for any action that may have a significant adverse effect on the human environment.<sup>47</sup> The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.<sup>48</sup> The actions proposed here fall within this categorical exclusion in the Commission's regulations.

## VI. Regulatory Flexibility Act Certification

69. The Regulatory Flexibility Act of 1980 (RFA) 49 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>50</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.51

70. Proposed Reliability Standard PRC-006-1 proposes to establish design, assessment, and documentation requirements for automatic UFLS program. It will be applicable to planning coordinators and entities that are responsible for the ownership, operation, or control of UFLS equipment. Proposed Standard EOP-003-2 proposes to remove balancing authorities from having to comply with R2 and M1 of the standard. Comparison of the NERC compliance registry with data submitted to the Energy Information Administration on Form EIA-861 indicates that perhaps as many as 8 small entities are registered as planning coordinators and 18 small entities are registered as balancing authorities. The Commission estimates that the small planning coordinators to

whom the proposed Reliability Standard will apply will incur compliance and recordkeeping costs of \$157,184 (\$19,648 per planning coordinator) associated with the Standard's requirements. The small balancing authorities will receive a savings of \$154,728 (\$8,596 per balancing authority). Accordingly, proposed Reliability Standards PRC-006-1 and EOP-003-2 should not impose a significant operating cost increase or decrease on the affected small entities.

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

#### VII. Comment Procedures

72. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due December 27, 2011. Comments must refer to Docket No. RM11–20–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

73. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at http://www.ferc.gov. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

74. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

75. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

#### VIII. Document Availability

76. 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 the Commission's Home Page (http://

www.ferc.gov) and in the Commission'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.

77. From the Commission'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.

78. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's 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.

### List of Subjects in 18 CFR Part 40

Electric power; Electric utilities; Reporting and recordkeeping requirements.

By direction of the Commission. Commissioner Spitzer is not participating. Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–27625 Filed 10–25–11; 8:45 am]

BILLING CODE 6717-01-P

### **DEPARTMENT OF ENERGY**

# Federal Energy Regulatory Commission

## 18 CFR Part 40

[Docket No. RM11-18-000]

# Transmission Planning Reliability Standards

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Transmission Planning (TPL) Reliability Standards are intended to ensure that the transmission system is planned and designed to meet an appropriate and specific set of reliability criteria. Reliability Standard TPL-002-Oa references a table which identifies different categories of contingencies and allowable system impacts in the planning process. The table includes a footnote regarding planned or controlled interruption of electric supply where a single contingency occurs on a transmission system. North American Electric Reliability Corporation (NERC), the Commission-certified Electric

<sup>&</sup>lt;sup>47</sup> Order No. 486, Regulations Implementing the National Environmental Policy Act of 1969, FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

<sup>48 18</sup> CFR 380.4(a)(2)(ii).

<sup>&</sup>lt;sup>49</sup> 5 U.S.C. 601-612.

<sup>&</sup>lt;sup>50</sup> 13 CFR 121.101.

<sup>&</sup>lt;sup>51</sup> 13 CFR 121.201, Sector 22, Utilities & n.1.

Reliability Organization, requests approval of a revision to the footnote. In this notice, the Commission proposes to remand NERC's proposed revision to the footnote.

**DATES:** Comments are due December 27, 2011

**ADDRESSES:** You may submit comments, identified by docket number by any of the following methods:

- Agency Web Site: http:// www.ferc.gov. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- Mail/Hand Delivery: Commenters unable to file comments electronically must mail or hand deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

#### FOR FURTHER INFORMATION CONTACT:

Robert T. Stroh (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502–8473.

Eugene Blick (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, *Telephone*: (202) 502–8066.

# SUPPLEMENTARY INFORMATION:

## **Notice of Proposed Rulemaking**

October 20, 2011.

1. On March 31, 2011, the North American Electric Reliability Corporation (NERC) filed a petition seeking approval of Table 1, footnote 'b' of four Reliability Standards: Transmission Planning: TPL-001-1-System Performance Under Normal (No Contingency) Conditions (Category A), TPL-002-1b—System Performance Following Loss of a Single Bulk Electric System Element (Category B), TPL-003-1a—System Performance Following Loss of Two or More Bulk Electric System Elements (Category C), and TPL-004-1- System Performance Following Extreme Events Resulting in the Loss of Two or More Bulk Electric System Elements (Category D). 1 Pursuant to section 215(d)(4) of the Federal Power Act (FPA) 2, the Commission proposes to remand the proposed Table 1, footnote b. As discussed below, the Commission believes that the proposed Reliability Standard does not meet the statutory

criteria for approval that it be just, reasonable, not unduly discriminatory or preferential, and in the public interest.<sup>3</sup> The Commission seeks comments on its proposal.

