

Recordkeeping for Institutional Dual Use Research of Concern (iDURC) Policy Compliance

EPA ICR 2530.01, OMB Control Number 2080-NEW

1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.

The White House Office of Science and Technology Policy issued the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (iDURC Policy) in September 2014. It became effective, September 24, 2015 (79 Federal Register 57589). All federal departments and agencies are required to implement this Policy. Institutions subject to the iDURC Policy are those that receive funding from a USG entity for research that involves a certain set of agents or toxins, or that receive funding from a non-USG entity for the same research and also receive funding from a USG entity for life sciences research. The iDURC Policy requires that institutions subject to the Policy train individuals within their institution that are conducting research involving any of the agents or toxins identified in the Policy. Additionally, institutions are to maintain records of that training. EPA is submitting an emergency information collection request for these recordkeeping requirements.

EPA is requesting emergency clearance of this ICR under 5 CFR 1320.13(a)(2)(i) because the iDURC policy's effective date has passed, but without PRA approval the recordkeeping provisions cannot yet be implemented. Standard processing of this ICR would further delay full implementation of the policy, which seeks to mitigate the risk of public harm from life sciences research being misapplied.

EPA requests that OMB authorize this ICR by Feb 29, 2016, for the maximum of 180 days.

2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.

The iDURC Policy requires that individuals conducting research involving a certain set of agents or toxins must be trained, and records of that training maintained. Institutions are to provide training and maintain their training records. EPA may choose to collect the records, if appropriate. EPA expects that private industry and the federal government, in the form of government-owned/contractor-operated laboratories, will be affected by this information collection. The information may be used to ensure EPA is in compliance with the Policy, and that institutions receiving EPA funding are in compliance as well.

- 3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.**

EPA may request records be transmitted electronically to the Agency by the institution. Institutions may provide training and maintain records as best fits their organization.

- 4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.**

There is no duplication as there are no other sources available to collect this information. EPA will only require the institutions it directly funds for research involving any of the agents or toxins listed in the iDURC Policy, or those referred to EPA by the National Institutes of Health (NIH) to maintain training records. EPA expects that the amount referred by NIH will be *de minimis*.

- 5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES, DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.**

This collection of information is not reasonably expected to impact small businesses or other small entities.

- 6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.**

The aim of the iDURC Policy is to ensure the benefits of certain types of research are conducted and communicated responsibly, while minimizing the risks that the results of such research are used in a manner that results in harm. If the collection is not conducted, EPA cannot guarantee that institutions are complying with and supporting the goal of the iDURC Policy.

- 7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:**

- REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN**

QUARTERLY;

- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**
- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**
- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**
- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**
- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**
- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**
- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES TO PROTECT THE INFORMATION'S CONFIDENTIALITY TO THE EXTENT PERMITTED BY LAW.**

The iDURC Policy requires that training records be maintained for the term of the research grant or contract, plus 3 years after its completion. EPA may ask institutions to comply with this section of the Policy and retain such records for more than the 3 years that is stated in the question above (requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years). There are no other special circumstances. The collection of information is conducted in a manner consistent with the

guidelines in 5 CFR 1320.6.

8. IF APPLICABLE, IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.

As this is being submitted as an Emergency Clearance, public comment is being requested concurrent with OMB review. Following approval of the Emergency ICR, EPA will follow standard public notice and comment procedures in renewing this ICR.

DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.

CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.

As this is a new collection being submitted according to emergency procedures, no efforts to consult respondents or interested parties in the collection have been made.

9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEEES.

No payments or gifts are to be provided to respondents.

10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.

EPA does not expect any issues of confidentiality to be relevant to this information collection.

- 11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO OBTAIN THEIR CONSENT.**

Questions of a sensitive nature are not found in this information collection.

- 12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION.**

THE STATEMENT SHOULD:

- INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**
- IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS.**

EPA currently has funded an average of 2-3 research projects each year involving any of the agents or toxins identified in the iDURC Policy over the past three years. EPA anticipates funding such projects at the same or lower rate in the coming years, whether through acquisition or assistance agreements. EPA estimates that such projects will be conducted by either private

industry or the federal government in the form of government-owned/contractor-operated labs. EPA consulted with a small sample of project officers to estimate burden on respondents. The total number of annual respondents is estimated to be 12-24, with about 6-8 respondents per research project. The training records, while not necessarily collected by EPA, are expected to be completed while or after the research agreement is finalized, and no more frequently than annually. The total annual hour burden, based on consultations and estimates of how long the training and recordkeeping will take, is 36-72, or about 3 hours per individual respondent. This burden was estimated by estimating that training will take 2 hours per individual and that retaining records of such training will take up to an hour per individual. EPA estimates that one-third of respondents will be from government-owned/contractor-operated labs, and two-thirds from private industry.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Based on the 3-hour estimate for 12-24 respondents, and at an average wage rate of \$40-\$60, the annualized cost to respondents is estimated to range from \$1,440 to \$4,320. The hourly wage rate was estimated based on consultation with project officers at EPA and Bureau of Labor Statistics data on appropriate disciplines and specialties, including Life Scientists and Environmental Engineers, among others.

13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).

- **THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND MAINTENANCE AND PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.**

- **IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.**
- **GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND USUAL BUSINESS OR PRIVATE PRACTICES.**

There are no capital, start-up, or ongoing operation or maintenance costs associated with this information collection.

- 14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.**

The Agency anticipates incurring some costs associated with this information collection. The costs are associated with employee labor and materials for analyzing, evaluating, summarizing, and/or reporting on the training records. The costs are summarized below.

The Agency estimates that 0.1 FTE of a GS-14 Employee will be required for potential audits and reviewing training records. The annual salary for a GS-14, Step 1 in Washington, DC is \$108,887. Including the standard overhead factor of 60%, the Agency estimates an annualized

cost of \$17,422.

15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS IN BURDEN ESTIMATES FROM THE PREVIOUS APPROVED ICR.

Not applicable, as this is a new Information Collection Request.

Information Collection	Reason	Previous Burden	New Burden	Difference	Type of Change
Recordkeeping for iDURC Training	New ICR	0	72	72	PC

PC = Program Change

A = Adjustment

16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.

The Agency does not intend to publish any information resulting from this information collection.

17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.

The Agency plans to display the expiration date for OMB approval of the information collection on all applicable instruments.

18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," IN ROCIS.

The Agency is able to certify compliance with all provisions under the PRA Certification.