developed by NERC and approved by the Commission.

107. TANC requests clarification that the Commission has not yet finalized its Regulatory Flexibility Act analysis and will not do so until NERC has submitted a proposed exemption process.

108. Public Power Council, NYPSC and Snohomish argue that implementing the 100-kV threshold will be enormously costly. Public Power Council, for its part, argues that the Commission's rejection of evidence of such increased compliance costs was arbitrary and capricious since, inter alia, Public Power Council did provide specific assertions as to how the Final Rule will have a significant economic impact on small entities. The NYPSC requests rehearing on whether the Commission's decision to direct NERC to revise the bulk electric system definition to include facilities operated at 100 kV and above where the Commission failed to determine sufficient benefits in relation to the costs, resulting in the imposition of unnecessary costs without reliability benefits, was arbitrary, capricious, and an abuse of discretion. Snohomish states that it and many other entities operating in the Western Interconnection provided evidence demonstrating that imposition of the 100-kV threshold in the Western Interconnection will result of enormous compliance costs with no benefit to reliability since the 115-kV systems operated by these entities generally are used only for local distribution and their operation therefore has little or no effect on the interconnected bulk system.

#### Commission Determination

109. The Commission does not agree with commenters that its Regulatory Flexibility Act analysis was deficient, and we continue to believe that our suggested approach in Order No. 743 will not have a significant economic impact on a substantial number of small entities. 103 With respect to comments that we did not adequately consider the costs of implementing a 100 kV threshold, we note that the current bulk electric system definition contains a general 100 kV threshold. Thus, the burden of our suggested proposal to eliminate the regional discretion in the current definition and maintain a brightline 100 kV threshold should be minimal in all regions except NPCC. Even within the U.S. portion of the NPCC region, the Commission estimated in the Final Rule that only four of the 33 transmission owners, transmission operators and transmission service

providers may fall within the definition of small entities. We also believe that the exemption process will further ensure that the Final Rule minimally affects small entities. Finally, we have clarified on rehearing that NERC may develop criteria to identify local distribution facilities and certain categories of radial facilities that qualify for exclusion from the definition of the bulk electric system and therefore do not need to apply for exemption. For these reasons the Commission rejects the comments objecting to the Commission's determinations regarding the cost of implementing a 100 kV threshold.

110. However, the Commission will grant APPA's and NRECA's request for clarification in part. The Commission clarifies that it will perform a new Regulatory Flexibility Act analysis to determine whether the revised bulk electric system definition will have a significant economic impact on small entities when NERC submits its proposed definition, criteria for exclusion and the exemption process. 104 We believe that the revisions NERC will propose will be sufficiently different from the initial NOPR proposal to warrant additional review to ensure that small entities are not unduly burdened.

#### III. Document Availability

111. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (http://www.ferc.gov) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

112. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

113. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or e-mail at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–

8371, TTY (202) 502–8659. E-mail the Public Reference Room at public.referenceroom@ferc.gov.

By the Commission.

Nathaniel J. Davis, Sr.,

 $Deputy\ Secretary.$ 

[FR Doc. 2011-6779 Filed 3-22-11; 8:45 am]

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#### **DEPARTMENT OF ENERGY**

# Federal Energy Regulatory Commission

# 18 CFR Part 40

[Docket No. RM10-16-000; Order No. 749]

# System Restoration Reliability Standards

**AGENCY:** Federal Energy Regulatory

Commission, DOE. **ACTION:** Final rule.

SUMMARY: Under section 215 of the Federal Power Act, the Commission approves three Emergency Operations and Preparedness (EOP) Reliability Standards, EOP-001-1 (Emergency Operations Planning), EOP-005-2 (System Restoration from Blackstart Resources), and EOP-006-2 (System Restoration Coordination) as well as the definition of the term "Blackstart Resource" submitted to the Commission for approval by the North American Electric Reliability Corporation (NERC), the Electric Reliability Organization certified by the Commission. The approved Reliability Standards require transmission operators, generation operators, and certain transmission owners and distribution providers to ensure that plans, facilities and personnel are prepared to enable system restoration from Blackstart Resources and require reliability coordinators to establish plans and prepare personnel to enable effective coordination of the system restoration process. The Commission also approves the NERC's proposal to retire four existing EOP Reliability Standards and a definition that are replaced by the Standards and definition approved in this Final Rule.

**DATES:** *Effective Date:* This rule will become effective May 23, 2011.

#### FOR FURTHER INFORMATION CONTACT:

Terence Burke (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6498.

David O'Connor (Technical Information), Office of Electric Reliability, Division of Reliability Standards, Federal Energy Regulatory

<sup>&</sup>lt;sup>103</sup> Order No. 743, 133 FERC ¶ 61,150 at P 169.

<sup>104</sup> This analysis will determine if an Initial Regulatory Flexibility Analysis is required or if the Commission can certify that the revised definition will not have a significant economic impact on a substantial number of small companies.

Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6695

#### SUPPLEMENTARY INFORMATION:

Before Commissioners: Jon Wellinghoff, Chairman; Marc Spitzer, Philip D. Moeller, John R. Norris, and Cheryl A. LaFleur.

# Final Rule

Issued March 17, 2011.

1. Under section 215 of the Federal Power Act (FPA), the Commission approves three Emergency Operations and Preparedness (EOP) Reliability Standards, EOP-001-1 (Emergency Operations Planning), EOP-005-2 (System Restoration from Blackstart Resources), and EOP-006-2 (System Restoration Coordination) as well as the definition of the term "Blackstart Resource" submitted to the Commission for approval by the North American Electric Reliability Corporation (NERC), the Electric Reliability Organization (ERO) certified by the Commission. The approved Reliability Standards require transmission operators, generation operators, and certain transmission owners and distribution providers to ensure that plans, facilities, and personnel are prepared to enable system restoration from Blackstart Resources and require reliability coordinators to establish plans and prepare personnel to enable effective coordination of the system restoration process. The Commission also approves NERC's proposal to retire four existing EOP Reliability Standards and the defined term "Blackstart Capability Plan" concurrent with the effectiveness of the Standards and the term Blackstart Resource approved in this Final Rule. In those jurisdictions where regulatory approval is required, Reliability Standard EOP-001-1 will not become effective until the first day of the first calendar quarter three months after regulatory approval is obtained, and EOP-005-2 and EOP-006-2 approved in this Final Rule will not become effective until 24 months after the first day of the first quarter after applicable

regulatory approval.

