certification that no investigator will be added to the treatment IDE before the agreement is signed; and

(x) If the device is to be sold, the price to be charged and a statement indicating that the price is based on manufacturing and handling costs only.

(2) A licensed practitioner who receives an investigational device for treatment use under a treatment IDE is an ''investigator'' under the IDE and is responsible for meeting all applicable investigator responsibilities under this part and parts 50 and 56 of this chapter.

(d) *FDA action on treatment IDE applications.* (1) *Approval of treatment IDE's.* Treatment use may begin 30 days after FDA receives the treatment IDE submission at the address specified in § 812.19, unless FDA notifies the sponsor in writing earlier than the 30 days that the treatment use may or may not begin. FDA may approve the treatment use as proposed or approve it with modifications.

(2) *Disapproval or withdrawal of approval of treatment IDE's.* FDA may disapprove or withdraw approval of a treatment IDE if:

(i) The criteria specified in § 812.36(b) are not met or the treatment IDE does not contain the information required in § 812.36(c);

(ii) FDA determines that any of the grounds for disapproval or withdrawal of approval listed in § 812.30(b)(1) through (b)(5) apply;

(iii) The device is intended for a serious disease or condition and there is insufficient evidence of safety and effectiveness to support such use;

(iv) The device is intended for an immediately life-threatening disease or condition and the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the device:

(A) May be effective for its intended use in its intended population; or

(B) Would not expose the patients to whom the device is to be administered to an unreasonable and significant additional risk of illness or injury;

(v) There is reasonable evidence that the treatment use is impeding enrollment in, or otherwise interfering with the conduct or completion of, a controlled investigation of the same or another investigational device;

(vi) The device has received marketing approval/clearance or a comparable device or therapy becomes available to treat or diagnose the same indication in the same patient population for which the investigational device is being used;

(vii) The sponsor of the controlled clinical trial is not pursuing marketing approval/clearance with due diligence;

(viii) Approval of the IDE for the controlled clinical investigation of the device has been withdrawn; or

(ix) The clinical investigator(s) named in the treatment IDE are not qualified by reason of their scientific training and/or experience to use the investigational device for the intended treatment use.

(3) *Notice of disapproval or withdrawal.* If FDA disapproves or proposes to withdraw approval of a treatment IDE, FDA will follow the procedures set forth in § 812.30(c).

(e) *Safeguards.* Treatment use of an investigational device is conditioned upon the sponsor and investigators complying with the safeguards of the IDE process and the regulations governing informed consent (part 50 of this chapter) and institutional review boards (part 56 of this chapter).

(f) *Reporting requirements.* The sponsor of a treatment IDE shall submit progress reports on a semi-annual basis to all reviewing IRB's and FDA until the filing of a marketing application. These reports shall be based on the period of time since initial approval of the treatment IDE and shall include the number of patients treated with the device under the treatment IDE, the names of the investigators participating in the treatment IDE, and a brief description of the sponsor's efforts to pursue marketing approval/clearance of the device. Upon filing of a marketing application, progress reports shall be submitted annually in accordance with § 812.150(b)(5). The sponsor of a treatment IDE is responsible for submitting all other reports required under § 812.150.

3. Section 812.150 is amended by revising paragraph (b)(5) to read as follows:

§ 812.150 Reports.

* * * * *

(b) * * *

(5) *Progress reports.* At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, a sponsor shall also submit progress reports to FDA. A sponsor of a treatment IDE shall submit semi-annual progress reports to all reviewing IRB's and FDA in accordance with § 812.36(f) and annual reports in accordance with this section.

* * * * *

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24735 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1404

Expedited Arbitration

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule.

SUMMARY: This addition to the arbitration regulations is intended to create a new service know as ''expedited arbitration.'' This service will provide a streamlined arbitration process for non-precedential and non-complex grievance arbitration cases while encouraging the parties to select new arbitrators in order to enhance their career development. This new service is the result of specific recommendations of the Arbitration Focus Group by FMCS on March 27, 1997.

EFFECTIVE DATE: This regulation is effective October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Peter Regner, 202–606–8181.

SUPPLEMENTARY INFORMATION: The Federal Mediation and Conciliation Service, in an effort to receive public input on its proposed new service of expedited arbitration, published the draft version of its proposed rule in the June 30, 1997 issue of the **Federal Register** (62 FR 35112). Nine arbitrators responded in writing to the proposed rule. In general, all individuals supported the new service. Almost all of them, however, objected to limiting eligibility to deliver this service to those arbitrators listed on the FMCS Roster of Arbitrators for five (5) years or less. More specific information about the public response is contained in the following section-by-section analysis.

Subpart D—Expedited Arbitration

Section 1404.17 Policy

The first section was further clarified by adding the ''unique'' issues would also be inappropriate for expedited arbitration, as would complex or precedential issues.

Section 1404.18 Procedures for Requesting Expedited Panels

Subsection (d). The procedures for requesting expedited arbitrators were modified slightly by allowing the parties to select a second arbitrator from the panel submitted to them in the event their first choice was not available to serve. This was in response to one comment opposing a direct appointment by FMCS in the event the original arbitrator selected by the parties was not able to serve. The parties now have an additional option.

Section 1404.19 Arbitration Process

Subsection (c). The language has been clarified to state that ''post hearing'' will not be allowed. This permits the parties to present pre-hearing summaries or briefs of their positions. One comment expressed concern that the ''no transcript'' provision of the rule might be interpreted to mean that the arbitrator could not tape the hearing for his/her own use. This is not the intention of the rule. Arbitrators may tape the proceedings, if both parties agree, as a supplement to his/her notes.

Section 1404.20 Arbitrator Eligibility

Eight of the nine individuals submitting comments about the proposed rule objected to the policy of having only arbitrators with five (5) years or less experience on the FMCS Roster automatically placed on the expedited arbitration panels. Some argued fairness, others stated that in order to be able to render quick decisions, more arbitration experience was required. FMCS has modified its policy to that at lease two more senior arbitrators will be listed on every expedited panel. Given the number of arbitrators with five (5) years of less listing on the Roster, it is possible that many, if not most, expedited arbitration panels will contain more than two more senior arbitrators. The parties continue to have the right to jointly request any special qualifications that they feel necessary.

The Federal Mediation and Consiliation Service amends 29 CFR part 1404 as follows:

PART 1404—ARBITRATION SERVICES

1. The authority citation for part 1404 continues to read as follows:

Authority: 29 U.S.C. 172 and 29 U.S.C. 173 *et seq.*

2. By adding Subpart D to read as follows:

Subpart D—Expedited Arbitration

Sec.
1404.17 Policy.
1404.18 Prcedures for requesting expedited panels.
1404.19 Arbitration process.
1404.20 Arbitrator eligibility.
1404.21 Proper use of expedited arbitration.

Subpart D—Expedited Arbitration

§ 1404.17 Policy

In an effort to reduce the time and expense of some grievance arbitrators, FMCS is offering expedited procedures that may be appropriate in certain non-precedential cases or those that do not involve complex or unique issues. Expedited Arbitrator is intended to be a mutually agreed upon process whereby arbitrator appointments, hearings and awards are acted upon quickly by the parties, FMCS, and the arbitrators. The process is streamlined by mandating short deadlines and eliminating requirements for transcripts, briefs and lengthy opinions.

§ 1404.18 Procedures for requesting expedited panels.

(a) With the excepting of the specific changes noted in this Subpart, all FMCS rules and regulations governing its arbitration services shall apply to Expedited Arbitration.

(b) Upon receipt of a joint Request for Arbitration Panel (Form R–43) indicating that expedited services are desired by both parties, the OAS will require a panel of arbitrators.

(c) A panel of arbitrators submitted by the OAS in expedited cases shall be valid for up to 30 days. Only one panel will be submitted per case. If the parties are unable to mutually agree upon an arbitrator or if prioritized selections are not received from both parties within 30 days, the OAS will make a direct appointment of an arbitrator not on the original panel.

(d) If the parties mutually select an arbitrator, but the arbitrator is not available, the parties may select a second name from the same panel or the OAS will make a direct appointment of another arbitrator not listed on the original panel.

§ 1404.19 Arbitration process.

(a) Once notified of the expedited case appointment by the OAS, the arbitrator must contact the parties within seven (7) calendar days.

(b) The parties and the arbitrator must attempt to schedule a hearing within 30 days of the appointment date.

(c) Absent mutual agreement, all hearings will be concluded within one day. No transcripts of the proceedings will be made and the filing of post-hearing briefs will not be allowed.

(d) All awards must be completed within seven (7) working days from the hearing. These awards are expected to be brief, concise, and not required extensive written opinion or research time.

§ 1404.20 Arbitrator eligibility.

In an effort to increase exposure for new arbitrators, those arbitrators who have been listed on the Roster of Arbitrators for a period of five (5) years or less will be automatically placed on expedited panels submitted to the parties. However, all panels will also contain the names of at least two more senior arbitrators. In addition, the parties may jointly request a larger pool of arbitrators or a direct appointment of their choice who is listed on the Roster.

§ 1404.21 Proper use of expedited arbitration.

(a) FMCS reserves the right to cease honoring request for Expedited Arbitration if a pattern of misuse of this becomes apparent. Misuse may be indicated by the parties' frequent delay of the process or referral of inappropriate cases.

(b) Arbitrators who exhibit a pattern of unavailability of appointments or who are repeatedly unable to schedule hearings or render awards within established deadlines will be considered ineligible for appointment for this service.

John Calhoun Wells,

Director.

[FR Doc. 97–24727 Filed 9–17–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[OR–1–0001; FRL–5891–5]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Oregon; Correction

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule; correction.

SUMMARY: On December 19, 1995, pursuant to sections 111 and 129 of the Clean Air Act (Act), the EPA promulgated new source performance standards (NSPS) applicable to new Municipal Waste Combustors (MWCs) and Emission Guidelines applicable to existing MWCs. On April 8, 1997, the United States Court of Appeals for the District of Columbia Circuit vacated 40 CFR part 60, subparts Cb and Eb, as they apply to MWC units with capacity to combust less than or equal to 250 tons/day of municipal solid waste (small MWCs), consistent with the opinion in *Davis County Solid Waste Management and Recovery District* v. *EPA*, 101 F.3d 1395 (D.C. Cir. 1996), *as amended*, 108 F.3d 1454 (D.C. Cir. 1997). As a result, 40 CFR part 60, subparts Eb and Cb, apply only to large MWC units which are defined as units with individual capacity to combust more than 250 tons/day of municipal solid waste.

In a July 10, 1997, **Federal Register** document (62 FR 36995), the EPA approved the State Plan submitted by Oregon to implement and enforce