### I. Background

- 2. Section 215 of the FPA requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Approved Reliability Standards are enforced by the ERO, subject to Commission oversight, or by the Commission independently.
- 3. Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO 4 and, subsequently, certified NERC as the ERO.5 On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards filed by NERC, including Reliability Standard TPL-002-0, Table 1, footnote 'b.' 6 In addition, pursuant to section 215(d)(5) of the FPA, the Commission directed NERC to develop modifications to 56 of the 83 approved Reliability Standards, including footnote 'b' of Reliability Standard TPL-002 - 0.8
- A. Transmission Planning (TPL) Reliability Standards
- 4. Currently-effective Reliability Standard TPL-002-0a addresses Bulk-Power System planning and related system performance for single element contingency conditions. Requirement R1 of TPL-002-0a requires that each Planning Authority and Transmission Planner "demonstrate through a valid assessment that its portion of the interconnected transmission system is planned such that the Network can be operated to supply projected customer demands and projected Firm Transmission Services, at all demand levels over the range of forecast system demands, under the contingency conditions as defined in Category B of

Table I." <sup>9</sup> Table I identifies different categories of contingencies and allowable system impacts in the planning process. With regard to system impacts, Table I further provides that a Category B (single) contingency must not result in cascading outages, loss of demand or curtailed firm transfers, system instability or exceeded voltage or thermal limits. With regard to the clause regarding loss of demand, current footnote 'b' of Table 1 states:

Planned or controlled interruption of electric supply to radial customers or some local Network customers, connected to or supplied by the Faulted element or by the affected area, may occur in certain areas without impacting the overall reliability of the interconnected transmission systems. To prepare for the next contingency, system adjustments are permitted, including curtailments of contracted Firm (non-recallable reserved) electric power Transfers.

## B. Order No. 693 Directive

5. In Order No. 693, the Commission stated that it believes that the transmission planning Reliability Standard should not allow an entity to plan for the loss of non-consequential firm load in the event of a single contingency. 10 The Commission directed the ERO to develop certain modifications, including a clarification of Table 1, footnote 'b'. The Commission stated that:

Based on the record before us, we believe that the transmission planning Reliability Standard should not allow an entity to plan for the loss of non-consequential load in the event of a single contingency. The Commission directs the ERO to clarify the Reliability Standard. Regarding the comments of Entergy and Northern Indiana that the Reliability Standard should allow entities to plan for the loss of firm service for a single contingency, the Commission finds that their comments may be considered through the Reliability Standards development process. However, we strongly discourage an approach that reflects the lowest common denominator. The Commission also clarifies that an entity may seek a regional difference to the Reliability Standard from the ERO for case-specific circumstances.11

<sup>&</sup>lt;sup>1</sup>While footnote 'b' appears in all four of the above referenced TPL Reliability Standards, its relevance and practical applicability is limited to TPL–002–0a.

<sup>&</sup>lt;sup>2</sup> 18 U.S.C. 824o(d)(4) (2006).

<sup>&</sup>lt;sup>3</sup> 16 U.S.C. 824o(d)(2) (2006).

<sup>&</sup>lt;sup>4</sup> Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval and Enforcement of Electric Reliability Standards, Order No. 672, FERC Stats. & Regs. ¶ 31,204, order on reh'g, Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

 $<sup>^5</sup>$  North American Electric Reliability Corp., 116 FERC  $\P$  61,062, order on reh'g & compliance, 117 FERC  $\P$  61,126 (2006), aff'd sub nom., Alcoa, Inc. v. FERC, 564 F.3d 1342 (D.C. Cir. 2009).

<sup>&</sup>lt;sup>6</sup> Mandatory Reliability Standards for the Bulk-Power System, Order No. 693, FERC Stats. & Regs. ¶ 31,242, order on reh'g, Order No. 693–A, 120 FERC ¶ 61,053 (2007).

<sup>&</sup>lt;sup>7</sup>16 U.S.C. 824o(d)(5)(2006).

 $<sup>^8</sup>$  Order No. 693, FERC Stats & Regs.  $\P$  31,242 at P 1797.

