Supporting Statement for Paperwork Reduction Act Submissions
The National Forensic Laboratory Information System
Collection of Analysis Data
OMB Approval #1117-0034

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision 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 (i.e., NFLIS-Drug). This submission request is for a revision to the Toxicology Survey of the NFLIS-Tox collection to: clarify some of the questions that are currently being asked, add 10 new questions and remove 7 questions.

Part A. Justification

1. Necessity of Information:

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. Needs and Uses:

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 is 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 including law enforcement affiliation, agencies served, size of staff, data elements available from the laboratory report, 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 laboratories and will be used in subsequent years to generate more accurate estimates in NFLIS reporting.

3. Use of Information Technology:

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. Efforts to Identify Duplication:

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 toDEA.

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 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.

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

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

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.

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 (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. Impact on Small Businesses or Entities:

This is a revision 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. Consequences of Less Frequent Collection:

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. Special Circumstances Influencing Collection:

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. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 85 FR 29743 , published May 18, 2020 and the 30-day Federal Register Notice of Information Collection, 85 FR 44928, published July 24, 2020. DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants:

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. Assurance of Confidentiality:

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. Justification for Sensitive Questions:

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

12. Estimate of Hour Burden:

Current collection of the continuous, ongoing NFLIS-Drug program:
Total number of respondents: 140
Frequency of response: Monthly (134 Respondents) and Quarterly (6 Respondents)
Total annual responses: 1632 Monthly (134 x 12) + Quarterly (6 x 4)
Average time per response: 0.13 hours (8 minutes)
Total annual hour burden: 218 hours

Average Burden:	Per Collection:	0.13 hours (8 minutes)
	Per Respondent:	1.6 hours

Survey of the NFLIS-Drug program:
Total number of respondents: 140
Frequency of response: Once in 2019 (140 respondents)
Total annual responses: 140

Average time per response: 0.5 hour
Total annual hour burden: 70 hours

Average Burden: Per Collection: .5 hour
Per Respondent: .5 hour

With the addition of the toxicology laboratories and MECs, system growth potential:

Future Collection of the NFLIS-MEC program:
Total number of respondents: 2,100
Frequency of response: Monthly and Quarterly (breakdown unknown)
Total annual responses: 2,100 (estimated)
Average time per response: 0.17 hours (10 minutes)
Total annual hour burden: 350 hours

Average Burden: Per Collection: 0.17 hours (10 minutes)
Per Respondent: 0.17 hours (10 minutes)

Survey of the NFLIS-MEC program:
Total number of respondents: 2,100
Frequency of response: Once in 2020 (2,100 respondents)
Total annual responses: 1260
Average time per response: 0.75 hours (45 minutes)
Total annual hour burden: 945 hours

Average Burden: Per Collection: 0.75 hours
Per Respondent: 0.45 hours

Collection of the NFLIS-Tox program:
Total number of respondents: 400
Frequency of response: Monthly and Quarterly (breakdown unknown)
Total annual responses: 400 (estimated)
Average time per response: 0.17 hours (10 minutes)
Total annual hour burden: 67 hours

Average Burden: Per Collection: 0.17 hours (10 minutes)
Per Respondent: 0.17 hours (10 minutes)

Survey of the NFLIS-Tox program:
Total number of respondents: 400
Frequency of response: Once in 2021 (400 respondents)
Total annual responses: 280
Average time per response: 0.75 hours (45 minutes)
Total annual hour burden: 210 hours

Average Burden:	Per Collection:	0.75 hours
	Per Respondent:	0.53 hours

All surveys combined:
Total number of respondents: 2,640
Frequency of response: 2.2015 (per year, average)
Total annual responses: 5,812

Burden dollars:

Estimated hourly wage ($/hour):[3]	28.44
Load for benefits (percent of labor rate):[4]	60.5%
Loaded labor rate ($/hour):[5]	45.65

Total annual hour burden (all surveys): 1,859

Total annual cost (all surveys): $84,876

Average burden per collection: $14.6035

13. Estimate of Cost Burden:

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. Estimated Annualized Cost to the Federal Government:

Project Manager:

1 GS-14 Chemist (50% of work year): $110,346

Statistician:

1 GS-13 Statistician (25% of work year): $46,691

Oversight of Contract Responsibilities:

1 GS-14 Contracting Officer (10% of work year): $22,069

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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 2019 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 – December 2019" (ECEC) reports that average benefits for "State and local government workers" is 37.7% of total compensation. The 37.7% of total compensation equates to 60.5% (37.7% / 62.3%) load on wages and salaries.
5 $28.44 x (1 + 60.5%) = $45.65.

Contracted Support: $2,000,000

Total cost to government: $2,179,106

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 60.51% for benefits based on the ECEC for "State and local government workers." The ECEC does not include figures for the Federal Government.

15. Reasons for Change in Burden:

The primary reason for the change in the number of responses and burden is due to a computational error in the 2019 Approved Burden. The corrected annual responses, annual hour burden, and annual cost are 6,050, 1,918, and $79,757, respectively. From the corrected 2019 approved burden, the difference for annual responses, annual hour burden, and annual cost are decrease of 238, decrease of 59, and incrase of $5,118. The decrease in annual responses and hour burden correspond to the adjustment of estimated number of resondents. The increase in annual cost is due to adjustment in loaded hourly rate for the occupation of the person expected to submit the responses. The table below summarizes the changes since the last renewal of this information collection.

	2019 Approved Burden	**2020 Requested Burden**	**Difference**
Annual responses	3,172	5,812	2,640
Annual hour burden	1,373	1,859	486
Annual cost ($)	9,047	84,876	75,829

16. Plans for Publication:

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. Expiration Date Approval:

DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

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

Part B. 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.