

clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019-09291 Filed 5-6-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14966-000]

Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications; Grid Balance Hydropower, LLC

On February 25, 2019, Grid Balance Hydropower, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Packer-Banks Pumped Storage Project to be located in Carbon County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A new 9,500-foot-long, 80- to 120-foot-high roller-compacted concrete and/or rock-filled dam or dike forming an upper reservoir having a surface area of 120 acres and a total storage capacity of approximately 9,300 acre-feet at a normal maximum water surface elevation between approximately 1,960 and 1,860 feet above mean sea level (msl); (2) a lower

reservoir with three different options: Option A (site 1) or B (site 2) would include a new 9,500-foot-long, 85- to 95-foot-high roller-compacted concrete and/or rock-filled dam or dike forming a lower reservoir having a surface area of 120 acres and a total storage capacity of approximately 9,300 acre-feet at a normal maximum water surface elevation between approximately 1,250 and 1,350 feet msl. Option C (site 3) would include a below grade mine pit with a surface area of 200 acres and a total storage capacity of approximately 10,000 acre-feet at a normal maximum water surface elevation between approximately 1,250 and 1,350 feet msl; (3) a 5,500-foot-long tunnel and/or penstock connecting the upper and lower reservoirs; (4) a powerhouse containing four turbine-generator units with a total rated capacity of 400 megawatts; (5) a transmission line connecting to an existing 230-kilovolt transmission line traversing the site; and (6) appurtenant facilities. Initial fill and make-up water for the project would come from a nearby abandoned mine drainage source. The proposed project would have an annual generation of 1,680,000 megawatt-hours.

Applicant Contact: Paul A. DiRenzo, Jr., Grid Balance Hydropower, LLC, 214 Norwegian Woods Drive, Pottsville, PA 17901; phone: 570-617-7810.

FERC Contact: Monir Chowdhury; phone: (202) 502-6736.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-14966-000.

More information about this project, including a copy of the application, can

be viewed or printed on the "eLibrary" link of the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-14966) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019-09294 Filed 5-6-19; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19-22-000]

Commission Information Collection Activities; (FERC Form Nos. 1, 1-F, and 3-Q); Comment Request; Extensions

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collections, FERC Form Nos. 1 (Annual Report of Major Electric Utilities, Licensees, and Others), 1-F (Annual Report for Nonmajor Public Utilities and Licensees), and 3-Q (Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies).

DATES: Comments on the collections of information are due July 8, 2019.

ADDRESSES: You may submit comments (identified by Docket No. IC19-22-000) by either of the following methods:

- *eFiling at Commission's Website:* <http://www.ferc.gov/docs-filing/efiling.asp>.

- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free), or (202) 502-8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading

comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502-8663, and fax at (202) 273-0873.

SUPPLEMENTARY INFORMATION:

Type of Request: Three-year extensions of the FERC Form Nos. 1, 1-F, and 3-Q with no changes to the current reporting requirements.¹

FERC Form No. 1, Annual Report of Major Electric Utilities, Licensees, and Others

OMB Control No.: 1902-0021.

Abstract: The FERC Form No. 1 is a comprehensive financial and operating report submitted annually for electric rate regulation, market oversight analysis, and financial audits by Major

electric utilities, licensees and others. Major is defined as having in each of the last three consecutive calendar years, sales or transmission services that exceed one of the following: (1) One million megawatt-hours of total sales; (2) 100 megawatt-hours of sales for resale; (3) 500 megawatt-hours of power exchanges delivered; or (4) 500 megawatt-hours of wheeling for others (deliveries plus losses).²

The FERC Form No.1 is designed to collect financial and operational information and is made available to the public. The FERC Form No.1 includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Income,
- Statement of Retained Earnings,
- Statement of Cash Flows,
- Statements of Accumulated Comprehensive Income,
- Comprehensive Income, and Hedging Activities, and

- Notes to Financial Statements. Supporting schedules contain:
 - Supplementary information and outlines of corporate structure and governance,
 - Information on formula rates, and
 - Description of important changes during the year.

Other schedules provide:

- Information on revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data, and
- Other statistical information.

Type of Respondent: Major electric utilities

*Estimate of Annual Burden*³: The Commission estimates the annual burden and cost⁴ for FERC Form No. 1 as follows:

FERC FORM NO. 1

Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours and average cost per response (\$)	Total annual burden hours and total annual cost (\$)	Cost per respondent (\$)
(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = (5)	(5) ÷ (1) = (6)
207	1	207	1,168 hrs.; \$92,272	241,776 hrs.; \$19,100,304	\$92,272

FERC Form No. 1-F, Annual Report for Nonmajor Public Utilities and Licensees

OMB Control No.: 1902-0029.

Abstract: The FERC Form No. 1-F is a financial and operating report submitted annually for electric rate regulation, market oversight analysis, and financial audits by Nonmajor electric utilities and licensees. Nonmajor is defined as utilities and licensees that are not classified as Major, and having total sales in each of the last three consecutive years of 10,000 megawatt-hours or more.⁵

The FERC Form No.1-F is designed to collect financial and operational information and is made available to the public. The FERC Form No.1-F includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Retained Earnings,
- Statement of Cash Flows,
- Statement of Comprehensive Income and Hedging Activities, and
- Notes to Financial Statements.

Supporting schedules contain:

- Supplementary information and include revenues and the related

quantities of electric sales and electricity transmitted,

- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data; and
- Other statistical information.

Type of Respondent: Nonmajor electric utilities

Estimate of Annual Burden: The estimated annual burden and cost follow. (The estimated hourly cost used for the FERC Form No. 1-F is \$79 (for wages plus benefits) and is described above, under the FERC Form No. 1.):

FERC FORM NO. 1-F

Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours and cost per response	Total annual burden hours and total annual cost (\$)	Cost per respondent (\$)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
5	1	5	122 hrs.; \$9,638	610 hrs.; \$48,190	\$9,638

¹ FERC Form Nos. 1, 1-F, and 3-Q (electric and natural gas) are part of the "Forms Refresh" effort, which is a separate activity and not addressed here. See *Revisions to the Filing Process for Commission Forms*, 166 FERC ¶ 61,027 (2019) (started in Docket No. AD15-11 and ongoing in Docket No. RM19-12). (OMB issued its decisions on the proposed changes in the Forms Refresh Notice of Proposed Rulemaking in Docket No. RM19-12 on March 14, 2019.)

² As detailed in 18 CFR 101 (Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provision of the Federal Power Act, General Instructions) and 18 CFR 141.1.

³ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

⁴ The Commission staff believes the FERC FTE (full-time equivalent) average cost for wages plus benefits is representative of the corresponding cost for the industry respondents. The FERC 2018 average salary plus benefits for one FERC FTE is \$164,820/year (or \$79.00/hour).

⁵ As detailed in 18 CFR 101 (Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provision of the Federal Power Act, General Instructions) and 18 CFR 141.2.

FERC Form No. 3-Q, Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies

OMB Control No.: 1902-0205.

Abstract: The FERC Form No. 3-Q is a quarterly financial and operating report for rate regulation, market oversight analysis, and financial audits which supplements the (a) FERC Form Nos. 1 and 1-F, for the electric industry, or the (b) FERC Form No. 2 (Annual Report for Major Natural Gas Companies; OMB Control No. 1902-0028) and FERC Form No. 2-A (Annual Report for Nonmajor Natural Gas Companies; OMB Control No. 1902-0030), for the natural gas industry. The FERC Form No. 3-Q is submitted for all

Major and Nonmajor electric utilities, licensees, and natural gas companies.⁶ FERC Form No. 3-Q includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Income and Statement of Retained Earnings,
- Statement of Cash Flows,
- Statement of Comprehensive Income and Hedging Activities, and
- Supporting schedules containing supplementary information.

Electric respondents report:

- Revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data; and
- Other statistical information.

Natural gas respondents include:

- Monthly and quarterly quantities of gas transported and associated revenues,
- Storage, terminaling and processing services,
- Natural gas customer accounts and details of service, and
- Operational expenses, depreciation, depletion and amortization of gas plant.

Type of Respondent: Major and nonmajor electric utilities, licensees, and natural gas companies.

Estimate of Annual Burden: The estimated annual burden and cost (as rounded) follow. (The estimated hourly cost used for the FERC Form No. 3-Q is \$79 (for wages plus benefits) and is described above, under the FERC Form No. 1.):

FERC FORM NO. 3-Q

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours and cost per response (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Annual cost per respondent (\$) (5) ÷ (1)
FERC 3-Q (electric)	212	3	636	168 hrs.; \$13,272	106,848 hrs.; \$8,440,992	\$39,816
FERC 3-Q (natural gas)	165	3	495	167 hrs.; \$13,193	82,665 hrs.; \$6,530,535	\$39,579
<i>Total for FERC 3-Q</i>	1,131	189,513 hrs.; \$14,971,527.

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: April 30, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-09297 Filed 5-6-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program." This guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device investigational device exemption (IDE) applications, premarket approval applications (PMAs), humanitarian

device exemption (HDE) applications, evaluation of automatic class III designations (De Novo requests), premarket notification (510(k)) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications, Dual 510(k) and CLIA Waiver by Application Submissions, Accessory Classification Requests, and certain investigational new drug (IND) applications and biologics license applications (BLAs).

DATES: The announcement of the guidance is published in the **Federal Register** on May 7, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

⁶ 18 CFR 260.1(b) states that for natural gas companies as defined by the Natural Gas Act, Major pertains to a company whose combined gas transported or stored for a fee exceed 50 million Dth

in each of the three previous calendar years. 18 CFR 260.2(b) states that for natural gas companies as defined by the Natural Gas Act, Non-Major pertains to a company not meeting the filing threshold for

FERC Form No. 2, but having total gas sales or volume transactions exceeding 200,000 Dth in each of the three previous calendar years.