2. "Blackstart" capability refers to the ability of a generating unit or station to start operating and delivering electric power without assistance from the electric system. Blackstart units are essential to restart generation and restore power to the grid in the event of an outage. As discussed below, NERC proposes to define "Blackstart Resource" as "a generating unit(s) and its associated set of equipment which has the ability to be started without support from the System or is designed to

remain energized without connection to the remainder of the System, with the ability to energize a bus. \* \* \*"

3. In Order No. 693, the Commission determined that it would not take action on certain proposed Reliability Standards that required supplemental information from a Regional Entity. Such Reliability Standards refer to regional criteria or procedures that had not been submitted to the Commission for approval and, as such, are referred to as "fill-in-the-blank" standards.2 Pending Reliability Standard EOP-007-0 is one such fill-in-the-blank standard. The Reliability Standards approved herein provide a standardized, national approach to address the Commission's concerns regarding pending EOP-007-0, as set forth in Order No. 693. Thus, in addition to the retirement of certain currently effective EOP Reliability Standards, we also approve the withdrawal of pending Reliability Standard EOP-007-0.

## I. Background

4. On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards filed by NERC,<sup>3</sup> including the Reliability Standards: EOP-001-0, EOP-005-1, EOP-006-1, and EOP-009-0.4 The Commission neither approved nor remanded EOP-007-0 because it applied only to regional reliability organizations, but Order No. 693 did provide guidance for the ERO's further consideration of the Reliability Standard.<sup>5</sup> In addition, under section 215(d)(5) of the FPA, the Commission directed NERC to develop modifications to the EOP Reliability Standards to address certain issues identified by the Commission. At issue in the immediate proceeding are two new EOP standards, EOP-005-2 and EOP-006-2 that would replace the currently effective Reliability Standards EOP-005-1, EOP-006-1, and EOP-009-0, pending Standard EOP-007-0, and necessitate a conforming change in EOP-001-0.

# A. Currently Effective EOP Reliability Standards

# Reliability Standard EOP-005-1

5. Currently effective Reliability Standard EOP-005-1 requires transmission operators, balancing authorities, and reliability coordinators to have a restoration plan, test the plan, train operating personnel in the restoration plan, and have the ability to restore the Interconnection using the plans following a blackout. In Order No. 693, the Commission directed the ERO to develop, through the Reliability Standard development process, a modification to EOP-005-1 that identifies time frames for training and review of restoration plan requirements to simulate contingencies and prepare operators for anticipated and unforeseen events.<sup>6</sup> The Commission also directed the ERO to consider various commenters' suggestions in future revisions of the Reliability Standard.<sup>7</sup>

# Reliability Standard EOP-006-1

6. In Order No. 693, the Commission also approved Reliability Standard EOP-006-1 addressing reliability coordination and system restoration. The Reliability Standard sets requirements for reliability coordinators during system restoration and requires that they have a coordinating role to ensure reliability is maintained during system restoration. Under section 215 of the FPA, the Commission directed the ERO to develop a modification to EOP-006-1 to ensure that the reliability coordinator is involved in the development and approval of system restoration plans.8

# Pending Reliability Standard EOP-007-0

7. Pending Reliability Standard EOP-007-0 deals with establishing, maintaining and documenting regional blackstart capability plans. In Order No. 693, the Commission did not act on EOP-007-0 pending NERC's providing additional information.9 The Commission, however, directed the ERO to consider various commenters' suggestions relating to assigning compliance obligations directly to the entities that provide the pertinent data rather than to the Regional Entity, placing responsibility for the regional blackstart plan with the reliability coordinator, recognizing that nuclear units have no blackstart capability, revising the definition of a blackstart unit, and committing arrangements for coordinating blackstart capability to contracts.10

#### Reliability Standard EOP-009-0

8. Currently effective Reliability Standard EOP–009–0 deals with implementing and documenting testing

<sup>&</sup>lt;sup>2</sup> Mandatory Reliability Standards for the Bulk-Power System, Order No. 693, 72 FR 16416 (Apr. 4, 2007), FERC Stats. & Regs. ¶ 31,242, at P 297, order on reh'g, Order No. 693–A, 120 FERC ¶ 61.053 (2007).

<sup>3</sup> Id. P 304-1899.

<sup>4</sup> Id. P 542-676.

<sup>&</sup>lt;sup>5</sup> *Id.* P 644.

<sup>6</sup> Id. P 630.

<sup>7</sup> Id. P 628.

<sup>8</sup> Id. P 638.

<sup>&</sup>lt;sup>9</sup> *Id.* P 297, 644.

<sup>10</sup> Id. P 642-643, 647.

<sup>&</sup>lt;sup>1</sup> 16 U.S.C. 824o.

of blackstart generating units. In Order No. 693, the Commission directed the ERO to consider suggestions for improvements raised during the comment period. One commenter stated the Reliability Standard should provide details on what constitutes a blackstart test and another stated that NERC should consolidate the Reliability Standard with EOP–007–0.11

# B. NERC Petition

9. In a December 31, 2009 filing (NERC Petition),12 NERC requests Commission approval of its proposed definition of the term "Blackstart Resource" and proposed Reliability Standards EOP-001-1 (Emergency Operating Planning), 13 EOP-005-2 (System Restoration from Blackstart Resources), and EOP-006-2 (System Restoration Coordination). NERC also seeks to concurrently retire four currently effective Reliability Standards: EOP-001-0, EOP-005-1, EOP-006-1, and EOP-009-0 as well as the definition of "Blackstart Capability Plan" and withdraw pending Reliability Standard EOP-007-0.

10. NERC states that the proposed Reliability Standards "represent significant revision and improvement from the current set of enforceable standards" and address the Commission's directives in Order No. 693 related to the EOP standards.14 NERC explains that, among other enhancements, "[t]he proposed revisions now clearly delineate the responsibilities of the Reliability Coordinator and Transmission Operator in the restoration process and restoration planning." 15 NERC describes the proposed Reliability Standards as providing "specific requirements for

what must be in a restoration plan, how and when it needs to be updated and approved, what needs to be provided to operators and what training is necessary for personnel involved in restoration processes." <sup>16</sup>

Proposed Definition of Blackstart Resource

11. NERC requests approval of the term "Blackstart Resource" and the concurrent retirement of the term "Blackstart Capability Plan." The proposed definition of "Blackstart Resource" is:

A generating unit(s) and its associated set of equipment which has the ability to be started without support from the System or is designed to remain energized without connection to the remainder of the System, with the ability to energize a bus, meeting the Transmission Operator's restoration plan needs for real and reactive power capability, frequency and voltage control, and that has been included in the Transmission Operator's restoration plan.

The term "Blackstart Capacity Plan" is currently used solely in EOP–007–0 and EOP–009–0, both of which are replaced with proposed Reliability Standards EOP–005–2 and EOP–006–2.

Proposed Reliability Standard EOP-001-1

12. Proposed Reliability Standard EOP-001-1 contains seven requirements for the stated purpose of requiring each transmission operator and balancing authority to develop, maintain, and implement a set of plans to mitigate operating emergencies and to coordinate these plans with other transmission operators, balancing authorities, and the reliability coordinator.<sup>17</sup> It modifies EOP-001-0 by deleting Requirement R3.4, which requires transmission operators and balancing authorities to develop, maintain and implement restoration plans, because proposed Reliability Standards EOP-005-2 and EOP-006-2 incorporate and expand upon this Requirement.

Proposed Reliability Standard EOP-005-2

13. Proposed Reliability Standard EOP–005–2 contains eighteen requirements for the stated purpose of ensuring that plans, facilities, and personnel are prepared to enable system restoration from Blackstart Resources, and to ensure reliability is maintained during restoration and priority is placed

on restoring the Interconnection. $^{18}$  The proposed Reliability Standard applies to transmission operators, generation operators, and transmission owners and distribution providers identified in the transmission operator's restoration plan. Requirement R1 requires each transmission operator to have a reliability coordinator-approved restoration plan utilizing Blackstart Resources and details the scope and elements of such a plan. Requirement R2 instructs each transmission operator to provide entities that have a role in the restoration plan with a description of their roles and tasks. Requirements R3 through R6 address annual plan reviews, updating practices, location of plans and plan verification. Following a disturbance, Requirements R7 and R8 provide guidance on following the plan or making needed adjustments and coordinating when re-synchronizing two systems together. Requirement R9 describes testing information the transmission operator must have to verify the Blackstart Resources meet required expectations. Requirements R10 through R12 cover system restoration training requirements for system operators and field switching personnel. Blackstart Resource agreements between the transmission operator and generator operator, or mutually agreed upon procedures or protocols are addressed in Requirement R13. Duties of a generator owner with a Blackstart Resource are provided in Requirements R14 through R18, which address operating procedures, change notification, testing for each Blackstart Resource and training of operating personnel on Blackstart Resources. Proposed Reliability Standard EOP-005–2 is intended to supersede all of currently effective Reliability Standard EOP-005-1.

Proposed Reliability Standard EOP-006-2

14. Proposed Reliability Standard EOP–006–2 contains ten requirements with the stated purpose of ensuring that the reliability coordinator establishes plans and prepares personnel to enable effective coordination of the system restoration process, to maintain reliability during restoration, and to place priority on restoring the Interconnection. Paquirement R1 requires reliability coordinators to have restoration plans that utilize Blackstart Resources and specifies the scope and elements of such plans. Requirement R2

<sup>11</sup> Id. P 674, 676.

 $<sup>^{12}</sup>$  North American Electric Reliability Corp., Dec. 31, 2009 Petition for Approval of Three Emergency Preparedness and Operations Reliability Standards and One New Glossary Term and for Retirement of Five Existing Reliability Standards and One Glossary Term. The three Reliability standards are included as Exhibit A to NERC's Petition. In addition, under 18 CFR 40.3 of the Commission's regulations, all Commission-approved Reliability Standards are available on NERC's Web site at  $http://www.nerc.com/page.php?cid=2\sqrt{20}.$  See 18 CFR 40.3.

<sup>&</sup>lt;sup>13</sup> Concurrent with its filing in this Docket, NERC filed a petition in Docket No. RM10–15–000 seeking approval of certain Interconnection Reliability Operations and Coordination (IRO) Reliability Standards. As part of its IRO filing, NERC proposed to retire Requirement R2 of EOP–001–0. Each petition proposes unique changes to EOP–001–0 reflecting the distinct issues addressed by the respective Reliability Standards drafting teams. In this Final Rule, the Commission is addressing Version 2 of EOP–001 contained in Exhibit B of the NERC Petition which reflects both the IRO and the EOP proposed changes.

<sup>&</sup>lt;sup>14</sup> NERC Petition at 4.

<sup>15</sup> *Id.* at 5.

<sup>&</sup>lt;sup>16</sup> *Id*.

 $<sup>^{17}\,\</sup>mathrm{Reliability}$  Standard EOP–001–1, Section A.3. (Purpose).

 $<sup>^{18}</sup>$  Reliability Standard EOP-005-2, Section A.4. (Purpose).

<sup>&</sup>lt;sup>19</sup>Reliability Standard EOP–006–2, Section A.3. (Purpose).

covers distribution of the reliability coordinator's restoration plan. Requirements R3 through R5 provide for review of the reliability coordinator's restoration plan and the plans of each neighboring reliability coordinator and each transmission operator located in the reliability coordinator's area. Any conflicts between neighboring reliability coordinators' plans are to be resolved within thirty days, and transmission operators' plans shall be approved or disapproved, with stated reasons, within thirty days of receipt by the reliability coordinator. Requirement R6 requires that the reliability coordinator must maintain copies of restoration plans in its primary and backup control rooms. Requirements R7 and R8 describe the roles of reliability coordinators to coordinate restoration efforts and authorize re-synchronization of "island" areas. Requirements R9 and R10 address training and participation in annual drills, exercises and simulations. Proposed Reliability Standard EOP-006-2 is intended to supersede all of currently effective Reliability Standard EOP-006-1.

# C. Notice of Proposed Rulemaking

15. On November 17, 2010, the Commission issued its Notice of Proposed Rulemaking (NOPR) proposing to approve the three proposed EOP Reliability Standards, EOP-001-1, EOP-005-2, and EOP-006-2 and defined term Blackstart Resource (and the retirement of the four superseded standards, EOP-001-0, EOP-005-1, EOP-006-1, and EOP-009-0, the definition of "Blackstart Capability Plan," and the ERO's withdrawal of EOP-007-0).20 With respect to proposed Reliability Standard EOP-005-2, the NOPR proposed to direct NERC to modify the Standard to address the Commission's concern regarding the periodic testing of telecommunication facilities needed to implement restoration plans. In addition, the Commission sought comment on: (i) What is intended by the term "unique tasks" as used in the context of proposed Requirement R11 of EOP-005-2; (ii) whether guidance should be provided regarding the term, and if so, how it should be provided; and (iii) whether those tasks should be indentified in each transmission operator's restoration plan. With respect to proposed Reliability Standard EOP-006-2, the NOPR sought comment as to why the Standard does not require reliability coordinators to maintain a database of

Blackstart Resources as is required of Regional Entities under currently effective EOP-007-0 and whether such a requirement would be beneficial. The NOPR also sought comment on: (i) Whether reliability coordinators should be required to verify their restoration planning through actual events, steady state and dynamic simulations or testing; and (ii) how a transmission operator should proceed when its restoration plan is rejected by a reliability coordinator. Lastly, the NOPR proposed that the ERO collect data on the performance of system restoration exercises conducted by transmission operators and reliability coordinators to assist the ERO and Commission in identifying the effectiveness of restoration plans, establishing best practices, and determining the effects on personnel performance.

16. In response to the NOPR, comments were filed by nine interested parties.<sup>21</sup> These comments assisted us in the evaluation of the NERC's proposal. In the discussion below, we address the issues raised by these comments.

### II. Discussion

# A. Approval of Proposed Reliability Standards

17. In the NOPR, the Commission proposed to approve the three EOP Reliability Standards and the glossary term filed by NERC in this proceeding. None of the nine interested parties filing comments to the NOPR objects to such an approval. For the reasons described below, the Commission adopts the NOPR proposal and approves Reliability Standards EOP-001-1, EOP-005-2, and EOP-006-2 as well as the proposed glossary term "Blackstart Resource" as just, reasonable, not unduly discriminatory or preferential, and in the public interest. 22 EOP-005-2 and EOP-006-2 clarify the responsibilities of the reliability coordinator and transmission operator in the restoration process and restoration planning and address the Commission's directives in Order No. 693 related to the EOP Standards. By enhancing the rigor of the restoration planning process, the Reliability Standards represent an improvement from the current Standards and will improve the reliability of the Bulk-Power System. The Commission is not directing any

modifications to the three new Reliability Standards. Nevertheless, as discussed below, commenters raised several issues for consideration, at the time these standards are next revisited. which we believe could improve these new Reliability Standards. The Commission also approves NERC retiring the four currently effective Reliability Standards, EOP-001-0, EOP-005-1, EOP-006-1, and EOP-009-0 as well as the definition of "Blackstart Capability Plan" and withdrawing pending Reliability Standard EOP-007-0 concurrent with the effectiveness of the EOP-001-1, EOP-005-2, and EOP-006-2 and the definition of the term "Blackstart Resource."

# B. Vagueness of Term "Unique Tasks"

18. Requirement R11 of EOP-005-2 requires that a minimum of two hours of system restoration training be provided every two years to field switching personnel performing "unique tasks" associated with the transmission operator's restoration plan. In the NOPR, the Commission expressed concern that the applicable entities may not understand what the term "unique tasks" means. We requested comment on what is intended by that term and on whether guidance should be provided to the transmission operators, transmission owners, and distribution providers who are responsible for providing training. In addition, the NOPR sought comment as to whether the unique tasks should be identified in each transmission operator's restoration plan.

## Comment

19. NERC comments that the term "unique tasks" is not intended to have any meaning beyond the dictionary definition of the words. Everyday tasks of field switching personnel are not considered unique, but tasks not included in the person's normal duties (e.g., operation of a synchroscope) would be considered unique. NERC and APPA do not perceive a reliability benefit in requiring identification of unique tasks in restoration plans. NERC acknowledges that it could promote the development of guidance to aid entities in complying with Requirement R11.

20. EEI comments that while it would be difficult to define "unique tasks" in a manner that could be broadly applied to affected entities, the standards drafting team believed that the term was clearly understood as a practical matter. Companies should be afforded discretion to determine how the term is defined within their restoration plans, but, to the extent that compliance issues arise, EEI would encourage NERC to consider developing compliance

<sup>&</sup>lt;sup>20</sup> System Restoration Reliability Standards, Notice of Proposed Rulemaking, 75 FR 71625 (Nov. 24, 2010), FERC Stats. & Regs. ¶ 32,666 (2010).

<sup>&</sup>lt;sup>21</sup> NERC, The Edison Electric Institute (EEI), American Public Power Association (APPA), the ISO/RTO Council (IRC), Pacificorp, City of Santa Clara, California (Santa Clara), Bonneville Power Administration (BPA), and NorthWestern Corporation (NorthWestern) filed comments. Wisconsin Electric Power Company filed supporting EEI's comments.

<sup>&</sup>lt;sup>22</sup> 16 U.S.C. 824o(d)(2).

guidance as needed. IRC also believes the term is generally understood by the applicable entities and that it is appropriate for each transmission operator's restoration plan to identify the particular tasks for which training is required.

21. APPA states that the diversity of entities and their specific approaches to system restoration prevented the standard drafting team from developing guidance on the term but agrees that registered entities could benefit from a best practices document that provides

examples of unique tasks.

22. Santa Clara comments that a onesize-fits-all definition would not be helpful, and the affected entities should define unique tasks on a case-by-case basis. It agrees that unique tasks should be included within the transmission operator's restoration plan. Pacificorp comments that training should be provided to field switching personnel performing any restoration tasks associated with implementing the transmission operator's restoration plan. Addressing each sub-Requirement of Requirement R1 would provide an appropriate framework for a system restoration training program. Pacificorp and NorthWestern oppose additional guidance or requirements in the Standard. BPA, on the other hand, is unsure what is intended by the term "unique tasks" and supports a specific definition to avoid any ambiguity.

#### Commission Determination

23. Based on NERC's comment that the term "unique tasks" is to be understood in accordance with the normal meaning of the words and the majority of the commenters' assertions that the variety of approaches to system restoration precludes greater specificity, we find that the term conveys as much precision as circumstances allow. To the extent that it would be helpful to the affected entities to specify in a transmission operator's restoration plan which tasks are deemed unique, the entities are encouraged to do so, but the Commission does not require such specificity at this time.

24. Both EEI and APPA recognize potential benefit in the development of further guidance as to the term "unique tasks," and BPA is uncertain as to the meaning of the term and consequently unsure as to how to demonstrate compliance with its training obligation. NERC, in its comments about the term, states that it "could promote the development of a guideline to aid registered entities in complying with Requirement R11."<sup>23</sup> The Commission

notes that this Reliability Standard will not become effective for at least 24 months, during which time ambiguities in language or differences of opinion among affected entities may be resolved in practical ways. Once the Standard is effective, if industry determines that ambiguity with the term arises, it would be appropriate for NERC to consider its proposal to develop a guideline to aid entities in their compliance obligations.

#### C. Telecommunication Facility Testing

25. Requirement R5 of Reliability Standard EOP-005-1 provides for periodic testing of telecommunication facilities needed to implement restoration plans, but this Requirement has no counterpart in EOP-005-2. In the NOPR, the Commission proposed requiring the ERO to develop a modification to EOP-005-2 to address the Commission's concern that entities involved in system restoration ensure restoration-specific telecommunications equipment, phone lists, and protocols are tested as part of ongoing restoration preparedness. The Commission further stated its concern that, in light of the importance of communication to the restoration process, testing should be done more frequently than during annual drills, exercises or simulations as is required under Reliability Standard EOP-005-1.

# Comments

26. Each of the commenters opposes adding a telecommunications requirement to EOP-005-2 on the basis that such a requirement would be redundant given Communications Reliability Standard COM-001-1.1, which requires testing of routine communication facilities on an on-going basis. Several comments noted that duplicative requirements can lead to potential confusion.

#### Commission Determination

27. Reliability Standard COM-001-1 does not apply to generation operators or distribution providers.24 Further, we do not accept that each entity whose telecommunications facilities will be needed during the system restoration process is currently subject to COM-001-1.1 Requirement R2 which provides that "[e]ach Reliability Coordinator, Transmission Operator and Balancing Authority shall manage, alarm, test and/or actively monitor vital telecommunications facilities. Special attention shall be given to emergency telecommunications facilities and

equipment not used for routine communications.'

28. NERC notes in its comments that the Reliability Coordination Standard Drafting Team is currently working on Project 2006-06 to develop a set of revisions to Reliability Standard COM-001-1.1 to tighten requirements relating to communication capabilities. The Commission believes the objectives of this project in managing, alarming, testing and/or actively monitoring vital primary and emergency telecommunication facilities will close this gap in the Reliability Standard after it is completed and approved. Accordingly, consistent with NERC's comments on its current project and concerns not to create redundancy in development of Reliability Standards, NERC should close the gap in the applicability of the draft COM-001-2 so it addresses generation operators and distribution providers.

# D. Emergency Operations Planning

29. Reliability Standard EOP-005-2 requires each transmission operator to identify each blackstart resource and its characteristics, but this requirement has no counterpart for reliability coordinators in EOP-006-2. The Commission expressed concern and invited comment in the NOPR on whether the absence of a required list of its Blackstart Resources could deny the reliability coordinator a potentially useful tool in maintaining reliability.

# Comments

30. NERC notes that the transmission operator, not the reliability coordinator, maintains direct contact with the blackstart resources, and reliability coordinators have sufficient authority to request information needed to identify blackstart resources should such information be required. NERC, EEI, IRC, and APPA do not believe a requirement to maintain a database of blackstart resources would improve reliability. Santa Clara, however, requests that the Commission direct NERC to revise Requirement R2 of Reliability Standard EOP-005-2 to specify that transmission operators provide copies of their restoration plans to those entities included in the plan within 60 days of the plan's approval by the appropriate reliability coordinator to ensure that resources identified in the plan are capable of complying with the plan.

# **Commission Determination**

31. Since a reliability coordinator obtains copies of all its constituent transmission operators' restoration plans and has the ability to obtain

<sup>&</sup>lt;sup>24</sup> Order No. 693, FERC Stats. & Regs. ¶ 31,242 at

information regarding the identity and characteristics of blackstart resources from its transmission operators, we agree there is no reliability need for it to maintain a duplicative database. With regard to Santa Clara's request, we believe that the determination whether resources in a restoration plan are capable of complying with the plan is made during the transmission operator's development of its plan as required by Requirement R1, not once the plan is approved by the reliability coordinator. For this reason, we do not see a need to direct the modification to Requirement R2 that Santa Clara requests.

# E. System Restoration Coordination

32. Reliability Standard EOP-005-2 requires each transmission operator to verify that its restoration plan achieves its intended function. There is no similar requirement in EOP-006-2 regarding the reliability coordinator's restoration plan. The Commission sought comment on whether the same or a similar requirement should apply to reliability coordinators. In addition, the Standard also requires reliability coordinators to approve, or disapprove with written reasons, the restoration plans of each of their constituent transmission operators. The Commission invited comment as to how a transmission operator should proceed when its restoration plan is rejected by a reliability coordinator.

#### Comments

33. NERC, EEI, and IRC comment that a reliability coordinator's restoration plan is essentially a compilation of the restoration plans of its constituent transmission operators. Given that EOP-005-2 requires transmission operators to verify their restoration plans and that EOP-006-2 requires reliability coordinators to conduct system restoration drills with their constituent transmission operators and generation owners, requiring further verification of the same plans by the reliability coordinator would be duplicative and not provide additional reliability benefit.

34. With respect to how a transmission operator should proceed when its reliability coordinator rejects its restoration plan, NERC states that when a restoration plan is rejected by a reliability coordinator, the reliability coordinator is required to supply one or more reasons for its rejection, and the transmission operator should then be able to re-submit a revised plan. NERC does not believe it is necessary to document this process in additional requirements since the dialogue between the two entities is no different

than the routine coordination that normally occurs between the transmission operator and its reliability coordinator. EEI, APPA, and IRC agree that there is no need for additional procedures to be spelled out.

35. IRC, BPA, and Santa Clara all comment that the reliability coordinator should be the final authority to resolve conflicts. Santa Clara nevertheless states that if the transmission operator and reliability coordinator cannot resolve their differences because the transmission operator believes compliance with the reliability coordinator's decision is infeasible, the transmission operator should be allowed to appeal either to the Regional Entity or, in the case of the Western Interconnect, the dispute should be brought to NERC.

36. EEI observes that the two-year implementation period for these Standards will likely provide sufficient time to resolve any differences in order for a reliability coordinator to approve a transmission operator's initial restoration plan. Any subsequent rejection of a revised restoration plan will not result in a reliability gap since the initial plan will remain in place. EEI further notes that any rejection of a restoration plan by a reliability coordinator will necessarily be based on generic reliability engineering criteria readily understood by the transmission operator. Pacificorp, on the other hand, notes that the requirement that the reliability coordinator give stated reasons for any disapproval of a submitted restoration plan does not ensure the reasons will specify the circumstances under which a transmission operator should revise its plan. Pacificorp states that a reliability coordinator must have formal criteria for reviewing, approving and disapproving restoration plans and standard procedures for those plans to be revised and resubmitted for review. Pacificorp also suggest a modification to Requirement R5 to provide that a transmission operator's submitted restoration plan shall be deemed approved if the reliability coordinator fails to approve or disapprove the plan within the required 30 days.

# **Commission Determination**

37. We accept the commenters' position that requiring verification of the reliability coordinators' restoration plan through a requirement in EOP–006–2 would be largely duplicative. As commenters point out, Reliability Standard EOP–006–2 requires reliability coordinators to conduct system restoration drills including their constituent transmission operators and

generation owners. Such drills, exercises or simulations, together with the verifications carried out by the transmission operators of their restoration plans and approval of their plans by the reliability coordinators under EOP–005–2, serve as verification of the reliability coordinators' plans and as such, should serve to identify difficulties in a reliability coordinator's restoration plan.

38. We agree with EEI that the basis on which a reliability coordinator rejects a restoration plan will necessarily be based on generic engineering criteria easily understood by the transmission operator. We also agree with those commenters who reaffirm that the ultimate arbiter of coordination and compatibility of transmission operators' restoration plans is the reliability coordinator. For these reasons, we do not see a need to direct modifications as Pacificorp and Santa Clara suggest that could circumvent the reliability coordinator's authority concerning the approval or disapproval of a restoration plan. However, we agree with Pacificorp that Reliability Standard EOP-006-2, which establishes requirements to enable coordinated system restoration and ensure reliability is maintained during system restoration, is not the appropriate place to include any specific criteria or procedures for the review and revision of transmission operators' restoration plans. We recognize that documenting such criteria and procedures may have utility in facilitating the settlement of disagreements when a reliability coordinator rejects a transmission operator's restoration plan. Nonetheless, we leave it to the ERO Reliability Standard development process to determine whether the merit is sufficient to compel the development of such criteria or procedures.

# F. Data Reporting

39. Given the importance of effective blackstart and restoration plans and well-trained personnel, the NOPR proposed that the ERO collect data on the performance of system restoration exercises and make such data available to transmission operators, reliability coordinators and the Commission. This data could then be used to identify the effectiveness of restoration plans and help identify improvements to enhance restoration. The Commission sought comment on the proposed data collection.

#### Comments

40. NERC notes that formal debriefings are held after each required

drill and is unclear whether there would be any additional reliability benefit arising from the data collection contemplated in the NOPR. EEI proposes that companies should be allowed to gather experience on the new requirements before undertaking data collection efforts and points out that the North American Transmission Forum (NATF) would be an appropriate venue for discussions on the efficacy of various training experiences. BPA and NorthWestern also cite NATF as an appropriate venue to share best practices. BPA views its restoration information as extremely sensitive and perceives risk that such information could fall into the wrong hands.

41. NERC, EEI, APPA, Pacificorp, and NorthWestern question the reliability benefit of creating such a database compared to the burden it would impose on the industry. NERC asks whether developing such a database would direct industry resources where they can best serve reliability. IRC does not see the value of the proposed data gathering, but notes section 1600—Requests for Data or Information of NERC's Rules of Procedure <sup>25</sup> could be an appropriate means of collecting data without creating an ongoing requirement.

# Commission Determination

42. The Commission agrees with NERC that the formal debriefing of system restoration drills, exercises and simulations can capture lessons learned and identify best practices. But lessons learned in such debriefings are not necessarily communicated to all who might benefit from them. In addition, the Commission understands that NATF

may be an appropriate forum to discuss industry activity and best practices, but we continue to believe that there would be a reliability benefit in the ERO aggregating and disseminating lessons learned derived from restoration drills, exercises and simulations. Nevertheless, we will allow the industry to develop some experience with the new Reliability Standards and then review whether or not to pursue this matter under section 39.2(d) of the Commission's regulations and the use of Requests for Data or Information under section 1600 of NERC's Rules of Procedure or through some other means.

# G. Violation Risk Factors/Violation Severity Levels

43. In the NOPR, the Commission proposed deferring action on the proposed violation risk factors (VRF) and violation severity levels (VSL) for the proposed Reliability Standards until the Commission acts on NERC's pending petition in Docket No. RR08-4-005, in which NERC proposes a "rollup" approach for VRF and VSL assignments by which NERC would only assign VRF and VSL to the main requirements and not to sub-Requirements.<sup>26</sup> Subsequent to the NOPR, on December 1, 2010, NERC made a compliance filing to the Commission in Docket No. RR08-04-006 submitting new VSL to supersede those presented in the NERC Petition.

#### Commission Determination

44. No comments were received regarding this matter. Accordingly, the Commission will defer discussion on the proposed violation risk factors and violation severity levels assigned to EOP-005-2 and EOP-006-2 until after

the Commission issues a final order acting on NERC's petition in Docket No. RR08–4–005 and Docket No. RR08–4–006.

# **III. Information Collection Statement**

45. The following collections of information contained in this Reliability Standard have been submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the Paperwork Reduction Act of 1955.<sup>27</sup> OMB's regulations require OMB to approve certain information collection requirements imposed by agency rule.<sup>28</sup>

46. The Commission solicited comments on the need for and the purpose of the information contained in these three Emergency Operations and Performance Reliability Standards and the corresponding burden to implement them. The commission received comments on its proposed data reporting requirement regarding the performance of system restoration exercises which we address in this Final Rule. The Commission has not directed any modifications to the Requirements in the three Reliability Standards being approved. As a result of this Final Rule the annual burden will increase by an estimated 47,472 hours. This is a reduction from the burden estimates provided in the NOPR, with respect to reporting data to NERC; however, we have not similarly reduced the estimated time expended by reliability coordinators on recordkeeping in order to better reflect their enhanced involvement in the planning process.

47. *Burden Estimate:* The estimated burden and for the requirements in this Final Rule follow:

FERC-725A data collection	Number of respondents	Number of annual responses per respondent	Hours per respondent per response	Total annual hours
	(A)	(B)	(C)	$(A \times B \times C)$
Reliability Coordinators data retention	26 176	2	Recordkeeping: 8	Recordkeeping: 416. Compliance: 20,416. Recordkeeping: 2,816.
Generator operator system restoration responsibilities including testing and maintaining records.  Transmission owner and distribution provider training and recordkeeping.	230 678	1	80	18,400. 5,424.
Total				47,472 hours.

<sup>&</sup>lt;sup>25</sup> North American Electric Reliability Corporation, Rules of Procedure 85–87 (2011), available at http://www.nerc.com/files/ NERC\_Rules\_of\_Procedure\_EFFECTIVE\_ 20110101.pdf.

<sup>&</sup>lt;sup>26</sup> Docket No. RR08–4–005 comprises NERC's March 5, 2010 Violation Severity Level Compliance Filing submitted in response to Order No. 722 and an August 10, 2009 informational filing in which NERC proposes assigning VRF and VSL only to the

main Requirements in each Reliability Standard and not to the sub-requirements.

<sup>&</sup>lt;sup>27</sup> 44 U.S.C. 3507(d).

<sup>&</sup>lt;sup>28</sup> 5 CFR 1320.11.

- Total Estimated Annual Hours for Collection: (Reporting/Compliance + recordkeeping) = 47,472 hours.
- Reporting/Compliance = 44,240 hours @ \$132/hour = \$5,839,680.
- Recordkeeping = 3,232 hours @ 17/hour = 54,944.
  - $Total\ Cost = \$5,894,624.$
- Title: Mandatory Reliability Standards for the Bulk-Power System.
- Action: FERC 725A, Proposed Modification to FERC-725A.
  - OMB Control No: 1902-0244.
- Respondents: Business or other for profit, and/or not for profit institutions.
- Frequency of Responses: On occasion.
- Necessity of the Information: This Final Rule would approve revised Reliability Standards that modify the existing requirement for system restoration from a blackstart. The proposed Reliability Standards require some entities to commit agreements or understandings to writing and/or to draft written procedures, and retain records. Other entities may have to produce and maintain training materials.
- 48. Interested persons may obtain information on the reporting requirements by contacting: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 Attention: Ellen Brown, Office of the Executive Director, e-mail: DataClearance@ferc.gov, Phone: (202) 502-8663, fax: (202) 273-0873]. Comments on the requirements of this order may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by e-mail to OMB at oira submission@omb.eop.gov. Please reference OMB Control Number 1902-0244 and the docket number of this rulemaking in your submission.

# IV. Environmental Analysis

49. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.29 The action taken in the Final Rule falls within the categorical exclusion in the Commission's regulations for rules that are clarifying, corrective or procedural, for information gathering, analysis, and

dissemination.30 Accordingly, neither an environmental impact statement nor an environmental assessment is required.

# V. Regulatory Flexibility Act

50. The Regulatory Flexibility Act of 1980 (RFA) 31 generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.<sup>32</sup> The SBA has established a size standard for electric utilities, stating that a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatt hours.33

51. Many of the entities to which the requirements of this rule would apply do not fall within the definition of small entities, but most transmission owners, and most distribution providers would be deemed small entities. The proposed Reliability Standards clarify the elements of restoration plans and training requirements and give reliability coordinators a greater role in review and approval of plans, but the proposed Reliability Standards reflect primarily a continuation of existing system restoration requirements currently applicable to reliability coordinators, transmission operators and generation operators.

52. Based on available information regarding NERC's compliance registry, and our best assessment of the application of the proposed Reliability Standards, approximately 1,110 entities will be responsible for compliance with proposed Reliability Standards EOP-005-2 and EOP-006-2, of which approximately 678 are transmission owners and distribution providers not already subject to the existing system restoration Reliability Standards. Of the 678 transmission owners and

distribution providers, only that subset whose field switching personnel are identified in the restoration plan as having unique tasks will be subject to a new requirement under the proposed

standards, i.e., providing two hours of system restoration training every two calendar years to such personnel. The Commission estimates that this requirement will impose a cost of perhaps \$1,056 per year on transmission owners and distribution providers, (and indeed for some entities there will be only de minimis additional cost because field personnel are already being trained in restoration tasks) and therefore should not present significant operating

53. Based on this understanding, the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required.

#### VI. Document Availability

54. In addition to publishing the full text of this document in the Federal **Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (http://www.ferc.gov) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

55. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

56. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or e-mail at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659, E-mail the Public Reference Room at public.referenceroom@ferc.gov.

# VII. Effective Date and Congressional Notification

57. These regulations are effective May 23, 2011. The Commission notes that although the determinations made in this Final Rule are effective May 23, 2011 in those jurisdictions where regulatory approval is required, Reliability Standard EOP–001–1 will not become effective until the first day of the first calendar quarter three months after regulatory approval is obtained, and EOP-005-2 and EOP-006-2 approved in this Final Rule will not become effective until 24 months

<sup>&</sup>lt;sup>29</sup> Regulations Implementing the National Environmental Policy Act, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Regulations Preambles 1986-1990 ¶ 30,783 (1987).

<sup>&</sup>lt;sup>30</sup> 18 CFR 380.4(a)(5).

<sup>31 5</sup> U.S.C. 601-12.

<sup>32 13</sup> CFR 121.101.

<sup>33 13</sup> CFR 121.201, Sector 22, Utilities & n. 1.

after the first day of the first quarter after applicable regulatory approval. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.

## Kimberly D. Bose,

Secretary.

[FR Doc. 2011-6739 Filed 3-22-11; 8:45 am]

BILLING CODE 6717-01-P

# DELAWARE RIVER BASIN COMMISSION

#### 18 CFR Part 410

Amendments to the Water Quality Regulations, Water Code and Comprehensive Plan To Update Water Quality Criteria for Toxic Pollutants in the Delaware Estuary and Extend These Criteria to Delaware Bay

**AGENCY:** Delaware River Basin

Commission.

ACTION: Final rule.

SUMMARY: By Resolution No. 2010–13 on December 8, 2010, the Delaware River Basin Commission (DRBC or "Commission") approved amendments to its Water Quality Regulations, Water Code and Comprehensive Plan to update the Commission's human health and aquatic life stream quality objectives (also called water quality criteria) for toxic pollutants in the Delaware Estuary (DRBC Water Quality Zones 2 through 5) and extended application of the criteria to Delaware Bay (DRBC Water Quality Zone 6).

**DATES:** Effective Date: March 23, 2011. The incorporation by reference of the publications listed in this rule is approved by the Director of the Federal Register as of March 23, 2011.

FOR FURTHER INFORMATION CONTACT: For questions about the technical basis for the rule, please contact Dr. Ronald MacGillivray at 609–477–7252.

SUPPLEMENTARY INFORMATION: The Delaware River Basin Commission is a federal-state regional agency charged with managing the water resources of the Delaware River Basin without regard to political boundaries. Its members are the governors of the four basin states—Delaware, New Jersey, New York, and Pennsylvania—and the North Atlantic Division Commander of the U.S. Army Corps of Engineers, representing the Federal government.

Notice of the proposed amendments appeared in the **Federal Register** (75 FR 41106) on July 15, 2010 as well as in the Delaware Register of Regulations (14 DE Reg. 70–83 (08/01/2010)) on August 1, 2010, the New Jersey Register (42 N.J.R. 1701(a)) on August 4, 2010, the New York State Register (p. 6) on July 21, 2010 and the Pennsylvania Bulletin (40 Pa. B. 4208) on July 31, 2010. A public hearing was held on September 23, 2010 and written comments were accepted through October 1, 2010. The commission received two written submissions and no oral testimony on the proposed changes. The Commission made minor revisions to the proposed amendments in response to the comments received. A comment and response document setting forth the Commission's responses and revisions in detail was approved by the Commission simultaneously with adoption of the final rule.

Resolution No. 2010–13, the text of the final rule, a copy of the comment and response document, and a basis and background document published simultaneously with the proposed rule are available on the Commission's Web site, at <a href="http://www.state.nj.us/drbc/toxics info.htm">http://www.state.nj.us/drbc/toxics info.htm</a>.

#### List of Subjects in 18 CFR Part 410

Incorporation by reference, Water audit, Water pollution control, Water reservoirs, Water supply, Watersheds.

For the reasons set forth in the preamble, the Delaware River Basin Commission amends part 410 of title 18 of the Code of Federal Regulations as follows:

# PART 410—BASIN REGULATIONS; WATER CODE AND ADMINISTRATIVE MANUAL—PART III WATER QUALITY REGULATIONS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Delaware River Basin Compact, 75 Stat. 688.

■ 2. Amend § 410.1 by revising the first sentence of paragraph (c) to read as follows:

# § 410.1 Basin regulations—Water Code and Administrative Manual—Part III Water Quality Regulations.

\* \* \* \* \*

(c) Work, services, activities and facilities affecting the conservation, utilization, control, development or management of water resources within the Delaware River Basin are subject to regulations contained within the Delaware River Basin Water Code with Amendments Through December 8, 2010 and the Administrative Manual—

Part III Water Quality Regulations with Amendments Through December 8, 2010. \* \* \*

Dated: March 15, 2011.

#### Pamela M. Bush,

Commission Secretary.

[FR Doc. 2011-6636 Filed 3-22-11; 8:45 am]

BILLING CODE 6360-01-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

# 21 CFR Part 172

[Docket No. FDA-2002-F-0198] (formerly Docket No. 2002F-0316)

# Food Additives Permitted for Direct Addition to Food for Human Consumption; Bacteriophage Preparation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; response to objections and denial of requests for a hearing and stay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is responding to objections and is denying requests that it has received for a hearing on the final rule that amended the food additive regulations to provide for the use of a bacteriophage preparation as an antimicrobial agent against Listeria monocytogenes on ready-to-eat (RTE) meat and poultry products. After reviewing the objections to the final rule and the requests for a hearing, the Agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the amendment to the regulation. FDA also is denying the request for a stay of the effective date of the final rule.

**DATES:** Effective date of the final rule published in the **Federal Register** of August 18, 2006 (71 FR 47729) confirmed: August 18, 2006.

# FOR FURTHER INFORMATION CONTACT:

James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS– 265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1303.

#### SUPPLEMENTARY INFORMATION:

# I. Introduction

FDA published a notice in the **Federal Register** of July 22, 2002 (67 FR 47823), announcing the filing of food additive petition, FAP 2A4738, by Intralytix Inc., to amend the food additive regulations by providing for the safe use of a