the sole purpose of applying existing rules and regulations. The 1992 JTPA amendments are effective July 1, 1993. The Department intends that contracts, awards and agreements entered into on or before June 30, 1993 are to be used to serve and/or train participants enrolled on or before June 30, 1993, unless the contracts and agreements are modified to comply with the new amendments and regulations.

§ 627.906 Determinations on State and SDA implementation.

(a) The Department expects that the States and SDA's will fully implement the provisions of the Act and these regulations, especially those regarding procurement, the cost principles, categories, and limitations and participant service requirements and eligibility beginning July 1, 1993.

(b) The Department expects that the implementation by the States and SDA's of the program design features in these regulations, particularly objective assessment and development of the ISS, may require additional time beyond July 1, 1992 to fully implement.

(c) In deciding to allow or disallow questioned costs related to the implementation of the provisions described in paragraph (b) of this section, the Grant Officer will consider the extent to which the State's and SDA's have made good faith efforts in properly implementing such provisions in the period July 1, 1993 through June 30, 1994.

2. Part 628 is revised to read as follows:

PART 628—PROGRAMS UNDER TITLE II OF THE JOB TRAINING PARTNERSHIP ACT

Subpart A—Scope and Purpose

Sec.

628.100 Scope and purpose of part 628.

Subpart B—State Planning

628.200 Scope and purpose.

628.205 Governor's coordination and special services plan.

628.210 State Job Training Coordinating Council.

628.215 State Human Resource Investment Council.

Subpart C—State Programs

628.300 Scope and purpose.

628.305 State distribution of funds.

628.310 Administration.

628.315 Education coordination and grants.

628.320 Services for older individuals.

628.325 Incentive grants, capacity building and technical assistance.

Subpart D—Local Service Delivery System

628.400 Scope and purpose.

628.405 Service delivery areas.

628.410 Private Industry Council.

628.415 Selection of SDA grant recipient and administrative entity.

628.420 Job training plan.

628.425 Review and approval.

628.426 Disapproval of the plan.

628.430 State SDA submission.

Subpart E—Program Design Requirements for Programs Under Title II of the Job Training Partnership Act

628.500 Scope and Purpose.

628.505 Eligibility.

628.510 Intake, referrals, and targeting.

628.515 Objective assessment.

628.520 Individual service strategy.

628.525 Limitations.

628.530 Referrals of participants to non-title II programs.

628.535 Limitations on job search assistance.

628.540 Volunteer program.

628.545 Linkages and coordination.

628.550 Transfer of funds.

Subpart F—The Adult Program

628.600 Scope and purpose.

628.605 Eligibility.

628.610 Authorized services.

Subpart G—The Summer Youth Employment and Training Program

628.700 Scope and purpose.

628.701 Program goals and objectives.

628.702 Eligibility.

628.705 SYETP authorized services.

628.710 Period of program operation.

Subpart H—Youth Training Program

628.800 Scope and purpose.

628.803 Eligibility.

628.804 Authorized services.

Authority: 29 U.S.C. 1579(a).

Subpart A—Scope and Purpose

§ 628.100 Scope and purpose of part 628.

(a) This part sets forth requirements for implementation of programs under title II of the Job Training Partnership Act. In this part, the provisions generally pertaining to title II are covered in subparts B, C, D and E of this part. Matters specific to titles II-A, II-B, or II-C are addressed in subparts F, G or H of this part respectively.

(b) Title II-A Adult Training programs are to prepare adults for participation in

the labor force by providing job training and other services that will result in increased employment and earnings, increased occupational and educational skills, reduced welfare dependency, and result in improved long-term employability.

(c) Title II-B Summer Youth Employment and Training programs are to provide eligible youth with exposure to the world of work, enhance the basic education skills of youth, to encourage school completion or enrollment in supplemental or alternative school programs and to enhance the citizenship skills of youth.

(d) Title II-C Youth Training programs are to improve the long-term employability of youth; enhance the educational, occupational and citizenship skills of youth; encourage school completion or enrollment in alternative school programs; increase the employment and earnings of youth; reduce welfare dependency; and to assist youth in addressing problems that impair their ability to make successful transition from school to work, to apprenticeship, to the military or to postsecondary education and training.

Subpart B—State Planning

§ 628.200 Scope and purpose.

This subpart provides requirements for the submission of the Governor's Coordination and Special Services Plan, as well as the procedures for plan review. This subpart also contains requirements for the composition and responsibilities of the State Job Training Coordinating Council and the State Human Resource Investment Council.

§ 628.205 Governor's coordination and special services plan.

(a)(1) *Submission.* By a date established by the Secretary, each State seeking financial assistance under the Act shall submit to the Secretary biennially the Governor's Coordination and Special Services Plan (GCSSP) encompassing two program years (section 121(a)).

(2) The GCSSP shall address the requirements of section 121(b) including a description of the Governor's coordination criteria, the measures taken by the State to ensure coordination and prevent duplication with the Job Opportunities and Basic Skills program, the certification of the implementation of the procurement system as required at section 164(a)(6), the technical assistance and training plan, goals, and the efforts to accomplish such goals. for the training and placement of women in nontraditional employment and apprenticeship, the projected use of

resources, including oversight of program performance, program administration, program financial management and audit resolution procedures, capacity building, priorities and criteria for State incentive grants, and performance goals for State supported programs (section 121(b)).

(b) *GCSSP review.* The Secretary shall review the GCSSP for overall compliance with the provisions of the Act. If the GCSSP is disapproved, the Secretary shall notify the Governor in writing within 45 days of submission of the reasons for disapproval so that the Governor may modify the plan to bring it into compliance with the Act (section 121(d)).

(c) *Information to SDA's.* Prior to December 31 of the year preceding the program years for which the plan is developed, the State shall make available to the service delivery areas in the State information on its plans to undertake State activities in program areas including education coordination grants, services to older workers, and capacity building.

§ 628.210 State Job Training Coordinating Council.

(a) The Governor shall appoint a State Job Training Coordinating Council (SJTCC) pursuant to section 122 of the Act. In lieu of a SJTCC, the Governor may establish and utilize a State Human Resource Investment Council pursuant to section 701 of the Act and in accordance with § 628.215 of this part.

(b) Consistent with section 122(a)(3) of the Act, the SJTCC shall be composed as follows: 30 percent, business and industry representatives; 30 percent, State and local government and local education agency representatives; 30 percent, organized labor and community-based organization representatives; and 10 percent, representatives from the general public. The SJTCC shall have the specific functions and responsibilities outlined in sections 122, 317, and 501 of the Act.

(c) Funding for the SJTCC shall be provided pursuant to sections 202(c)(1)(A) and 262(c)(1)(A) of the Act.

§ 628.215 State Human Resource Investment Council

(a) *Establishment and responsibilities.* The State may, in accordance with sections 701, 702, and 703, establish a State Human Resource Investment Council (HRIC). The HRIC's responsibilities are described at section 701(a) of the Act. The HRIC shall carry out the following responsibilities:

(1) Review the provision of services and the use of funds and resources under applicable Federal human

resource programs and advise the Governor on methods of coordinating such provision of services and use of funds and resources consistent with the laws and regulations governing such programs;

(2) Advise the Governor on the development and implementation of State and local standards and measures relating to applicable Federal human resource programs and coordination of such standards and measures; and

(3) Carry out the duties and functions prescribed for existing State councils described under the laws relating to the applicable Federal human resource programs.

(4) Perform other functions as specified by the Governor (section 701).

(b) *Applicable Programs.* For the purposes of this section, the programs included are those listed at section 701(b)(2) of the Act. A program shall be included only if the Governor and the head of the State agency responsible for the administration of the program jointly agree to include such program. In addition, programs under the Carl Perkins Vocational and Applied Technology Act shall require the agreement of the State council on vocational education (section 701(b)(1)(B)).

(c) *Composition.* The Governor shall establish procedures to ensure appropriate representation on the HRIC from among the categories of representation specified in section 702 of the Act.

(d) *Funding.* (1) Funding to carry out the functions of the HRIC shall be available pursuant to section 703(a) of the Act.

(i) Each State agency participating in a HRIC under title II is encouraged to provide funds to support such council in a manner consistent with its representation on the HRIC (section 703(d)).

(ii) The costs associated with the operation of the HRIC shall be allocated among the funding sources on the basis of benefits received.

(2) A HRIC which meets the requirements of title VII and includes each of the programs listed at section 701(b)(2)(A) of the Act shall be authorized to use JTPA State Education and Coordination Grant funds (section 123(a)(2)(D)(ii)).

(e) *Replacement of other councils.* A HRIC meeting the requirements of title VII shall replace the councils of the participating agencies listed at section 701(b)(2)(A) of the Act.

(f) *Expertise.* The Governor shall ensure that in the composition of the HRIC and the staff of the HRIC there exists the proper expertise to carry out

the functions of the HRIC and the council(s) it replaces (sections 702(c)(2) and 703(b)).

(g) *Certification.* Each State shall certify to the Secretary the establishment and membership of the HRIC at least 90 days before the beginning of each period of 2 program years for which a job training plan is submitted under the Act (section 703(c)).

Subpart C—State Programs

§ 628.300 Scope and purpose.

This subpart provides requirements for the State-operated programs including the education coordination and grants, services to older workers, and incentive grants to SDA's and grants to SDA's for capacity building and technical assistance.

§ 628.305 State distribution of funds.

(a) The funds made available to the Governor under sections 202(c) and 262(c) shall be used to carry out activities and services under this subpart.

§ 628.310 Administration.

Funds provided to the Governor under sections 202(c)(1)(A) and 262(c)(1)(A) of the Act may be used for overall administration, management, oversight of program performance; technical assistance to SDA's failing to meet performance standards as described in section 106(j)(1); auditing; and activities under sections 121 and 122.

§ 628.315 Education coordination and grants.

(a) *Governor's responsibilities.* The Governor shall allocate funds to any State education agency, or agencies. For the purposes of this section, "State education agency" shall not include the State agency which administers the JTPA program within the State or other agencies which do not have education as a primary function, such as correctional agencies, although this limitation shall not preclude such an agency from being an ultimate subrecipient of funds (section 123(a)(1)).

(b) *Agreements.* (1) Each State education agency to be allocated funds under section 123(a)(1) of the Act shall participate in joint planning activities with the Governor in order to develop a plan which shall be submitted in the GCSSP (section 123(c)).

(2) The Governor and the State education agency(ies) shall jointly agree on the plan required in paragraph (b)(1) of this section, which shall include a description of the agreements described

in paragraph (b)(3) of this section (section 123(c)).

(3) Projects to undertake the activities set forth in section 123(a)(2) shall be conducted in accordance with agreements between the State education agency(ies) and administrative entities in service delivery areas in the State. The agreements may include other entities such as State agencies, local education agencies and alternative service providers (section 123(b)(1)(B)).

(4)(i) When there is a failure by the State education agency and the Governor in development of the joint plan described in paragraph (b)(2) of this section, the Governor shall not allocate funds under section 123(a)(1) to such education agency, nor shall such funds be available for expenditure by the Governor (section 123(c)).

(ii) When any State education agency declines the allocation of funds under section 123(a)(1), or when there is a failure to reach the agreement(s) specified in paragraph (b)(3) of this section, the funds may be used by the Governor for the education and coordination activities described in section 123(a)(2) (A), (B), and (C) of the Act (section 123(e)).

(c) *Allowable activities.* (1) Funds made available for education coordination and grants under section 123 of the Act shall be used to pay the Federal share of education coordination and grants projects (section 123(a)(2)).

(2) Projects conducted for eligible individuals found at section 123(a)(2) (A), (B) and (C) including those which:

(i) Provide school-to-work services of demonstrated effectiveness, including youth apprenticeship programs;

(ii) Provide literacy and lifelong learning opportunities and services of demonstrated effectiveness, including basic education and occupational skills training, and

(iii) Provide statewide coordinated approaches to education and training services, including model programs, designated to train, place, and retain women in nontraditional employment. (section 123(a)).

(3) Projects for coordination of education and training which may include support activities pertaining to the HRIC which meets the requirements of title VII.

(d) *Expenditure requirements.* (1)(i) At least 80 percent of the funds allocated under section 202(c)(1)(C) of the Act shall be expended to pay for the Federal share of projects described in paragraph (c)(2) of this section (section 123(d)(2)(B)).

(ii) The Governor shall assure that not less than 75 percent of the funds expended for such projects are

expended for eligible economically disadvantaged participants each of whom shall be an individual experiencing barriers to employment (section 123(d)(2)(C)).

(iii) Priority for funds not expended on noneconomically disadvantaged participants shall be given to individuals determined eligible for title III programs and persons experiencing barriers to employment.

(iv) The Governor may assure compliance with the requirements to serve participants with barriers to employment by targeting of projects to particular barrier groups (e.g. school dropouts).

(2) Not more than 20 percent of funds allocated under section 202(c)(1)(C) of the Act may be expended to:

(i) Facilitate coordination of education and training services for participants in the projects described in section 123(a)(2) (A), (B) and (C), or

(ii) (A) Support activities pertaining to a HRIC that meets the requirements of § 628.215 of this part, or

(B) Support activities pertaining to a State council which carries out functions similar to those of a HRIC if such council was established prior to July 1, 1992.

(e) *Matching.* The Governor shall define and assure the provision of adequate resources by the State (including funds available to the State from State and federal sources, as appropriate) to meet the matching requirement of section 123(b) of the Act.

(f) Eligible youth, age 14 through 15, may be served in the program under this section to the extent set forth in the agreements under paragraph (b)(3) of this section.

§ 628.320 Services for older individuals.

(a) *Consultation.* (1) The Governor shall consult with the appropriate PIC's and chief elected official(s) prior to entering into agreements to provide services under section 204(d) and to assure that services provided to participants under section 204(d) are consistent with the programs and activities provided in the SDA to eligible older participants.

(2) The GCSSP shall specify the process for accomplishing the consultation required by paragraph (a)(2) of this section.

(b) Funds available under section 204(d) shall be used by the Governor to provide services on an equitable basis throughout the State, taking into account the relative share of the population of eligible older individuals residing in each SDA and the participation of such older individuals in the labor force.

(c) *Delivery of services.* (1) Services to participants eligible under section 204(d) shall be delivered through agreements with SDA's private industry councils, public agencies, private nonprofit organizations (including veterans organizations) and private-for-profit organizations.

(2) Priority for delivery of services under this section shall be given to agencies and organizations which have a demonstrated effectiveness in providing training and employment services to such older individuals.

(d) *Eligibility.* Individuals provided services under section 204(d) shall be economically disadvantaged, based on criteria applicable in the SDA in which they reside, and shall be individuals age 55 or older, except that each program year not more than 10 percent of participants enrolled under section 204(d) may be individuals who are not economically disadvantaged but have serious barriers to employment as identified by the Governor and have been determined within the last 12 months to meet the income eligibility requirements for title V of the Older Americans Act of 1965 (section 204(d)(5)(B)(i)).

(e) *Applicable requirements.* Except as provided in the Act, the provisions of title II-A shall apply to programs conducted under section 204(d) (section 204(d)(6)).

(f) The Governor shall make efforts to coordinate the delivery of services under section 204(d) with the delivery of services under title V of the Older Americans Act of 1965. Such coordination may include coenrollment, coordination of a continuum of services between this section and title V of the Older Americans Act and other appropriate linkages.

(g) The Governor shall give consideration to assisting programs involving training for jobs in growth industries and jobs reflecting the use of new technological skills (section 204(d)(3)).

§ 628.325 Incentive grants, capacity building and technical assistance.

(a) Funds available to the Governor under sections 202(c)(1)(B) and 262(c)(1)(B) shall be used to provide incentive grants to SDA's and for capacity building and technical assistance.

(b) *Incentive grants.* (1) Not less than 67 percent of the funds available under sections 202(c)(1)(B) and 262(c)(1)(B) shall be used by the Governor to provide incentive grants for programs, except programs under section 204(d), exceeding title II performance standards, (section 106(b)(7)).

(2) Incentive grant funds under this section shall be distributed by the Governor among SDA's within the State pursuant to section 106(b)(7).

(3) In addition to other activities, SDA's may use incentive grant funds for capacity building and technical assistance activities.

(4) The Governor shall, as part of the annual statement of goals and objectives required by section 121(a)(1) of the Act, provide SDA's with the specific policies and procedures to implement section 106(b)(7) of the Act.

(5) In a State which is the service delivery area, incentive grant funds shall be distributed in a manner determined by the Governor and as described in the GCSSP. The Governor shall give consideration to recognizing the performance of service providers within the State.

(6) Incentive grant funds may be used to conduct allowable title II activities for either eligible youth, eligible adults, or both at the discretion of the SDA.

(c) Capacity building and technical assistance.

(1) Up to 33 percent of the funds available under section 202(c)(1)(B) may be used by the Governor to provide capacity building and technical assistance efforts aimed at improving the competencies of the personnel who staff JTPA and other related human service systems that serve JTPA participants.

(2) In providing capacity building and technical assistance activities, the Governor shall:

(i) Consult with SDA's concerning capacity building and technical assistance activities consistent with the process specified in the GCSSP;

(ii) Ensure that the use of funds will assist staff providing services to SDA and service provider staff for capacity building efforts, building a statewide capacity building strategy based on an assessment of local capacity building needs developed in cooperation with the SDA's, and delivering training and technical assistance directly to the local level;

(iii) Ensure that expenditures for the purchase of hardware/software to develop Statewide communications and training mechanisms involving computer-based communication technologies directly facilitate interaction with the National Capacity Building and Information Dissemination Network (National Network) described in section 453 of the Act and facilitate the use of computer-based training techniques;

(iv) Ensure that technical assistance materials developed with funds under

this section are made available to be shared with other States and SDA's in coordination with the National Network; and

(v) Technical assistance is provided to service delivery areas failing to meet performance standards pursuant to section 106(j)(2) of the Act.

(d) Cost sharing. (1) Cost sharing approaches are encouraged among States, SDA's and/or among other Federal, State, and local human service programs in developing electronic communications, training mechanisms and/or contributing to the National Network.

(2) All shared costs shall be allocated among the contributing funding sources on the basis of benefits received.

Subpart D—Local Service Delivery System

§ 628.400 Scope and purpose.

This subpart sets forth requirements for the selection of service delivery areas, the establishment and responsibilities of the private industry council, and the selection of the SDA grant recipient and administrative entity. This subpart also contains the requirements for the local job training plan as well as the procedures for its review and approval by the State.

§ 628.405 Service delivery areas.

(a)(1) The Governor, after receiving recommendations from the SJTCC, shall designate SDA's within the State in accordance with the provisions of section 101 of the Act.

(2) Each request for designation as an SDA shall be submitted in a form and by a date established by the Governor, but not more frequently than once every two years to coincide with the development of the GCSSP and local job training plans.

(3) The Governor shall provide instructions on whether existing SDA's are required to request SDA designation in accordance with paragraph (a)(2) of this section.

(b)(1) The Governor shall approve SDA designation requests from entities with a population of 200,000 or more that satisfy the criteria specified in section 101(a)(4)(A) of the Act.

(2) When there are competing applications under paragraph (b)(1) of this section for the same geographic area, the Governor shall designate the entity with the population closest to 200,000, if the remaining reduced area also continues to satisfy the criteria specified in section 101(a)(4)(A) of the Act. The Governor shall offer to designate the remaining reduced area as an SDA as well.

(3) When there are competing applications under paragraph (b)(1) of this section for the same geographic area and the designation of the entity with the population closest to 200,000 would have the effect of reducing the population of the competing entity to below a population of 200,000, the Governor has the discretion to determine which request to honor.

(d) The Governor may, in accordance with section 101(a)(4)(B) of the Act, approve a request to be a SDA from any unit, or contiguous units, of general local government, without regard to population, which serves a substantial portion of a labor market area. In making such designations, the Governor shall evaluate the degree to which a proposed service delivery area meets criteria established by the Governor which, at a minimum, shall include:

(1) The capability to effectively deliver job training services;

(2) The capacity to administer the job training program in accordance with the Act, applicable rules and regulations and State standards; and

(3) The portion of a labor market served.

(e) For the purposes of SDA designations under sections 101(a)(4)(A) and (B), the term "substantial part" and "substantial portion" of a labor market area shall be defined by the Governor, but shall not be less than 10% of the population of a labor market area.

(f) All areas within the State shall be covered by designated SDA's. After honoring all requests for designation from eligible entities under section 101(a)(4)(A) of the Act, and making any qualified discretionary designations under section 101(a)(4)(B), the Governor shall include uncovered areas in the State within other designated SDA's willing to accept them or within another new SDA within the State.

(g) Appeals. (1) Only an entity which meets the requirements of section 101(a)(4)(A) of the Act for designation as a service delivery area, but which has had its request to be an SDA denied, may appeal the Governor's denial of service delivery area designation to the Secretary of Labor.

(2) Appeals made pursuant to paragraph (g)(1) of this section shall be submitted by certified mail, return receipt requested, to the Secretary, U.S. Department of Labor, Washington, DC 20210, Attention: ASET. A copy of the appeal shall simultaneously be provided to the Governor.

(3) The Secretary shall not accept an appeal dated later than 30 days after receipt of written notification of the denial from the Governor.

(4) The appealing party shall explain why it believes the denial is contrary to the provisions of section 101 of the Act.

(5) The Secretary shall accept the appeal and make a decision only with regard to whether or not the denial is inconsistent with section 101 of the Act. The Secretary may consider any comments submitted by the Governor. The Secretary shall make a final decision within 30 days after the appeal is received. (Section 101(a)(4)(C)).

(6) The Secretary shall notify the Governor and the appellant in writing of the Secretary's decision.

§ 628.410 Private Industry Council.

(a) Certification of the PIC. (1) The chief elected official(s) of the SDA shall establish and the Governor shall certify the private industry council (PIC) pursuant to section 102 of the Act.

(2) The Governor shall recertify the PIC biennially, one year prior to the date for submittal of the 2-year SDA job training plan to the Governor.

(3) The Governor shall issue a schedule and instructions for the submission of materials needed to certify the PIC; the instructions shall at a minimum, require the submission of:

(i) A written statement of the PIC composition which shall be consistent with section 102 (a), (b), (c), and (d), of the Act and shall include the names of individuals nominated and their qualifications;

(ii) A description of the nomination process;

(iii) The written agreement(s) among the appropriate chief elected official(s) and the PIC, including procedures for the development of the SDA job training plan and the selection of the grant recipient and administrative entity; and

(iv) A description of the basic organizational structure and operational framework through which the PIC intends to carry out its role under the Act.

(b) Responsibilities of the PIC. Pursuant to section 103 of the Act, the PIC shall:

(1) Provide policy and program guidance for all activities under the job training plan for the SDA;

(2) In accordance with agreements negotiated with the appropriate chief elected official(s), determine the procedures for development of the job training plan and select the grant recipient and administrative entity for the SDA;

(3) As specified in subpart D of part 627 of this chapter, exercise independent oversight over programs and activities under the job training plan, which oversight shall not be circumscribed by agreements with the

appropriate chief elected official(s) of the SDA;

(4) Be a party to the designation of substate grantees under title III, as set forth in § 631.35 of this chapter;

(5) Establish guidelines for the level of skills to be provided in occupational skills training programs funded by the administrative entity;

(6) Consult with the Governor on agreements to provide services for older individuals under section 204(d) of the Act;

(7) Establish youth and adult competency levels consistent with performance standards established by the Secretary, based on such factors as entry level skills and other hiring requirements, in consultation with educational agencies and, where appropriate, with representatives of business, organized labor and community-based organizations pursuant to section 106(b)(5) and 107(d); and

(8) Identify occupations for which there is a demand in the area served.

(c) Substate plan. The PIC shall be provided the opportunity to review and comment on a substate grantee plan under title III of the Act prior to the submission of such plan to the Governor (section 313(a)).

(d) The State Employment Service agency shall develop jointly with each appropriate PIC and chief elected official(s) for the SDA those components of the plans required under the Wagner-Peyser Act, which are applicable to the SDA. (See part 652 of this chapter.)

(e) Single SDA States. (1) In any case in which the service delivery area is a State, the SJTCC may be reconstituted as a PIC when the PIC meets the requirements of section 102(a).

(2) When the service delivery area is a State and the functions of the SJTCC are embodied in the HRIC, the HRIC may be reconstituted as a PIC if the requirements for private sector business representation at section 102(a)(1) are met (section 102(h)).

§ 628.415 Selection of SDA grant recipient and administrative entity.

(a) Selection of SDA grant recipient.

(1) The SDA grant recipient and the entity to administer the SDA's job training plan for title II, developed pursuant to section 104 of the Act, shall be selected by agreement of the PIC and chief elected official(s) of the SDA. These may be the same or different entities.

(2) The specific functions and responsibilities of the entities described in paragraph (a)(1) of this section shall be spelled out in the agreement between the PIC and the chief elected official(s),

and shall specifically address the provisions of section 141(i) of the Act. (Section 103(b)(1).)

(b) Subrecipient requirements. (1) The Governor may establish requirements pertaining to subrecipient, including SDA grant recipient, responsibility for JTPA funds.

(2) The requirements described in paragraph (b)(1) of this section shall not preclude the selection of any entity identified in section 103(b) as SDA grant recipient.