 $<sup>^{9}\,\</sup>mbox{Reliability Standard TPL-002-0a, Requirement R1.}$ 

<sup>&</sup>lt;sup>10</sup> See Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 1794. Non-consequential load loss includes the removal, by any means, of any planned firm load that is not directly served by the elements that are removed from service as a result of the contingency. Currently-effective footnote 'b' deals with both consequential load loss and non-consequential load loss. NERC's proposed footnote 'b' characterizes both types of load loss as "Firm Demand." The focus of this NOPR is NERC's proposed treatment of non-consequential load loss or planned interruption of "Firm Demand."

<sup>&</sup>lt;sup>11</sup> Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 1794 (footnotes omitted).

6. In a subsequent clarifying order, the Commission stated that it believed that a regional difference, or a case-specific exception process that can be technically justified, to plan for the loss of firm service "at the fringes of various systems" would be an acceptable approach in limited circumstances. 12 Specifically, the Commission clarified that:

Moreover, the Commission, in \* \* \* Order No. 693, then provided a clarification that an entity may seek a regional difference to the Reliability Standard from the ERO for casespecific circumstances. We believe that a regional difference, or a case-specific exception process that can be technically justified, to plan for the loss of firm service 'at the fringes of various systems' would be an acceptable approach. Thus, the Commission did not dictate a single solution as NERC and others now claim. In any event, NERC must provide a strong technical justification for its proposal. 13

## C. NERC's Petition for Approval of TPL-002–0a, Footnote b

7. On March 31, 2011, NERC filed a petition seeking approval of its proposal to revise and clarify footnote 'b' "in regard to load loss following a single contingency." 14 NERC stated that it did not eliminate the ability of an entity to plan for the loss of non-consequential load in the event of a single contingency but drafted a footnote that, according to NERC, "meets the Commission's directive while simultaneously meeting the needs of industry and respecting jurisdictional bounds."  $^{15}$  NERC states that its proposed footnote 'b' establishes the requirements for the limited circumstances when and how an entity can plan to interrupt Firm Demand for Category B contingencies. It allows for planned interruption of Firm Demand when "subject to review in an open and transparent stakeholder process." 16 NERC's proposed footnote 'b' states:

An objective of the planning process should be to minimize the likelihood and magnitude of interruption of firm transfers or Firm Demand following Contingency events. Curtailment of firm transfers is allowed when achieved through the appropriate redispatch of resources obligated to re-dispatch, where it can be demonstrated that Facilities, internal and external to the Transmission Planner's planning region, remain within applicable Facility Ratings and the redispatch does not result in the shedding of any Firm Demand. It is recognized that Firm Demand will be interrupted if it is: (1) Directly served by the Elements removed

from service as a result of the Contingency, or (2) Interruptible Demand or Demand-Side Management Load. Furthermore, in limited circumstances Firm Demand may need to be interrupted to address BES performance requirements. When interruption of Firm Demand is utilized within the planning process to address [Bulk Electric System] performance requirements, such interruption is limited to circumstances where the use of Demand interruption are documented, including alternatives evaluated; and where the Demand interruption is subject to review in an open and transparent stakeholder process that includes addressing stakeholder comments.

## D. Supplemental Information

8. On June 7, 2011, in response to a Commission deficiency letter, NERC explained that "the approach proposed in footnote 'b' is equally efficient because many of the stakeholder processes that will be used in footnote 'b' planning decisions are already in place, as implemented by FERC in Order No. 890 and in state regulatory jurisdictions." 17 NERC also pointed to state public utility commission processes or processes existing in local jurisdictions that address transmission planning issues that could serve to provide a case-specific review of the planned interruption of Firm Demand. NERC added that an ERO-sponsored planning process is not likely to be efficient or effective because of extensive jurisdictional issues between NERC, the Commission, and the many authorities having jurisdiction that would have to be resolved before implementation could occur. NERC added that an ERO-specific process would lead to conflicts among federal, provincial, state and local governing bodies that have jurisdiction over various parts of the planning, siting and construction process. NERC also believes that a NERC-centered process would duplicate planning actions occurring elsewhere (e.g., where resource allocation decisions are actually being made), and such a process could lead to inconsistent results. NERC concluded that a more reasonable and expeditious path would be to rely on existing stakeholder processes. According to NERC, such processes would more likely engage the appropriate local-level decision-makers and policy-makers.

9. With respect to review and oversight by NERC and the Regional Entities, NERC submitted that an EROspecific process would place the ERO in the position of managing and actively participating in a planning process, which conflicts with its role as the

compliance monitor and enforcement authority. NERC also stated that neither the ERO nor the Regional Entities will review decisions regarding planned interruptions. Their role will be limited to reviewing whether the registered entity participated in a stakeholder process when planning to interrupt Firm Demand. NERC explained that Regional Entities will have oversight after-the-fact by auditing the entity's implementation of footnote 'b' to determine if the entity planned on interrupting Firm Demand and whether the decision by the entity to rely on planned interruption of Firm Demand was vetted through the stakeholder process and qualified as one of the situations identified in footnote b.

10. Furthermore, NERC stated that an objective of the planning process should be to minimize the likelihood and magnitude of planned Firm Demand interruptions. NERC recognizes that there may be topological or system configurations where allowing planned interruptions of Firm Demand may provide more reliable service. NERC contends that due to the wide variety of system configurations and regulatory compacts, it is not feasible for the ERO to develop a one-size-fits-all criterion for limiting the planned firm load interruptions for Category B events. According to NERC, the standards drafting team evaluated setting a certain magnitude of planned interruption of Firm Demand, but there was no analytical data to support a single value, and it would be viewed as arbitrary.

### II. Discussion

11. The Commission proposes to remand NERC's proposal to modify Reliability Standard TPL-002-0a, Table 1, footnote 'b.' The Commission believes that NERC's proposal does not meet the directives in Order No. 693 and the June 2010 Order and does not clarify or define the circumstances in which an entity can plan to interrupt Firm Demand for a single contingency. Specifically, the Commission is concerned that the procedural and substantive parameters of NERC's proposed stakeholder process are too undefined to provide assurances that the process will be effective in determining when it is appropriate to plan for interrupting Firm Demand, does not contain NERC-defined criteria on circumstances to determine when an exception for planned interruption of Firm Demand is permissible, and could result in inconsistent results in implementation. In proposing a stakeholder process without specification of any technical means by which exceptions are to be evaluated,

<sup>12</sup> Mandatory Reliability Standards for the Bulk Power System, 131 FERC ¶ 61,231, at P 21 (2010) (June 2010 Order).

<sup>13</sup> Id

<sup>14</sup> NERC Petition at 10.

<sup>15</sup> Id.

<sup>16</sup> Id.

<sup>&</sup>lt;sup>17</sup> NERC Data Response at 4.

the proposed footnote effectively turns the processes into a reliability standards development process outside of NERC's existing procedures. Furthermore, the Commission believes that regardless of the process used, the result could lead to inconsistent reliability requirements within and across reliability regions. While the Commission recognizes that some variation among regions or entities is reasonable given varying grid topography and other legitimate considerations, there are no technical or other criteria to determine whether varied results are arbitrary or based on meaningful distinctions. While the Commission acknowledges that NERC has flexibility in developing alternative approaches, we believe that the proposed approach is not equally efficient or effective as the Commission's directives and that NERC has failed to provide a strong technical justification for its proposal.

12. As an initial matter, the Commission is concerned that the process lacks parameters. The standard requires that, when planning to interrupt Firm Demand, the Firm Demand interruption must be "subject to review in an open and transparent stakeholder process that includes addressing stakeholder comments." 18 However, without any substantive parameters governing the stakeholder process, the enforceability of this obligation by NERC and the Regional Entities' would be limited to a review to ensure only that a stakeholder process occurred. Indeed, NERC's explanation appears to confirm this concern, as NERC explained that Regional Entities' involvement is limited to oversight after-the-fact by auditing the entity's implementation of footnote 'b' to determine if the entity planned on interrupting Firm Demand and whether the decision by the entity to rely on planned interruption of Firm Demand was vetted through the stakeholder process and qualified as one of the situations identified in footnote 'b'.

13. Further, the Commission is concerned that the NERC proposal leaves undefined the circumstances in which it is allowable to plan for Firm Demand to be interrupted in response to a Category B contingency. The TPL—002—0a Reliability Standard requires Planning Authorities and Transmission Planners to demonstrate through a valid assessment that the transmission system is planned and can be operated to supply projected Firm Demand at all demand levels over a range of forecasted

system demands.<sup>19</sup> Moreover, the planner must consider all single contingencies applicable to Table I, Category B and demonstrate that system performance is met. For those instances where system performance is not met, the planner must provide a written summary of its plans to achieve system performance including implementation schedules, in service dates of facilities and implementation lead times.<sup>20</sup> In regard to NERC's proposal, the Commission is concerned that footnote 'b' would function as a means to override the reliability objective and system performance requirements of the TPL Reliability Standard without any technical or other criteria specified to determine when planning to interrupt Firm Demand would be allowable. In this case NERC has provided no technically sound means of determining situations in which planning to interrupt Firm Demand would be allowable, and instead has removed such decision-making to an unspecified stakeholder process without any assurance that such processes will deploy technically sound means of approving or denying exceptions. Without any technical or other criteria specified to determine when planning to interrupt Firm Demand would be allowable, the Commission is concerned that multiple stakeholder processes across the country engaging in such determinations could lead to inconsistent and arbitrary exceptions including, potentially, allowing entities to plan to interrupt any amount of Firm Demand in any location and at any voltage level. While the Commission recognizes that some variation among regions or entities is reasonable given varying grid topography and other legitimate considerations, there are no technical or other criteria to determine whether varied results are arbitrary or based on meaningful distinctions. The Commission is thus concerned that there may be a lack of consistency in determinations to allow the planned interruption of Firm Demand. The proposed stakeholder process does not have any parameters except for openness and transparency. As a result, multiple processes that could be adopted across the country would likely lead to inconsistent determinations to allow for the planned interruption of Firm Demand.

14. The Commission believes that a remand would give NERC and industry flexibility to develop an approach that

would address the issues identified by the Commission with the proposed footnote 'b' stakeholder process including, as discussed below, definition of the process and criteria or guidelines for the process.

## A. Lack of Technical or Other Criteria

15. NERC's proposal does not prescribe the criteria that would define the parameters of permissible interruption of Firm Demand. In Order No. 693 the Commission expressed concern that, as a general rule, footnote 'b' should not allow an entity to plan for the loss of non-consequential load in the event of a single contingency and directed NERC to clarify the standard. The Commission stated in the June 2010 Order that a regional difference or a case-specific exception process that could be technically justified would be acceptable. While the Commission allows NERC to propose an equally effective and efficient solution to a Commission's proposed solution, the Commission does not believe that the proposal is equally effective and efficient. First, NERC's proposed footnote 'b' contains no constraints and could allow an entity to plan to interrupt any amount of Firm Demand, in any location or at any voltage level as needed for any single contingency, provided that it is documented and subjected to a stakeholder process. This result is contrary to the underlying standard and our prior orders.<sup>21</sup> Further, NERC did not technically justify its proposal, instead relying on the benefit of having transparency in the process. The Commission does not believe transparency in this instance can substitute for a technical justification.

16. In its supplemental filing, NERC states that it is not feasible for the ERO to develop a one-size-fits-all criterion for limiting the planned interruption of Firm Demand due to the wide variety of system configurations and regulatory compacts.<sup>22</sup> NERC states that the standards drafting team believes there is no analytical data to support a single level and therefore any single value was viewed as arbitrary.

17. We are not persuaded by NERC's reasoning. First, both NERC and the Commission have developed thresholds in other reliability contexts that have overcome similar claims of arbitrariness. For example, the threshold for conducting vegetation management pursuant to Reliability Standard FAC–003–1 applies to all transmission lines operated at 200 kV and above.<sup>23</sup> In the

<sup>&</sup>lt;sup>19</sup>Reliability Standard TPL–002–0a, Requirement R1.

<sup>&</sup>lt;sup>20</sup> Reliability Standard TPL–002–0a, Requirements R1.5 and R2.

<sup>&</sup>lt;sup>21</sup> See Order No. 693, see also June 2010 Order.

<sup>&</sup>lt;sup>22</sup> NERC Data Response at 6.

<sup>&</sup>lt;sup>23</sup> Reliability Standard FAC–003–1.

same vein, NERC's Statement of Compliance Registry Criteria has numerous thresholds for determining eligibility for registration.<sup>24</sup> The Commission did not suggest a one size fits all exceptions process. If the ERO were to perform an exception process, it might include flexibility in decisions based on disparate topology or on other matters since it could utilize its technical expertise to determine the reliability impact from one region to another. Moreover, the Commission's proposal to remand revised footnote 'b' due to a lack of criteria does not preclude NERC from developing another alternative, provided that it is equally "efficient and effective."

18. Finally, the Commission understands that there are a wide variety of system configurations and regulatory compacts. NERC indicates that the standards drafting team considered a variety of limits; however, it is not clear whether NERC considered a blend of quantitative and qualitative thresholds. For example, a standard could require a process with a quantitative limitation on how much Firm Demand could be planned for interruption and that standard could provide an exception process where a registered entity would submit documents and explanation to the ERO or a Regional Entity for approval based upon certain considerations.<sup>25</sup> In short, we believe that a more defined process would be needed but, by itself, would not be adequate without NERC-defined technical or other criteria to determine planned interruption of Firm Demand. The Commission seeks comment on these proposals.

### B. Stakeholder Process

19. The Commission believes that NERC's proposed footnote 'b' stakeholder process does not meet Order No. 693 and the June 2010 Order directive. According to NERC, the type of stakeholder process used under its proposed footnote 'b' can vary from one planning entity to the next. NERC offers several stakeholder processes as examples, such as the Order 890-type process, a state public utility commission or local jurisdiction process, or a Regional Transmission Organization/Independent System

<sup>24</sup> See, e.g., NERC Statement of Registry Criteria, Section III. The Commission approved Statement of Registry Criteria in Order No. 693. Operator (RTO/ISO) stakeholder process.

20. First, because NERC's proposed footnote 'b' does not define the stakeholder process, the express terms of the standard would allow an applicable entity to form or participate in any stakeholder process and be compliant with the proposed standard. Second, as we have mentioned, NERC has offered no technical justification for exceptions to be granted through the stakeholder process and therefore no means for the Commission to judge whether the process will protect the reliability of the Bulk-Power System. Nothing in the proposed footnote 'b' restricts the stakeholder process, other than that it must be an open and transparent stakeholder process that includes addressing stakeholder comments. The Commission is concerned that any meeting that is open to stakeholders could meet this standard. Further, because the stakeholder process is not defined, the proposal could allow a transmission planner to develop a process that provides insufficient process and transparency and still comply with the standard. The Commission believes that such process would be insufficient because it allows any stakeholder process to essentially become a reliability standards development processes outside of NERC's existing procedures. Furthermore, the Commission believes that regardless of the stakeholder process used, the outcome could lead to inconsistent results, with no technical or other criteria to determine whether varied results are arbitrary or based on meaningful distinctions. The Commission seeks comment on whether a stakeholder process is the appropriate vehicle to approve or deny exceptions to allow entities to plan to interrupt Firm Demand for a single contingency and if so, whether the proposed footnote 'b' would require any stakeholder due process.

21. Nor does the standard describe what would be entailed in addressing the stakeholder comments. As described above, the process under the standard does not provide for any technical rigor to address stakeholder concerns. While the standard requires transparency and an opportunity for stakeholder comments on the transmission planner's proposed plan to interrupt Firm Demand, it does not mandate any particular stakeholder involvement, nor does it mandate that interested governmental authorities be afforded notice and an opportunity to comment. As we read the proposed standard, a responsible entity could define when it

would plan to interrupt Firm Demand on its own, then ask for stakeholder input on that plan. While the standard requires the responsible entity to ''address'' stakeholder comments, the responsible entity is not required to specify or support the technical basis upon which it rendered a decision. The Commission believes that the stakeholder process in proposed footnote 'b' would allow the transmission planner to define the circumstances when it would rely on planned interruption of Firm Demand, provide that definition for review by regulators and other stakeholders, receive comments from regulators and stakeholders requesting a more narrow definition, and explain to the regulators and stakeholders why it is declining the request and maintaining the broader definition, even if every other transmission planner facing similar circumstances would reach the opposite conclusion.

22. In Order No. 693 and the June 2010 Order, the Commission stated that a regional difference or a case-specific exception process, among other things, would be an acceptable approach. With regard to a case-specific process, NERC replied it would "create undesirable delays and uncertainty in the transmission planning process." 26 However, the proposed footnote 'b' does not provide a time limitation by which planning decisions to interrupt Firm Demand must be made. The Commission is not persuaded that NERC's proposed approach ameliorates this concern. The Commission seeks comment on whether an exceptions process that provides defined criteria, with some allowance or consideration for unique circumstances, could be crafted that would resolve NERC's concerns of "undesirable delays" and "uncertainty.'

23. In sum, the Commission is concerned that the stakeholder process set forth in the NERC proposal is not sufficiently defined, rendering it potentially unenforceable. As mentioned above, the proposed stakeholder process includes no parameters other than openness and transparency. NERC states that it and the Regional Entities will review a responsible entity's decision to plan to interrupt Firm Demand using an afterthe-fact audit, to determine if the entity's implementation of footnote 'b' to plan Firm Demand interruption and whether the decision by the entity was vetted through the stakeholder process and qualified as one of the situations

<sup>&</sup>lt;sup>25</sup> While we encourage NERC to exercise flexibility in designing an appropriate standard, under this example, the exception process could consist of a stakeholder process that has some level of due process as long as that process does not allow the entity that proposes its exception to make the decision on whether to grant the exception.

<sup>&</sup>lt;sup>26</sup> NERC Data Response at 2.

identified in footnote 'b.' 27 The Commission believes that this could result in a transmission planner invoking a process that provides for minimal stakeholder involvement, providing scant reasons to reject any stakeholder input and then defending its decision by claiming that it has satisfied the provision. While the Compliance Enforcement Authority would verify that the process fulfilled the letter of NERC's proposed footnote 'b'—that some open, transparent stakeholder process was involved and that the responsible entity in some way addressed stakeholder concerns—there is no mechanism for the ERO or a Regional Entity to enforce a finding that the evidence does not support an acceptable instance of planned interruption of Firm Demand. The Commission seeks comment on the concerns raised above.

## C. Commission Proposal

24. The Commission believes that NERC's proposed footnote 'b' does not meet the Commission's Order No. 693 directives, nor is it an equally effective and efficient alternative. On this basis, the Commission proposes to remand the

proposal to NERC.

25. The Commission also proposes to provide further guidance on acceptable approaches to footnote 'b'. We seek comment on all of the options below. In addition, while the Commission is proposing certain options for revising footnote 'b', we also seek comment on other potential options to solve the concerns outlined in this NOPR. As noted above, the Commission understands that there are a wide variety of system configurations and regulatory compacts. We believe that a more defined process than that provided in the proposed footnote 'b' would be needed but, by itself, would not be adequate without NERC-defined technical or other criteria to determine an acceptable planned interruption of Firm Demand at the fringes of the system.28

26. We acknowledge that the standards drafting team considered a variety of limits; however, setting some form of criteria within the standard itself for planning to interrupt Firm Demand may be an acceptable approach to setting criteria for footnote 'b' and would be an option for NERC to consider. We also seek comment on whether existing protocols could provide guidance to NERC in devising

criteria. For example, the Department of Energy's Electric Emergency Incident and Disturbance Report (Form OE-417) requires, among other things, an entity to report the uncontrolled loss of 300 Megawatts or more of firm system loads for more than 15 minutes from a single incident, load shedding of 100 Megawatts or more implemented under emergency operational policy, and the loss of service for more than 1 hour to 50,000 customers. While these are reporting requirements for the operational timeframe, and may include distribution level load shedding, the Commission requests comments on whether they could also serve as a basis for setting limits on when an entity can plan to interrupt Firm Demand on the Bulk-Power System. Another existing document that could provide guidance on how to set a limit on the planned interruption of Firm Demand is NERC's Statement of Compliance Registry Criteria, which uses, for example, 25 MW as a threshold in determining when a load-serving entity or distribution provider should register with NERC. We seek comments on this proposed option, and any other external documents that could be used to guide a revision to footnote 'b.'

27. Second, as stated above, it is not clear whether NERC considered a blend of quantitative and qualitative thresholds. The Commission seeks comments on whether this would be an option for providing criteria that would be generally applicable, but also for allowing for certain cases that may exceed the criteria. For example, a standard could require a process with a quantitative limitation on how much Firm Demand could be planned for interruption and that standard could provide an exception process where a registered entity would submit documents and explanation to the ERO or a Regional Entity for approval based upon certain considerations. NERC has raised concerns about conflicts among federal, provincial, state and local governing bodies that have jurisdiction over various parts of the planning, siting and construction process. The Commission believes that this approach may satisfy the need for technical criteria that we have described, while accounting for NERC's concerns about the difficulty of developing a one-sizefits-all criterion for limiting planned Firm Demand interruptions and the appropriateness and feasibility of managing and actively participating in each planning process. As NERC states, the objective of footnote 'b' should be to minimize the likelihood and magnitude of planned Firm Demand interruptions.

The Commission believes that setting generally applicable criteria for when an applicable entity can plan to shed Firm Demand, coupled with an exceptions process overseen by NERC and the Regional Entities, could mean that few exception requests must be processed by NERC and the Regional Entities. We seek comment on this option, and which entities should be involved in the review and subsequent determination as to whether an exception should be allowed.

28. NERC has raised concerns about conflicts among federal, provincial, state and local governing bodies that have jurisdiction over various parts of the planning, siting and construction process. There also may be concerns about the costs of planning to avoid Firm Demand shedding. The Commission seeks comment on whether a feasible option would be to revise footnote 'b' to allow for the planned interruption of Firm Demand in circumstances where the transmission planner can show that it has customer or community consent and there is no adverse impact to the Bulk-Power System. This presumably would not require affirmative consent by every individual retail customer, but we recognize that either term, customer or community, would need to be adequately defined. The Commission therefore seeks comments on who might be able to represent the customer or community in this option and how customer or community consent might be demonstrated. Additionally, we seek comment on how it would be determined that firm demand shedding with customer consent would not adversely impact the Bulk-Power System. However, we also seek comment on whether a customer who would otherwise consent to having its planning authority or transmission planner plan to interrupt Firm Demand pursuant to this option could instead select interruptible or conditional firm service under the tariff to address cost concerns.

29. Finally, regardless of how NERC revises footnote 'b' to resolve the concerns outlined in this NOPR and in previous orders, the Commission notes that NERC will need to support the revision to footnote 'b.' If there is a threshold component to the revised footnote, the Commission believes that NERC would need to support the threshold and show that instability, uncontrolled separation, or cascading failures of the system will not occur as a result of planning to shed Firm Demand up to the threshold. In addition, if there is an individual exception option, the Commission

 $<sup>^{27}</sup>$  NERC Data Response at 7–8.

<sup>&</sup>lt;sup>28</sup> Any exceptions process to determine specific requests for planned interruption of Firm Demand may not necessarily be limited to the fringes of the system.

believes that the applicable entities should be required to find that there is no adverse impact to the Bulk-Power System from the exception and that it is considered in wide-area coordination and operations. Further, we believe that any exception should be subject to further review by the Regional Entity, NERC, and the Commission. This does not necessarily mean that the Regional Entity, NERC, or the Commission should have to approve the exception, but that any of the three could later audit its implementation.

30. In conclusion, while the Commission provides three options for revising footnote 'b' in this Notice of Proposed Rulemaking, we seek comments on the feasibility of the options and on ways in which the options might be improved. In addition, we seek comment on whether there are other ways for NERC to solve the concerns outlined above in an equally effective and efficient manner.

#### III. Information Collection Statement

31. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.<sup>29</sup> The information contained here is also subject to review under section 3507(d) of the Paperwork Reduction Act of 1995.<sup>30</sup>

32. As stated above, the subject of this NOPR is NERC's proposed modification to Table 1, footnote 'b' applicable in four TPL Reliability Standards. This NOPR proposes to remand the footnote 'b' modification to NERC. By remanding footnote 'b' the applicable Reliability Standards and any information collection requirements are unchanged. Therefore, the Commission will submit this NOPR to OMB for informational purposes only.

33. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE. Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, e-mail: data.clearance@ferc.gov, phone: (202) 502–8663, or fax: (202) 273–0873].

## IV. Regulatory Flexibility Act

34. The Regulatory Flexibility Act of 1980 (RFA) <sup>31</sup> 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.32 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 The RFA is not implicated by this NOPR because the Commission is remanding footnote' b' and not proposing any modifications to the existing burden or reporting requirements. With no changes to the Reliability Standards as approved, the Commission certifies that this NOPR will not have a significant economic impact on a substantial number of small entities.

## V. Comment Procedures

35. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due 60 days from publication in the Federal Register. Comments must refer to Docket No. RM11–18–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

36. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at http://www.ferc.gov. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

37. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

38. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

#### VI. Document Availability

39. 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.

40. 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.

41. 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 direction of the Commission. Commissioner Spitzer is not participating. Nathaniel J. Davis, Sr.,

Deputy Secretary.

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration** 

21 CFR Parts 201 and 610

[Docket No. FDA-2011-N-0719]

Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563; Request for Comments

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

**ACTION:** Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a review of the "Bar Code Final Rule," under Executive Order 13563, "Improving Regulation and Regulatory Review." The Bar Code Final Rule, which was published in 2004, requires

<sup>&</sup>lt;sup>29</sup> 5 CFR 1320.11.

<sup>30 44</sup> U.S.C. 3507(d).

<sup>&</sup>lt;sup>31</sup> 5 U.S.C. 601–612.

<sup>&</sup>lt;sup>32</sup> 13 CFR 121.201.

<sup>&</sup>lt;sup>33</sup> *Id.* n.22.