SUPPORTING STATEMENT FOR
The National Forensic Laboratory Information System Collection of Analysis Data

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) of an existing collection of information that was previously approved by OMB – OMB Approval #1117-0034, The National Forensic Laboratory Information System Collection of Analysis Data. The currently approved data collection is a continuous data collection from publicly-funded crime laboratories that conduct drug analyses. This submission request is for a revision to the Medical Examiner/Coroner (MEC) Survey of the NFLIS-MEC collection to: clarify some of the questions that are currently being asked, add ten new questions and remove nine questions. In addition, DEA would be adding six core data elements to the NFLIS-MEC continuous data collection and DEA has further refined our MEC sampling strategy for that effort.

A. JUSTIFICATION

1. The National Forensic Laboratory Information System (NFLIS) collections provide DEA with a national database on analyzed drug samples from law enforcement activities, antemortem toxicology samples (toxicology laboratories), and post-mortem toxicology samples (medical examiner/coroner offices [MECs]) from federal, state, and local laboratories. Specifically, NFLIS-Drug data provide DEA current, precise, and representative estimates of drugs seized by law enforcement and analyzed by forensic laboratories. Since 2001, DEA has had case and drug report estimates for all drugs reported in NFLIS that are statistically representative of the nation and of census regions. The estimates, which are made possible by updating the laboratory profiles through the survey effort (see draft survey in Appendix), have given DEA the ability to track national and regional drug trends; a clearer national picture of illicit or diverted drug availability; additional information about the temporal changes in drug availability by geographic region; and the ability to detect new or emerging drugs. Information from NFLIS is combined with other existing databases to develop more accurate, up-to-date information on abused drugs. This database represents a voluntary, cooperative effort on the part of participating laboratories and MECs to provide a centralized source of analyzed drug data.

Existing federal drug abuse databases do not provide the type, scope, timeliness, or quality of information necessary to effectively estimate the actual or relative abuse potential of drugs as required under the Controlled Substances Act (21 U.S.C. 811(b)) and international treaties in a timely and efficient manner. For example, much of the trafficking data for federal drug scheduling actions is presently obtained on a case-by-case basis from state and local laboratories. Occasionally scientific personnel from DEA's Diversion Control Division, Drug and Chemical Evaluation Section, have contacted specific laboratories and requested files. In addition, some DEA field offices routinely subpoena MEC records for use in case work. The development of the National Forensic Laboratory Information System (NFLIS) greatly enhances the collection of such data. Submission of information for this collection is voluntary. DEA is not mandating this information collection.

2. NFLIS provides DEA with a computerized data collection and retrieval system on information associated with analyzed drug evidence which is submitted from forensic laboratories. In addition, antemortem and post-mortem toxicology data will be collected from toxicology laboratories and MECs. This information supplements and complements information obtained from other databases and surveys such as the SAMHSA National Survey on Drug Use and Health (NSDUH) and NIDA's monitoring the Future Survey. The information from these sources combined with the data from the non-federal laboratories presents a more complete, timely indicator of the extent of and activities associated with the illicit trafficking of a substance. The data is used to provide information in support of drug scheduling actions and enables DEA to better monitor the diversion of legitimately marketed drugs, drug trafficking and abuse.

The data obtained from the system are under the control of DEA. Data are used primarily by DEA, with consideration given to other federal agencies such as the Office of National Drug Control Policy (ONDCP), and state and local agencies, as agreed with DEA. Participating laboratories, law enforcement agencies and other government agencies are permitted limited access to the database. The level and type of access is controlled by DEA.

Data from the NFLIS surveys will provide key information about each laboratory and MEC office, including agency affiliation, agencies served, size of staff, data elements available, annual case load, backlog size, testing policies, technical procedures, analysis turnaround time, and other pertinent information (see draft survey in Appendix). These survey data enable DEA to better understand the drug analyses received from participating agencies and will be used in subsequent years to generate more accurate estimates in NFLIS reporting.

3. NFLIS collects data through the electronic transmittal of reports, for a response rate of 100% of the ongoing data collection. Forensic laboratories submit reports via e-mail, the file transfer protocol (FTP) site, or the Internet. Electronic reporting minimizes the burden by eliminating the time and expense necessary to print, package and mail hard copy reports or portable drives and allows for more efficient processing of the data reported.

4. DEA has not been able to identify duplicate efforts that mirror the ongoing NFLIS-Drug program or planned expansion of the NFLIS-Tox program. DEA has made efforts to identify and prevent duplication of the collection of information. The existing Collection of Laboratory Analysis Data of Samples Tested by Forensic Laboratories is unique to DEA.

With regard to DEA's planned NFLIS-MEC program, the only data collections that are marginally close include the Centers for Disease Control and Prevention's (CDC's) National Violent Death Reporting System (NVDRS) and the National Vital Statistics System (NVSS). Currently, 42 states/territories participate in the NVDRS, which collects data about violent deaths each year, including homicides, suicides, and deaths where individuals are killed by law enforcement in the line of duty.[1] Thus, the types of death that are of interest to the NVDRS are narrow and do not represent the full spectrum of deaths that would be caused by drug abuse (e.g., accidental ingestions, drugged driving that results in vehicular accidents). The Diversion Control

[1] Centers for Disease Control and Prevention (CDC). National Violent Death Reporting System. Website accessed May 29, 2018: https://www.cdc.gov/violenceprevention/nvdrs/.

Division needs data from a broader pool of deaths to support scheduling decisions. Moreover, toxicological data regarding drug concentrations from laboratories are not included in the NVDRS data collection.

The NVSS collects data from all states based on standard certificates of death that include cause and manner of death. Although the NVSS would include all deaths, the data are limited in that the drug-related data that are collected are based on the cause of death statement rendered by the medical examiner or coroner and do not include drug concentration levels. Moreover, cause of death statements vary widely in their identification of drugs. For some coroners or medical examiners, a cause of death statement involving drugs may range from listing simply drug classes (e.g., opioids, benzodiazepines) to very specific drugs implicated (e.g., a combination of oxycodone and diazepam). These cause of death statement conventions vary across all jurisdictions and the generalized drug categories are not of much use to the Diversion Control Division to make important drug scheduling decisions that impact the public safety and health of our Nation. Moreover, and similar to the NVDRS, the NVSS collection does not include the drug concentrations from the laboratories.

The Fatality Analysis Reporting System (FARS), which is administered by the National Highway Traffic Safety Administration, collects data from death certificates and coroner and medical examiner reports for deaths caused by motor vehicular accidents. However, the types of death that are collected by FARS is even more narrow than that of the NVDRS and thus, the FARS data collection does not replicate or reflect the information DEA requires to serve its mission.

The CDC also operates the Overdose Data to Action (OD2A) collection, which provides support to jurisdictions in order to collect data from these states regarding nonfatal and fatal overdoses. However, the OD2A data are not as useful for DEA either, because to support DEA's mission, it is crucial to know all the specific drugs identified in all death investigations, not just those substances to which the death resulted in an overdose.

With regard to the NFLIS-Drug survey (the first new activity listed under Section 1), the Bureau of Justice Statistics (BJS) periodically conducts the Census of Publicly Funded Forensic Crime Laboratories (2002, 2005, 2009, and 2014). This BJS survey effort includes a similar pool of respondents of the NFLIS-Drug survey, but there is little topical overlap across the surveys. BJS's next iteration of the survey[2] is expected to include the following items: types of forensic functions performed; annual operating budget; total number of employees; number of forensic requests received and completed during the year; types of proficiency tests performed; types of professional accreditations and staff certifications; extent of standardization in data collection and coding; use of or contributions to other databases; and policies regarding acceptance or referral of cases.

In contrast, the next iteration of the NFLIS-Drug survey will include similar measures from previous iterations of the survey, including: administrative information, such as an enumeration of laboratories within laboratory state and local systems; drug chemistry caseload information

[2] See page 8 of BJS's recent *2019 Census of Publicly Funded Forensic Crime Laboratories* Solicitation: https://www.bjs.gov/content/pub/pdf/cpffcl19_sol.pdf.

(e.g., outsourced cases, backlogs and solutions for eliminating backlogs); laboratory drug chemistry context (e.g., circumstances for reasons why cases would not be submitted to the laboratory); drug chemistry technical procedures (e.g., types of analytical instruments used; frequency of testing and quantitative analysis across several drugs/drug classes); practices regarding the testing of emerging drugs (e.g., circumstances under which the laboratory attempts to identify non-controlled drugs); and perceptions of NFLIS benefits (e.g., perceived value of NFLIS products such as reports and web tables).

5. This is a extension of an existing collection of information, The National Forensic Laboratory Information System Collection of Analysis Data and requests approval for the three additional activities listed in Section 1. DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. Small private toxicology laboratories, small drug laboratories, or small MECs do not have to participate in NFLIS as it is a voluntary program. The collection will not have a significant economic impact on small businesses or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

6. Not collecting the information would compromise federal efforts to prevent diversion. The collection of this data provides valuable, timely information to DEA and other drug regulatory enforcement agencies. Existing federal drug abuse databases do not provide the type, scope or quality of information necessary to effectively estimate the actual or relative abuse potential of drugs as required under the Controlled Substances Act (21 U.S.C. 811(b)) and international treaties in a timely and efficient manner.

7. Some respondents report monthly, others quarterly. Respondents decide how frequently they submit these voluntary reports. Less frequent reporting would reduce DEA's ability to monitor actual and relative abuse potential of drugs. Other special circumstances in item 7 of the supporting statement are not applicable to this information collection.

8. Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 89 FR 93350, published November 26, 2024. DEA did not receive any comments concerning this collection. DEA has also published a 30-day Federal Register Notice of Information Collection, 90 FR 8534, on January 30, 2025.

The DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. The ongoing collection of information does not propose to provide any payment or gift to respondents. However, newly recruited laboratories may receive a computer or peripheral equipment to aid in NFLIS reporting. Additionally, for the proposed NFLIS-Drug survey, reference books worth $25 will be sent to all laboratories with the survey packets.

10. Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of

Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. This collection of information does not ask any questions of a sensitive nature, however, the information is law enforcement sensitive.

12.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response (Hours)	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
Current collection of the continuous, ongoing NFLIS-Drug Program	140	134 respondents monthly, 6 respondents quarterly	1632	0.13 (8 minutes)	218	$50.67	$11,046
Survey of the NFLIS-Drug Program	140	once in 2019	140	0.5 (30 minutes)	70	$50.67	$3,547
Collection of the NFLIS-MEC Program	2100	monthly and quarterly (unknown breakdown)	2100	0.17 (10 minutes)	350	$50.67	$17,735
Survey of the NFLIS-MEC Program	2100	once in 2020	1260	0.75 (45 minutes)	945	$50.67	$47,883
Collection of the NFLIS-Tox Program	400	monthly and quarterly (unknown breakdown	400	0.17 (10 minutes)	67	$50.67	$3,395

		)					
Survey of the NFLIS-Tox Program	400	once in 2021	280	0.75 (45 minutes)	210	$50.67	$10,641
Unduplicated Totals	***2,640***	***2.2015***	***5,812***	***0.32003***	***1,860***	***50.67***	***$94,246***

Hourly rate*

Estimated hourly wage ($/hour)[3]	31.22
Load for benefits (percent of labor rate)[4]	62.30%
Loaded labor rate ($/hour)[5]	50.67006
Loaded labor rate (rounded)	50.67

Average burden per collection: $16.1774
Average frequency per response: 2.2015

13. The estimated annual cost burden is zero. Respondents are estimated to not incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14.

Labor Category	Number	Annual Rate	Load	% of time	Cost
Chemist GS-14	1	157,982	1.623	50%	$ 128,202
Statistician GS-13	1	133,692	1.623	25%	$ 54,246
Contracting Officer GS-14	1	157,982	1.623	10%	$ 25,640
Contracted Support					$ 2,000,000
Total					$ 2,208,088

Estimated Annualized cost to the Federal Government: $2,208,088

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a. Government salaries above include a load of 62.3% for benefits based on the ECEC for "State and local government workers." The ECEC does not include figures for Federal

[3] Average of median hourly wages for 19-4092 Forensic Science Technicians is used to represent the occupation of persons who will submit responses. May 2023 National Occupational Employment and Wage Estimates United States. http://www.bls.gov/oes/current/oes_nat.htm.
[4] Bureau of Labor Statistics, "Employer Costs for Employee Compensation – June 2024" (ECEC) reports that average benefits for "State and local government workers" is 38.4% of total compensation. The 38.4% of total compensation equates to 62.3% (38.4% / 61.6%) load on wages and salaries.
[5] $31.22 x (1 + 62.3%) = $50.67.

government workers. Load for State and local workers is used as an estimate for Federal government workers.

15. There is no change in the estimated annual responses. The change in annual hour burden is due to rounding in the calculation. The change in annual cost is due to change in method. Previously, the approved 2021 figure represented the "Monetized Value of Respondent Time" calculated in section 12. The new requested annual cost represents the figure from section 13. The table below summarizes the changes since the last renewal of this information collection.

	2021 Approved Burden	2025 Requested Burden	Difference
Annual responses	**5,812**	**5,812**	**0**
Annual hour burden	**1,859**	**1,860**	**1**
Annual cost ($)	**84,876**	**0**	**(84,876)**

16. DEA will continue to publish the results of the information collected from the continuous, ongoing NFLIS-Drug program via the regularly produced annual, midyear, special reports, brief reports, conference presentations and posters, and web tables. The NFLIS-Drug survey results will be published in a report akin to what has been produced in prior years (e.g., 2013 Survey of Crime Laboratory Drug Chemistry Sections). When the two future continuous NFLIS-MEC and NFLIS-Tox collections have been established and the data collected support a publication, DEA will produce similar products to the aforementioned NFLIS-Drug program.

17. DEA does not object to OMB displaying the expiration date.

18. DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

Estimates for all drugs reported in NFLIS that are statistically representative of the nation and of census regions are produced. With 95% of the national caseload being reported to NFLIS-Drug for any given period, the National Estimates based on All Reports (NEAR) approach to estimation is used for reporting. Two types of trend analyses are completed for each midyear and annual report: (1) *long-term trends method* tests for polynomial regression curves and (2) p*rior-year comparisons* test for differences between estimates for the current reporting period and estimates for the prior year reporting period. The NFLIS-Drug survey results (i.e., the first activity listed under Section 1) will inform the reporting estimates for the NFLIS-Drug program. DEA will use past NFLIS-Drug experience to establish sampling frames for the future NFLIS-

Tox and NFLIS-ME/C programs. Appropriate weighting, imputation, and estimation methods for both NFLIS-TOX and NFLIS-ME/C data collection efforts will be developed for long-term reporting that mirror the NFLIS-Drug statistical methodology.