§ 628.420 Job training plan.

(a) The Governor shall issue instructions and schedules to assure that job training plans and plan modifications for SDA's within the State conform to all requirements of the Act.

(b) The Governor's instructions for development of the SDA's job training plan shall require that the plan contain the following information:

(1) A complete and detailed discussion of the elements found in section 104(b) of the Act;

(2) A discussion of the SDA's compliance with the Secretary's program goals, as outlined in the planning guidance provided to the Governor; and

(3) An oversight plan for the SDA which includes: (i) A description of the oversight activities of the PIC and the chief elected official(s), and (ii) the SDA administrative entity's monitoring plan which includes the Governor's monitoring requirements for service providers.

(c) The Governor may also require that the SDA job training plan contain a capacity building and technical assistance strategy that includes plans for designating capacity building as a staff function, assessing local capacity building needs, and developing and participating in computerized communication mechanisms.

(d) The SDA job training plan shall be submitted to the Governor jointly by the PIC and the chief elected official(s) (section 103(d)).

(e) Modifications. Modifications to the SDA job training plan shall be submitted jointly by the PIC and chief elected official(s) of the SDA to the Governor for approval.

§ 628.425 Review and approval.

(a) Standards and procedures. (1) The Governor shall establish standards and procedures for the review and approval or disapproval of the SDA job training plan and plan modifications that shall be provided to the SDA's at the same time as the instructions and schedules for preparation of the plans are provided.

(2) The procedures and standards described in paragraph (a)(1) of this section shall provide for approval or disapproval of the SDA job training plan.

(b) *Plan approval.* Except when the Governor makes a finding under the provisions of section 105(b)(1) of the Act, the Governor shall approve the SDA job training plan or plan modification. The notice of approval shall be provided to the chief elected official(s) and to the private industry council.

§ 628.426 Disapproval of the plan.

(a) If the Governor disapproves the SDA job training plan or plan modification for any reason, the Governor shall notify the PIC and chief elected official(s) for the SDA in writing as provided in section 105(b)(2) of the Act.

(b) If the Governor disapproves the SDA job training plan or plan modification, the Governor shall provide the PIC and the chief elected official(s) for the SDA 20 days to correct the deficiencies and resubmit the plan or plan modification. Within 15 days after the plan or plan modification is resubmitted, the Governor shall make a final decision and shall notify the PIC and the appropriate chief elected official(s) of the SDA of the final disapproval or approval.

(c) *Governor mediation.* If the PIC and the appropriate chief elected official(s) of an SDA are unable to reach an agreement under the provisions of section 103(b)(1) or (d) of the Act, any such party may request the Governor to mediate such agreements.

(d) *Failure to reach agreement.* If the PIC and the chief elected official(s) fail to reach the required agreements in sections 103(b)(1) or (d) of the Act, funds may not be made available to an SDA under section 104 of the Act and the Governor shall merge the affected area into one or more other existing service delivery areas (section 105(c)(1)).

(e) *Appeals.* (1) In accordance with section 105(b)(2) of the Act, any final disapproval by the Governor of the SDA job training plan or modification may be appealed by the PIC or chief elected official(s) of the SDA to the Secretary.

(2) The Secretary shall not accept an appeal dated later than 30 days after receipt by the PIC and chief elected official(s) of the final disapproval of the SDA job training plan or modification from the Governor.

(3) The Secretary shall accept an appeal under this paragraph (e) and shall determine only whether or not the disapproval is clearly erroneous under

section 105(b)(1) of the Act. The Secretary may consider any comments submitted by the Governor. In accordance with section 105(b)(2) of the Act, the Secretary shall make a final decision within 45 days after the appeal is received by the Secretary.

(4) The Secretary shall notify the Governor and the appellant in writing of the Secretary's decision.

(f) *Appeals of plan revocations.* Pursuant to section 164(b)(1) of the Act, a notice of intent to revoke approval of all or part of a plan may be appealed to the Secretary. Such appeals shall be treated as a disapproval under paragraphs (c) and (e) of this section, except that the revocation shall not become effective until the later of:

(1) The time for appeal under paragraph (e) of this section has expired; or

(2) The date on which the Secretary issues a decision affirming the revocation.

(f) In the event that a plan is disapproved and the Governor's decision is upheld upon appeal, the Governor shall merge the affected area into other designated SDA's willing to accept it or include it in another SDA within the State.

§ 628.430 State SDA submission.

(a) Pursuant to section 105(d) of the Act, when the SDA is the State, the Governor, not less than 60 days before the beginning of the first of the two program years covered by the job training plan and in accordance with instructions issued by the Secretary, shall submit to the Secretary a SDA job training plan covering two-program-years. When the SDA is the State, modifications to the plan shall be submitted to the Secretary for approval.

(b) When a State submits an SDA job training plan or plan modification pursuant to paragraph (a) of this section, the Secretary shall review the plan or plan modification for overall compliance with the provisions of the Act. The State's plan shall be considered approved unless, within 45 days of receipt of the submission described in paragraph (a) of this section, the Secretary notifies the Governor in writing of inconsistencies between the submission and requirements of specific provisions of the Act. If the plan or plan modification is disapproved, the Governor may appeal the decision by requesting a hearing before an administrative law judge pursuant to subpart H of part 627 of this chapter.

Subpart E—Program Design Requirements for Programs Under Title II of the Job Training Partnership Act

§ 628.500 Scope and purpose.

This subpart contains the regulations pertaining to the program design requirements common to all programs conducted under title II of the Act. Regulations specifically pertaining to the Adult Program can be found in subpart F of this part. Regulations pertaining to the Summer Youth Employment and Training Program can be found in subpart G of this part. Regulations pertaining to the Youth Training Program can be found in subpart H of this part.

§ 628.505 Eligibility.

(a) *Eligibility Criteria.* (1) Individuals who apply to participate in a program under title II shall be evaluated for eligibility based on age and economic disadvantage. Specific eligibility criteria for programs under title II, parts A, B, and C are described in this part.

(2) Individuals served under title II shall be residents of the SDA, as determined by local government policy, except for the limited exceptions described in the job training plan, including joint programs operated by SDA's (section 141(e)).

(b) *Eligibility documentation.* (1) In order to promote the uniform and standard application of eligibility criteria for participation in the JTPA program, the Department shall issue guidance on eligibility documentation requirements.

(2) SDA utilization of eligibility guidance. The Grant Officer shall give consideration to the extent that the State and the SDA adopt and follow the guidance described in paragraph (b)(1) of this section in deciding to allow or disallow questioned costs related to the required documentation concerning an individual's eligibility.

§ 628.510 Intake, referrals and targeting.

(a) *Collection of personal data.* In addition to determining an applicant's eligibility, the intake process shall include a preliminary review of information relating to whether an applicant is included in one or more of the categories listed in section 203(b) of the Act.

(b) *Information on services.* Upon application, an eligible individual shall be provided information by the SDA or its service providers on the full array of services available through the SDA and its service providers, including information for women about the

opportunities for nontraditional training and employment.

(c) *Assessment during intake.* At the discretion of the service provider, some assessment activities may be conducted during the intake process in order to determine an eligible applicant's suitability for title II program services.

(d) *Referral of applicants.* During the intake process, determinations may be made prior to enrollment to refer an eligible applicant to another human service, training or education program deemed more suitable for the individual.

(e) *Referrals from service providers to service delivery areas for additional assessment.* (1) Each service provider shall ensure that an eligible applicant who cannot be served by its particular program shall be referred to the SDA for further assessment, as necessary, and suitable referral to other appropriate programs.

(2) Each SDA shall take the appropriate steps (e.g., contract provisions, local administrative issuances, and/or PIC policies, etc.) to ensure that its service providers adhere to the provisions of this section, and that they maintain documentation of referrals.

(3) Each SDA shall develop an appropriate mechanism to assess applicants referred by service providers and describe such mechanism in its SDA job training plan.

(f) *"Most in need."* SDA's that satisfy the requirements of sections 203(b) and 263(b) pertaining to hard to serve individuals shall be deemed to meet the "most in need" criteria at section 141(a) of the Act.

(g) The SDA's method of meeting the requirements of sections 203(b) and 263(b) pertaining to hard to serve individuals shall be implemented consistent with the equal opportunity provisions of 29 CFR parts 31, 32, and 34.

§ 628.515 Objective assessment.

(a) *General.* The requirements of this section shall apply to programs conducted under title I and title II, parts A, B and C.

(b) *Definition.* (1) For purposes of this part, an *objective assessment* means an examination of the capabilities, needs, and vocational potential of a participant and is to be used to develop a service strategy and employment goal. Such assessment is to be client-centered and a diagnostic evaluation of a participant's employment barriers taking into account the participant's family situation, work history, education, occupational skills, interest, aptitudes (including interests and aptitudes for nontraditional

occupations), attitude towards work, motivation, behavior patterns affecting employment potential, financial resources and needs, supportive service needs, and personal employment information as it relates to the local labor market.

(2) For the program under title II-B, the objective assessment shall include an examination of the basic skills and supportive service needs of each participant and may include the other areas listed in paragraph (b)(1) of this section (Sections 204(a)(1)(A), 253(c)(1) and 264(b)(1)(A)).

(c) *Methods of objective assessment.*

(1) The SDA shall choose the most appropriate means to measure skills, abilities, attitudes, and interests of the participants. The methods used in conducting the objective assessment may include but are not limited to structured interviews, paper and pencil tests, performance tests (e.g. skills, and/or work samples, including those that measure interest and capability to train in nontraditional employment), behavioral observations, interest and/or attitude inventories, career guidance instruments, aptitude tests, and basic skills tests.

(2) Instruments used for objective assessment may be developed at the local level; however, any formalized instruments nationally available should be used only for the specific populations for which they are normed.

(d) *Updating of assessments.* Objective assessment should be treated as an ongoing process. As additional relevant information relating to a participant becomes available, it should be reviewed and considered, as appropriate.

(e) *Other sources of objective assessment.* Other non-JTPA assessments (e.g. through the Job Opportunities and Basic Skills (JOBS) program under title IV of the Social Security Act, or through schools) which have been completed within one year of application for services, and which meet the requirements of this section, may be used to comply with the requirement to assess each participant.

§ 628.520 Individual service strategy.

(a) *General.* The requirements of this section shall apply to programs conducted under title I and title II, parts A, B and C.

(b) *Definition.* (1) *Individual service strategy (ISS)* means an individual plan for a participant, which plan shall include an employment goal (including, for women, consideration of nontraditional employment), appropriate achievement objectives, and the appropriate combination of services

for the participant based on the objective assessments conducted pursuant to § 628.515 of this part, Objective assessment. In developing the ISS, the participant shall be counseled regarding required loan repayments if enrollment in an education program requires the participant's personal indebtedness. The participant shall also be apprised of the requirements for self sufficiency and the occupational demands within the labor market.

(2) Decisions concerning appropriate services shall be client-centered, and ensure that the participant is not excluded from training or career options consistent with the provisions of 29 CFR parts 31, 32 and 34 concerning nondiscrimination and equal opportunity.

(3) For the program under title II-B, the ISS may include the components specified in paragraph (b)(1) of this section. (sections 204(a)(1)(B), 253(c)(2) and 264(b)(1)(B)).

(c) *Joint Development of ISS.* The ISS shall be developed in partnership with the participant and reflect the needs indicated by the objective assessment and the expressed interests and desires of the participant.

(d) *Review of ISS.* The ISS shall be reviewed periodically to evaluate the progress of each participant in meeting the objectives of the service strategy including an evaluation of the participant's progress in acquiring basic skills and occupational skills as appropriate, and the adequacy of the supportive services provided.

(e) *Provision of services.* If JTPA resources are not sufficient to provide the full range of training or support services which might be identified in the ISS, the SDA shall make every reasonable effort to arrange for, through other community resources, basic and occupational skills training and supportive services identified as needed in the ISS for participants under titles II-A and II-C and, in addition, preemployment and work maturity skills training and work experience combined with skills training for participants under title II-C (sections 204(a)(1)(D) and 264(b)(1)(D)).

(f) *SDA review of objective assessment and ISS.* (1) The objective assessment and development of the ISS may be conducted by service providers.

(2) The SDA administrative entity shall ensure that development of the ISS and the services provided, respond to the individual needs of the participant and that the combination of services to the participant is indicated by the results of the objective assessment.

(g) *ISS and documentation of decisions.* The ISS shall be used as the

basic instrument for the SDA to document the appropriateness of the decisions made about the mix and combination of services for the participant, including referrals to other programs for specified activities.

§ 628.525 Limitations.

Participation in a JTPA program does not create an entitlement to services, and nothing in the Act or this part shall be construed to establish a private right of action for a participant to obtain services described in the objective assessment or ISS.

§ 628.530 Referrals of participants to non-title II programs.

(a) When a participant is determined, through the objective assessment and the ISS, to be better served by a program other than one under title II (e.g. Job Corps, Vocational Rehabilitation, State or local education, substance abuse treatment center, and/or dislocated worker programs), the participant shall be referred to the appropriate program. Such referral shall be documented in the ISS.

(b) In cases where there will be a continuing relationship with an individual, a referral to another program(s) for specific services will be part of the participant's title II program participation and documented in the ISS.

(c) In cases when there will not be a continuing relationship with an individual as the result of a referral to a program other than title II, only an assessment has been provided and no ISS has been developed, the individual shall not be counted for purposes of calculating performance against the SDA's performance standards.

§ 628.535 Limitations on job search assistance.

(a) *General.* Job search assistance is designed to give a participant skills in acquiring full-time employment. See § 626.5 of this chapter, Definitions.

(b) *Conditions.* Job Search activities may be conducted only:

(1) For participants when specified as appropriate in the ISS; and

(2) When delivered in conjunction with other training or educational services designed to increase the participant's ability to acquire employment. Examples include completion of a classroom training course combined with a job search assistance class; a work experience activity followed by job search training; a pre-apprenticeship training program combined with a job search club; or office skills development training combined with job search training.

(c) *Exceptions.* Job search assistance activities including job search skills training and job clubs may be provided without the accompanying services specified in paragraph (b) of this section only when:

(1) The objective assessment and the ISS indicate that the additional services are not appropriate; and

(2) The activities are not available or accessible through other public agencies, including Employment Service as determined by the SDA.

(d) *Determination of job search availability.* For purposes of this section, job search assistance activity will normally be considered to be available from a local employment service office within the commuting area.

§ 628.540 Volunteer program.

(a) Requirement. Pursuant to sections 204(c)(6) and 264(d)(7) of the Act, the SDA shall make opportunities available for individuals who have successfully participated in programs under this part to volunteer assistance, in the form of mentoring, tutoring, and other activities.

(1) The SDA should develop local goals and objectives regarding their efforts to engage the volunteer assistance of former participants.

(2) The SDA shall maintain documentation of its efforts to implement the locally established volunteer program.

(b) [Reserved]

§ 628.545 Linkages and coordination.

(a) *General requirements.* In the conduct of programs under this part, the SDA shall establish appropriate linkages and coordination procedures with other federal programs and with appropriate education and training agencies which shall be described in the SDA job training plan. (Sections 104(b) (3) and (4), 205 (a) and (b) and 265).

(b) *Requirements for youth.* For the youth programs under this part, formal agreements shall be established with local educational agencies, which, at a minimum, shall specify:

(1) The procedures for referring and serving in-school youth;

(2) The methods of assessment of in-school youth; and

(3) Procedures for notifying the SDA when a youth drops out of the school system.

(c) *Schoolwide projects.* (1) In conducting a schoolwide project for low income individuals under sections 263(g) and 275(d) the SDA shall establish a cooperative agreement with the appropriate local educational agency.

(2) In addition to the requirements listed in paragraphs (a) and (b) of this

section, the cooperative agreement shall include:

(i) A description of the ways in which the JTPA schoolwide project will supplement the educational program of the school;

(ii) Identification of measurable goals to be achieved by the schoolwide project and a provision for assessing the extent to which such goals are met;

(iii) A description of the ways in which the program will use available JTPA and other education program resources;

(iv) A description of the number of individuals to be served by the schoolwide project; and

(v) Assurances that JTPA resources shall be used to supplement and not supplant existing sources of funds.

(3) In areas where there is more than one local educational agency, cooperative agreements for schoolwide projects are required only with those local education agencies that will participate in programs under schoolwide projects (section 263(g)).

§ 628.550 Transfer of funds.

If described in the job training plan and approved by the Governor:

(a) An amount up to 10 percent of the funds allocated to the SDA under section 202(b) of the Act for title II-A may be transferred to the program under title II-C of the Act;

(b) An amount up to 10 percent of the funds allocated to the SDA under section 252(b) of the Act for title II-B may be transferred to the program under title II-C of the Act; and

(c) An amount up to 10 percent of the funds allocated to the SDA under section 262(b) of the Act for title II-C may be transferred to the program under title II-A of the Act.

Subpart F—The Adult Program

§ 628.600 Scope and purpose.

This subpart contains the regulations specifically pertaining to programs conducted under title II-A, the Adult Program.

§ 628.605 Eligibility.

(a) *Age and economic disadvantage.* Except as provided in paragraph (b), an individual shall be eligible to participate under this part only if he or she is economically disadvantaged and 22 years of age or older.

(b) *Non-economically disadvantaged individuals.* Up to 10 percent of the individuals served under this subpart in each SDA may be individuals who are not economically disadvantaged, if such individuals face serious barriers to

employment in accordance with section 203(c) of the Act.

(c) *Requirement to assist hard-to-serve individuals.* Not less than 65 percent of individuals served under this subpart shall have one or more of the additional barriers to employment as described in section 203(b) of the Act.

(d) *Addition of barrier.* An SDA may identify and add one additional serious barrier to employment to the categories listed at sections 203(b) of the Act in accordance with the specific procedures and requirements in section 203(d).

(e) *Criteria for older workers under joint programs.* (1) The SDA may establish written financial or non-financial agreements with sponsors of programs under title V of the Older Americans Act to carry out joint programs.

(2) Joint programs under this paragraph (e) may include referrals between programs, co-enrollment and provision of services.

(3) Under agreements pursuant to this paragraph (e), individuals eligible under title V of the Older Americans Act individuals shall be deemed to satisfy the requirements of section 203(d)(5)(A) of the Act. (Older Americans Act, Pub. L. 102-375, section 510.)

§ 628.610 Authorized services.

(a) The services that may be provided under this subpart are those described at section 204(b) of the Act.

(b) *Counseling and supportive services:* Counseling and supportive services provided under this subpart may be provided to a participant for a period of up to 1 year after the date on which the participant completes the program.

Subpart G—The Summer Youth Employment and Training Program

§ 628.700 Scope and purpose.

This subpart contains the regulations for the Summer Youth Employment and Training Program (SYETP) under part B of title II of the Act. The regulations in part 627 of this chapter and subpart E of this part apply to the SYETP to the extent that they do not conflict with the provisions of this subpart.

§ 628.701 Program goals and objectives.

(a) Each SDA shall establish written goals and objectives that shall be used in evaluating the effectiveness of its SYETP activities. Such goals and objectives may include improvement in school retention, academic performance (including mathematics and reading comprehension) and employability skills, and demonstrated coordination with other appropriate community organizations.

(b) The SDA shall ensure that the activities and services offered under the SYETP are consistent with and will contribute to the achievement of the goals and objectives developed pursuant to paragraph (a) of this section.

§ 628.702 Eligibility.

(a) *Age and economic disadvantage.* An individual is eligible to participate in programs funded under title II-B of the Act, if such individual is

- (1) Age 14 through 21; and
- (2)(i) Economically disadvantaged; or
- (ii) Has been determined to meet the eligibility requirements for free meals under the National School Lunch Act during the most recent school year (see paragraph (b) of this section). "Most recent school year" means the current school year unless the eligibility determination is made during an interim period between school terms, in which case the term means the preceding school year.

(b) *Eligibility determination verification.* The SDA may accept the same documentation utilized by the local educational agency for approving free lunch meals or an assurance by school officials concerning the students' participation in the free school lunch program under the National School Lunch Act.

§ 628.705 SYETP Authorized services.

(a) The services that may be provided under this subpart are those described at section 253 of the Act.

(b) *Basic and remedial education.* The SDA shall ensure the availability of basic or remedial education for SYETP participants pursuant to the assessment process described in § 628.515 of this part from funds available to the SDA or by other education and training programs, including but not limited to the Job Corps, the JOBS program, youth corps programs or alternative or secondary schools.

(c) *Work Experience.* Work experience shall be conducted consistent with the provisions of § 627.245.

(d) *Concurrent Enrollment.* Youth being served under the SYETP or the Youth Training Program authorized under title II, part C, of the Act (see subpart H of this part) are not required to be terminated from participation in one program to enroll in the other. The SDA may enroll such youth concurrently in programs under this subpart and subpart H of this part, pursuant to guidance to be issued by the Secretary, in order to promote continuity and coordination of services.

§ 628.710 Period of program operation.

(a) Except as provided under paragraph (b) of this section, the SYETP

shall be conducted during the school vacation period occurring during the summer months.

(b) An SDA operating within the jurisdiction of one or more local educational agencies that operate schools on a year-round full-time basis may offer SYETP activities to participants in such a jurisdiction during the school vacation period(s) treated as the period(s) equivalent to a school summer vacation.

Subpart H—Youth Training Program

§ 628.800 Scope and purpose.

(a) This subpart implements title II-C of the Act. Title II-C programs and activities have as their primary objective to increase the long-term employability of eligible youth. The Youth Training Program provides for year-round youth programs to address the employment needs and skill deficiencies of in-school and out-of-school youth.

(b) This subpart establishes program design (e.g., objective assessment, and development of the participant ISS) elements and additional requirements that must be followed by the SDA's and service providers. The youth services authorized by this subpart are intended to be comprehensive. Coordination of Youth Training Program activities with other community and youth service opportunities is strongly encouraged.

§ 628.803 Eligibility.

(a) *Out-of-school youth.* An out-of-school youth shall be eligible to participate in programs under this subpart, if such individual is:

- (1) Age 16 through 21; and
 - (2) Economically disadvantaged.
- (b) *In-school youth.* An in-school youth shall be eligible to participate in programs under this subpart, if such individual is:
- (1)(i) Age 16 through 21; or
 - (ii) If provided in the job training plan, age 14 through 21 inclusive; and
 - (2)(i) Economically disadvantaged;
 - (ii) Participating in a compensatory education program under Chapter I of title I of the Elementary and Secondary Education Act of 1965; or
 - (iii) Has been determined to meet the eligibility requirements for free meals under the National School Lunch Act during the most recent school year. *Most recent school year* means the current school year unless the eligibility determination is made during an interim period between school terms, in which case the term means the preceding school year.

(c) *Eligibility determination verification.* The SDA may accept the same documentation utilized by the

local educational agency for approving free lunch meals or an assurance by school officials concerning the students' participation in the free school lunch program under the National School Lunch Act.

(d) *Requirement to serve hard-to-serve individuals.* (1) Not less than 65 percent of the in-school youth who participate in an SDA's program under this subpart shall have one or more additional barriers to employment, as described in section 263(b) of the Act.

(2) Not less than 65 percent of the out-of-school youth who participate in an SDA's program under this subpart shall have one or more barriers to employment, as described in section 263(d) of the Act, in addition to any criterion listed in paragraph (b)(2) of this section.

(e) *Addition of barrier.* An SDA may identify and add one additional serious barrier to employment to the categories listed at sections 263 (b) and (d) of the Act in accordance with the specific procedures and requirements in section 263(h) of the Act.

(f) *Services to non-economically disadvantaged individuals.* Up to 10 percent of the youth served by an SDA under this subpart may be individuals who are not economically disadvantaged, but such individuals shall face one or more serious barriers to employment in accordance with section 263(e) of the Act.

(g) *Eligibility based on schoolwide project participation.* (1) In addition to the individuals who meet the conditions described in § 628.803 of this part, individuals who are not economically disadvantaged may participate in programs under this subpart if they are enrolled in accordance with a schoolwide project pursuant to section 263(g) of the Act.

(2) For purposes of this section, the term "school" means an individual building, facility, campus or a portion of the school such as the 11th or 12th grade.

(h)(1) *Out-of-school ratio.* Not less than 50 percent of the total title II-C participants in each SDA shall be out-of-school individuals, in accordance with section 263(f)(1) of the Act.

(2) *Schoolwide project ratios.* Those in-school participants who are served under a schoolwide project shall not be counted in determining the ratio of in-school to out-of-school youth in paragraph (h)(1) of this section.

§ 628.804 Authorized services.

(a) The SDA and the PIC shall take into consideration exemplary program strategies and services, including those selected for replication pursuant to

section 453(c) of the Act concerning capacity building, in the development of services for programs under this subpart.

(b) Except as provided in paragraph (c) of this section, in order to participate in programs under this part an individual who is under the age of 18 and a school dropout shall enroll in and attend a school, course or programs described in sections 264(d)(2)(B) (ii) and (iii).

(c) An individual who is a school dropout and under the age of 18 may participate in programs under this part without meeting the requirements of paragraph (b) of this section for a limited interim period which may be during the summer months, during periods between school terms, or when a course of study is not immediately available.

(d) The provision of preemployment and work maturity skills training shall be accompanied either by work experience or by other additional services which are designed to increase the basic education or occupational skills of the participant (section 264(d)(3)(A)).

(e) The provision of work experience, job search assistance, job search skills training, and job club activities under programs conducted under this subpart shall be accompanied by other additional services which are designed to increase the basic education or occupational skills of the participant (section 264(d)(3)(B)).

(f) The additional services offered pursuant to paragraphs (d) and (e) of this section may be provided concurrently or sequentially with services provided under other education and training programs (e.g., Job Opportunities and Basic Skills programs under title IV of the Social Security Act, Job Corps (see part 638 of this chapter), schools, etc.).

(g) Schoolwide projects for low-income schools shall meet the conditions in sections 263(g) (1) and (2) of the Act.

(h) Entry employment experiences in public or private non-profit agencies under this subpart shall not exceed 500 hours, and shall increase or develop the long-term employability of eligible in-school and out-of-school youth. Entry employment experiences may include:

(1) Work experience as described in § 627.245 of this chapter;

(2) Cooperative education programs that coordinate educational programs with work in the private sector; and

(i)(1) Limited internships in the private sector under this subpart which shall involve assignments in the private for-profit sector, not to exceed 500 hours

and shall be designed to enhance the long-term employability of youth.

(2) The limited internship shall provide on-site private sector exposure to work and the requirements for successful job retention.

(3) A limited internship may be combined with classroom instruction relating to a particular position, occupation, industry or on the basic skills and abilities to successfully compete in the local labor market.

(j)(1) On-the-job (OJT) training activities approved under this subpart shall be consistent with the provisions of subpart B of part 627 of this chapter and shall:

(i) Be for positions that pay the participant a wage that equals or exceeds the average wage at placement in the preceding program year in the SDA for participants under title II-A;

(ii) Be for positions that have career advancement potential; and

(iii) Include a formal, written program of structured job training that will provide the participant with an orderly combination of instruction in work maturity skills, general employment competencies, and occupational specific skills.

(2) In those cases where the OJT participant is a school dropout, the participant shall participate in a program in accordance with the provisions of paragraph (b) of this section.

(k) Counseling and supportive services provided under this subpart may be provided to a participant for a period of up to 1 year after the date on which the participant completes the program.

(l) *Year-Round Operations.* Programs for youth under this subpart shall:

(1) Provide for a year-round education and training program that is coordinated with the appropriate local educational agencies, service providers, and other programs; and

(2) As appropriate, ensure services for youth are available on a multiyear basis, consistent with the determined needs and goals of the youth served.

(3) The year-round program delivery requirement of this paragraph does not prohibit schools on a 9-month operations schedule, from providing services for programs under this part.

PART 629—[REMOVED AND RESERVED]

4. Part 629 is removed and reserved.

PART 630—[REMOVED AND RESERVED]

5. Part 630 is removed and reserved.

6. Part 631 is revised to read as follows:

PART 631—PROGRAMS UNDER TITLE III OF THE JOB TRAINING PARTNERSHIP ACT

Subpart A—General Provisions

- Sec.
631.1 Scope and purpose.
631.2 Definitions.
631.3 Participant eligibility.
631.4 Approved training rule.

Subpart B—Additional Title III Administrative Standards and Procedures

- 631.11 Allotment and obligation of funds by the Secretary.
631.12 Reallocation of funds by the Secretary.
631.13 Classification of costs at State and substate levels.
631.14 Limitations on certain costs.
631.15 Federal reporting requirements.
631.16 Complaints, investigations, and penalties.
631.17 Federal monitoring and oversight.
631.18 Federal bypass authority.
631.19 Appeals.

Subpart C—Needs-Related Payments

- 631.20 Needs-related payments.

Subpart D—State Administration

- 631.30 Designation or creation and functions of a State dislocated worker unit or office and rapid response assistance.
631.31 Monitoring and oversight.
631.32 Allocation of funds by the Governor.
631.33 State procedures for identifying funds subject to mandatory Federal reallocation.
631.34 Designation of substate areas.
631.35 Designation of substate grantees.
631.36 Biennial State plan.
631.37 Coordination activities.
631.38 State bypass authority.

Subpart E—State Programs

- 631.40 State program operational plan.
631.41 Allowable State activities.

Subpart F—Substate Programs

- 631.50 Substate plan.
631.51 Allowable substate program activities.
631.52 Selection of service providers.
631.53 Certificate of continuing eligibility.

Subpart G—Federal Delivery of Dislocated Worker Services Through National Reserve Account Funds

- 631.60 General.
631.61 Application for funding and selection criteria.
631.62 Cost limitations.
631.63 Reporting.
631.64 General administrative requirements.

Subpart H—[Reserved]

Subpart I—Disaster Relief Employment Assistance

- 631.80 Scope and purpose.
631.81 Availability of funds.
631.82 Substate allocation.
631.83 Coordination.
631.84 Allowable projects.

- 631.85 Participant eligibility.
631.86 Limitations on disaster relief employment.
631.87 Definitions.

Authority: 29 U.S.C. 1579(a); sec. 6305(f), Pub. L. 100-418, 102 Stat. 1107; § 631.30(d)(7) also issued under 29 U.S.C. 2107(a); § 631.37(e) also issued under sec. 402, Pub. L. 100-689, 102 Stat. 4178-4179 (29 U.S.C. 1751 note).

Subpart A—General Provisions

§ 631.1 Scope and purpose.

This part implements title III of the Act. Title III programs seek to establish an early readjustment capacity for workers and firms in each State; to provide comprehensive coverage to workers regardless of the cause of dislocation; to provide early referral from the unemployment insurance system to adjustment services as an integral part of the adjustment process; to foster labor, management and community partnerships with government in addressing worker dislocation; to emphasize retraining and reemployment services rather than income support; to create an on-going substate capacity to deliver adjustment services; to tailor services to meet the needs of individuals; to improve accountability by establishing a system of mandated performance standards; to improve financial management by monitoring expenditures and reallocating available funds; and to provide the flexibility to target funds to the most critical dislocation problems.

§ 631.2 Definitions.

In addition to the definitions contained in sections 4, 301, and 303(e) of the Act and part 626 of this chapter, the following definitions apply to programs under title III of the Act and this part:

Substantial layoff (for participant eligibility) means any reduction-in-force which is not the result of a plant closing and which results in an employment loss at a single site of employment during any 30 day period for:

(a)(1) At least 33 percent of the employees (excluding employees regularly working less than 20 hours per week); and

(2) At least 50 employees (excluding employees regularly working less than 20 hours per week); or

(b) At least 500 employees (excluding employees regularly working less than 20 hours per week).

Substantial layoff (for rapid response assistance) means any reduction-in-force which is not the result of a plant closing and which results in an employment loss at a single site of employment during any 30 day period

for at least 50 employees (excluding employees regularly working less than 20 hours per week) (section 314(b)(4)).

§ 631.3 Participant eligibility.

(a) Eligible dislocated workers, as defined in section 301 of the Act, are eligible to participate in programs under this part. For the purposes of determining eligibility under the provisions of section 301(a)(1)(A) of the Act, the term "eligible for" unemployment compensation includes any individual whose wages from employment would be considered in determining eligibility for unemployment compensation under Federal or State unemployment compensation laws.

(b)(1) Except as provided in paragraph (b)(3) of this section, workers who have not received an individual notice of termination but who are employed at a facility for which the employer has made a public announcement of planned closure shall be considered eligible dislocated workers with respect to the provision of basic readjustment services specifically identified in section 314(c) of the Act with the exception of supportive services and relocation assistance.

(2) Such individuals identified in (b)(1) of this section shall be eligible to receive all services authorized in sections 314 of the Act after a date which is 180 days prior to the scheduled closure date of the facility, subject to the provisions of § 631.20 of this part and other applicable provisions regarding receipt of supportive services.

(3) Paragraphs (b)(1) and (b)(2) of this section shall not apply to individuals who are likely to remain employed with the employer or to retire instead of seeking new employment.

(4) For the purposes of paragraph (b)(1) of this section, the Governor shall establish criteria for defining "public announcement". Such criteria shall include provisions that the public announcement shall be made by the employer and shall indicate a planned closure date for the facility. (Section 314(h)).

(c) Eligible dislocated workers include individuals who were self-employed (including farmers and ranchers) and are unemployed:

(1) Because of natural disasters, subject to the provisions of paragraph (e) of this section; or

(2) As a result of general economic conditions in the community in which they reside.

(d) For the purposes of paragraph (c) of this section, categories of economic conditions resulting in the dislocation

of a self-employed individual may include, but are not limited to:

(1) Failure of one or more businesses to which the self-employed individual supplied a substantial proportion of products or services;

(2) Failure of one or more businesses from which the self-employed individual obtained a substantial proportion of products or services;

(3) Substantial layoff(s) from, or permanent closure(s) of, one or more plants or facilities that support a significant portion of the State or local economy.

(e) The Governor is authorized to establish procedures to determine the eligibility to participate in programs under this part of the following categories of individuals:

(1) Self-employed farmers, ranchers, professionals, independent tradespeople and other business persons formerly self-employed but presently unemployed.

(2) Self-employed individuals designated in paragraph (d)(1) of this section who are in the process of going out of business, if the Governor determines that the farm, ranch, or business operations are likely to terminate.

(3) Family members and farm or ranch hands of individuals identified under paragraphs (d)(1) and (2) of this section, to the extent that their contribution to the farm, ranch, or business meets minimum requirements as established by the Governor.

(f) The Governor is authorized to establish procedures to identify individuals permanently dislocated from their occupations or fields of work, including self-employment, because of natural disasters. For the purposes of this paragraph (f), categories of natural disasters include, but are not limited to, any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, drought, fire, or explosion.

(g) The State may provide services to displaced homemakers (as defined in section 4 of the Act) under this part only if the Governor determines that such services may be provided without adversely affecting the delivery of such services to eligible dislocated workers. (Section 311(b)(4).)

(h) An eligible dislocated worker issued a certificate of continuing eligibility as provided in § 631.53 of this part shall remain eligible for assistance under this part for the period specified in the certificate not to exceed 104 weeks. The 45-day enrollment provisions described in subpart B of part 627 of this chapter shall be waived

for eligible individuals who possess a valid certificate under this paragraph and it is not required that a new application be taken prior to participation.

(i) An eligible dislocated worker who does not possess a valid certificate shall remain eligible if such individual:

(1) Remains unemployed, or
(2) Accepts temporary employment for the purpose of income maintenance prior to, and/or during participation in a training program under this part with the intention of ending such temporary employment at the completion of the training and entry into permanent unsubsidized employment as a result of the training. Such temporary employment must be with an employer other than that from which the individual was dislocated. This provision applies to eligible individuals both prior to and subsequent to enrollment.

§ 631.4 Approved training rule.

An eligible dislocated worker who is participating in any retraining activity, except on-the-job training, under Title III of the Act or this part shall be deemed to be in training with the approval of the State agency for purposes of section 3304(a)(8) of the Internal Revenue Code of 1986. Participation in the approved training shall not disqualify the individual from receipt of unemployment benefits to which the individual is otherwise entitled. (Section 314(f)(2).)

Subpart B—Additional Title III Administrative Standards and Procedures

§ 631.11 Allotment and obligation of funds by the Secretary.

(a) Funds shall be allotted among the various States in accordance with section 302(b)(1) of the Act, subject to paragraph (b) of this section.

(b) Funds shall be allotted among the various States in accordance with section 302(b)(2)(A) and (B) of the Act as soon as satisfactory data are available under section 462(e) of the Act.

(c) Allotments for the Commonwealth of the Northern Mariana Islands and other territories and possessions of the United States shall be made by the Secretary in accordance with the provisions of section 302(e) of the Act.

§ 631.12 Reallotment of funds by the Secretary.

(a) Based upon reports submitted by States pursuant to § 631.15 of this part, the Secretary shall make determinations regarding total expenditures of funds within the State with reference to the amount required to be reallotted

pursuant to section 303(b) of the Act.

For purposes of this paragraph (a)—

(1) The funds to be reallotted will be an amount equal to the sum of:

(i) Unexpended funds in excess of 20 percent of the prior program year's formula allotment to the State, and

(ii) All unexpended funds from the formula allotment for the program year preceding the prior program year.

(2)(i) The current program year is the year in which the determination is made; and

(ii) The prior program year is the year immediately preceding the current program year.

(3) Unexpended funds shall mean the remainder of the total funds made available by formula that were available to the State for the prior program year minus total accrued expenditures at the end of the prior program year.

(4) Reallotted funds will be made available from current year allotments made available by formula.

(b) Based upon the most current and satisfactory data available, the Secretary shall identify eligible States, pursuant to the definitions in section 303(e) of the Act.

(c) The Secretary shall recapture funds from States identified in paragraph (a) of this section and reallot and reobligate such funds by a Notice of Obligation (NOO) adjustment to current year funds to eligible States as identified in paragraph (b) of this section, as set forth in section 303 (a), (b), and (c) of the Act.

(d) Reallotted funds shall be subject to allocation pursuant to § 631.32 of this part, and to the cost limitations at § 631.14 of this part.

§ 631.13 Classification of costs at State and substate levels.

(a)(1) Allowable costs under title III shall be planned, controlled, and charged by either the State or the substate grantee against the following cost categories: rapid response services, basic readjustment services, retraining services, needs-related payments and supportive services, and administration. Costs shall be reported to the Secretary of Labor in accordance with the reporting requirements established pursuant to § 631.15 of this part.

(2) Except for administrative cost pools described in subpart D of part 627 of this chapter, all costs shall be allocable to a particular cost category to the extent that benefits are received by such category; and no costs shall be chargeable to a cost category except to the extent that benefits are received by such category.

(b) Rapid response services shall include the cost of rapid response

activities identified at section 314(b) of the Act.

(1) Staff salary and benefit costs are chargeable to the rapid response services cost category only for that portion of staff time actually spent on rapid response activities.

(2) All other costs are chargeable to the rapid response services cost category only to the extent that they are for response purposes.

(c) Basic readjustment services shall include the cost of basic readjustment services identified at section 314(c) of the Act, except that the cost of supportive services under section 314(c)(15) of the Act shall be charged to the needs-related payments and supportive services cost category, as provided in paragraph (e) of this section.

(d) Retraining services shall include the cost of retraining services identified at section 314(d) of the Act.

(e) Needs-related payments and supportive services shall include the cost of needs-related payments identified in section 314(e) of the Act, and supportive services identified in section 4(24) of the Act and provided for in section 314(c)(15) of the Act.

(f)(1) Administration shall include the costs incurred by recipients and subrecipients in the administration of programs under title III of the Act, and shall be that portion of necessary and allowable costs which is not directly related to the provision of services and otherwise allocable to the cost categories in paragraphs (b) through (e) of this section. The description of administrative costs in subpart D of part 627 shall be used by States and substate grantees as guidance in charging administration costs to title III programs.

(2) Administration does not include the costs of activities under section 314(b) of the Act and which are provided for in paragraph (b) of this section.

(3) Administration shall include title III funds used for coordination of worker adjustment programs with the Federal-State unemployment compensation system and with chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2271 *et seq.*) and part 617 of this chapter. (Sections 311(b)(10) and 314(f)).

§ 631.14 Limitations on certain costs.

(a) Retraining Services. Of the funds allocated to a substate grantee under part A of title III for any program year, not less than 50 percent shall be expended for retraining services specified under section 314(d) of the Act, unless a waiver of this requirement is granted by the Governor. The

Governor shall prescribe criteria that will allow substate grantees to apply in advance for a waiver of this requirement, pursuant to section 315(a)(2) of the Act. The Governor shall prescribe the time and form for the submission of an application for such a waiver, as provided for at section 315(a)(3) of the Act. The Governor shall not grant a waiver that allows less than 30 percent of the funds expended by a substate grantee to be expended for retraining activities.

(b) Needs-Related Payments and Supportive Services. Of the funds allocated to the Governor, or allocated to any substate grantee, under part A of title III for any program year, not more than 25 percent may be expended to provide needs-related payments and other supportive services.

(c) Administrative cost. Of the funds allocated to the Governor, or allocated to any substate grantee, under part A of title III for any program year, not more than 15 percent may be expended to cover the administrative cost of programs.

(d) Reallotted funds are subject to the limitations on certain costs contained in paragraphs (a), (b) and (c) of this section.

(e) Funds allocated (or distributed) to substate areas under the provisions of section 302(c)(1)(E) of the Act shall be considered funds allocated to a substate grantee for the program year of the funds' initial allotment to the State, and included the cost limitations defined in paragraphs (a), (b) and (c) of this section.

(f) Funds reserved by the Governor under the provisions of section 302(c)(1) of the Act, other than funds distributed to substate grantees under the provisions of JTPA section 302(c)(1)(E), shall be considered funds allocated to the Governor for the program year of the funds' initial allotment to the State and included in the cost limitations applicable to the Governor.

(g) States and substate grantees have the full period of time that the funds are available to them to comply with the cost limitations described in JTPA section 315 and paragraphs (a), (b), and (c) of this section.

(h) Combination of Funds. (1) Substate grantees within a State may combine funds allocated under part A of title III for provision of services to eligible dislocated workers from two or more substate areas. Funds contributed by the substate grantees under this section remain subject to the cost limitations which apply to each substate grantee's total allocation (section 315(d)).

(2) To combine funds under this provision, substate grantees must be in contiguous substate areas or part of the same labor market area.

(i) For the purposes of this section:

(1) *Allotment to the State* means allotted by the formula described in section 302(b) of the Act, as adjusted by reallocations among the States, in accordance with section 303 of the Act. For purposes of determining availability and of applying cost limitations, funds will retain the identity of the program year in which they were initially allotted to a State, irrespective of subsequent reallocations.

(2) *Allocated to the substate grantee* means allocated by the formula prescribed by the Governor under section 302(b) of the Act, and allocated (or distributed) under the provisions of section 302(c)(1)(E), as adjusted by within State reallocations implemented by the Governor through procedures established pursuant to section 303(d) of the Act. For purposes of determining availability and of applying cost limitations, funds will retain the identity of the program year in which they were initially allotted to the State.

(3) *Allocated to the Governor* refers to funds reserved by the Governor for use in accordance with the provisions of section 302(c)(1) of the Act, exclusive of any such funds which are distributed or allocated to substate grantees pursuant to section 302(c)(1)(E).

(j) The cost limitations described in this section do not apply to any designated substate grantee which served as a concentrated employment program grantee for a rural area under the Comprehensive Employment and Training Act. (Section 108(d).)

§ 631.15 Federal reporting requirements.

Notwithstanding the requirements described in subpart D of part 627 of this chapter, the Governor shall report to the Secretary pursuant to instructions issued by the Secretary for programs and activities funded under this part. Such reports shall include a cost breakdown of all funds made available under this part used by the State Dislocated Worker Unit for administrative expenditures, in accordance with instructions issued by the Secretary. Reports shall be provided to the Secretary within 45 calendar days after the end of the report period. (Sections 165(a)(2) and 311(b)(11).)

§ 631.16 Complaints, investigations, and penalties.

The provisions of this section apply in addition to the sanctions provided in subpart G of part 627 of this chapter.

(a) The Secretary shall investigate a complaint or report received from an aggrieved party or a public official which alleges that a state is not complying with the provisions of the State plan required under section 311(a) of the Act. (Section 311(e)(1).)

(b) Where the Secretary determines that a State has failed to comply with its State plan, and that other remedies under the Act and part 627 of this chapter are not available or are not adequate to achieve compliance, the Secretary may withhold an amount not to exceed 10 percent of the allotment to the State for the program year in which the determination is made for each such violation. (Section 311(e)(2)(A).)

(c) The Secretary will not impose the penalty provided for under paragraph (b) of this section until all other remedies under the Act and part 627 of this chapter for achieving compliance have been exhausted or are determined to be unavailable or inadequate to achieve State compliance with the terms of the State plan.

(d) The Secretary will make no determination under this section until the affected State has been afforded adequate written notice and an opportunity to request and to receive a hearing before an administrative law judge pursuant to the provisions of subpart H of part 627 of this chapter. (Section 311(e)(2)(B).)

§ 631.17 Federal monitoring and oversight.

The Secretary shall conduct oversight of State administration of programs under this part, including the administration by each State of the rapid response assistance services provided in such State. The Secretary may review and determine the effectiveness, efficiency and timeliness of service conducted by the State in accordance with § 631.30(b) of this part, and may specify any corrective actions deemed appropriate and necessary (section 314(b)(3)).

§ 631.18 Federal by-pass authority.

(a) In the event that a State fails to submit a biennial State plan that is approved under § 631.36 of this part, the Secretary shall make arrangements to use the amount that would be allotted to the State for the delivery in that State of the programs, activities, and services authorized under title III of the Act and this part.

(b) No determination may be made by the Secretary under this section until the affected State is afforded written notification of the Secretary's intent to exercise by-pass authority and an opportunity to request and to receive a hearing before an administrative law

judge pursuant to the provisions of subpart H of part 627 of this chapter.

(c) The Secretary will exercise by-pass authority only until such time as the affected State has an approved plan under the provisions of § 631.36 of this part. (Section 321(b).)

§ 631.19 Appeals.

Except as provided in this part, disputes arising in programs under this part shall be adjudicated under the appropriate State or local grievance procedures required by subpart E of part 627 of this chapter or other applicable law. Complaints alleging violations of the Act or this part may be filed with the Secretary, pursuant to subpart F of part 627 of this chapter. Paragraphs (a) through (e) of this section refer to appeal rights set forth in this part.

(a) Subpart D of part 628 of this chapter (appeals of denial of SDA designation) shall apply to denial of substate area designations under § 631.34(c) (1) and (3) of this part.

(b) Subpart D of part 628 of this chapter (appeals of final disapproval of SDA job training plans or modifications) shall apply to final disapproval of substate plans under § 631.50(f) of this part.

(c) Subpart D of part 628 of this chapter (appeals of a Governor's notice of intent to revoke approval of all or part of a plan) shall apply to a Governor's notice of intent to exercise by-pass authority under § 631.38 of this part.

(d) Subpart D of part 628 of this chapter (appeals of the Secretary's disapproval of a plan when the SDA is the State) shall apply to plan disapproval when the substate area is the State, as set forth in § 631.50 (g) and (h) of this part.

(e) Decisions pertaining to designations of substate grantees under § 631.35 of this part are not appealable to the Secretary.

Subpart C—Needs-related payments

§ 631.20 Needs-related payments.

(a) Title III funds available to States and substate grantees may be used to provide needs-related payments to participants in accordance with the approved State or substate plan, as appropriate.

(b) In accordance with the approved substate plan, needs-related payments shall be provided to an eligible dislocated worker only in order to enable such worker to participate in training or education programs under this part. To be eligible for needs-related payments:

(1) An eligible worker who has ceased to qualify for unemployment

compensation must have been enrolled in a training or education program by the end of the thirteenth week of the worker's initial unemployment compensation benefit period, or, if later, by the end of the eighth week after an employee is informed that a short-term layoff will in fact exceed 6 months.

(2) For purposes of paragraph (b)(1) of this section, the term *enrolled in a training or education program* means that the worker's application for training institution has furnished written notice that the worker has been accepted in the approved training program beginning within 30 calendar days.

(3) An eligible worker who does not qualify for unemployment compensation must be participating in a training or education program. (Section 314(e)(1).)

(c) Needs-related payments shall not be provided to any participant for the period that such individual is employed, enrolled in or receiving on-the-job training, out-of-area job search, or basic readjustment services in programs under the Act, nor to any participant receiving trade readjustment allowances, on-the-job training, out-of-area job search allowances, or relocation allowances under chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2271 *et seq.*) or part 617 of this chapter. (Section 314(e)(1).)

(d) The level of needs-related payments to an eligible dislocated worker in programs under this part shall not exceed the higher of:

- (1) The applicable level of unemployment compensation; or
- (2) The poverty level (as by the published by the Secretary of Health and Human Services). (Section 314(e)(2).)

Subpart D—State Administration

§ 631.30 Designation or creation and functions of a State dislocated worker unit or office, and rapid response assistance.

(a) *Designation or creation of State dislocated worker unit or office.* The State shall designate or create an identifiable State dislocated worker unit or office with the capabilities and functions identified in paragraph (b) of this section. Such unit or office may be an existing organization or new organization formed for this purpose. (Section 311(b)(2).) The State dislocated worker unit or office shall:

- (1) Make appropriate retraining and basic adjustment services available to eligible dislocated workers through substate grantees, and in statewide, regional or industrywide projects;
- (2) Work with employers and labor organizations in promotion labor-

management cooperation to achieve the goals of this part;

(3) Operate a monitoring, reporting, and management system to provide adequate information for effective program management, review, and evaluation;

(4) Provide technical assistance and advice to substate grantees;

(5) Exchange information and coordinate programs with the appropriate economic development agency, State education and training and social services programs;

(6) Coordinate with the unemployment insurance system, the Federal-State Employment Service system, the Trade Adjustment Assistance program and other programs under this chapter;

(7) Receive advance notice of plant closings and mass layoffs as provided at section 3(a)(2) of the Worker Adjustment and Retraining Notification Act (29 U.S.C. 2102(a)(2)) and part 639 of this chapter;

(8) Immediately notify (within 48 hours) the appropriate substate grantees following receipt of an employer notice of layoff or plant closing or of any other information that indicates a projected layoff or plant closing by an employer in the grantee's substate area, in order to continue and expand the services initiated by the rapid response team (section 311(b)(3)(D));

(9) Fully consult with labor organizations where substantial numbers of their members are to be served; and

(10) Disseminate throughout the State information on the availability of services and activities under title III of the Act and this part.

(b) *Rapid response capability.* The dislocated worker unit shall have one or more rapid response specialists, and the capability to provide rapid response assistance, on-site, for dislocation events such as permanent closures and substantial layoffs throughout the State. The State will not transfer the responsibility for the rapid response assistance functions of the State dislocated worker unit to another entity, but the State may contract with another entity to perform rapid response assistance services. Nothing in this paragraph shall remove or diminish the dislocated worker unit's accountability for ensuring the effective delivery of rapid response assistance services throughout the State. Section 311(b)(12)).

(1) State rapid response specialists should be knowledgeable about the resources available through programs under this part and all other appropriate resources available through public and

private sources to assist dislocated workers. The expertise required by this part includes knowledge of the Federal, State, and local training and employment systems; labor-management relations and collective bargaining activities; private industry and labor market trends; programs and services available to veterans; and other fields necessary to carry out the rapid response requirements of the Act.

(2) The rapid response specialists should have:

(i) The ability to organize a broad-based response to a dislocation event, including the ability to coordinate services provided under this part with other State-administered programs available to assist dislocated workers, and the ability to involve the substate grantee and local service providers in the assistance effort;

(ii) The authority to provide limited amounts of immediate financial assistance for rapid response activities, including, where appropriate, financial assistance to labor-management committees formed under paragraph (c)(2) of this section;

(iii) Credibility among employers and in the employer community in order to effectively work with employers in difficult situations; and

(iv) Credibility among employee groups and in the labor community, including organized labor, in order to effectively work with employees in difficult situations.

(3) The dissemination of information on the State dislocated worker unit's services and activities should include efforts to ensure that major employers, organized labor, and groups of employees not represented by organized labor, are aware of the availability of rapid response assistance. The State dislocated worker unit should make equal effort in responding to dislocation events without regard to whether the affected workers are represented by a union.

(4) In a situation involving an impending permanent closure or substantial layoff, a State may provide funds, where other public or private resources are not expeditiously available, for a preliminary assessment of the advisability of conducting a comprehensive study exploring the feasibility of having a company or group, including the workers, purchase the plant and continue it in operation.

(5) Rapid response specialists may use funds available under this part:

(i) To establish on-site contact with employer and employee representatives within a short period of time (preferably 48 hours or less) after becoming aware of a current or projected permanent

closure or substantial layoff in order to—

(A) Provide information on and facilitate access to available public programs and services; and

(B) Provide emergency assistance adapted to the particular permanent closure or substantial layoff; such emergency assistance may include financial assistance for appropriate rapid response activities, such as arranging for the provision of early intervention services and other appropriate forms of immediate assistance in response to the dislocation event;

(ii) To promote the formation of labor-management committees as provided for in paragraph (c) of this section, by providing—

(A) Immediate assistance in the establishment of the labor-management committee, including providing immediate financial assistance to cover the start-up costs of the committee;

(B) A list of individuals from which the chairperson of the committee may be selected;

(C) Technical advice as well as information on sources of assistance, and liaison with other public and private services and programs; and

(D) Assistance in the selection of worker representatives in the event no union is present;

(iii) To provide ongoing assistance to labor-management committees described in paragraph (c) of this section by—

(A) Maintaining ongoing contact with such committees, either directly or through the committee chairperson;

(B) Attending meetings of such committees on an *ex officio* basis; and

(C) Ensuring ongoing liaison between the committee and locally available resources for addressing the dislocation, including the establishment of linkages with the substate grantee or with the service provider designated by the substate grantee to act in such capacity;

(iv) To collect information related to—

(A) Economic dislocation (including potential closings or layoffs); and

(B) All available resources within the State for serving displaced workers, which information shall be made available on a regular basis to the Governor and the State Council to assist in providing an adequate information base for effective program management, review, and evaluation;

(v) To provide or obtain appropriate financial and technical advice and liaison with economic development agencies and other organizations to assist in efforts to avert worker dislocations;

(vi) To disseminate information throughout the State on the availability of services and activities carried out by the dislocated worker unit or office; and

(vii) To assist the local community in developing its own coordinated response and in obtaining access to State economic development assistance.

(6) Notwithstanding the definition of "substantial layoff (for rapid response assistance)" at § 631.2 of this part, the Governor may, under exceptional circumstances, authorize rapid response assistance provided by a State dislocated worker unit when the layoff of 50 or more individuals is not at a single site of employment or is not during a single 30 day period. For purposes of this provision, "exceptional circumstances" include those situations in which layoffs or permanent closures would have a major impact upon the community(ies) in which they occur. (Section 314(b)).

(c) *Labor-management committees.* As provided for in sections 301(b)(1) and 314(b)(1)(B) of the Act, labor-management committees are a form of rapid response assistance which may be voluntarily established to respond to actual or prospective worker dislocation.

(1) Labor management committees ordinarily include (but are not limited to) the following—

(i) Shared and equal participation by workers and management, with members often selected in an informal fashion;

(ii) Shared financial participation between the company and the State, using funds provided under Title III of the Act, in paying for the operating expenses of the committee; in some instances, labor union funds may help to pay committee expenses;

(iii) A chairperson, to oversee and guide the activities of the committee who—

(A) Shall be jointly selected by the labor and management members of the committee;

(B) Is not employed by or under contract with labor or management at the site; and

(C) Shall provide advice and leadership to the committee and prepare a report on its activities;

(iv) The ability to respond flexibly to the needs of affected workers by devising and implementing a strategy for assessing the employment and training needs of each dislocated worker and for obtaining the services and assistance necessary to meet those needs;

(v) A formal agreement, terminable at will by the workers or the company

management, and terminable for cause by the Governor; and

(vi) Local job identification activities by the chairperson and members of the committee on behalf of the affected workers.

(2) Because they include employee representatives, labor-management committees typically provide a channel whereby the needs of eligible dislocated workers can be assessed, and programs of assistance developed and implemented, in an atmosphere supportive to each affected worker. As such, committees must be perceived to be representative and fair in order to be most effective.

§ 631.31 Monitoring and oversight.

The Governor is responsible for monitoring and oversight of all State and substate grantee activities under this part. In such monitoring and oversight of substate grantees, the Governor shall ensure that expenditures and activities are in accordance with the substate plan or modification thereof, and with the cost limitations described in § 631.14 of this part.

§ 631.32 Allocation of funds by the Governor.

Of the funds allotted to the Governor by the Secretary under §§ 631.11 and 631.12 of this part.

(a) The Governor shall issue allocations to substate grantees, the sum of which shall be no less than 50 percent of the State's allotment. (Section 302(d)).

(b)(1) The Governor shall prescribe the formula to be used in issuing substate allocations required under paragraph (a) of this section to substate grantees.

(2) The formula prescribed pursuant to paragraph (b)(1) of this section shall utilize the most appropriate information available to the Governor. In prescribing the formula, the Governor shall include (but need not be limited to) the following information:

(i) Insured unemployment data;

(ii) Unemployment concentrations;

(iii) Plant closing and mass layoff data;

(iv) Declining industries data;

(v) Farmer-rancher economic hardship data; and

(vi) Long-term unemployment data.

(3) The Governor may allow for an appropriate weight for each of the formula factors set forth in paragraph (b)(2) of this section. A weight of zero for any of the factors required in section 302(d) of the Act and identified in paragraph (b)(2) of this section shall only be made when a review of available data indicates that the factor is

not relevant to determining the incidence of need for worker dislocation assistance within the State. The formula may be amended no more frequently than once each program year. (Section 302(d)).

(c) The Governor may reserve an amount equal to not more than 40 percent of the funds allotted to the State under § 631.11 and § 631.12 of this part for State activities and for discretionary allocations to substate grantees. (Section 302(c)(1)).

(d) The Governor may reserve an additional amount equal to not more than 10 percent of the funds allotted to the State under § 631.11 of this part. The Governor shall allocate such funds, subject to the SJTCC or HRIC review and comment, during the first three quarters of the program year among substate grantees on the basis of need. Such funds shall be allocated to substate grantees and shall not be used for statewide activities. Such funds shall be included in each substate grantee's allocation for purposes of cost limitations, as described in § 631.14 of this part. (Sections 302(c)(2) and 317(1)(B)).

§ 631.33 State procedures for identifying funds subject to mandatory Federal reallocation.

The Governor shall establish procedures to assure the equitable identification of funds required to be reallocated pursuant to section 303(b) of the Act. Funds so identified may be funds reserved by the State pursuant to section 302(c)(1)(A) through (D) of the Act and/or allocated to substate grantees pursuant to section 302(c)(1)(E), (c)(2) and/or (d) of the Act. (Section 303(d).) Such procedures may not exempt either State or substate funds from reallocation.

§ 631.34 Designation of substate areas.

(a) The Governor, after receiving recommendations from the SJTCC or HRIC, shall designate substate areas for the State. (Section 312(a).)

(b) In designating substate areas, the Governor shall:

(1) Ensure that each service delivery area within the State is included within a substate area and that no SDA is divided among two or more substate areas; and

(2) Consider the availability of services throughout the State, the capability to coordinate the delivery of services with other human services and economic development programs, and the geographic boundaries of labor market areas within the State.

(c) Subject to paragraph (b) of this section, the Governor shall designate as a substate area:

(1) Any single SDA that has a population of 200,000 or more;

(2) Any two or more contiguous SDA's that:

(i) In the aggregate have a population of 200,000 or more; and

(ii) Request such designation; and

(3) Any concentrated employment program grantee for a rural area as described in section 101(a)(4)(A)(iii) of the Act.

(d) In addition to the entities identified in paragraph (c) of this section, the Governor may, without regard to the 200,000 population requirement, designate SDAs with smaller populations as substate areas.

(e) The Governor may deny a request for substate area designation from a consortium of two or more SDAs that meets the requirements of paragraph (c)(2) of this section only upon a determination that the request is not consistent with the effective delivery of services to eligible dislocated workers in the relevant labor market area, or would not otherwise be appropriate to carry out the purposes of title III. The Governor will give good faith consideration to all such requests by a consortium of SDAs to be a substate area. In denying a consortium's request for substate area designation, the Governor shall set forth the basis and rationale for the denial. (Section 312(a)(5).)

(f) In the case where the service delivery area is the State, the entire State shall be designated as a single substate area.

(g)(1) Entities described in paragraphs (c)(1) and (3) of this section may appeal the Governor's denial of substate area designation to the Secretary of Labor. The procedures that apply to such appeals shall be those set forth at subpart D of part 627 for appeals of the Governor's denial of SDA designation.

(2) An entity described in paragraph (c)(2) of this section that has been denied substate area designation may utilize the State-level grievance procedures required by section 144(a) of the Act and subpart E of part 627 of this chapter for the resolution of disputes arising from such a denial.

(h) Designation of substate areas shall not be revised more than once each two years. All such designations must be completed no later than four months prior to the beginning of any program year. (Section 312(a)(6).)

§ 631.35 Designation of substate grantees.

The Governor may establish procedures for the designation of substate grantees.

(a) Designation of the substate grantee for each substate area shall be made on a biennial basis.

(b) Entities eligible for designation as substate grantees include:

(1) Private industry councils in the substate area;

(2) Service delivery area grant recipients or administrative entities designated under Title II of the Act;

(3) Private non-profit organizations;

(4) Units of general local government in the substate area, or agencies thereof;

(5) Local offices of State agencies; and

(6) Other public agencies, such as community colleges and area vocational schools.

(c) Substate grantees shall be designated in accordance with an agreement among the Governor, the local elected official or officials of such area, and the private industry council or councils of such area. Whenever a substate area is represented by more than one such official or council, the respective officials and councils shall each designate representatives, in accordance with procedures established by the Governor (after consultation with the SJTCC or HRIC), to negotiate such agreement.

(d) The agreement specified in paragraph (c) of this section shall set forth the conditions, considerations, and other factors related to the selection of substate grantees in accordance with section 312(b) of the Act.

(e) The Governor shall negotiate in good faith with the parties identified in paragraph (c) of this section and shall make a good faith effort to reach agreement. In the event agreement cannot be reached on the selection of a substate grantee, the Governor shall select the substate grantee.

(f) Decisions under paragraphs (c), (d), and (e) of this section are not appealable to the Secretary. (Section 312 (b) and (c)).

§ 631.36 Biennial State plan.

(a) In order to receive an allotment of funds under § 631.11 and § 631.12 of this part, the State shall submit to the Secretary, in accordance with instructions issued by the Secretary, on a biennial basis, a biennial State plan. (Section 311). Such plan shall include:

(1) Assurances that—

(i) The State will comply with the requirements of Title III of the Act and this part;

(ii) Services will be provided only to eligible displaced workers, except as provided in paragraph (a)(2) of this section;

(iii) Services will not be denied on the basis of State of residence to eligible dislocated workers displaced by a

permanent closure or substantial layoff within the State; and may be provided to other eligible dislocated workers regardless of the State of residence of such workers;

(2) Provision that the State will provide services under this part to displaced homemakers only if the Governor determines that the services may be provided to such workers without adversely affecting the delivery of services to eligible dislocated workers;

(3) A description of the substate allotment and reallocation procedures and assurance that they meet the requirements of the Act and this part;

(4) A description of the State procurement system and procedures to be used under title III of the Act and this part which are consistent with the provisions in subpart D of part 627 of this chapter; and

(5) Assurance that the State will not prescribe any performance standard which is inconsistent with subpart D of part 627 of this chapter.

(b) The State biennial plan shall be submitted to the Secretary on or before the May 1 immediately preceding the first of the two program years for which the funds are to be made available.

(c) Any plan submitted under paragraph (a) of this section may be modified to describe changes in or additions to the programs and activities set forth in the plan. No plan modification shall be effective unless reviewed pursuant to paragraph (d) of this section and approved pursuant to paragraph (e) of this section.

(d) The Secretary shall review State biennial plans and plan modifications, including any comments thereon submitted by the SJTCC or HRIC, for overall compliance with the provisions of the Act, this part, and the instructions issued by the Secretary.

(e) A State biennial plan or plan modification is submitted on the date of its receipt by the Secretary. The Secretary shall approve a plan or plan modification within 45 days of submission unless, within 30 days of submission, the Secretary notifies the Governor in writing of any deficiencies in such plan or plan modification.

(f) The Secretary shall not finally disapprove the State biennial plan or plan modification of any State except after written notice and an opportunity to request and to receive a hearing before an administrative law judge pursuant to the provisions of subpart H of part 627 of this chapter.

§ 631.37 Coordination activities.

(a) Services under this part shall be integrated or coordinated with services

and payments made available under chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2271 *et seq.*) and part 617 of this chapter and programs provided by any State or local agencies designated under section 239 of the Trade Act of 1974 (19 U.S.C. 2311) or part 617 of this chapter. (Section 311 (b)(10).) Such coordination shall be effected under provisions of an interagency agreement when the State agency responsible for administering programs under this part is different from the State agency administering Trade Act programs.

(b) States may use funds allotted under §§ 631.11 and 631.12 of this part for coordination of worker readjustment programs, (*i.e.*, programs under this part and trade adjustment assistance under part 617 of this chapter) and the unemployment compensation system consistent with the limitation on administrative expenses (see § 631.14(a)(1) of this part). Each State shall be responsible for coordinating the unemployment compensation system and worker readjustment programs. (Section 314(f).)

(c) Services under this part shall be coordinated with dislocated worker services under title III of the Carl D. Perkins Vocational Education Act (20 U.S.C. 2351 *et seq.*). (Section 311(b)(5).)

(d) In promoting labor management cooperation, including the formation of labor-management committees under this part, the dislocated worker unit shall consider cooperation and coordination with labor-management committees established under other authorities. (Section 311(b)(3)(B).)

(e) In accordance with section 402 of the Veterans' Benefits and Programs Improvement Act of 1988, 29 U.S.C. 1751 note, services under this part shall be coordinated with programs administered by the Department of Veterans Affairs and with other veterans' programs such as the Veterans' Job Training Act (29 U.S.C. 1721 note), title IV-C of the Job Training Partnership Act (29 U.S.C. 1721 *et seq.*), part 635 of this chapter, and the Transition Assistance Program.

§ 631.38 State by-pass authority.

(a)(1) In the event that a substate grantee fails to submit a plan, or submits a plan which is not approved by the Governor (see § 631.50(f) of this part), the Governor may direct the expenditure of funds allocated to the substate area.

(2) The Governor's authority under this paragraph (a) to direct the expenditure of funds remains in effect only until such time as a plan is submitted and approved, or a new

substate grantee is designated. (Section 313(c).)

(3) The Governor shall not direct the expenditure of funds under this paragraph (a) until after the affected substate grantee has been afforded advance written notice of the Governor's intent to exercise such authority and an opportunity to appeal to the Secretary pursuant to the provisions of subpart D of part 628 of this chapter.

(b)(1) If a substate grantee fails to expend funds allocated to it in accordance with its plan, the Governor, subject to appropriate notice and opportunity for comment in the manner required by section 105(b)(1), (2), and (3) of the Act, may direct the expenditure of funds only in accordance with the substate plan.

(2) The Governor's authority under this paragraph (b) to direct the expenditure of funds remain in effect only until:

(i) The substate grantee corrects the failure;

(ii) The substate grantee submits an acceptable modification; or

(iii) A new substate grantee is designated. (Sections 313 (a) and (d).)

(3) The Governor shall not direct the expenditure of funds under this paragraph (b) until after the affected substate grantee has been afforded advance written notice of the Governor's intent to exercise such authority, and an opportunity to appeal to the Secretary pursuant to the provisions of § 628.5(c) of this chapter.

(c) When the substate area is the State, the Secretary shall have the same authority as the Governor under paragraphs (a) and (b) of this section.

Subpart E—State Programs

§ 631.40 State program operational plan.

(a) The Governor shall submit to the Secretary biennially, in accordance with instructions issued by the Secretary, a State program operational plan describing the specific activities, programs and projects to be undertaken with the funds reserved by the Governor under § 631.32(c) of this part.

(b) The State program operational plan shall include a description of the mechanisms established between the Federal-State Unemployment Compensation System, the Trade Adjustment Assistance Program, the State Employment service and programs authorized under title III of the Act and this part to coordinate the identification and referral of dislocated workers and the exchange of information.

§ 631.41 Allowable State activities.

(a) States may use funds reserved under § 631.32(c) of this part, subject to

the provisions of the State biennial and program operational plans, for:

- (1) Rapid response assistance;
- (2) Basic readjustment services when undertaken in Statewide, regional or industrywide projects, or, initially, as part of rapid response assistance;
- (3) Retraining services, including (but not limited to) those in section 314(d) of the Act when undertaken in Statewide, industrywide and regional programs;
- (4) Coordination with the unemployment compensation system, in accordance with § 631.37(b) of this part;
- (5) Discretionary allocation for basic readjustment and retraining services to provide additional assistance to substate areas that experience substantial increases in the number of dislocated workers, to be expended in accordance with the substate plan or a modification thereof;
- (6) Incentives to provide training of greater duration for those who require it; and
- (7) Needs-related payments in accordance with section 315(b) of the Act.

(b) Activities will be coordinated with other programs serving dislocated workers, including training under chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2271 *et seq.*) and part 617 of this chapter.

(c) Where appropriate, State-level activities should be coordinated with activities and services provided by substate grantees.

(d) Retraining services provided to individuals with funds available to a State should be limited to those individuals who can most benefit from and are in need of such services.

(e) Other than basic and remedial education, literacy and English for non-English speakers training, retraining services provided with funds available to a State shall be limited to those for occupations in demand in the area or another area to which the participant is willing to relocate, or in sectors of the economy with a high potential for sustained demand or growth.

(f) Services provided to displaced homemakers should be part of ongoing programs and activities under title III and this part and not separate and discrete programs.

(g) Basic readjustment services described in § 631.3(b)(1), provided to individuals who have not received a specific notice of termination or layoff and work at a facility at which the employer has made a public announcement that such facility will close, shall to the extent practicable be funded by the State with funds reserved under § 631.32(c). (Section 314(h).)

(h) The provisions of section 107(a), (b) and (e) of the Act (but not subsections (c) and (d) of section 107) and subpart D of part 627 of this chapter apply to State selection of service providers for funded activities authorized in § 631.32(c) of this part.

Subpart F—Substate Programs

§ 631.50 Substate plan.

(a) In order to receive an allocation of funds under § 631.32 of this part, the substate grantee shall submit to the Governor a substate plan, in accordance with instructions issued by the Governor. Such plan shall meet the requirements of this section and shall be approved by the Governor prior to funds being allocated to a substate grantee.

(b) The Governor shall issue instructions and schedules that assure that substate plans and plan modifications conform to all requirements of the Act and this part and contain the statement required by section 313(b) of the Act.

(c) Substate plans shall provide for compliance with the cost limitation provisions of § 631.14 of this part.

(d) The SJTCC or HRIC shall review and submit to the Governor written comments on substate plans.

(e) Prior to the submission of the substate plan to the Governor, the substate grantee shall submit the plan to the parties to the agreement described in § 631.35(c) of this part for review and comment. (Section 313(a).)

(f) The Governor's review and approval (or disapproval) of a substate plan or plan modification, and appeals to the Secretary from disapprovals thereof, shall be conducted according to the provisions of section 105 of the Act and subpart D of part 628 of this chapter. (Section 313(c).)

(g) If a substate grantee fails to meet the provisions for plan submission and approval found in this section, the Governor may exercise the by-pass authority set forth at § 631.38 of this part.

(h) When the substate area is the State, the substate plan (and plan modification(s)) shall be submitted by the Governor to the Secretary. The dates for submission and consideration and the Secretary's review and approval (or disapproval) of the plan or plan modification, and appeals to administrative law judges from disapproval thereof, shall be conducted according to the provisions of subpart D of part 628 of this chapter.

§ 631.51 Allowable substate program activities

(a) The substate grantee may use JTPA section 302(c)(1), (c)(2), and (d) funds

allocated by the Governor under § 631.32 of this part for basic readjustment services, retraining services, supportive services and needs-related payments.

(b) The provisions of subpart D of part 627 of this chapter (procurement, cost principles and allowable costs) apply to funds allocated to substate grantees under this part unless otherwise specifically provided for.

(c) Other than basic and remedial education, literacy and English for non-English speakers training, retraining services provided with funds available to a substate area shall be limited to those for occupations in demand in the area or another area to which the participant is willing to relocate, or in sectors of the economy with a high potential for sustained demand or growth.

(d) Retraining services provided to individuals with funds available to a substate area should be limited to those individuals who can most benefit from and are in need of such services. (Sections 312(e) and 141(a).)

§ 631.52 Selection of service providers.

(a) The substate grantee shall provide authorized JTPA title III services within the substate area, pursuant to an agreement with the Governor and in accordance with the approved State plan and substate plan, including the selection of service providers.

(b) The substate grantee may provide authorized JTPA Title III services directly or through contract, grant, or agreement with service providers. (Section 312(d).)

(c) Services provided to displaced homemakers should be part of ongoing programs and activities under title III of the Act and this part and not separate and discrete programs.

(d) The provisions of section 107 (a), (b), (c) and (e) of the Act and subpart D of part 627 of this chapter apply to substate grantee selection of service providers as specified in this section.

§ 631.53 Certificates of continuing eligibility.

(a) A substate grantee may issue to any eligible dislocated worker who has applied for the program authorized in this part a certificate of continuing eligibility. Such a certificate of continuing eligibility:

(1) May be effective for periods not to exceed 104 weeks;

(2) Shall not include any reference to any specific amount of funds;

(3) Shall state that it is subject to the availability of funds at the time any such training services are to be provided, and

(4) Shall be non-transferable.

(b) Acceptance of a certificate of continuing eligibility shall not be deemed to be enrollment in training.

(c) Certificates of continuing eligibility may be used, subject to the conditions included on the face of the certificate, in two distinct ways:

(1) To defer the beginning of retraining: Any individual to whom a certificate of continuing eligibility has been issued under paragraph (a) of this section shall remain eligible for retraining and education services authorized under this part for the period specified in the certificate, notwithstanding the definition of "eligible dislocated worker" in section 301(a) of the Act or the participant eligibility provisions in § 631.3 of this part, and may use the certificate in order to receive retraining services, subject to the limitations contained in the certificate; or

(2) To permit eligible dislocated workers to seek out and arrange their own retraining with service providers approved by the substate grantee; retraining provided pursuant to the certificate shall be in accord with requirements and procedures established by the substate grantee and shall be conducted under a grant, contract, or other arrangement between the substate grantee and the service provider.

(d) Substate grantees shall ensure that records are maintained showing to whom such certificates of continuing eligibility have been issued, the dates of issuance, and the number redeemed by the substate grantees.

Subpart G—Federal Delivery of Dislocated Worker Services Through National Reserve Account Funds

§ 631.60 General.

Of the funds appropriated for title III of the Act, 20 percent (less those amounts allotted in accordance with section 302(e) of the Act) shall be used for Federal responsibilities, described in section 323 of the Act. Subject to the provisions of section 324 of the Act, the Secretary may reserve funds under this part for awards to entities submitting applications for such funds based upon selection criteria published by the Secretary. The Secretary may utilize reserve funds to provide additional assistance to States to assist the States in carrying out programs under this part.

§ 631.61 Application for funding and selection criteria.

To qualify for consideration for funds reserved by the Secretary for activities

under section 323 of the Act, applications shall be submitted to the Secretary pursuant to instructions issued by the Secretary specifying application procedures, selection criteria, and approval process. Separate instructions will be issued for each category of grant awards, as determined by the Secretary.

§ 631.62 Cost limitations.

The expenditure of funds provided to grantees under this subpart shall be consistent with the cost limitations specified in section 315 of the Act and described in paragraphs (a), (b) and (c) of § 631.14 of this part, except as provided in the instructions under § 631.61.

§ 631.63 Reporting.

(a) Grantees under part B of title III of the Act shall submit reports as prescribed by the Secretary.

(b) Significant developments: Grantees shall notify the Secretary of developments that have a significant impact on the grant or subgrant supported activities, including problems, delays, or adverse conditions which may materially impair the ability to meet the objectives of the project. This notification shall include a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.

§ 631.64 General administrative requirements.

(a) Activities under this subpart may be carried out and funding provided directly to grantees other than States.

(b) All grantees and subgrantees under this subpart which are States or substate grantees are subject to the provisions in part 627 of this chapter.

(c) For grantees other than States and substate grantees, the following provisions shall apply to grants under this subpart.

(1) *Grievance procedures.* (i) Each grantee shall establish and maintain a grievance procedure for grievances or complaints about its programs and activities from participants, subgrantees, subcontractors, and other interested persons. Hearings on any grievance shall be conducted within 30 days of filing of a grievance and decisions shall be made not later than 60 days after the filing of a grievance. Except for complaints alleging fraud or criminal activity, complaints shall be made within one year of the alleged occurrence.

(ii) Grantees shall be subject to the provisions of section 144 of the Act, 29 CFR part 97 and 41 CFR part 29-70.

(iii) If the grantee is already subject to the grievance procedure process and

requirements established by the Governor (i.e., through another JTPA grant, subgrant, or contract), its adherence to that procedure shall meet the requirements of this paragraph (c)(1).

(2) *Uniform Administrative Standards.* Grantees shall be subject to the standards and requirements described in 29 CFR Part 97 or 41 CFR parts 29-70 (1984 ed.), as appropriate, as well as any additional standards prescribed in grant documents or Secretarial guidelines. If the grantee/subgrantee is already subject to additional standards established by the Governor (i.e., through another JTPA grant, subgrant, or contract), its adherence to those standards shall meet the requirements of this paragraph (c)(2).

Subpart H—[Reserved]

Subpart I—Disaster Relief Employment Assistance

§ 631.80 Scope and purpose.

This subpart establishes a Disaster Relief Employment Assistance program under title IV, part J of JTPA which shall be administered in conjunction with the title III National Reserve Grants Programs.

§ 631.81 Availability of funds.

Funds appropriated to carry out this part may be made available by grant to the Governor of any State within which is located an area that has suffered an emergency or a major disaster as defined in paragraphs (1) and (2), respectively, of section 102 of the Disaster Relief Act of 1974 (42 U.S.C. 5122 (1) and (2)) (referred to in this subpart as the "disaster area"). The Secretary shall prescribe procedures for applying for funds.

§ 631.82 Substate allocation.

(a) Not less than 80 percent of the grant funds available to any Governor under § 631.81 of this part shall be allocated by the Governor to units of general local government located, in whole or in part, within such disaster areas. The remainder of such funds may be reserved by the Governor for use, in concert with State agencies, in cleanup, rescue, repair, renovation, and rebuilding activities associated with such major disaster.

(b) The JTPA title III program SSG for the disaster area shall be designated local entity for administration of the grant funds under this subpart.

§ 631.83 Coordination.

Funds made available under this subpart to Governors and units of

general local government shall be expended in consultation with—

(a) Agencies administering programs for disaster relief provided under the Disaster Relief Act of 1974; and

(b) The JTPA title II administrative entity and the private industry council in each service delivery area within which disaster employment programs will be conducted under this subpart.

§ 631.84 Allowable projects.

Funds made available under this subpart to any unit of general local government in a disaster area—

(a) Shall be used exclusively to provide employment on projects to provide food, clothing, shelter and other humanitarian assistance for disaster victims; and on projects regarding demolition, cleanup, repair, renovation, and reconstruction of damaged and destroyed structures, facilities, and lands located within the disaster area; and

(b) May be expended through public and private non-profit agencies and organizations engaged in such projects.

§ 631.85 Participant eligibility.

An individual shall be eligible to be offered disaster employment under this subpart if such individual is—

(a)(1) Eligible to participate, enroll, or is a participant or enrolled, in a program under title III of the Act, other than an individual who is actively engaged in a training program; or

(2) Eligible to participate in programs or activities through the Native American and Migrant programs; or

(3) Unemployment as a consequence of the disaster.

(b) [Reserved]

§ 631.86 Limitations on disaster relief employment.

No individual shall be employed under this subpart for more than 6 months for work related to recovery from a single natural disaster (described in § 631.3(f) of this part).

§ 631.87 Definitions.

As used in this subpart, the term "unit of general local government" includes:

(a) In the case of a community conducting a project in an Indian reservation or Alaska Native village, the grantee designated under the JTPA Section 401 Indian and Native American Program (see part 632 of this chapter), or a consortium of such grantees and the State; and

(b) In the case of a community conducting a project in a migrant or seasonal farmworker community, the grantee designated under the JTPA Section 402 Migrant and Seasonal

Farmworker Program (see part 633 of this chapter), or a consortium of such grantees and the State.

7. Part 637 is revised to read as follows:

PART 637—PROGRAMS UNDER TITLE V OF THE JOB TRAINING PARTNERSHIP ACT

Subpart A—General Provisions

Sec.

637.100 Scope and purpose.

637.105 Definitions.

Subpart B—Program Planning and Operation

637.200 Allotments to States.

637.205 Notice of intent to participate.

637.210 Incentive bonus program applications.

637.215 Review and approval of applications for incentive bonus payments.

637.220 Eligibility criteria for individuals to be counted in determining incentive bonuses.

637.225 Determination of incentive bonus.

637.230 Use of incentive bonuses.

Subpart C—Additional Title V Administrative Standards and Procedures

637.300 Management systems, reporting and recordkeeping.

637.305 Federal monitoring and oversight.

637.310 Audits.

Subpart D—Data Collection [Reserved]

Authority: 29 U.S.C 1579(a); 29 U.S.C. 1791(e).

Subpart A—General Provisions

§ 637.100 Scope and purpose.

(a) This part implements title V of the Act which creates a program to provide incentive bonuses to States for providing certain employable dependent individuals with job training to reduce welfare dependency, to promote self-sufficiency, to increase child support payments, and to increase employment and earnings (section 501).

(b) This part applies to programs operated with funds under title V of the Job Training Partnership Act.

§ 637.105 Definitions.

In addition to the definitions contained in sections 4, 301, 303(e), and in § 626.4 of this chapter, the following definitions apply to the administration of title V of the Act and this part:

Absent parent means an individual who is continuously absent from the household and who is a non-custodial parent of a dependent child receiving aid to families with dependent children (AFDC) under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.).

Disability assistance means benefits offered pursuant to title XVI of the

Social Security Act, relating to the supplemental security income program.

Federal contribution means the amount of the Federal component of cash payments to individuals within the participating State under welfare and/or disability assistance programs, including part A of title IV of the Social Security Act.

Subpart B—Program Planning and Operation

§ 637.200 Allotments to States.

(a) For each program year for which funds are appropriated to carry out programs under this part, the Secretary shall pay to each participating State the amount the State is eligible to receive in accordance with this part. No payments shall be made for any years for which funds are not appropriated and/or not available (section 502(a)).

(b) If the appropriation is not sufficient to pay to each State the amount it is eligible to receive in accordance with this part, the State shall receive a percentage of the total available funds equal to the percentage of its bonus compared to the national total of bonuses (section 502(b)).

(c) If an additional amount is made available after the application of paragraph (b) of this section, such additional amount shall be allocated among the States by increasing payment in the same manner as was used to reduce payment, except that no State shall be paid an amount which exceeds the amount to which it is eligible (section 502(c)).

§ 637.205 Notice of intent to participate.

(a) Any State seeking to participate in the incentive bonus program shall notify the Secretary of its intent to do so no later than 30 days before the beginning of its first program year of participation (i.e., June 1) (section 505(a)).

(b) Pursuant to instructions issued by the Secretary, the notification referenced in paragraph (a) of this section shall be in the form of a letter from the Governor to the Secretary advising the Secretary of the State's intention to apply for, receive and expend bonuses under this program in a manner consistent with this part (section 505(b)).

(c) After the State's submission of a notice of intent to participate, incentive bonuses may be claimed by a State for any individual who:

(1)(i) Was an absent parent of any child receiving AFDC at the time such individual was determined to be eligible for participation in programs under the Act;

(ii) Has participated in education, training, or other activities (including

the Job Corps) funded under the Act; and

(iii) Pays child support for a child specified in paragraph (c)(1) of this section following termination from activities funded under the Act; or

(i) Is blind or disabled;

(ii) Was receiving disability assistance at the time such individual was determined to be eligible for participation in programs under the Act;

(iii) Has participated in education, training, or other activities (including the Job Corps) funded under the Act; and

(iv) Earns from employment a wage or an income (section 506).

(d) A Governor may withdraw the State's participation in the incentive bonus program in any program year by submitting a written notice of withdrawal.

§ 637.210 Incentive bonus program applications.

(a) Any State seeking to receive an incentive bonus under this title shall submit an Incentive Bonus Program application pursuant to instructions issued by the Secretary that will contain the criteria for approval of such application. Each application shall contain, at a minimum, the following information:

(1) A list of eligible individuals who met the requirements of § 637.14 of this part during the program year;

(2) The amount of the incentive bonus attributable to each eligible individual who is claimed by the State; and

(3) A statement certifying the availability of documentation to verify the eligibility of participants and the amount of the incentive bonus claimed by the State (section 505(b)).

(b) Such application for any program year shall be submitted by the State to the Secretary no later than August 31 following the end of the program year for which the bonus is being claimed. A copy of such application shall also be submitted at the same time to the appropriate DOL Employment and Training Administration Regional Office.

§ 637.215 Review and approval of applications for incentive bonus payments.

(a) The Secretary shall review all applications for overall compliance with JTPA, the requirements of this part, and the instructions issued by the Secretary.

(b) The Secretary shall inform a State within 30 days after receipt of the application as to whether or not its application has been approved.

(c) If the application is not approved, the Department shall issue an initial notice of denial of payment indicating

the reasons for such denial. The Governor will then have 30 days to respond to the reasons for the denial before a final decision is made.

(d) If the Department determines that the additional information provided does not adequately respond to the questions raised in the initial review process, a final denial of payment shall be issued. The Governor may then appeal the decision in accordance with the procedures at subpart H of part 627 of this chapter (sections 504(c) and 505(c)).

§ 637.220 Eligibility criteria for individuals to be counted in determining incentive bonuses.

An individual shall be eligible to be counted as part of the State's request for an incentive bonus payment under this part if the individual:

(a)(1) Was an absent parent of any child receiving AFDC at the time such individual was determined to be eligible for participation in programs under the Act;

(2) Has participated in education, training, or other activities (including the Job Corps) funded under the Act; and

(3) Pays child support for a child specified in paragraph (a)(1) of this section following termination from activities funded under the Act; or

(b)(1) Is blind or disabled;

(2) Was receiving disability assistance at the time such individual was determined to be eligible for participation in programs under the Act;

(3) Has participated in education, training, or other activities (including the Job Corps) funded under the Act; and

(4) Earns from employment a wage or an income (section 506).

§ 637.15 Determination of incentive bonus.

The amount of the incentive bonus to be paid to each State shall be the total of the incentive bonuses claimed for each eligible individual within the State. The amount of the incentive bonus to be paid each State shall be determined by the sum of

(a) An amount equal to the total of the amounts of child support paid by each individual who is eligible under § 637.14(a) of this part, for up to 2 years after such individual's termination from JTPA; and,

(b) An amount equal to the total reduction in the Federal contribution to the amounts received under title XVI of the Social Security Act (42 U.S.C. 1381 *et seq.*) by each individual who is eligible under § 637.14(b) of this part, for up to 2 years after such individual's termination from JTPA (section 503).

§ 637.230 Use of incentive bonuses.

(a) During any program year, the Governor may use an amount not to exceed 5 percent of the State's total bonus payment for the administrative costs incurred under this program, including data and information collection and compilation, recordkeeping, or the preparation of applications for incentive bonuses (section 504(a)(1)(A)).

(b) The remainder, not less than 95 percent of the incentive bonuses received, shall be distributed to SDAs and Job Corps Centers within the State in a manner consistent with an agreement between the Governor and these SDAs and centers. This agreement shall reflect an equitable method of distribution which is based on the degree to which the effort of the SDA and/or Center contributed to the State's qualification for incentive bonus funds under title V (section 504(a)(1)(B)).

(c) Not more than 10 percent of the incentive bonus received in any program year by each SDA and/or Job Corps Center may be used for the administrative costs of establishing and maintaining systems necessary for operation of programs under title V, including the costs of providing incentive payments described in paragraph (d) of this section, technical assistance, data and information collection and compilation, management information systems, post-program followup activities, and research and evaluation activities (section 504(a)(2)).

(d) Each SDA and/or Job Corps Center may make incentive payments to service providers, including participating State and local agencies, and community-based organizations, that demonstrate effectiveness in delivering employment and training systems to eligible individuals under this title (section 504(b)).

(e) All remaining funds received by each SDA shall be used for activities described in sections 204 and 264 of

JTPA and shall be subject to regulations governing the operation of programs under titles II-A and II-C of JTPA. All remaining funds received by each Job Corps Center shall be used for activities authorized under part B of title IV (section 504(a)(2)).

Subpart C—Additional Title V Administrative Standards and Procedures

§ 637.300 Management systems, reporting and recordkeeping.

(a) The Governor shall ensure that the State's financial management system and recordkeeping system comply with subpart D of part 627 of this chapter.

(b) Notwithstanding the provisions of § 629.36 of this chapter, the Governor shall report to the Secretary pursuant to instructions issued by the Secretary regarding activities funded under this part. Reports shall be required semi-annually and annually. Reports shall be provided to the Secretary within 45 calendar days after the end of the report period.

(c) The Governor shall assure that appropriate and adequate records are maintained for the required time period to support all incentive bonus payment applications. Such records shall include documentation to support individuals' eligibility under this part.

§ 637.305 Federal monitoring and oversight.

The Secretary shall conduct oversight of the programs and activities conducted in accordance with this part.

§ 637.310 Audits.

The Governor shall ensure that the State complies with the audit provisions at § 629.42 of this chapter.

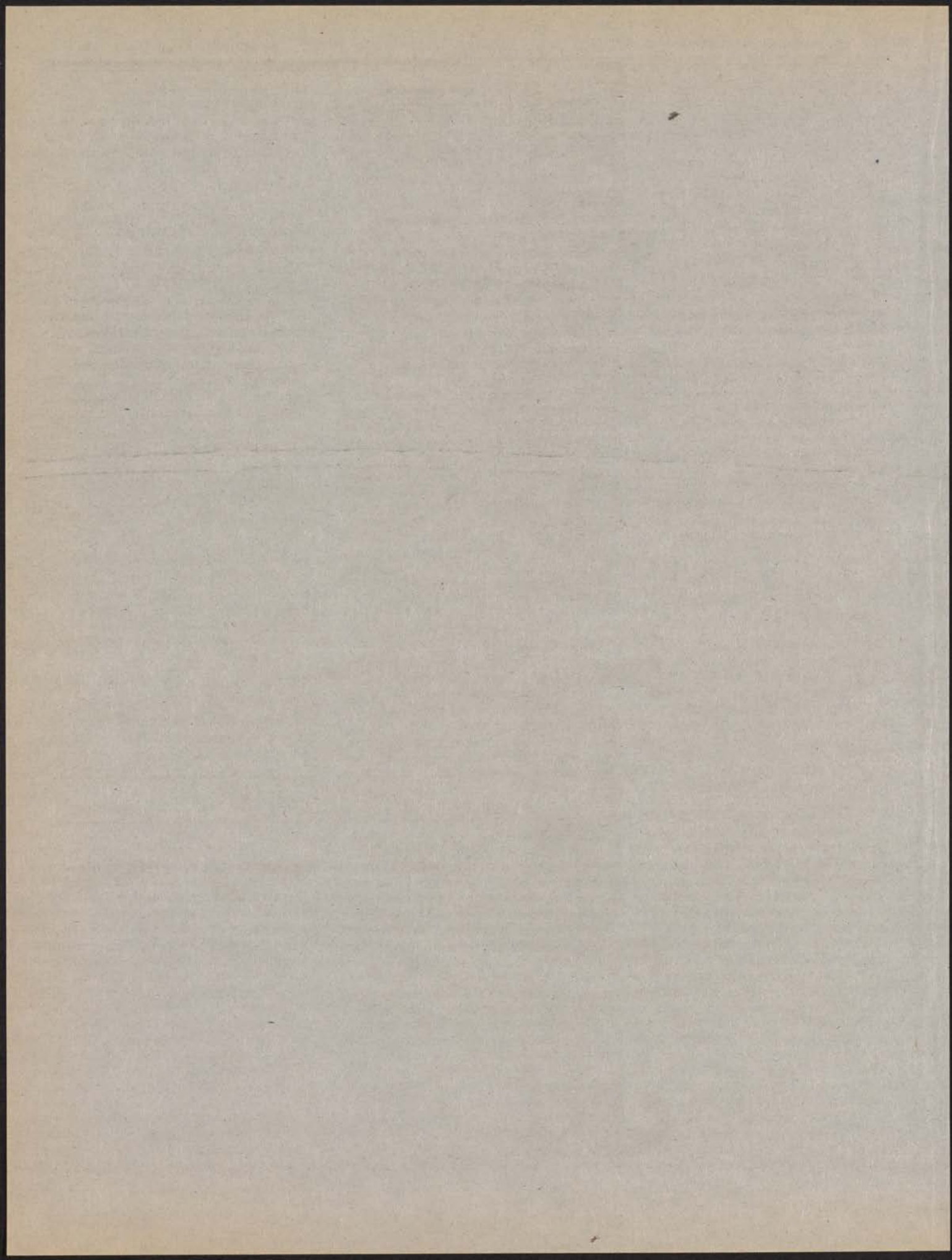
Subpart D—Data Collection [Reserved]

Signed at Washington, DC, this 17th day of December 1992.

Lynn Martin,
Secretary of Labor.

[FR Doc. 92-31075 Filed 12-28-92; 8:45 am]

BILLING CODE 4510-30-M



**Tuesday
December 29, 1992**

Part IV

**Department of
Health and Human
Services**

Food and Drug Administration

**21 CFR Part 316
Orphan Drug Regulations: Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 316

[Docket No. 85N-0493]

RIN 0905-AB55

Orphan Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations to implement section 2 of the Orphan Drug Act, which consists of four sections added to the Federal Food, Drug, and Cosmetic Act (the act). In the Federal Register of January 29, 1991 (56 FR 3338), the agency proposed regulations to implement this section of the Orphan Drug Act. The Orphan Drug Act directs FDA to provide written recommendations on studies required for approval of a marketing application for an orphan drug. It also provides for the designation of drugs, including antibiotics and biological products, as orphan drugs when certain conditions are met, and it provides conditions under which a sponsor of an approved orphan drug enjoys exclusive approval for that drug for the orphan indication for 7 years following the date of the drug's marketing approval. Finally, section 2 of the Orphan Drug Act encourages sponsors to make orphan drugs available for treatment on an "open protocol" basis before the drug has been approved for general marketing. This action will benefit consumers by encouraging manufacturers to develop and make available to patients drugs for diseases and conditions that are rare in the United States.

EFFECTIVE DATE: January 28, 1993.

FOR FURTHER INFORMATION CONTACT: Emery J. Sturniolo, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4718.

SUPPLEMENTARY INFORMATION:

I. Background

In enacting the Orphan Drug Act (Pub. L. 97-414), Congress required FDA to issue regulations for the implementation of sections 525 and 526 (21 U.S.C. 360aa-360bb) that the Orphan Drug Act added to the act. These sections relate to written FDA recommendations on studies required for approval of marketing applications for orphan drugs

and for the designation of eligible drugs as orphan drugs. Accordingly, in the Federal Register of January 29, 1991 (56 FR 3338), FDA issued a notice of proposed rulemaking entitled "Orphan Drug Regulations" for the implementation of these sections as well as for the implementation of sections 527 and 528 of the act (21 U.S.C. 360cc-360dd), which relate to exclusive marketing for orphan drugs and the encouragement of sponsors to make orphan drugs available for treatment on an "open protocol" basis before the drug has been approved for general marketing. This notice of proposed rulemaking will hereinafter be referred to as the "NPRM."

FDA announced that the proposed regulations codified existing administrative practices implementing the Orphan Drug Act as amended. The agency noted that the proposed regulations would, where possible, attempt to ensure that the act's incentives were available only when they would further the purposes of the Orphan Drug Act and that the act should never be used to block significant improvements in the treatment of rare diseases.

II. Summary of and Response to Comments

In response to FDA's NPRM, the agency received 40 public comments. Most comments came from either companies or trade associations of companies that are marketing or hope to market orphan drugs and from two associations representing patients with rare diseases or conditions. FDA has responded to all comments that were received and filed in FDA's Dockets Management Branch. Most comments are proposed in the numerical order of the proposed sections to which they are related.

A. General Comments on the Preamble

1. One comment addressed the following statement in the Preamble: "FDA proposes that this regulation, when final, will apply only prospectively. Therefore, FDA does not plan to reconsider any prior actions under the Orphan Drug Act, or change any orphan-drug status, to conform to the final regulation." (See NPRM, section II.B., paragraph 18). The comment expressed the fear that the prospective-only application of the regulation might mean that FDA would be unable to approve a clinically superior subsequent drug otherwise identical to a pioneer that had been approved and obtained orphan drug exclusive marketing prior to the effective date of this rule.

FDA advises that the fear expressed in the comment is groundless. FDA meant only to rule out reconsideration of previous drug designation and approval decisions. FDA did not mean that it would refuse to approve a clinically superior drug that might not have been approvable prior to promulgation of this rule.

2. Another comment objected to the use of the proposed rule as operational policy prior to issuance of final regulations. The comment argued that the final rule should not apply retrospectively to drugs that held orphan designation prior to the effective date of the final rule.

FDA has not relied on the proposed rule to dictate operational policy during the interim period between the publication of the NPRM and the publication of this final rule. However, FDA decision's during this period have as a matter of fact been consistent with the provisions of the proposed rule. As to retrospective application of the proposed rule, FDA does not regard the application of these regulations to already designated drugs as a retrospective application as long as FDA does not reconsider previous decisions concerning these drugs.

3. One comment stated that designated orphan drugs should be exempt from all investigational new drug application (IND), new drug application (NDA), product license application (PLA), and Establishment License Application (ELA) user fees, as user fees for review of these drugs would be inconsistent with the intent of the Orphan Drug Act.

FDA advises that the question of user fees is outside the purview of this regulation. However, in the future, when and if user fees are considered, designated orphan drugs will be considered for exemption from them.

4. Several comments urged that marketing applications for drugs whose approvals are temporarily barred by the exclusive marketing provisions of the Orphan Drug Act nevertheless be completely reviewed so that they may be quickly approved upon the expiration of the 7 years' exclusive marketing period.

FDA advises that, once the agency determines that approval of a drug would be temporarily barred by the exclusive marketing provisions of the Orphan Drug Act, the timing of the review will be decided on a case-by-case basis by the appropriate division of the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research. Such decisions will be based on time and resource considerations as well as on

the complexity of information to be considered.

5. Some comments argued that the proposed regulations go too far in protecting exclusive marketing rights, while other comments argued that they do not go far enough.

On the whole, based on the legislative history of the Orphan Drug Act and FDA's understanding of its purposes, the agency came to its conclusions by seeking as much as possible to protect the incentives of the Orphan Drug Act without allowing their abuse. FDA believes the final rule achieves the best balance possible between protecting exclusive marketing rights and fostering competition.

B. Sameness Versus Difference

6. One comment suggested that proposed § 316.3(b)(3)(ii) be amended to include a reference to "severe" adverse reactions in addition to "frequent" adverse reactions. Another comment suggested substituting the word "meaningful" for "substantial" in the same paragraph and substituting the phrase, "clinically significant adverse effects" for "relatively frequent effects."

FDA has carefully considered the suggested changes and concludes that it will not amend the final rule as requested because the proposed changes would not add to the clarity of the regulation. The use of the words, "frequent," "meaningful," and "relatively frequent adverse effects" are intended as examples of considerations that might be relevant in determining clinical superiority and are not intended as the only routes to demonstrating greater safety of a drug. FDA's decision not to use the suggested words and phrases does not mean that FDA would not consider less severe adverse reactions in a meaningful portion of the target population or a diminution of clinically significant adverse effects as being evidence of greater safety.

7. One comment pointed out that § 316.3(b)(13)(i) and (b)(13)(ii) should both use the phrase, "intended for the same use," which was used in proposed § 316.3(b)(13)(i) but was omitted from paragraph (b)(13)(ii).

FDA agrees, and the phrase, "intended for the same use," which was inadvertently omitted, has been added to § 316.3(b)(13)(ii).

8. Another comment stated that § 316.3(b)(3)(i) refers to "the same kind of evidence to support a comparative effectiveness claim for two different drugs." The comment asked that FDA make clear that the standard in the NPRM will be consistent with FDA's prescription drug advertising standard,

which requires a showing of clinical significance of the claim.

FDA believes that it is more accurate to draw a comparison between the clinical superiority standard in this rule with FDA's standards for use of such claims in prescription drug labeling found in 21 CFR 201.57(c)(3)(v) (as distinguished from drug standards for advertising).

9. Several comments asked that examples be provided and the difference between "minor" and "major" convenience be clarified as stated in the NPRM preamble statement (section II.E. (56 FR 3341 at 3343)) "This third basis for finding a subsequent drug to be clinically superior is intended to constitute a narrow category, and its proposed use is not intended to open the flood gates to FDA approval for every drug for which a minor convenience over and above that attributed to an already approved orphan drug can be demonstrated."

FDA does not believe that it can anticipate all or even most possible bases for categorizing some contributions as major and others as minor. Each will vary with the facts. Hence, examples could be as misleading as they could be helpful.

10. Another comment proposed that the concept of "active moiety" be applied to macromolecular products as well as to micromolecular products and that differences in active moieties by themselves be used as the sole criterion for establishing product differences.

FDA disagrees, because it does not believe that the concept of active moiety, as used for small molecules, is useful for macromolecular entities. For micromolecular products, the active moiety is the whole covalently bound part of the molecule that is active. This means that it generally consists of all of the molecule except added parts that make it a salt or ester. Essentially, any change in covalent structure creates a new active moiety whose properties may well differ from the old active moiety. With macromolecules, it would be trivially easy to make minor covalent changes that would leave the activity of the drug unaltered, but would create a "different drug" if the micromolecular definition of active moiety were to be used. This would render exclusive marketing of macromolecular drugs meaningless and would decrease incentives to develop orphan drugs. When such a change is meaningful, of course, it deserves, and under the rule would gain, exclusive marketing.

11. A comment suggested that FDA should assume that macromolecular drugs made by different manufacturers are by definition different.

FDA strongly disagrees, because this would result in a de facto exclusion of all biological products from eligibility for exclusive marketing rights, the major incentive of the Orphan Drug Act. Regardless of how similar they were to each other, each sponsor's drug would be entitled to exclusive marketing, or, put another way, would not be kept from marketing by the exclusive marketing status of the prior drug, rendering such status meaningless for these drugs. Because macromolecules, and particularly recombinant products, offer great promise for the diagnosis and treatment of rare diseases and conditions, and because FDA does not believe that Congress intended to eliminate them from the operation of the Orphan Drug Act's exclusive marketing incentive, FDA will not consider every drug manufactured by a different manufacturer to be different for purposes of the act. This matter was fully discussed in the preamble to the NPRM (56 FR 3341 through 3343.)

12. Another comment suggested that the rule should define the term, "arbitrary," (as used in the NPRM, section II.B (56 FR 3339)) and provide examples for greater ease in determining what is "salami slicing" or artificial and medically implausible subsets.

FDA believes that the term "arbitrary" needs no further explanation. The NPRM by implication defines the term "arbitrary" as "medically implausible." Setting forth examples could mislead as easily as it could assist because every FDA decision on arbitrariness would necessarily be highly fact dependent.

13. A comment proposed that:

* * * closely related, complex partly definable drugs with similar therapeutic intent be considered the same if they are derived from the same source and manufactured by a similar process, such as two live viral vaccines for the same indication, would be considered the same drug unless the subsequent drug were shown to possess different quantitative in vitro biologic activity or to be clinically superior.

FDA disagrees. Whereas a difference in in vitro quantitative biologic activity may constitute part of the evidence needed to support a claim of clinical superiority, it will not normally suffice for that purpose. Because such differences do not all correlate with clinical superiority, if no such correlation is independently proven with respect to an orphan drug, no meaningful difference for purposes of the Orphan Drug Act will have been shown. In addition, FDA sees no significance for purposes of the Orphan Drug Act with regard to the source from which the drugs are derived and the processes by which they are

manufactured, unless such factors lead to clinical superiority.

14. Another comment suggested that the NPRM preamble could be read to indicate that glycosylation is not a post-translational modification.

FDA certainly did not intend such a meaning and takes this opportunity to make clear that it views glycosylation as a post-translational modification.

15. The comment addressed in the previous paragraph also stated the view that, under the proposed rule, clinical superiority will always lead to approval of a subsequent drug.

FDA agrees with the comment's viewpoint. Assuming that a subsequent drug's marketing application is otherwise approvable, FDA will not interpret the Orphan Drug Act to block approval of any drug proved to be clinically superior to a drug with currently effective exclusive marketing rights.

16. One comment noted a disparity between: (1) FDA's firmness in requiring comparative clinical trials to demonstrate greater efficacy, and (2) FDA's stated intent to enforce such a requirement only "in some cases" to demonstrate safety.

FDA agrees that reliable information on safety differences may require comparative trials. Valid safety information may, however, come from other sources as well; the agency believes that the requirements for approving a drug because it is safer than an approved orphan drug may not always need to include the conduct of comparative clinical trials.

17. Two comments questioned why FDA treats micromolecular drugs and macromolecular drugs differently.

As discussed in comment 10, and in detail in the NPRM, FDA does not believe that the concept of active moiety, which has been useful when applied to micromolecular drugs, is adequate to deal with the different situation that obtains with macromolecular drugs.

18. Two comments challenged the use of the concept of clinical superiority, contending that the criteria for demonstrating it are insufficiently clear. Also, the comments noted that, to a sick patient, removing even a minor adverse reaction can result in clinical superiority.

FDA agrees that a small demonstrated improvement in efficacy or diminution in adverse reactions may be sufficient to allow a finding of clinical superiority. Despite the agency's inability to define "clinical superiority" as precisely as some would like, the agency believes that it is a useful concept.

FDA also believes that it constitutes the best tool for giving effect to the intent of Congress to provide incentives for potential sponsors to develop safer and more effective orphan drugs.

19. A comment suggested that, as proof of clinical superiority, FDA should always require a demonstration of it in rigorous double-blind, head-to-head comparative clinical trials such as those required to support other comparative safety and efficacy claims. Such studies, according to the comment, should be done using the licensed product and the subsequent product formulated with the same biologically active units and the same excipients.

While randomized double-blind, concurrently controlled clinical trials are usually the most reliable sources of evidence, other kinds of studies can be considered adequate and well-controlled studies within the meaning of (21 CFR 314.126) to support a finding of clinical superiority. This final rule should not preclude that possibility even if concurrently controlled trials will usually be needed. As stated, the kinds of data needed to demonstrate clinical superiority for purposes of the Orphan Drug Act will be the same as the kinds of data required to allow label claims of superiority.

20. Two comments suggested that, for drugs indicated for acquired immunodeficiency syndrome (AIDS) and other similar serious diseases, a lower dose with little or no loss of effectiveness should qualify the drug as clinically superior.

FDA believes that a lower dose per se, without diminution of side effects or enhanced patient convenience should not constitute clinical superiority for purposes of this rule.

21. One comment argued that a subsequent drug should not be approved unless the subsequent drug is shown to be both "materially different" and clinically superior. Specifically, the comment stated, peptides which mimic the active sites of a protein drug should not be considered different from the protein drug.

FDA advises that, under "criterion 3," which states that "two drugs would be considered the same drug if the principal, but not necessarily all, structural features of the two drugs were the same, unless the subsequent drug were shown to be clinically superior" (NPRM, section I.E. (56 FR 3341 through 3342)), which the agency is adopting, either differences in active moiety or clinical superiority will be sufficient to make two micromolecular drugs different. With regard to macromolecular drugs, clinical superiority by itself will render a

subsequent drug different. However, even if clinical superiority cannot be proven, macromolecular drugs may be different because of major differences in molecular structure apart from post-translational events. In other words, FDA believes that there are certain major differences in the chemical composition of drugs that make them different for purposes of the Orphan Drug Act regardless of whether they produce different clinical responses.

As to the peptide example, in order for a peptide that resembles a portion of a protein product to be considered a different drug, FDA will require a clear demonstration that the peptide is clinically superior to the entire protein.

22. One comment suggested that the final rule must state how much superiority would represent a major contribution to patient care.

There is no way to quantify such superiority in a general way. The amount and kind of superiority needed would vary depending on many factors, including the nature and severity of the disease or condition, the quality of the evidence presented, and diverse other factors.

23. Another comment argued that the concept of clinical superiority is neither supported by the act nor appropriately defined. Further, the comment argued that direct comparative clinical trials usually needed to demonstrate clinical superiority would be difficult because subjects would be scarce, the time to perform the trials would exceed the period of exclusive marketing, and the cost would be prohibitive.

Congress left it to FDA to define "such drug" as used in 21 U.S.C. 360cc and provided no guidance on the meaning of this term. Thus, it is within FDA's authority to define what is the "same" and what is a "different" drug. "Clinical superiority" is a rational and permissible means of making this distinction. FDA understands the difficulties inherent in proving clinical superiority but believes the requirement is necessary in order to protect the value of the primary incentive that Congress created in the Orphan Drug Act. If FDA allows exclusive marketing rights to be eliminated without evidence of clinical superiority or based on shoddy evidence, the incentive will be worthless.

24. Several comments argued that FDA must recognize the effect of price on access to patient care and urged that cost considerations must be used in determining whether a subsequent drug makes a major contribution to patient care. On the other hand, several other comments stated that cost should not be a factor in decisions about whether a

drug represents a major contribution to patient care.

FDA agrees with the latter comments. Although FDA understands that costs can indeed have a major impact on access to a drug, FDA has no authority over drug pricing or any authority to consider it in drug approval. Further, considering price as a factor in whether or not a drug makes a major contribution to patient care is problematic. If FDA could approve a drug because its relatively low cost were deemed to constitute a major contribution to patient care, there would be no effective tool that FDA could use to prevent the sponsor of the subsequent drug from quickly raising its price to the level of its competitor's price after approval.

25. Several comments suggested that FDA should liberally construe the concept, "major contribution to patient care." These comments advanced the following examples of factors that the comments would have the agency consider: convenient treatment location; duration of treatment; patient comfort; improvements in drug efficiency; advances in the ease and comfort of drug administration; longer periods between doses; and potential for self administration.

FDA agrees that these factors, when applicable to severe or life-threatening diseases, might sometimes be legitimately considered to bear on whether a drug makes a major contribution to patient care. However, this determination will have to be made on a case-by-case basis.

26. In contrast to the previous comments, three comments argued that the concept of "major contribution to patient care" should be narrowly construed so that only truly important differences could result in a finding of a "major contribution" if greater safety and/or effectiveness are not involved. The comments urged that minor improvements in patient convenience, such as a change that allows for home use of a drug for the first time, or "political considerations" should not qualify and that, in any case, head-to-head comparative clinical trials should be required.

Home use or improved patient access may or may not constitute a major contribution to patient care, depending on the drug and the nature of the disease, among other things. While comparative trials are, of course, preferred and will usually be required, it is possible that, in some circumstances, a demonstration of a major contribution to patient care can be made without such trials.

27. Several comments argued that a subsequent drug should be deemed to be clinically superior to the first approved drug if its delivery system results in enhanced compliance among patients who would otherwise experience compliance difficulties. Examples provided for variations in drug delivery warranting such a finding included: novel inhalation therapy; oral, intranasal, inhalational, transdermal vehicles of administration where intravenous means were once all that was available; innovative time-release delivery mechanisms; the availability of an improved delivery system that eliminates the risk of hemophilia B; and a new parenteral administration that permits once-a-day administration rather than four-times-a-day injections or infusions.

FDA agrees that a change in drug delivery systems might in some cases constitute a major contribution to patient care, but this can only be decided on a case-by-case basis, considering the nature of the disease or condition, the nature of the drug, the nature of the mode of administration, and other factors.

28. Three comments stated that investigational drugs that are significantly purer than approved drugs should be considered clinically superior without comparative clinical trials. An example provided was investigational factor IX products, which are 90 percent factor IX as compared to currently marketed factor IX products, which are only 10 percent factor IX.

If sponsors provide evidence to demonstrate that an improvement in purity will cause a drug to meet one or more of the criteria for clinical superiority, FDA will consider such evidence, which should normally include comparative clinical trials.

29. A comment argued that the NPRM ignores the precedent set in *Genentech v. Bowen and Young*, 676 F. Supp. 301 (D.D.C. 1987), in which the court allegedly held that one amino acid difference made a different drug. The comment argued that the final rule should reflect this alleged holding in order to allow FDA to fend off future legal challenges.

FDA disagrees with the comment's characterization of the *Genentech v. Bowen and Young* holding. In that case, the court held only the orphan-drug designation of a subsequent drug during the pioneer's period of exclusive marketing was lawful because the subsequent drug was of synthetic origin and did not present the danger of contamination with disease that the pioneer, which was manufactured from human cadavers, did. Although in that

case it was argued that one amino acid difference made a different drug, the court never so held. For reasons described above (see comment 10) and in the NPRM, FDA has not adopted this principle in the final rule.

30. One comment suggested that differences in those parts of macromolecules demonstrated to be important for function should form the basis for determining whether two given molecules are different.

Although some changes in critical parts of the molecule, e.g., in the primary structure at the active site, would alter the function of the macromolecule, FDA does not agree that any change in the part of a molecule important for function should be considered a basis for defining a drug as different. Many changes, even in those parts of the molecule, would be of no significance. The agency believes that the changes that are of significance can be evaluated in preclinical laboratory and animal studies and in clinical trials, and, if they show promise of causing a chemically significant difference, the sponsor can develop the drug and demonstrate the difference. A showing of such a difference would represent a basis for approving the drug as a different drug.

31. Another comment urged FDA to develop a guidance document describing differences in amino acid sequence of a protein which would be considered "minor."

FDA declines to set forth hypothetical situations of the kind asked for, as such determinations will be highly fact-dependent.

32. One comment urged that function should play some role in defining when drugs composed of protein are the same. When drugs show similar qualitative activity that appears related to their effectiveness, in vivo or in vitro, the comment said, and the amino acid sequence of the subsequent product is coincident with that of the pioneer, the drug should be considered the same drug.

FDA agrees with the comment generally. Under the criterion 3 proposed for adoption in the NPRM (see comment 21), drugs with similar qualitative activity and similar amino acid sequence would not be considered different from the pioneer unless some clinical superiority could be demonstrated.

33. One comment urged that FDA should deem a drug different from the pioneer if FDA would require a full NDA with original supporting data before approving the subsequent drug. The comment found this approach preferable to "FDA's proposed mixture

of sometimes relying on physical structure, sometimes relying on functional effect, sometimes refusing to consider functional effect, and making presumptions about whether particular physical structures are likely to have a functional effect * * *."

In developing the NPRM, FDA considered deeming drugs to be different if the agency would normally require a full NDA or PLA with original supporting data before approving the subsequent drug. However, such a rule would make it too easy to break exclusive marketing by making small modifications in molecular structure or in the drug's indications, changes that would usually trigger a requirement for a full NDA. Indeed, for many complex macromolecular products, there is no degree of similarity that would lead to approval of an application without a full NDA or PLA. This would mean that most macromolecules would be ineligible for exclusive marketing rights, an outcome that, for reasons described above, does not seem compatible with the purpose of the Orphan Drug Act.

34. One comment requested that FDA make available the report of the Institute of Medicine, National Academy of Sciences (IOM) concerning issues discussed in section II.E. of the NPRM, i.e., reasonable criteria for identifying drugs as different for purposes of determining orphan-drug exclusive marketing rights.

The report of this workshop, held on November 19, 1990, is available from National Academy Press (Report of a Workshop, "Microheterogeneity of Biological Macromolecules," Forum on Drug Development, 1991. Division of Health Science Policy, Institute of Medicine, National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418).

As was mentioned in the preamble to the proposed rule (56 FR 3338 at 3343), FDA's choice of the third criterion (NPRM, section II.E. (56 FR 3338 at 3341 through 3342)) in the NPRM and in this final rule is consistent with the discussions at the IOM's "Workshop on Microheterogeneity of Biological Macromolecules."

C. Written Recommendations for Investigations of Orphan Drugs

35. One comment expressed a view that information on the current regulatory and marketing status and history of the drug product that the sponsor is required to submit under proposed § 316.10(b)(7) should be specific only to the sponsor's regulatory and marketing activities.

In order to provide useful recommendations on the studies

necessary to support marketing approval of a drug, FDA needs whatever information is known or accessible to the sponsor concerning approved indications, recalls, adverse experience, other uses, abuse potential, etc., on the drug. This would include both the sponsor's regulatory and marketing activities and those of others about which the sponsor knows or could reasonably find out about.

36. Two comments requested that FDA inform sponsors, as soon as possible, when the agency no longer believes that its (previously given) recommendations are adequate to obtain marketing approval and give the reason for its change of opinion along with the scientific rationale.

FDA does not have the resources to monitor all factors affecting continued validity of all guidance previously given. Therefore, FDA must place the burden on the sponsor periodically to seek confirmation that the recommendations it received from FDA still apply. This is not difficult if the sponsor is in frequent touch with FDA's review divisions and if the sponsor diligently reviews literature on relevant subjects. FDA will undertake to respond to specific inquiries by a sponsor concerning any change of FDA's position or previous advice.

37. Another comment suggested that FDA should, on request, provide recommendations concerning how to prove clinical superiority of a drug in order to show that it is "different" within the meaning of proposed § 316.3.

FDA advises that, if asked such a question, FDA will ordinarily recommend head-to-head clinical trials between the drugs, as this will normally be what is necessary to demonstrate clinical superiority to FDA's satisfaction. In addition, FDA may suggest endpoints for such studies.

38. Another comment requested that FDA develop a mechanism to notify sponsors early in the development process whether their drugs are the same as one being developed by another sponsor and whether either drug is considered a macromolecular drug or a micromolecular drug.

FDA advises that information on the existence of investigational products generally is confidential and may not be disclosed. In addition, FDA would normally not be able to determine whether drugs are the same or different until all data for marketing applications for both drugs are submitted. Hence, FDA declines to provide the requested early information and advice.

39. Another comment expressed concern that small firms are disadvantaged compared to multi-

national corporations with respect to their ability to learn about parallel research of another firm on the same drug. To investigate this possible bias against small firms, the comment proposed a full-scale economic assessment of this rule.

FDA does not agree that small firms are at a unique information disadvantage when developing orphan drugs. Imperfect knowledge about competitors' research is an expected risk factor in any research program, and, while small firms are inherently less able to tolerate excessive financial risk-taking, imperfect knowledge about competitor research is probably a less important risk factor for orphan drugs than for other pharmaceuticals. Orphan product development has been extensively publicized, both in the trade press and in sponsors' and investigators' efforts to locate test subjects, so that subsequent researchers in product areas where high research costs are likely almost always to have considerable information about competitors' efforts. Even if small firms had such a disadvantage, FDA cannot make confidential commercial information available. Therefore, FDA believes that a full-scale economic assessment of this aspect of the rule would be pointless.

40. Several comments suggested that FDA adopt time limits for response to requests for written recommendations as well as responses to requests on all matters associated with administration of the Orphan Drug Act.

Due to resource limitations, FDA cannot now impose time limits on itself for response to applications and requests pursuant to the Orphan Drug Act. However, the agency will respond to requests as expeditiously as its resources will allow.

41. One comment asked that the rule include the address for submitting requests for FDA action under this rule.

FDA agrees and has added the address of the Office of Orphan Products Development to the final rule in new § 316.4.

D. Designation of Orphan Drugs Based on Prevalence

42. Another comment recommended the removal of the requirement that a drug be designated as an orphan drug in order for the sponsor to be entitled to apply for orphan-product grants. The comment expressed a need for grants to support clinical studies on orphan devices and medical foods.

FDA advises that the Orphan Drug Amendments of 1988 (Pub. L. 100-290) provided that medical foods and medical devices for rare disease or conditions are eligible for grants and

contracts to support clinical studies of safety and effectiveness. The preamble to the NPRM was in error to the extent that it implied the contrary. FDA solicits grant applications for clinical studies on medical devices and medical foods as well as on drugs and biologicals intended for rare diseases or conditions.

43. One comment suggested that there should be a process for designating medical foods and medical devices for rare diseases or conditions in light of the fact that the act now recognizes these and provides for grants and contracts to support clinical studies on these products.

FDA does not agree that a process for designating medical foods and medical devices for rare diseases or conditions is necessary. Although eligible for grants and contracts, sponsors of orphan medical devices and medical foods are not eligible for exclusive marketing rights. Hence, the main purpose for designation does not exist so far as these products are concerned. Further, with respect to grants and contracts, FDA's experience to date shows that a designation process would be unnecessary in order to establish eligibility for grants and contracts.

44. On its own initiative, FDA is adding to § 316.20(b)(4) a requirement that a description of the product for which orphan-drug designation is requested be submitted with the application for designation. This obviously important requirement clearly was within the scope of the NPRM and its omission was an oversight.

45. A comment requested that FDA make clear that the agency can grant orphan-drug designation to new versions of currently marketed orphan drugs if they are clinically superior to the original.

Orphan-drug designation can be granted to new sponsors of drugs currently protected by orphan-drug exclusive marketing if such sponsors provide a plausible scientific rationale in an application submitted pursuant to § 316.20 that studies to be conducted on the drug may result in a finding of clinical superiority over the marketed drug.

46. Another comment stated that authoritative information required to establish prevalence of a disease or condition and/or cost recovery estimates may not be available and the final rule should require only the best information available or all available references known to the sponsor.

FDA expects that applicants for orphan-drug designation will make every effort to survey the literature and obtain all information available on the prevalence of the indicated disease or

condition and cost and marketing information, where required. Obviously, if information is not available, it cannot be submitted, but FDA expects sponsors to make a diligent search.

47. A comment expressed a fear that basing the prevalence criterion on the number of diagnosed patients who could benefit from the treatment makes possible orphan designation for a drug with a huge patient class.

FDA acknowledges that improved methods of diagnosis, better screening, or altered attitudes towards the need for therapy may produce a large increase in the number of patients who are diagnosed with a disease and could benefit from a drug. Prior to the development of such new diagnostic methods, better screening or new attitudes, however, FDA has no way of determining the likely treatment population other than by relying on current diagnostic methods and treatment attitudes.

48. A comment stated that it is unclear how FDA intends to handle investigational orphan drugs that are also being studied for common indications.

FDA advises that when a drug is being studied for a common as well as a rare disease, the rare disease indication will be handled just as it would be for a drug being studied only for a rare disease.

49. A comment requested that the agency provide substantive guidance, clarification, or definition on how an applicant can demonstrate that a subset of patients is "medically plausible."

FDA declines to provide examples of medical plausibility or to further develop the definition of this term. Application of the concept is a matter of judgment based on the specific facts of each case. Also, any hypothetical examples FDA might provide could well be misleading.

50. One comment argued that the proposed requirement that sponsors show the actual number of diagnosed cases in order to obtain orphan drug designation would be burdensome. For many diseases, the comment argued, there is little epidemiological data giving the actual number of affected patients. It suggested that the appropriate number for determining prevalence of a disease is one which reflects both diagnosed and undiagnosed people.

FDA has already stated its strong preference for counting only diagnosed symptomatic patients in determining prevalence as the best approach to fulfill the purposes of the Orphan Drug Act. There is a lack of existing data and of precise methods for identifying the number of undiagnosed and asymptomatic patients who have a given

disease. To impose such a requirement would add considerably to the cost of submitting requests for orphan drug designation without significant improvement of the factual bases for such requests.

51. Another comment agreed with the requirement that sponsors demonstrate that the actual number of diagnosed cases does not exceed 200,000 persons in the United States as of the date of application of designation. However, the comment requested that the agency go further and include the requirement in the final regulation itself rather than just in the preamble.

FDA agrees and is amending § 316.21(b) in the final rule accordingly.

52. Two comments argued that the requirement in proposed § 316.21(b)(2) that a sponsor show estimated prevalence of any other disease or condition for which the drug has been approved or is being developed is immaterial and burdensome.

The agency has reconsidered the proposed requirement and decided that such information would only be necessary in special circumstances, and will not be routinely required to make a decision on applications for designation. The regulation has been revised to require the information only upon request by FDA.

53. One comment suggested that FDA should divulge its sources and the processes whereby it verifies that the sponsor's prevalence data are correct.

FDA will on request provide a list of its sources used for verification of its conclusion as to the prevalence of a disease or condition. In the process, FDA will not provide any materials which it is obligated to treat as trade secret or confidential.

54. A comment suggested that in the case of vaccines, disease prevalence should be calculated based on an average annual target population over the prior 7 years rather than on the target population at the time of submission of the application for orphan designation. This, the comment argued, would provide greater predictability to the prospective sponsor of an orphan vaccine.

Under the terms of 21 U.S.C. 360bb, determinations "shall be made on the basis of the facts and circumstances as of the date such drug is designated * * *." FDA has interpreted this language to require that estimates of target population should reflect numbers of persons who would receive the vaccine as of the date of designation. The agency does not believe that the law contemplates the use of predictive models for growth or decline of disease populations.

55. Another comment stated that, because data on the side effects of cancer or its treatment are limited or nonexistent, sponsors requesting designation of drugs for patients refractory to primary cancer therapies or other cancer subgroups should be able to rely on references to published incidence data, mortality tables, and expert medical testimony.

FDA advises that, where data are limited, sponsors should provide the best data available. Where published incidence data, mortality tables, and expert medical testimony are all that is available, this will normally be sufficient.

The comment further recommended that the final rule provide guidance including references to methods for deriving estimated prevalence data by using published incidence data.

FDA declines to provide such guidance as part of this published final rule but will provide data on methods of extrapolation when asked about this by potential sponsors regarding specific diseases.

56. One comment argued that FDA should provide for denial of designation if it is obvious that the drug will be used for nonorphan diseases or conditions with prevalence in excess of 200,000.

FDA will deny an orphan-drug designation application if it finds that the proposed orphan indication is a counterfeit, i.e., an artificial subset of the total population of potential users of the drug. However, the agency will continue to grant orphan drug designations for drugs that are being investigated for or are already approved for common diseases and conditions when there is also a rare disease for which the drug may be useful and is being studied, if the drug meets the orphan-drug criteria. The incentives of the Orphan Drug Act are needed to encourage testing and development of drugs for rare diseases or conditions even when a drug in question is being tested or approved for a more common indication. Otherwise, sponsors may be deterred by the lack of potential profit from testing drugs for rare diseases.

57. One comment suggested that § 316.26, which deals with amendments to orphan-drug designation, be broadened to allow such amendments when there are changes in medical technology or where diagnostic capabilities for a disease are improved.

FDA agrees that such changes are warranted, but only when the advances concerned are unanticipated. FDA has amended the final rule to this effect.

58. Several comments suggested that orphan-drug designation and exclusive marketing should be revoked when FDA

determines that a drug that it has designated is later proved to have commercial potential or when the prevalence of the indicated rare disease or condition later exceeds 200,000 people in the United States.

FDA advises that legislation that would have authorized FDA to take such actions was vetoed by the President in 1990.

59. One comment argued that FDA had not sufficiently considered when and on what terms it will suspend (as distinguished from revoke) an orphan drug designation under § 316.29. The comment inquired as to when and under what terms FDA would restore a suspended designation.

After considering this comment, the agency concludes that it should not suspend an orphan drug designation on the grounds stated in § 316.29 but should only revoke it. The possibility of suspension raises troublesome questions about bases for and conditions of reinstatement of designation and the rights of subsequent sponsors. Hence, FDA has decided that, when the conditions set forth in § 316.29 occur (untrue statement of material fact, or omission of material information, or ineligibility of the drug at the time of designation), the appropriate remedy is permanent revocation of designation and suspension or withdrawal of exclusive marketing rights, with no eligibility for reinstatement of such rights. FDA has amended § 316.29 to reflect this conclusion.

E. Designation of Orphan Drugs Based on Nonrecovery of Cost

60. One comment concerning § 316.21 suggested a different approach for verifying data estimates and their justifications. The comment suggested that the sponsor be required to obtain an independent certified public accountant (CPA) report on certain agreed-upon procedures with respect to data, estimates and justification provided. Next, FDA, the sponsor, and the CPA would agree on procedures tailored to address matters of specific interest to the agency. Then, the independent CPA would report on the results of applying these procedures in a summary of findings—negative, assurance, or both. Lastly, the level of assurance provided in the independent CPA's report on how the agreed upon procedures would be applied would depend on the nature and scope of the procedures.

The comment suggested the following specific change in the text of § 316.21(c)(8):

(8) the sponsor shall submit a report of an independent Certified Public Accountant in accordance with Statement on Standards for

Attestation established by the American Institute of Certified Public Accountants on agreed upon procedures performed with respect to the data, estimates, and justifications submitted pursuant to this section. Cost data shall be determined in accordance with generally accepted accounting principles.

FDA agrees that the suggested change is appropriate and has added the quoted passage to the final rule.

61. A comment stated that FDA has seriously underestimated the impact on multi-national corporations of demonstrating a lack of profitability in light of the fact that multi-national corporations will find it very difficult to collect information on the costs of orphan drug development and to separate those costs from costs of other research and development activities. According to the comment, the requirement of collection and separation will discourage use of orphan-drug incentives by multi-national corporations.

FDA believes that, although multi-national corporations may face problems that others do not, the potential benefits of orphan drug exclusive marketing would seem to outweigh the burden of separating costs between profitable ventures and orphan drug research and development projects.

62. Another comment correctly noted a typographical error in § 316.24(a): A reference to § 316.26, should have been a reference to § 316.25.

The error is being corrected in the final rule.

63. A comment suggested that orphan-drug designation should be denied for drugs that are likely to have commercial and competitive viability, even in small populations. The comment expressed concern that the exclusive marketing provisions of the act will limit the competition that has existed among manufacturers of blood clotting factor in the past. Alleging that this competition has kept prices down.

Existing provisions of the act do not provide a "commercial viability" basis for denial of requests for orphan drug designation when such drugs are for populations of 200,000 or less. Indeed, upon enacting an amendment to the Orphan Drug Act in 1984, Congress expressed its determination to accept the possibility that a designated orphan drug might be commercially viable with or without orphan drug exclusive marketing. (See 130 Congressional Record, S.14254 Floor Debates, October 11, 1984).

F. FDA Procedures

64. On its own initiative, FDA has added new § 316.30, requiring sponsors

of designated orphan drugs to submit annual reports detailing progress made in the development of their orphan drugs in the past year. The agency believes that this provision is within the scope of the NPRM and will allow FDA to follow the development of orphan drugs and to identify and help to remove roadblocks to drug development and marketing.

65. A comment concerning § 316.27 argued that submission to FDA of copies of agreements embodying transfers of ownership of orphan-drug designation rights should be voluntary and not mandatory.

FDA agrees, and § 316.27(a)(2)(iii) has been changed in the final rule to make clear that either a list of rights assigned and reserved or copies of relevant agreements will meet the requirement of this paragraph.

66. Several comments argued that FDA should establish a process whereby the agency routinely informs sponsors when they are investigating drugs whose approval is likely to be barred by the Orphan Drug Act.

FDA believes that it is now adequately making this information available. The agency provides a list (updated monthly) of all designated orphan drugs to all sponsors who file a request for orphan-drug designation. Additionally, this list is available upon request from the National Information Center for Orphan Drugs and Rare Diseases (NICODARD), P.O. Box 1133, Washington, DC 20013-1133 (phone 1-800-456-3505). Hence, no new procedure is necessary.

66a. On its own initiative, FDA is revising proposed § 316.28 to reflect current practice of making available monthly an updated list of all designated orphan drugs and making available annually a cumulative updated list of all designated orphan drugs. In the past, the agency published an annual list in the *Federal Register*; however, it has found that its current practice is a more effective means of making the information available in a timely manner. The lists are on display at the FDA Dockets Management Branch and are available from NICODARD (see comment 66).

67. Several comments by holders of orphan-drug exclusive approval requested that such holders be accorded notice and an opportunity for a hearing when faced with the imminent approval of a similar drug that FDA considers to be a different drug for purposes of the act.

On March 4, 1987, in response to a citizen petition filed by Genentech, Inc., FDA declined to establish such a challenge procedure, citing the

following grounds: (1) There is no property right to exclusive approval under the Orphan Drug Act; and (2) procedures are already in place that accord a holder of exclusive approval all the process that would be due under these circumstances. These procedures include the citizen petition procedure (21 CFR 10.30) and a right of subsequent judicial review in the courts.

In the NPRM (section II.I. (56 FR 3344)), FDA cited the following reasons for declining to create such procedures: (1) Neither the Constitution, nor the Administrative Procedure Act, nor the Orphan Drug Act requires a hearing of this kind; (2) hearings are time consuming and resource intensive; and (3) the citizen petition procedure is available to a holder of exclusive approval. Furthermore, in the NPRM, FDA refused to propose creation of a less formal nonhearing administrative challenge procedure because: (1) There is no requirement for it under the Constitution or any statute; (2) postdecisional judicial review is preferable to an administrative challenge procedure because a predecisional challenge procedure would be time consuming and could be used for purposes of delay; (3) it would be difficult to determine who should have the right to challenge an incipient approval and who would be entitled to what notice of what anticipated agency action; and, finally, (4) a predecisional administrative challenge procedure would present difficulty due to the nondisclosability of relevant information under FDA's public information regulations.

Despite a careful reconsideration of its position on the question of establishing predecisional challenge procedures, the agency declines to adopt such procedures. The other reasons given in the NPRM for declining to do so are still valid and even if a reviewing court were to hold that orphan drug exclusivity is a constitutionally protected property right, such a holding would not automatically require that a firm whose drug has been granted exclusivity be accorded a predecisional hearing. *Matthews v. Eldridge*, 424 U.S. 319 (1976); *Mackey v. Monttrym*, 443 U.S. 1 (1979); *Barry v. Barchi*, 443 U.S. 1 (1979). Under these and other cases, the "property" right to exclusive marketing, if it exists, does not always require that a hearing take place before approval of what FDA concludes is a similar but different drug.

FDA is still persuaded that its current regulations satisfy any applicable requirement of due process. Insofar as notice is concerned, in FDA's view, a holder of exclusive approval would

learn that a potential competitor drug has been designated, as FDA is required to publish all such designations. See 21 U.S.C. 360bb(c) and § 316.52(d), the latter of which is codified by this notice. As to a procedure for challenging an approval, either impending or after the fact, the citizen petition procedure provides such a procedure, and the holder of the earlier designation has a right to seek judicial review of an adverse decision. This procedure is sufficient under *Barry v. Barchi*, *supra*.

In addition, FDA is still concerned about the potential for holders of exclusive approval to delay the marketing of competitors' approvable subsequent drugs by use of any challenge procedure. The fact that all challenge procedures, particularly hearings, are time consuming and expensive, adds to FDA's reluctance to create such procedures.

For the above reasons, FDA has, after careful consideration, decided that the final rule should not include an opportunity for a hearing or other challenge procedures for holders of exclusive approval to challenge subsequent drug approvals.

68. One comment argued that FDA should notify sponsors of marketing applications for orphan drugs when another sponsor of the same drug for the same use has attained orphan drug exclusive marketing status. The comment suggested that the sponsor barred from marketing approval by orphan drug exclusive marketing should be informed, within 30 days, of the approval of the drug receiving exclusive approval.

FDA disagrees. As stated previously, FDA usually does not know that approval of a marketing application is barred by the Orphan Drug Act until the review of that application shows that the subsequent drug is the same as the pioneer. Hence, FDA cannot set a time limit on notification of subsequent sponsors. In addition, FDA routinely publicizes all marketing application approvals. Therefore, it is reasonable to expect that subsequent sponsors can, with minimal effort, learn of these approvals.

G. Orphan-Drug Exclusive Approval

69. A comment suggested that § 316.30 be reworded to allow more than one company to share exclusive marketing rights if the first company to obtain FDA approval agrees.

FDA advises that § 316.30(a)(3) provides that a holder of exclusive approval may give consent for other marketing applications to gain approval. This provision enables the holder to share exclusive marketing rights with

any number of other sponsors. The agency believes that the current wording of this paragraph need not be changed in order to achieve the objective of the comment.

70. A comment requested that the high cost of an orphan drug be considered evidence that "sufficient quantities" of the drug are not available "to meet the needs of persons with the disease or condition for which the drug was designated." Such a finding would then allow for the approval of subsequent identical drugs.

FDA does not have the authority under existing law to equate high cost with lack of sufficient quantities, even though cost may affect access to a drug. As Congress used the term, "sufficient quantities" refers only the presence of enough drug and the means of its administration to meet the needs of all in the United States with the disease or condition for which the drug was designated.

71. Two comments urged that § 316.36 clearly set forth the criteria and procedure for a determination of whether "sufficient quantities" are available. One comment suggested that the lack of sufficient quantities must be "long-term" or "deliberate."

Alternatively, the comment suggested that a finding of a lack of commitment on the part of the exclusive marketing holder should be necessary to break exclusive marketing. A third comment suggested as a standard for agency action the inability to provide the drug for 1 year. Two comments requested that FDA make allowances for temporary production difficulties, disruptions caused by natural disasters, interruptions in supplies and component parts, economic crises, or other causes beyond the holder's control. One comment suggested that the sponsor should be given adequate time to restore supplies and that the revocation should not occur unless another sponsor can supply at least 75 percent of the market at least 12 months earlier than the first-approved sponsor. This comment urged a right of appeal by the pioneer.

FDA advises that it will act quickly to approve another marketing application when there are insufficient supplies of the drug or insufficient means of its administration for any reason. In granting FDA authority to revoke exclusive marketing because of insufficient quantities, Congress did not refer in any way to the behavior or attitude of the initial holder, and revocation is in no sense a punishment. The provision exists solely in order to get drugs quickly to the people who need them. Accordingly, in determining

whether there are "sufficient quantities" of a drug, FDA will always make the needs of patients its primary concern. For the same reason, the agency declines to create an administrative appeals process for reviewing decisions under § 316.36.

72. Another comment proposed that FDA impose, as a condition of maintaining exclusive marketing rights, a requirement that holders of such rights must sell whatever quantities are necessary to subsequent sponsors in order to conduct required comparative studies. If the holder refused, it would be given 60 days to comply or lose exclusive marketing rights.

FDA believes that most subsequent sponsors will have access to the holder's product. However, if that is not the case, FDA would be without authority to impose the condition described. Congress has set forth only two situations in which exclusive marketing rights can be removed. The situation described above is not one of them.

73. Another comment, which agreed with FDA's decision to rule out cost considerations in determining the existence of sufficient quantities of orphan drugs, suggested that the agency amend the final rule to specify that no authority to do so exists.

FDA believes that statements in the preambles to the NPRM and to this final rule are sufficient notification that the agency believes it lacks authority to consider costs of drugs in rendering decisions under § 316.36. Hence, no change in the rule is necessary.

H. Open Protocols

74. One comment argued that FDA should make clear that the final rule will require parallel controlled studies in order to obtain marketing approval. The comment noted that open protocols may be a threat to encouraging placebo-controlled studies for marketing approval.

FDA understands that the existence of open protocols may increase the difficulty of recruiting subjects for placebo-controlled studies. However, Congress has mandated that FDA encourage open protocols, and this final rule will do so. This does not mean that FDA is relaxing its standards for the approval of drugs. The requirements for demonstrating safety and effectiveness are not any less for orphan drugs than for any other drugs.

I. Availability of Information

75. One comment suggested that § 316.52 should be amended to provide that notice in the *Federal Register* be published concurrently with each orphan-drug designation decision.

FDA disagrees with this suggestion. A current list of drugs designated as orphan drugs is freely available from NICODARD (see comment 66 for address and telephone number). Publishing each orphan-drug designation in the *Federal Register* would be an unduly burdensome task.

76. A comment suggested that as much information as possible regarding details about designated orphan drugs and applications for designation should be made available because of the public's "right to know."

FDA advises that the agency releases as much information as it can consistent with the Freedom of Information Act, FDA's regulations, and long-standing policies concerning the protection of trade secret data and confidential commercial information.

77. Two comments suggested that FDA inform a holder of exclusive marketing rights when a subsequent sponsor has applied for designation for the same drug for the same indication and that a decision concerning the sameness or difference of the products should be made prior to the decision to designate the second drug.

FDA disagrees. As previously stated, current information on all designated orphan drugs is available from NICODARD (see comment 66). FDA is treating the filing of applications for designation as a submission of confidential information which will not be disclosed until and unless designation is granted. In addition, for reasons stated previously, FDA cannot make preliminary decisions as to the sameness or difference of any two drugs. Also, as stated in the NPRM preamble, FDA will designate a structurally identical subsequent drug as an orphan drug, even in the face of a holder's exclusive marketing rights, if the subsequent sponsor advances a plausible basis on which to conclude that its product may be proven "clinically superior." This is because FDA does not want to stifle research and development of potentially better drugs.

78. One comment stated that the impact of the regulation would be "major" for purposes of Executive Order 12291, which requires extensive regulatory impact and flexibility analyses prior to promulgation of regulations having a "major" impact on small businesses. The comment added an opinion that such an analysis would demonstrate that the agency's "original test" (the comment's meaning for this term is unclear) for determining sameness/difference presented a more cost-effective alternative without the adverse effect on competition, unlike the proposed policy.

FDA disagrees with the premise that analyses under Executive Order 12291 are the appropriate means for evaluating the relative usefulness of methods for determining sameness/differences. FDA has consulted with the IOM in developing the adopted approach and will evaluate and propose revisions to the approach if necessary in the interests and needs of people with rare diseases and conditions.

79. One comment stated that FDA should be required to prepare an economic impact statement under the Regulatory Flexibility Act on grounds that the proposed rule adversely affects a significant number of small entities.

FDA disagrees because the overall impact of the Orphan Drug Act benefits small businesses, many of which would otherwise be unable to bear the substantial cost of new product development. Moreover, the economic effects of the proposed rule, and the final rule, are simply those contemplated by Congress in its enactment of the Orphan Drug Act. (See the discussion below in section III.)

III. Economic Impact

The agency has examined the economic impact of the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354) and concludes that this is not a major rule as defined by Executive Order 12291 and will not have a significant impact on a substantial number of small entities.

It is clear that the Orphan Drug Act, as implemented by existing administrative practices, has significantly increased the rate at which new orphan drugs are marketed. While two or three drugs that might be eligible as orphan drugs were approved annually prior to the Orphan Drug Act, an average of eight designated orphan drugs have been approved per year and marketed since 1984. Moreover, orphan-drug designation has been granted to an average of 41 drugs per year since 1984. Thus, the Orphan Drug Act, as implemented since 1983, has provided an effective stimulus for the development and marketing of drugs for diseases or conditions that are rare in the United States. In debating the need for orphan drug exclusive marketing, Congress weighed the potential dangers of granting orphan drug exclusive marketing, which would limit competition, against the benefits to be gained by encouraging sponsors to develop drugs of marginal commercial value. In passing the law, Congress determined that the benefits exceeded the dangers. Any form of exclusive marketing may have negative

consequences, such as noncompetitive pricing. To date, however, there has been insufficient experience with the implementation of the statute to judge whether an optimal benefit-cost balance has been attained. It is clear, nonetheless, that these incentives have been highly successful in contributing to the development and approval of orphan drugs that would not otherwise have been developed. Thus, in FDA's view, the essential benefit-cost considerations of Executive Order 12291 have been satisfied in favor of the rule as here published.

The agency also recognizes that changes in the statutory incentive structure would theoretically produce corresponding changes in the level of benefits, i.e., the number of orphan drugs developed. FDA, however, concludes that further incremental analysis of the statutory provisions would be highly conjectural and beyond the availability of meaningful data from experience to date.

The Regulatory Flexibility Act requires that the agency consider the impact of the regulation on small entities. FDA believes that these rules benefit, rather than disadvantage, most affected small businesses. Prior to enactment of the Orphan Drug Act, few small businesses could afford to devote resources to the discovery of new treatments for rare diseases, because the small market for such products severely limited the profitability of this research. Subsequent to enactment, the combined stimulus of research grants, tax credits, and exclusive marketing influenced many small firms to develop new products for formerly inaccessible markets. FDA finds therefore that, in general, the incentives provided under the act will serve to enhance the viability and competitiveness of small entities.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1980

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The information collections will not be effective until OMB approval is obtained. The title, description, and identification of those who will respond to the information

collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Orphan Drug Regulations.

Description: These final regulations specify the procedures for sponsors of orphan drugs to use in availing themselves of the incentive provided for in the Orphan Drug Act and set forth the procedures FDA would use in administering it.

Description of Respondents: Businesses or other for-profit organizations.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	Annual number of respondents	Annual frequency	Average burden hours per response	Annual burden hours
316.2 and 316.10 ..	3	1	125	375
316.20	90	1.78	125	20,025
316.22	5	1	2	10
316.27	5	1	4	20
316.30	450	1	2	900
316.36	0.2	3	15	9
Total				21,339

List of Subjects in 21 CFR Part 316

Administrative practice and procedures, drugs, Orphan drugs, Reporting and recordkeeping requirement.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 316 is added as follows:

PART 316—ORPHAN DRUGS

Subpart A—General Provisions

- Sec.
- 316.1 Scope of this part.
 - 316.2 Purpose.
 - 316.3 Definitions.
 - 316.4 Address for submissions.

Subpart B—Written Recommendations for Investigations of Orphan Drugs

- 316.10 Content and format of a request for written recommendations.
- 316.12 Providing written recommendations.
- 316.14 Refusal to provide written recommendations.

Subpart C—Designation of an Orphan Drug

- 316.20 Content and format of a request for orphan-drug designation.
- 316.21 Verification of orphan-drug status.
- 316.22 Permanent-resident agent for foreign sponsor.

- 316.23 Timing of requests for orphan-drug designation; designation of already approved drugs.
- 316.24 Granting orphan-drug designation.
- 316.25 Refusal to grant orphan-drug designation.
- 316.26 Amendment to orphan-drug designation.
- 316.27 Change in ownership of orphan-drug designation.
- 316.28 Publication of orphan-drug designations.
- 316.29 Revocation of orphan-drug designation.
- 316.30 Annual reports of holder of orphan-drug designation.

Subpart D—Orphan-drug Exclusive Approval

- 316.31 Scope of orphan-drug exclusive approval.
- 316.34 FDA recognition of exclusive approval.
- 316.36 Insufficient quantities of orphan drugs.

Subpart E—Open Protocols for Investigations

- 316.40 Treatment use of a designated orphan drug.

Subpart F—Availability of Information

- 316.50 Guidelines.
- 316.52 Availability for public disclosure of data and information in requests and applications.

Authority: Secs. 525, 526, 527, 528, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371).

Subpart A—General Provisions

§ 316.1 Scope of this part.

(a) This part implements sections 525, 526, 527, and 528 of the act and provides procedures to encourage and facilitate the development of drugs for rare diseases or conditions, including biological products and antibiotics. This part sets forth the procedures and requirements for:

- (1) Submissions to FDA of:
 - (i) Requests for recommendations for investigations of drugs for rare diseases or conditions;
 - (ii) Requests for designation of a drug for a rare disease or condition; and
 - (iii) Requests for gaining exclusive approval for a drug product for a rare disease or condition.

(2) Allowing a sponsor to provide an investigational drug product under a treatment protocol to patients who need the drug for treatment of a rare disease or condition.

(b) This part does not apply to food, medical devices, or drugs for veterinary use.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 316.2 Purpose.

The purpose of this part is to establish standards and procedures for determining eligibility for the benefits provided for in section 2 of the Orphan Drug Act, including written recommendations for investigations of orphan drugs, a 7-year period of exclusive marketing, and treatment use of investigational orphan drugs. This part is also intended to satisfy Congress' requirements that FDA promulgate procedures for the implementation of sections 525(a) and 526(a) of the act.

§ 316.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act as amended by section 2 of the Orphan Drug Act (sections 525–528 (21 U.S.C. 360aa–360dd)).

(2) *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

(3) *Clinically superior* means that a drug is shown to provide a significant therapeutic advantage over and above that provided by an approved orphan drug (that is otherwise the same drug) in one or more of the following ways:

- (i) Greater effectiveness than an approved orphan drug (as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trials). Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials would be necessary; or
- (ii) Greater safety in a substantial portion of the target populations, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary; or
- (iii) In unusual cases, where neither greater safety nor greater effectiveness has been shown, a demonstration that the drug otherwise makes a major contribution to patient care.

(4) *Director* means the Director of FDA's Office of Orphan Products Development.

(5) *FDA* means the Food and Drug Administration.

(6) *Holder* means the sponsor in whose name an orphan drug is designated and approved.

(7) *IND* means an investigational new drug application under part 312 of this chapter.

(8) *Manufacturer* means any person or agency engaged in the manufacture of a drug that is subject to investigation and approval under the act or the biologics provisions of the Public Health Service Act (42 U.S.C. 262–263).

(9) *Marketing application* means an application for approval of a new drug filed under section 505(b) of the act, a request for certification of an antibiotic under section 507 of the act, or an application for a biological product/establishment license submitted under section 351 of the Public Health Service Act (42 U.S.C. 262).

(10) *Orphan drug* means a drug intended for use in a rare disease or condition as defined in section 526 of the act.

(11) *Orphan-drug designation* means FDA's act of granting a request for designation under section 526 of the act.

(12) *Orphan-drug exclusive approval* or *exclusive approval* means that, effective on the date of FDA approval as stated in the approval letter of a marketing application for a sponsor of a designated orphan drug, no approval will be given to a subsequent sponsor of the same drug product for the same indication for 7 years, except as otherwise provided by law or in this part.

(13) *Same drug* means:

(i) If it is a drug composed of small molecules, a drug that contains the same active moiety as a previously approved drug and is intended for the same use as the previously approved drug, even if the particular ester or salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative such as a complex, chelate or clathrate has not been previously approved, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug.

(ii) If it is a drug composed of large molecules (macromolecules), a drug that contains the same principal molecular structural features (but not necessarily all of the same structural features) and is intended for the same use as a previously approved drug, except that, if the subsequent drug can be shown to be clinically superior, it will not be considered to be the same drug. This criterion will be applied as follows to different kinds of macromolecules:

(A) Two protein drugs would be considered the same if the only differences in structure between them were due to post-translational events or infidelity of translation or transcription or were minor differences in amino acid sequence; other potentially important differences, such as different glycosylation patterns or different tertiary structures, would not cause the drugs to be considered different unless the differences were shown to be clinically superior.

(B) Two polysaccharide drugs would be considered the same if they had identical saccharide repeating units, even if the number of units were to vary and even if there were postpolymerization modifications, unless the subsequent drug could be shown to be clinically superior.

(C) Two polynucleotide drugs consisting of two or more distinct nucleotides would be considered the same if they had an identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars), unless the subsequent drug were shown to be clinically superior.

(D) Closely related, complex partly definable drugs with similar therapeutic intent, such as two live viral vaccines for the same indication, would be considered the same unless the subsequent drug was shown to be clinically superior.

(14) *Sponsor* means the entity that assumes responsibility for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations. A sponsor may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of drugs. For purposes of the Orphan Drug Act, FDA considers the real party or parties in interest to be a sponsor.

§ 316.4 Address for submissions.

All correspondence and requests for FDA action pursuant to the provisions of this rule should be addressed as follows: Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Subpart B—Written Recommendations for Investigations of Orphan Drugs

§ 316.10 Content and format of a request for written recommendations.

(a) A sponsor's request for written recommendations from FDA concerning

the nonclinical and clinical investigations necessary for approval of a marketing application shall be submitted in the form and contain the information required in this section. FDA may require the sponsor to submit information in addition to that specified in paragraph (b) of this section if FDA determines that the sponsor's initial request does not contain adequate information on which to base recommendations.

(b) A sponsor shall submit two copies of a completed, dated, and signed request for written recommendations that contains the following:

(1) The sponsor's name and address.
(2) A statement that the sponsor is requesting written recommendations on orphan-drug development under section 525 of the act.

(3) The name of the sponsor's primary contact person and/or resident agent, and the person's title, address, and telephone number.

(4) The generic name and trade name, if any, of the drug and a list of the drug product's components or description of the drug product's formulation, and chemical and physical properties.

(5) The proposed dosage form and route of administration.

(6) A description of the disease or condition for which the drug is proposed to be investigated and the proposed indication or indications for use for such disease or condition.

(7) Current regulatory and marketing status and history of the drug product, including:

(i) Whether the product is the subject of an IND or a marketing application (if the product is the subject of an IND or a marketing application, the IND or marketing application numbers should be stated and the investigational or approved indication or indications for use specified);

(ii) Known marketing experience or investigational status outside the United States;

(iii) So far as is known or can be determined, all indications previously or currently under investigation anywhere;

(iv) All adverse regulatory actions taken by the United States or foreign authorities.

(8) The basis for concluding that the drug is for a disease or condition that is rare in the United States, including the following:

(i) The size and other known demographic characteristics of the patient population affected and the source of this information.

(ii) For drugs intended for diseases or conditions affecting 200,000 or more people in the United States, or for a

vaccine, diagnostic drug, or preventive drug that would be given to 200,000 or more persons per year, a summary of the sponsor's basis for believing that the disease or condition described in paragraph (b)(6) of this section occurs so infrequently that there is no reasonable expectation that the costs of drug development and marketing will be recovered in future sales of the drug in the United States. The estimated costs and sales data should be submitted as provided for in § 316.21(c).

(9) A summary and analysis of available data on the pharmacologic effects of the drug.

(10) A summary and analysis of available nonclinical and clinical data pertinent to the drug and the disease to be studied including copies of pertinent published reports. When a drug proposed for orphan drug designation is intended to treat a life-threatening or severely debilitating illness, especially where no satisfactory alternative therapy exists, the sponsor may wish voluntarily to provide this information. A sponsor of such a drug may be entitled to expeditious development, evaluation, and marketing under 21 CFR part 312, subpart E.

(11) An explanation of how the data summarized and analyzed under paragraphs (b)(9) and (b)(10) of this section support the rationale for use of the drug in the rare disease or condition.

(12) A definition of the population from which subjects will be identified for clinical trials, if known.

(13) A detailed outline of any protocols under which the drug has been or is being studied for the rare disease or condition and a summary and analysis of any available data from such studies.

(14) The sponsor's proposal as to the scope of nonclinical and clinical investigations needed to establish the safety and effectiveness of the drug.

(15) Detailed protocols for each proposed United States or foreign clinical investigation, if available.

(16) Specific questions to be addressed by FDA in its recommendations for nonclinical laboratory studies and clinical investigations.

§ 316.12 Providing written recommendations.

(a) FDA will provide the sponsor with written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of a marketing application if none of the reasons described in § 316.14 for refusing to do so applies.

(b) When a sponsor seeks written recommendations at a stage of drug

development at which advice on any clinical investigations, or on particular investigations would be premature, FDA's response may be limited to written recommendations concerning only nonclinical laboratory studies, or only certain of the clinical studies (e.g., Phase 1 studies as described in § 312.21 of this chapter). Prior to providing written recommendations for the clinical investigations required to achieve marketing approval, FDA may require that the results of the nonclinical laboratory studies or completed early clinical studies be submitted to FDA for agency review.

§ 316.14 Refusal to provide written recommendations.

(a) FDA may refuse to provide written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of a marketing application for any of the following reasons:

(1) The information required to be submitted by § 316.10(b) has not been submitted, or the information submitted is incomplete.

(2) There is insufficient information about:

(i) The drug to identify the active moiety and its physical and chemical properties, if these characteristics can be determined; or

(ii) The disease or condition to determine that the disease or condition is rare in the United States; or

(iii) The reasons for believing that the drug may be useful for treating the rare disease or condition with that drug; or

(iv) The regulatory and marketing history of the drug to determine the scope and type of investigations that have already been conducted on the drug for the rare disease or condition; or

(v) The plan of study for establishing the safety and effectiveness of the drug for treatment of the rare disease or condition.

(3) The specific questions for which the sponsor seeks the advice of the agency are unclear or are not sufficiently specific.

(4) On the basis of the information submitted and on other information available to the agency, FDA determines that the disease or condition for which the drug is intended is not rare in the United States.

(5) On the basis of the information submitted and on other information available to the agency, FDA determines that there is an inadequate basis for permitting investigational use of the drug under part 312 of this chapter for the rare disease or condition.

(6) The request for information contains an untrue statement of material fact.

(b) A refusal to provide written recommendations will be in writing and will include a statement of the reason for FDA's refusal. Where practicable, FDA will describe the information or material it requires or the conditions the sponsor must meet for FDA to provide recommendations.

(c) Within 90 days after the date of a letter from FDA requesting additional information or material or setting forth the conditions that the sponsor is asked to meet, the sponsor shall either:

(1) Provide the information or material or amend the request for written recommendations to meet the conditions sought by FDA; or

(2) Withdraw the request for written recommendations. FDA will consider a sponsor's failure to respond within 90 days to an FDA letter requesting information or material or setting forth conditions to be met to be a withdrawal of the request for written recommendations.

Subpart C—Designation of an Orphan Drug

§ 316.20 Content and format of a request for orphan-drug designation.

(a) A sponsor that submits a request for orphan-drug designation of a drug for a specified rare disease or condition shall submit each request in the form and containing the information required in paragraph (b) of this section. A sponsor may request orphan-drug designation of a previously unapproved drug, or of a new orphan indication for an already marketed drug. In addition, a sponsor of a drug that is otherwise the same drug as an already approved orphan drug may seek and obtain orphan-drug designation for the subsequent drug for the same rare disease or condition if it can present a plausible hypothesis that its drug may be clinically superior to the first drug. More than one sponsor may receive orphan-drug designation of the same drug for the same rare disease or condition, but each sponsor seeking orphan-drug designation must file a complete request for designation as provided in paragraph (b) of this section.

(b) A sponsor shall submit two copies of a completed, dated, and signed request for designation that contains the following:

(1) A statement that the sponsor requests orphan-drug designation for a rare disease or condition, which shall be identified with specificity.

(2) The name and address of the sponsor; the name of the sponsor's primary contact person and/or resident agent including title, address, and

telephone number; the generic and trade name, if any, of the drug or drug product; and the name and address of the source of the drug if it is not manufactured by the sponsor.

(3) A description of the rare disease or condition for which the drug is being or will be investigated, the proposed indication or indications for use of the drug, and the reasons why such therapy is needed.

(4) A description of the drug and a discussion of the scientific rationale for the use of the drug for the rare disease or condition, including all data from nonclinical laboratory studies, clinical investigations, and other relevant data that are available to the sponsor, whether positive, negative, or inconclusive. Copies of pertinent unpublished and published papers are also required.

(5) Where the sponsor of a drug that is otherwise the same drug as an already-approved orphan drug seeks orphan-drug designation for the subsequent drug for the same rare disease or condition, an explanation of why the proposed variation may be clinically superior to the first drug.

(6) Where a drug is under development for only a subset of persons with a particular disease or condition, a demonstration that the subset is medically plausible.

(7) A summary of the regulatory status and marketing history of the drug in the United States and in foreign countries, e.g., IND and marketing application status and dispositions, what uses are under investigation and in what countries; for what indication is the drug approved in foreign countries; what adverse regulatory actions have been taken against the drug in any country.

(8) Documentation, with appended authoritative references, to demonstrate that:

(i) The disease or condition for which the drug is intended affects fewer than 200,000 people in the United States or, if the drug is a vaccine, diagnostic drug, or preventive drug, the persons to whom the drug will be administered in the United States are fewer than 200,000 per year as specified in § 316.21(b), or

(ii) For a drug intended for diseases or conditions affecting 200,000 or more people, or for a vaccine, diagnostic drug, or preventive drug to be administered to 200,000 or more persons per year in the United States, there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States as specified in § 316.21(c).

(9) A statement as to whether the sponsor submitting the request is the real party in interest of the development and the intended or actual production and sales of the product.

(c) Any of the information previously provided by the sponsor to FDA under Subpart B of this part may be referenced by specific page or location if it duplicates information required elsewhere in this section.

§ 316.21 Verification of orphan-drug status.

(a) So that FDA can determine whether a drug qualifies for orphan-drug designation under section 526(a) of the act, the sponsor shall include in its request to FDA for orphan-drug designation under § 316.20 either:

(1) Documentation as described in paragraph (b) of this section that the number of people affected by the disease or condition for which the drug product is indicated is fewer than 200,000 persons; or

(2) Documentation as described in paragraph (c) of this section that demonstrates that there is no reasonable expectation that the sales of the drug will be sufficient to offset the costs of developing the drug for the U.S. market and the costs of making the drug available in the United States.

(b) For the purpose of documenting that the number of people affected by the disease or condition for which the drug product is indicated is less than 200,000 persons, "prevalence" is defined as the number of persons in the United States who have been diagnosed as having the disease or condition at the time of the submission of the request for orphan-drug designation. To document the number of persons in the United States who have the disease or condition for which the drug is to be indicated, the sponsor shall submit to FDA evidence showing:

(1) The estimated prevalence of the disease or condition for which the drug is being developed, together with a list of the sources (including dates of information provided and literature citations) for the estimate;

(2) Upon request by FDA, the estimated prevalence of any other disease or condition for which the drug has already been approved or for which the drug is currently being developed, together with an explanation of the bases of these estimates; and

(3) The estimated number of people to whom the drug will be administered annually if the drug is a vaccine or is a drug intended for diagnosis or prevention of a rare disease or condition, together with an explanation of the bases of these estimates

(including dates of information provided and literature citations).

(c) When submitting documentation that there is no reasonable expectation that costs of research and development of the drug for the disease or condition can be recovered by sales of the drug in the United States, the sponsor shall submit to FDA:

(1) Data on all costs that the sponsor has incurred in the course of developing the drug for the U.S. market. These costs shall include, but are not limited to, nonclinical laboratory studies, clinical studies, dosage form development, record and report maintenance, meetings with FDA, determination of patentability, preparation of designation request, IND/marketing application preparation, distribution of the drug under a "treatment" protocol, licensing costs, liability insurance, and overhead and depreciation. Furthermore, the sponsor shall demonstrate the reasonableness of the cost data. For example, if the sponsor has incurred costs for clinical investigations, the sponsor shall provide information on the number of investigations, the years in which they took place, and on the scope, duration, and number of patients that were involved in each investigation.

(2) If the drug was developed wholly or in part outside the United States, in addition to the documentation listed in paragraph (c)(1) of this section:

(i) Data on and justification for all costs that the sponsor has incurred outside of the United States in the course of developing the drug for the U.S. market. The justification, in addition to demonstrating the reasonableness of the cost data, must also explain the method that was used to determine which portion of the foreign development costs should be applied to the U.S. market, and what percent these costs are of total worldwide development costs. Any data submitted to foreign government authorities to support drug pricing determinations must be included with this information.

(ii) Data that show which foreign development costs were recovered through cost recovery procedures that are allowed during drug development in some foreign countries. For example, if the sponsor charged patients for the drug during clinical investigations, the revenues collected by the sponsor must be reported to FDA.

(3) In cases where the drug has already been approved for marketing for any indication or in cases where the drug is currently under investigation for one or more other indications (in addition to the indication for which

orphan-drug designation is being sought), a clear explanation of and justification for the method that is used to apportion the development costs among the various indications.

(4) A statement of and justification for any development costs that the sponsor expects to incur after the submission of the designation request. In cases where the extent of these future development costs are not clear, the sponsor should request FDA's advice and assistance in estimating the scope of nonclinical laboratory studies and clinical investigations and other data that are needed to support marketing approval. Based on these recommendations, a cost estimate should be prepared.

(5) A statement of and justification for production and marketing costs that the sponsor has incurred in the past and expects to incur during the first 7 years that the drug is marketed.

(6) An estimate of and justification for the expected revenues from sales of the drug in the United States during its first 7 years of marketing. The justification should assume that the total market for the drug is equal to the prevalence of the disease or condition that the drug will be used to treat. The justification should include:

(i) An estimate of the expected market share of the drug in each of the first 7 years that it is marketed, together with an explanation of the basis for that estimate;

(ii) A projection of and justification for the price at which the drug will be sold; and

(iii) Comparisons with sales of similarly situated drugs, where available.

(7) The name of each country where the drug has already been approved for marketing for any indication, the dates of approval, the indication for which the drug is approved, and the annual sales and number of prescriptions in each country since the first approval date.

(8) A report of an independent certified public accountant in accordance with Statement on Standards for Attestation established by the American Institute of Certified Public Accountants on agreed upon procedures performed with respect to the data estimates and justifications submitted pursuant to this section. Cost data shall be determined in accordance with generally accepted accounting principles.

(d) A sponsor that is requesting orphan-drug designation for a drug designed to treat a disease or condition that affects 200,000 or more persons shall, at FDA's request, allow FDA or FDA-designated personnel to examine at reasonable times and in a reasonable

manner all relevant financial records and sales data of the sponsor and manufacturer.

§ 316.22 Permanent-resident agent for foreign sponsor.

Every foreign sponsor that seeks orphan-drug designation shall name a permanent resident of the United States as the sponsor's agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the sponsor. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent-resident agent may be an individual, firm, or domestic corporation and may represent any number of sponsors. The name of the permanent-resident agent shall be provided to: Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 316.23 Timing of requests for orphan-drug designation; designation of already approved drugs.

(a) A sponsor may request orphan-drug designation at any time in the drug development process prior to the submission of a marketing application for the drug product for the orphan indication.

(b) A sponsor may request orphan-drug designation of an already approved drug product for an unapproved use without regard to whether the prior marketing approval was for an orphan-drug indication.

§ 316.24 Granting orphan-drug designation.

(a) FDA will grant the request for orphan-drug designation if none of the reasons described in § 316.25 for requiring or permitting refusal to grant such a request applies.

(b) When a request for orphan-drug designation is granted, FDA will notify the sponsor in writing and will publicize the orphan-drug designation in accordance with § 316.28.

§ 316.25 Refusal to grant orphan-drug designation.

(a) FDA will refuse to grant a request for orphan-drug designation if any of the following reasons apply:

(1) The drug is not intended for a rare disease or condition because:

(i) There is insufficient evidence to support the estimate that the drug is intended for treatment of a disease or condition in fewer than 200,000 people in the United States, or that the drug is intended for use in prevention or in

diagnosis in fewer than 200,000 people annually in the United States; or

(ii) Where the drug is intended for prevention, diagnosis, or treatment of a disease or condition affecting 200,000 or more people in the United States, the sponsor has failed to demonstrate that there is no reasonable expectation that development and production costs will be recovered from sales of the drug for the orphan indication in the United States. A sponsor's failure to comply with § 316.21 shall constitute a failure to make the demonstration required in this paragraph.

(2) There is insufficient information about the drug, or the disease or condition for which it is intended, to establish a medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition.

(3) A drug that is otherwise the same drug as one that already has orphan-drug exclusive approval for the same rare disease or condition and the sponsor has not submitted a medically plausible hypothesis for the possible clinical superiority of the subsequent drug.

(b) FDA may refuse to grant a request for orphan-drug designation if the request for designation contains an untrue statement of material fact or omits material information.

§ 316.26 Amendment to orphan-drug designation.

(a) At any time prior to approval of a marketing application for a designated orphan drug, the sponsor holding designation may apply for an amendment to the indication stated in the orphan-drug designation if the proposed change is due to new and unexpected findings in research on the drugs, information arising from FDA recommendations, or unforeseen developments in treatment or diagnosis of the disease or condition.

(b) FDA will grant the amendment if it finds that the initial designation request was made in good faith and that the amendment is intended to conform the orphan-drug designation indication to the results of unanticipated research findings, to unforeseen developments in the treatment or diagnosis of the disease or condition, or to changes based on FDA recommendations, and that, as of the date of the submission of the amendment request, the amendment would not result in exceeding the prevalence or cost recovery thresholds in § 316.21 (a)(1) or (a)(2) upon which the drug was originally designated.

§ 316.27 Change in ownership of orphan-drug designation.

(a) A sponsor may transfer ownership of or any beneficial interest in the orphan-drug designation of a drug to a new sponsor. At the time of the transfer, the new and former owners are required to submit the following information to FDA:

(1) The former owner or assignor of rights shall submit a letter or other document that states that all or some rights to the orphan-drug designation of the drug have been transferred to the new owner or assignee and that a complete copy of the request for orphan-drug designation, including any amendments to the request, supplements to the granted request, and correspondence relevant to the orphan-drug designation, has been provided to the new owner or assignee.

(2) The new owner or assignee of rights shall submit a statement accepting orphan-drug designation and a letter or other document containing the following:

(i) The date that the change in ownership or assignment of rights is effective;

(ii) A statement that the new owner has a complete copy of the request for orphan-drug designation including any amendments to the request, supplements to the granted request, and correspondence relevant to the orphan-drug designation; and

(iii) A specific description of the rights that have been assigned and those that have been reserved. This may be satisfied by the submission of either a list of rights assigned and reserved or copies of all relevant agreements between assignors and assignees; and

(iv) The name and address of a new primary contact person or resident agent.

(b) No sponsor may relieve itself of responsibilities under the Orphan Drug Act or under this part by assigning rights to another person without:

(1) Assuring that the sponsor or the assignee will carry out such responsibilities; or

(2) Obtaining prior permission from FDA.

§ 316.28 Publication of orphan-drug designations.

Each month FDA will update a publicly available list of drugs designated as orphan drugs. A cumulative, updated list of all designated drugs will be provided annually. These will be placed on file at the FDA Dockets Management Branch, and will contain the following information:

(a) The name and address of the manufacturer and sponsor;

(b) The generic name and trade name, if any, of the drug and the date of the granting of orphan-drug designation;

(c) The rare disease or condition for which orphan-drug designation was granted; and

(d) The proposed indication for use of the drug.

§ 316.29 Revocation of orphan-drug designation.

(a) FDA may revoke orphan-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this part; or

(3) FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request therefor.

(b) For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor's exclusive marketing rights for the drug but not the approval of the drug's marketing application.

(c) Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

§ 316.30 Annual reports of holder of orphan-drug designation.

Within 14 months after the date on which a drug was designated as an orphan drug and annually thereafter until marketing approval, the sponsor of a designated drug shall submit a brief progress report to the FDA Office of Orphan Products Development on the drug that includes:

(a) A short account of the progress of drug development including a review of preclinical and clinical studies initiated, ongoing, and completed and a short summary of the status or results of such studies.

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the orphan-drug status of the product. For example, for products nearing the end of the approval process, sponsors should discuss any disparity

between the probable marketing indication and the designated indication as related to the need for an amendment to the orphan-drug designation pursuant to § 316.26.

Subpart D—Orphan-drug Exclusive Approval

§ 316.31 Scope of orphan-drug exclusive approval.

(a) After approval of a sponsor's marketing application for a designated orphan-drug product for treatment of the rare disease or condition concerning which orphan-drug designation was granted, FDA will not approve another sponsor's marketing application for the same drug before the expiration of 7 years from the date of such approval as stated in the approval letter from FDA, except that such a marketing application can be approved sooner if, and such time as, any of the following occurs:

(1) Withdrawal of exclusive approval or revocation of orphan-drug designation by FDA under any provision of this part; or

(2) Withdrawal for any reason of the marketing application for the drug in question; or

(3) Consent by the holder of exclusive approval to permit another marketing application to gain approval; or

(4) Failure of the holder of exclusive approval to assure a sufficient quantity of the drug under section 527 of the act and § 316.36.

(b) If a sponsor's marketing application for a drug product is determined not to be approvable because approval is barred under section 527 of the act until the expiration of the period of exclusive marketing of another drug product, FDA will so notify the sponsor in writing.

§ 316.34 FDA recognition of exclusive approval.

(a) FDA will send the sponsor (or, the permanent-resident agent, if applicable) timely written notice recognizing exclusive approval once the marketing application for a designated orphan-drug product has been approved. The written notice will inform the sponsor of the requirements for maintaining orphan-drug exclusive approval for the full 7-year term of exclusive approval.

(b) When a marketing application is approved for a designated orphan drug that qualifies for exclusive approval, FDA will publish in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" information identifying the sponsor, the drug, and the date of termination of the orphan-drug exclusive approval. A subscription to this publication and its

monthly cumulative supplements is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325.

§ 316.36 Insufficient quantities of orphan drugs.

(a) Under section 527 of the act, whenever the Director has reason to believe that the holder of exclusive approval cannot assure the availability of sufficient quantities of an orphan drug to meet the needs of patients with the disease or condition for which the drug was designated, the Director will so notify the holder of this possible insufficiency and will offer the holder one of the following options, which must be exercised by a time that the Director specifies:

(1) Provide the Director in writing, or orally, or both, at the Director's discretion, views and data as to how the holder can assure the availability of sufficient quantities of the orphan drug within a reasonable time to meet the needs of patients with the disease or condition for which the drug was designated; or

(2) Provide the Director in writing the holder's consent for the approval of other marketing applications for the same drug before the expiration of the 7-year period of exclusive approval.

(b) If, within the time that the Director specifies, the holder fails to consent to the approval of other marketing applications and if the Director finds that the holder has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated, the Director will issue a written order withdrawing the drug product's exclusive approval. This order will embody the Director's findings and conclusions and will constitute final agency action. An order withdrawing the sponsor's exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Once withdrawn under this section, exclusive approval may not be reinstated for that drug.

Subpart E—Open Protocols for Investigations

§ 316.40 Treatment use of a designated orphan drug.

Prospective investigators seeking to obtain treatment use of designated orphan drugs may do so as provided in § 312.34 of this chapter.

Subpart F—Availability of Information**§ 316.50 Guidelines.**

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidelines that apply to the regulations in this part. The list states how a person can obtain a copy of each guideline. A request for a copy of the list or for any guideline should be directed to the Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 316.52 Availability for public disclosure of data and information in requests and applications.

(a) FDA will not publicly disclose the existence of a request for orphan-drug designation under section 526 of the act prior to final FDA action on the request unless the existence of the request has

been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Upon final FDA action on a request for designation, FDA will determine the public availability of data and information in the request in accordance with part 20 and § 314.430 of this chapter and other applicable statutes and regulations.

(d) In accordance with § 316.28, FDA will make a cumulative list of all orphan drug designations available to the public and update such list monthly.

(e) FDA will not publicly disclose the existence of a pending marketing

application for a designated orphan drug for the use for which the drug was designated unless the existence of the application has been previously publicly disclosed or acknowledged.

(f) FDA will determine the public availability of data and information contained in pending and approved marketing applications for a designated orphan drug for the use for which the drug was designated in accordance with part 20 and § 314.430 of this chapter and other applicable statutes and regulations.

Dated: May 21, 1992.

David A. Kessler,
Commissioner of Food and Drugs.

Louis W. Sullivan,
Secretary of Health and Human Services.
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