

Company	FR Docket	Published
Noramco, Inc. ....	81 FR 7587 .....	February 12, 2016.
Cayman Chemical Company .....	81 FR 9217 .....	February 24, 2016.
Janssen Pharmaceutical, Inc. ....	81 FR 9219 .....	February 24, 2016.
Insys Therapeutics, Inc. ....	81 FR 9220 .....	February 24, 2016.
Siemens Healthcare Diagnostics, Inc. ....	81 FR 15565 .....	March 23, 2016.
Siegfried USA, LLC .....	81 FR 15567 .....	March 23, 2016.
Patheon Pharmaceuticals, Inc. ....	81 FR 15571 .....	March 23, 2016.
Navinta, LLC .....	81 FR 20418 .....	April 7, 2016.
Patheon API Manufacturing, Inc. ....	81 FR 22122 .....	April 14, 2016.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed persons.

Dated: August 2, 2016.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

[FR Doc. 2016-18921 Filed 8-9-16; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *Dan Eoff v. United States Environmental Protection Agency*, Civil Action No. 4:13-cv-00368-DPM, was lodged with the United States District Court for the Eastern District of Arkansas, Western Division, on August 4, 2016.

This proposed Consent Decree concerns a complaint filed by Plaintiff and Counterclaim Defendant Dan Eoff against the United States Environmental Protection Agency, and an answer and counterclaim filed by the United States, on behalf of the United States Environmental Protection Agency, against Dan Eoff pursuant to Section 301(a) of the Clean Water Act, to obtain injunctive relief from and impose civil penalties against the Plaintiff and Counterclaim Defendant for violating

the Clean Water Act by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations by requiring Mr. Eoff to restore the impacted areas, perform mitigation and pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Lisa Bell, Trial Attorney and John E. Sullivan, Trial Attorney for the United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, Post Office Box 7611, Washington, DC 20044 and refer to *Dan Eoff v. United States Environmental Protection Agency*, DJ # 90-5-1-4-19920.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Eastern District of Arkansas, Western Division, 600 West Capitol Avenue, Suite A149, Little Rock, AR 72201. In addition, the proposed Consent Decree may be examined electronically at <http://www.justice.gov/enrd/consent-decrees>.

**Cherie L. Rogers,**

*Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.*

[FR Doc. 2016-18933 Filed 8-9-16; 8:45 am]

**BILLING CODE 4410-15-P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On August 4, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Pennsylvania in the lawsuit entitled *United States and the Pennsylvania Department of Environmental Protection v. CONSOL Energy Inc., et al.*, Civil Action No. 2:16-CV-01178.

The proposed Consent Decree will resolve Clean Water Act and associated

state claims alleged in this action by the United States and the Pennsylvania Department of Environmental Protection Against CONSOL Energy Inc., CNX Coal Resources LP, and Consol Pennsylvania Coal Company LLC for the discharge of pollutants from the Bailey Mine Complex in Greene and Washington Counties, Pennsylvania, into state waters and waters of the United States in violation of limits in National Pollutant Discharge Elimination System ("NPDES") permits. Under the proposed Consent Decree, Defendants will perform injunctive relief including implementing water management measures to prevent contaminated discharge, conducting long-term monitoring to ensure sufficient storage capacity to prevent future discharges, developing contingency plans should future discharges become likely, and implementing an environmental management system to ensure compliance with the Clean Water Act and other applicable environmental laws. In addition, Defendants will pay a total civil penalty of \$3 million in three installments, with the last payment on January 15, 2018.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the Pennsylvania Department of Environmental Protection v. CONSOL Energy Inc. et al.*, D.J. Ref. No. 90-5-1-1-10614. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email .....	<a href="mailto:pubcomment-ees.enrd@usdoj.gov">pubcomment-ees.enrd@usdoj.gov</a> .
By mail .....	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: <https://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$15.25 (25 cents per page reproduction cost) payable to the United States Treasury.

**Jeffrey Sands,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2016–18931 Filed 8–9–16; 8:45 am]

**BILLING CODE 4410–15–P**

## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–482; NRC–2016–0162]

### Wolf Creek Generating Station; Use of Optimized ZIRLO™ Fuel Rod Cladding Material

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Exemption; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a January 27, 2016, request, as supplemented on May 19, 2016, from Wolf Creek Nuclear Operating Corporation (WCNOC or the licensee) in order to use Optimized ZIRLO™ fuel rod cladding material at Wolf Creek Generating Station (WCGS).

**DATES:** The exemption was issued on August 2, 2016.

**ADDRESSES:** Please refer to Docket ID NRC–2016–0162 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2016–0162. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the

ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Carl F. Lyon, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2296, email: [Fred.Lyon@nrc.gov](mailto:Fred.Lyon@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The licensee is the holder of Renewed Facility Operating License No. NPF–42, which authorizes operation of WCGS. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of a pressurized-water reactor located in Coffey County, Kansas.

##### II. Request/Action

Pursuant to § 50.12 of title 10 of the *Code of Federal Regulations* (10 CFR), “Specific exemptions,” the licensee requested by letter dated January 27, 2016, as supplemented by letter dated May 19, 2016 (ADAMS Accession Nos. ML16033A470 and ML16161A509, respectively), an exemption from specific requirements of 10 CFR 50.46, “Acceptance criteria for emergency core cooling systems [ECCS] for light-water nuclear power reactors,” and 10 CFR part 50, appendix K, “ECCS Evaluation Models,” to allow the use of fuel rod cladding with Optimized ZIRLO™ alloy for future reload applications. The regulations in 10 CFR 50.46 contain acceptance criteria for the ECCS for reactors fueled with zircaloy or ZIRLO™ fuel rod cladding material. In addition, 10 CFR part 50, appendix K, requires that the Baker-Just equation be used to predict the rates of energy release, hydrogen concentration, and cladding oxidation from the metal/water reaction. The Baker-Just equation assumes the use of a zirconium alloy, which is a material different from

Optimized ZIRLO™. The licensee requested the exemption because these regulations do not have provisions for the use of fuel rod cladding material other than zircaloy or ZIRLO™. Because the material specifications of Optimized ZIRLO™ differ from the specifications for zircaloy or ZIRLO™, a plant-specific exemption is required to support the reload applications for WCGS.

The exemption request relates solely to the cladding material specified in these regulations (*i.e.*, fuel rods with Zircaloy or ZIRLO™ cladding material). This exemption would provide for the application of the acceptance criteria of 10 CFR 50.46 and 10 CFR part 50, appendix K, to fuel assembly designs using Optimized ZIRLO™ fuel rod cladding material. In its letter dated January 27, 2016, as supplemented by letter dated May 19, 2016, the licensee indicated that it was not seeking an exemption from the acceptance and analytical criteria of these regulations. The intent of the request is to allow the use of the criteria set forth in these regulations for application of the Optimized ZIRLO™ fuel rod cladding material.

##### III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Under 10 CFR 50.12(a)(2), special circumstances include, among other things, when application of the specific regulation in the particular circumstance would not serve, or is not necessary to achieve, the underlying purpose of the rule.

##### A. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 and 10 CFR part 50, appendix K, is to establish acceptance criteria for ECCS performance. The regulations in 10 CFR 50.46 and 10 CFR part 50, appendix K, are not directly applicable to Optimized ZIRLO™, even though the evaluations described in the following sections of this exemption show that the intent of the regulation is met. Therefore, since the underlying purposes of 10 CFR 50.46 and 10 CFR part 50, appendix K,