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

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 compound 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


(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

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.


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

NEW JERSEY REGISTER, MONDAY, MARCH 4, 2013 (CITE 45 N.J.R. 455)
The Board has provided a 60-day comment period on this notice of proposal. Comments may be submitted through May 3, 2013 by email to rule.comments@rpu.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. 14:8-2.3, 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.

Jobs Impact
The proposed amendments to the RPS rules, which decreases the SACP, is not anticipated to have any material impact on the agriculture industry in New Jersey. Thus, these amendments are anticipated to have a positive impact on jobs in the development, construction, and operation of offshore wind projects. The Board does not expect the proposed amendments to have a direct material effect on the agriculture industry in New Jersey.
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. 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:

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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: