

the time remaining until the product’s expiration date or six months, whichever is earlier;

ii. Where a United States Pharmacopeia–National Formulary (USP–NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substance is the source of the active ingredient, the beyond-use date shall not be later than six months or the expiration date of the ingredient, whichever is earlier; and

iii. Where there is more than one ingredient, the beyond-use date shall be no longer than six months or the expiration date of the first ingredient to expire, whichever is earlier;

2. For water-containing formulations (prepared from ingredients in solid form), the beyond-use date shall not be later than 14 days for liquid preparations when stored at cold temperatures between two degrees and eight degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

3. For all other formulations, the beyond-use date shall not be later than the intended duration of therapy or 30 days, whichever is earlier.

(c) The beyond-use date limits established in this section may be exceeded only when there is supporting valid scientific stability information that is directly applicable to the specific preparation (that is, the same drug concentration range, pH, excipients, vehicle, water content, etc.).

13:39-11A.12 Ingredient selection

(a) All ingredients used to compound non-sterile preparations shall be United States Pharmacopeia–National Formulary (USP–NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substances. If a USP–NF, AR, ACS, or FCC grade substance ingredient is not available, the pharmacist shall establish the purity and safety of the ingredient by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source study.

(b) A manufactured drug product may be utilized as the source of an active ingredient. Only manufactured drug products from containers labeled with a batch control number and an unexpired expiration date shall be utilized as sources of active ingredients. When compounding with manufactured drug products, the compounding pharmacist shall consider all ingredients present in the drug product relative to the intended use of the compounded non-sterile preparation.

(c) Components used in the compounding of non-sterile preparations such as aliquots, triturates, stock solutions, buffering agents, or isotonic solutions may be prepared in advance and stored as pharmacy stock. The preparation of such products shall be documented in accordance with the requirements of N.J.A.C. 13:39-11A.15(b)1 and 6 through 14.

13:39-11A.13 Information required to appear on prescription label

(a) The dispensed container for any compounded non-sterile preparation shall bear a permanently affixed label with at least the following information:

1. In a retail pharmacy only, the name of the prescriber.

i. An institutional pharmacy compounding non-sterile preparations for out-patient use shall include the name of the prescriber on the label, consistent with the requirements of N.J.A.C. 13:39-9.1(b);

2. The name of the patient;

3. The name of all active ingredients;

4. Directions for use;

5. The use by date, consistent with the requirements of N.J.A.C. 13:39-11A.11;

6. The name, address, and telephone number of the pharmacy;

7. Any ancillary and cautionary instructions as needed; and

8. As pertinent, the requirements for proper storage.

13:39-11A.14 Pharmacy technicians, pharmacy interns, and pharmacy externs; required supervision

(a) The compounding pharmacist shall provide immediate personal supervision to pharmacy technicians, pharmacy interns, or

pharmacy externs who are performing non-sterile preparation compounding.

1. Supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured, or counted, and the finished label.

(b) The compounding pharmacist may delegate to pharmacy technicians, pharmacy interns, or pharmacy externs only the following tasks: recording of the prescription, selection of the drugs and container, typing of labels, and compounding of preparations. The compounding pharmacist shall ensure that each task has been performed correctly.

13:39-11A.15 Audit trail; compounding record documentation

(a) A pharmacy shall maintain an audit trail for all non-sterile compounded preparation prescriptions dispensed consistent with the requirements of N.J.A.C. 13:39-7.6.

(b) Except as provided in (c) below, a pharmacy shall maintain a compounding record for each compounded non-sterile preparation that contains the following information:

1. Selection of the ingredients and documentation of source, lot numbers, and expiration dates of all ingredients used;

2. Verification that ingredients comply with the prescription or medication order;

3. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39-11A.13;

4. Verification that the prescription or medication order is complete and ready to be dispensed, including any necessary ancillary supplies;

5. Strength of preparation;

6. Date of preparation;

7. Name or personal identifier of the person(s) who performed each step of the compounding process and the compounding pharmacist(s) who verified the preparation;

8. Reference(s) for formulation, if available;

9. Total quantity;

10. Detailed steps of the compounding process to ensure that the exact same compound can be duplicated at a future date;

11. Type of dispensing container used when a drug has specific storage requirements;

12. Beyond-use date of the finished product consistent with the requirements in N.J.A.C. 13:39-11A.11;

13. The assigned internal identification number for the preparation or the prescription number; and

14. Instructions for use, storage, and handling of the compounded preparation.

(c) A compounding record shall not be required for:

1. Mixing, reconstituting, or assembling a drug according to the product’s labeling or the manufacturer’s directions; and

2. Product flavoring.

PUBLIC UTILITIES

(a)

BOARD OF PUBLIC UTILITIES

Renewable Energy and Energy Efficiency Definitions; Using RECs and SRECs for RPS Compliance; Alternative Compliance Payments (ACPs and SACPs)

Proposed Amendments: N.J.A.C. 14:8-2.2, 2.8, and 2.10

Authorized By: New Jersey Board of Public Utilities, Robert M. Hanna, President, Jeanne M. Fox, Joseph L. Fiordaliso, Nicholas Asselta, and Mary-Anna Holden, Commissioners.

Authority: N.J.S.A. 48:2-1 et seq., in particular 48:2-13, and 48:3-87. Calendar Reference: See Summary below for explanation of exception to calendar requirement.

BPU Docket Number: EX13010006.
 Proposal Number: PRN 2013-037.

Comments may be submitted through May 3, 2013 by email in **Microsoft Word format**, or in a format that can be easily converted to Word, to: rule.comments@bpu.state.nj.us or on paper to:

Kristi Izzo, Secretary
 New Jersey Board of Public Utilities
 ATTN: BPU Docket Number: EX13010006
 44 S. Clinton Ave., 9th floor
 P.O. Box 350
 Trenton, NJ 08625-0350

The agency proposal follows:

Summary

The Board of Public Utilities (Board) is proposing amendments to two sections of N.J.A.C. 14:8-2, specifically to conform the existing rules to provisions within the Solar Act of 2012, P.L. 2012, c. 24, which prescribed changes to the schedule for Solar Alternative Compliance Payments (SACP) and extended the time period during which Solar Renewable Energy Certificates (SREC) and Offshore Wind Renewable Energy Certificates (OREC) may be used to satisfy Renewable Portfolio Standards (RPS). The proposed amendments are prescribed by statute and are proposed to bring the Board's rules into compliance with the law.

At N.J.A.C. 14:8-2.2, the Board proposes to add a definition of "offshore wind renewable energy credit" (OREC) by referencing the definition at N.J.A.C. 14:8-6.1.

At N.J.A.C. 14:8-2.8(a), the Board proposes to add ORECs. Paragraph (a)1 is proposed for amendment to indicate that an OREC may be used to satisfy the New Jersey RPS for three years when generated on or after July 23, 2012. Paragraph (a)1 is further amended to indicate that SRECs that apply to this paragraph, must be generated between July 1, 2010 and July 23, 2012, and not merely after July 1, 2010. Existing paragraphs (a)3 and 4 are proposed for deletion as the time periods they refer to have passed. Finally, new paragraph (a)3 applies to SRECs generated on or after July 23, 2012 and proposes that the number of energy years for which an SREC may be used to satisfy the RPS be five years.

At N.J.A.C. 14:8-2.10(h), the Board is proposing to decrease the amount of the SACP for Energy Year (EY) 2014 from \$625.00 to \$339.00, for EY 2015 from \$609.00 to \$331.00, and for EY 2016 from \$594.00 to \$323.00. The Board also proposed to extend the SACP schedule to EY 2028 and to change "reporting year" to "energy year." Finally, reporting years 2009 through 2012 are proposed to be deleted from the SACP schedule as they no longer apply.

It is anticipated that the use of ORECs to finance offshore wind development will be structured differently than SRECs. As currently envisioned, offshore wind developers will propose to the Board an OREC value and forecast of annual generation. Electricity generated by a Board-approved offshore wind project up to the forecast amount of annual generation will form the basis for an OREC, and be allocated to load serving entities, third-party suppliers and basic generation service (BGS) providers, based on their market share of retail electricity sales. When approved offshore wind projects produce more electricity than forecast, the excess production is anticipated to be used as the basis of class I RECs useful in satisfying the RPS.

The Board has provided a 60-day comment period on this notice of proposal. Accordingly, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendments to the Renewable Portfolio Standards rules will have a positive social impact for New Jersey, helping to encourage the development of cleaner energy resources while reducing the cost of this development. The decrease in the SACP will act as a cap on the cost of SRECs, so that in the event the market becomes "short" again, the load-serving entities that are required to comply with the RPS will experience a reduced compliance cost, which in turn will mean a lesser impact on ratepayers. Extending the schedule out to 2028 will provide greater stability to the market, supporting the continued development of solar energy throughout New Jersey, while providing those benefits

associated with renewable generation: the reduction of pollution and a decreased demand for new power plants powered by fossil fuels.

The increased time for SRECs to be eligible for use in satisfying the RPS will permit the owners of these assets greater flexibility in determining when to trade and/or retire them. This greater flexibility means that these determinations are more likely to be made in a way that maximizes the value of the asset, which in turn supports the solar market and thus benefits New Jersey ratepayers. While there are as of yet no ORECs being created, allocated for retirement, or carried over and traded in New Jersey as class I RECs, the increase in their eligibility from two to three years may be anticipated to have a similarly beneficial effect when carried over as and used as a New Jersey class I REC.

Economic Impact

The proposed amendments will update the rules to bring them into compliance with P.L. 2012, c. 24, which was enacted with an intention of maintaining New Jersey's briefly held position as the largest and fastest-growing solar energy market in the country. The amendment to the RPS rules, which decreases the SACP, is not anticipated to have any immediate economic impact because the SREC market is over-supplied at this time and thus prices are not likely to approach the cost of paying the SACP, which typically occurs only when there is a shortage of SRECs to meet the solar RPS. In the future, should the SREC market experience a shortage of the SRECs needed to satisfy the solar RPS, the decreased SACP would have a positive economic impact, as the price of an SACP effectively caps the cost of an SREC: purchasers will not pay more for an SREC than it would cost them to buy an SACP. At this point, the reduced SACP will cap the cost of compliance. BGS providers and electric power suppliers recoup these costs through the pricing of their electricity supply; the suppliers directly, and the BGS providers through the electric distribution companies, pass on these costs to electricity customers through rates. Thus, the potential cost to the ratepayer from the solar RPS, should the market revert to one characterized by a shortage of SRECs, will be reduced.

When offshore wind projects begin to contribute to the State's renewable energy goals, the ability to use the New Jersey class I RECs created from the excess electricity produced by offshore wind project for an additional year as a New Jersey class I REC will provide developers added flexibility and mitigate volatility in the REC market. This potential for substitution of New Jersey class I RECs from New Jersey offshore wind projects will reduce the requirement for ratepayers to purchase class I RECs from out-of-State renewable electricity generating facilities.

In the long term, the Board's programs for developing renewable energy generation are anticipated to act as a spur to development of renewable energy markets, thus reducing use of environmentally damaging fossil fuels. Ultimately, this will have an important beneficial economic impact on the country as a whole.

Federal Standards Statement

Executive Order No. 27 (1994) and N.J.S.A. 52:14B-1 et seq. require State agencies that adopt, readopt, or amend State rules exceeding any Federal standards or requirements to include in the rulemaking document a Federal standards analysis. The RPS rules have no Federal analogue and are not promulgated under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, Federal standards, or Federal requirements. Accordingly, Executive Order No. 27 (1994) and N.J.S.A. 52:14B-1 et seq. do not require a Federal standards analysis for the proposed amendments.

Jobs Impact

The proposed amendments to the RPS are designed to encourage the development of clean sources of energy in the State. The increased useful life of SRECs and ORECs, and the extended SACP schedule, are concrete strategies to support the solar and offshore wind markets in New Jersey. Thus, these amendments are anticipated to have a positive impact on jobs in the development, construction, and operation of renewable energy facilities.

Agriculture Industry Impact

The Board does not expect the proposed amendments to have a direct material effect on the agriculture industry in New Jersey. To the extent

that the proposed amendments result in the stimulation of the renewable energy market, a greater number of renewable energy facilities will benefit the agriculture industry, if increased renewable electric generation displaces fossil-fueled generation that is linked to acid rain, global warming, and other air pollution that can harm agricultural crops.

Regulatory Flexibility Statement

A small business, as defined in the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., is a business that has fewer than 100 full-time employees. The proposed amendments do not impose additional reporting, recordkeeping, or other compliance requirements on small businesses operating renewable electric generation facilities in New Jersey or in the rest of the PJM region. Accordingly, no regulatory flexibility analysis is required.

Housing Affordability Impact Analysis

The proposed amendments will have an insignificant impact on affordable housing in New Jersey because the amendments are directed to increasing the value and utility of SRECs. These existing regulatory incentives, while they may in the future have some effect on electricity rates, do not affect the availability or price of housing. The rules address only renewable energy generation and do not affect housing prices or the housing market.

Smart Growth Development Impact

The proposed amendments will have an insignificant impact on smart growth and would have no impact on housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan because the proposed amendments pertain to limiting the impact of subsidizing SRECs on ratepayers and increasing the periods of time for which ORECs and SRECs may be used to satisfy the New Jersey RPS.

Full text of the proposal follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

SUBCHAPTER 2. RENEWABLE PORTFOLIO STANDARDS

14:8-2.2 Definitions

The following words and terms, when used in this subchapter, shall have the meanings given below, unless the context clearly indicates otherwise:

... **“Offshore wind renewable energy certificate” or “OREC” shall mean as defined at N.J.A.C. 14:8-6.1.**

14:8-2.8 Using RECs, [and] SRECs, **and ORECs** for RPS compliance

(a) [A] **An REC, [or] SREC, or OREC** shall be used to meet New Jersey RPS requirements for specific energy years, based on the type of renewable energy upon which the REC, [or] SREC, **or OREC** is based, and the energy year during which the renewable energy was generated, as follows:

1. A class I REC [or SREC] based on energy generated on or after July 1, 2010, **an SREC based on energy generated on or after July 1, 2010 but before July 23, 2012, or an OREC based on energy generated on or after July 23, 2012,** shall be used to comply with RPS requirements for any one of the following three energy years:

- i.-ii. (No change.)
- 2. (No change.)

[3. An SREC based on energy generated before July 1, 2010 shall be used only to comply with the requirements of this subchapter for the energy year during which the underlying energy was generated, and/or the subsequent energy year; and

4. A class I REC based on energy generated before July 1, 2012 shall be used only to comply with the requirements of this subchapter for the energy year during which the underlying energy was generated.]

3. An SREC based on energy generated on or after July 23, 2012 shall be used to comply with RPS requirements for any of the following energy year periods:

i. The energy year in which the underlying energy was generated;
or

ii. Any of the four energy years immediately following the energy year in which the underlying energy was generated.

(b) (No change.)

14:8-2.10 Alternative compliance payments (ACPs and SACPs)

(a)-(g) (No change.)

(h) Table C sets forth the SACP for each [reporting] **energy year** from [reporting] **energy year [2009] 2013** through [reporting] **energy year [2016] 2028**:

Table C
SACP Schedule

[Reporting] Energy Year	SACP
[June 1, 2008-May 31, 2009	\$711.00
June 1, 2009-May 31, 2010	\$693.00
June 1, 2010-May 31, 2011	\$675.00
June 1, 2011 – May 31, 2012	\$658.00]
June 1, 2012-May 31, 2013	\$641.00
June 1, 2013-May 31, 2014	[\$625.00] 339.00
June 1, 2014-May 31, 2015	[\$609.00] 331.00
June 1, 2015-May 31, 2016	[\$594.00] 323.00
June 1, 2016-May 31, 2017	\$315.00
June 1, 2017-May 31, 2018	\$308.00
June 1, 2018-May 31, 2019	\$300.00
June 1, 2019-May 31, 2020	\$293.00
June 1, 2020-May 31, 2021	\$286.00
June 1, 2021-May 31, 2022	\$279.00
June 1, 2022-May 31, 2023	\$272.00
June 1, 2023-May 31, 2024	\$266.00
June 1, 2024-May 31, 2025	\$260.00
June 1, 2025-May 31, 2026	\$253.00
June 1, 2026-May 31, 2027	\$250.00
June 1, 2027-May 31, 2028	\$239.00

OTHER AGENCIES

(a)

NEW JERSEY ECONOMIC DEVELOPMENT AUTHORITY

Administrative Rules; Closing Fees Authority Assistance Programs; Direct Loan Program

Proposed Amendments: N.J.A.C. 19:30-6.3 and 19:31-3.1

Authorized By: New Jersey Economic Development Authority, Michele Brown, Chief Executive Officer.

Authority: N.J.S.A. 34:1B-1 et seq.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2013-043.

Submit written comments by May 3, 2013 to:

Maureen Hassett, Senior Vice President
New Jersey Economic Development Authority
PO Box 990
Trenton, NJ 08625-0990

The agency proposal follows: