

in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing this training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

**II. Regulatory Project Management Site Tours and Regulatory Interaction Program**

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow

professionally by gaining a better understanding of industry processes and procedures.

**III. Site Selection**

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

Firms interested in offering a site tour or learning more about this training opportunity should respond within 60 days of this notice by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION CONTACT**).

Dated: August 24, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Proposed Information Collection: Request for Public Comment: 30-Day Notice**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Request for public comment: 30-day proposed information collection: IHS Urban Indian Health Program Common Reporting Requirements.

**SUMMARY:** The Indian Health Service, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collection of information in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval. The IHS received no comments in response to the 60-day **Federal Register** notice (FR 04-8721) published on 4/19/04. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

**Proposed Collection**

*Title:* 0917-0007, "IHS Urban Indian Health Program Common Reporting Requirements."

*Type of Information Collection Request:* Extension of a currently approved information collection.

*Form Number:* The report formats are contained in IHS instruction manual, "Urban Indian Health Programs Common Reporting Requirements." The reporting formats have been computerized for electronic data submission.

*Need and Use of Information Collection:* IHS contracts with urban Indian organizations to: access and identify health services available to urban Indians; provide health education and health services to urban Indians; identify the unmet health needs of urban Indians; and, make recommendations on methods to improve health services provided to urban Indians. The information is collected annually and used to: monitor contractor performance; prepare budget reports; allocate resources; and, assess and evaluate the urban Indian health contract programs.

*Affected Public:* Individuals or households, not-for-profit institutions, and State, Local or Tribal Government.

*Type of Respondents:* Urban Indian Health care organizations.

The table below provides the following: types of data collection instruments, estimated number of respondents, number of responses per respondent, annual number of responses, average burden hours per response, and total annual burden hours.

Data collection instruments	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hrs per response*	Total annual burden hrs
Face Sheet .....	34	1	34	0.50 (30 mins) .....	17.0
Table 1 .....	34	1	34	2.00 (120 mins) .....	68.0
Table 2 .....	34	1	34	0.75 (45 mins) .....	25.5
Table 3 .....	34	1	34	2.25 (135 mins) .....	76.5
Table 3A .....	34	1	34	1.05 (65 mins) .....	36.0
Table 3B .....	34	1	34	0.25 (15 mins) .....	8.5
Table 3C .....	34	1	34	0.33 (20 mins) .....	11.0
Table 3D .....	34	1	34	1.25 (75 mins) .....	42.5
Table 4 .....	(**)	1	.....	0.50 (30 mins) .....	17.0

Data collection instruments	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hrs per response*	Total annual burden hrs
Table 5 .....	34	1	34	2.00 (120 mins) .....	68.0
Table 6 .....	34	1	34	2.00 (120 mins) .....	68.0
Table 7 .....	34	1	34	1.00 (60 mins) .....	34.0
Table 8 .....	34	1	34	1.25 (75 mins) .....	42.5
Total .....	408	14	408	15.13 (910 mins) .....	514.5

\* For ease of understanding, burden hours are also provided in actual minutes.

\*\* Excludes Urban Indian Health projects with no medical component.

There are no Capital Costs, Operating Costs and/or Maintenance Costs required for this collection of information.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, directly to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Allison Eydt, Desk Officer for IHS.

Send requests for more information on the proposed collection or to obtain a copy of the data collection instrument(s) and instructions to: Ms. Christina Ingersoll, IHS Reports Clearance Office, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852-1601, call non-toll free (301) 443-5938, send via facsimile to (301) 443-2316, or send your e-mail requests, comments, and return address to: [cingerso@hqe.ihs.gov](mailto:cingerso@hqe.ihs.gov).

For further information directly pertaining to the proposed data collection instruments and/or the process, please contact Karen Boyle, Reyes Building, 801 Thompson Avenue,

Suite 200, Rockville, MD 20852-1627, Telephone (301) 443-4680.

*Comment Due Date:* Your comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 6, 2004.

**Charles W. Grim,**

*Assistant Surgeon General, Director, Indian Health Service.*

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**BILLING CODE 4160-16-M**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[CGD01-04-115]

### Notice, Request for Comments; Letter of Recommendation, Keyspan LNG Facility Providence, RI

**AGENCY:** Coast Guard, DHS.

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

**SUMMARY:** In accordance with the requirements in 33 CFR 127.009, the U.S. Coast Guard Captain of the Port (COTP) Providence is preparing a letter of recommendation as to the suitability of the Narragansett Bay waterways for liquefied natural gas (LNG) marine traffic. The letter of recommendation is in response to a Letter of Intent to modify the Keyspan LNG facility Providence, Rhode Island, to accept shipments of LNG by water. The COTP Providence is seeking comments and related material pertaining specifically to the maritime operation and waterways management aspects of the proposed LNG facility modifications. In preparation for issuance of the letter of recommendation, the COTP Providence will consider comments received from the public, as well as information submitted by the owner or operator under the requirements of 33 CFR 127.007. Specific items suitable for comment are listed later in this notice under *Background and Purpose*.

**DATES:** Comments and related material must reach the Coast Guard on or before November 1, 2004.

**ADDRESSES:** The Commanding Officer, U.S. Coast Guard Marine Safety Office Providence maintains the public docket for this notice. Comments and documents will become part of this docket and will be available for inspection and copying at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. You may submit comments and related material by:

1. Mail or delivery to Commanding Officer, U.S. Coast Guard Marine Safety Office, 20 Risho Avenue, East Providence, RI 02914-1208.

2. Fax to (401) 435-2399.

3. Electronically via e-mail at [Elambie@msoprov.uscg.mil](mailto:Elambie@msoprov.uscg.mil).

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call Ms. Erin G. Lambie at Coast Guard Marine Safety Office Providence, RI, 401-435-2355. For assistance using the FERC internet Web site we reference, please contact FERC online support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll free at 1-866-208-3676, or for TTY contact 1-202-502-8659.

### SUPPLEMENTARY INFORMATION:

#### Request for Comments

We encourage you to submit comments and related material pertaining specifically to the maritime operation and waterways management aspects of the proposed modification to the existing LNG facility. If you do so, please include your name and address, identify the docket number for this notice (CGD01-04-115), and give the reason for each comment. You may submit your comments and material by mail, hand delivery, fax, or electronic means, as described in **ADDRESSES**, but please submit your comments and material by only one means. If you submit them by mail or hand delivery, please submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached