Supporting Statement A for

National Toxicology Program Level of Concern Categories Study

(NIH/NIEHS)

NEW

(OMB NO. 0925-XXXX)

Submitted: Day Month Year

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Summary

The National Toxicology Program (NTP) conducts literature-based evaluations to identify substances in our environment that are hazards for human health. NTP has used a five-point scale to communicate its opinion, or "level of concern" (LoC) conclusion, regarding the potential for environmental substances, physical agents, or mixtures (collectively referred to as "substances") to cause adverse health effects in humans under specific exposure conditions or for a specific population. Recently, NTP implemented a new approach with systematic-review methodologies for conduct of these evaluations. Although LoC categories have been a useful communication tool, NTP has identified confusion among some of its scientific advisors and the public regarding what the LoC categories mean and how conclusions are reached. As part of its implementation of systematic-review methodologies, NTP is now conducting preliminary work to facilitate the updating of the LoC framework. This includes re-assessing the LoC categories, to determine what changes are needed to ensure integrated consideration of relevant and reliable data and enhance transparency in describing how conclusions are reached. This exploratory study is intended to facilitate the effort toward improving the LoC framework as a risk communication tool.

A. Justification for Collection of Information

A.1. Circumstances Making the Collection of Information Necessary

The NTP Level of Concern Categories Study is supported by NIEHS' general mandate as defined by U.S. Code Title 42, Chapter 6A, Subchapter III, Part C, Subpart 12, Section 285*l*, as amended by the Health Research Extension Act of 1985, which states the institute's purpose is "the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly."

We are all affected by our environment including by the products and substances that we come in contact with at home, at work, and at play. NTP was established in 1978 as a federal, interagency program whose goal is to safeguard the public by identifying substances in the environment that may affect human health (NTP 1978). NTP is headquartered at the National Institute of Environmental Health Sciences, which is part of the National Institutes of Health.[1]

For more than 37 years, the NTP has been the world leader in the design, conduct, analysis, and interpretation of studies to identify environmental hazards for human health and has studied over 2500 substances for a variety of health outcomes including cancer, reproductive and developmental toxicity, and effects on the immune and nervous systems. NTP plays a critical role in providing a strong scientific basis for the American public and U.S. government agencies at the state and federal levels to make credible decisions that protect public health. Its work includes both laboratory-based research and testing and literature-based evaluations of environmental substances for a variety of health-related effects including cancer, general toxicity, and effects on reproduction, development, and the immune and nervous systems (NTP 2014).

[1] For more information about NTP and its programs, visit http://ntp.niehs.nih.gov/

In 1998, NTP initiated literature-based evaluations to assess the scientific evidence on environmental chemicals, physical agents, or mixtures (collectively referred to as "substances") and provide its opinion on whether selected substances might be of concern for causing adverse effects on human reproduction and development given what is known about their toxicity, level of human exposure, and pharmacokinetics. NTP opinions are referred to as "level of concern?" (LoC) conclusions and expressed using a 5-point LoC framework. LoC conclusions are qualitative in nature and range from "negligible concern" to "serious concern" for adverse effects, with an additional category of "insufficient data" that is used when information is lacking on hazard and/or exposure to reach a conclusion (Bucher et al. 2011). NTP has used this LoC framework to describe concern for human reproductive or developmental effects for 20 environmental substances. In 2011, NTP expanded the scope of these evaluations to be more comprehensive and include all non-cancer health outcomes (Bucher et al. 2011), and in 2014, NTP implemented a new approach for conducting these literature-based evaluations that uses system-review methodologies (Birnbaum et al. 2013; NTP 2013; Rooney et al. 2014).

LoC categories are not strictly defined, and conclusions regarding the appropriate category are based on a number of factors including the following: the hazard identification assessment of the potential adversity to humans of the health outcomes(s) identified in animal and/or human studies, the extent and nature of exposure, and pharmacokinetic factors. The LoC framework has been very useful as an approach for integrating conclusions on hazard identification with what is known about human exposure without conducting a quantitative risk assessment, which falls outside the scope of NTP's activities.

NTP's decision to update the LoC framework is influenced by several factors. First, it appears that the public and some of NTP's scientific advisors have experienced confusion regarding the meanings of LoC categories, e.g. "negligible concern" versus "minimal concern" or "some concern" versus "concern" (NTP 2008). This confusion indicates a need to clarify what the LoC categories mean and how NTP reaches conclusions about them, as well as to re-assess whether the current 5-point "concern" scale is optimal or the most intuitive. Second, as part of its implementation of systematic review

methodologies in literature-based evaluations, NTP has changed the approach and categories it uses to reach and describe hazard conclusions (Rooney et al. 2014), and these changes need to be incorporated into the LoC framework. In particular, the current approach for developing LoC conclusions is based on separate hazard identification assessments of animal and human studies. The new approach for reaching hazard conclusions identifies relevant and reliable data, integrates across animal and human evidence, and considers the degree of support from in-vitro, cellular, and molecular based studies, or mechanistic studies, to reach a single category for hazard identification. The single category for hazard identification will be integrated with information about exposure to reach a LoC conclusion. As a result, NTP now plans to conduct exploratory work into how the LoC framework may be updated in order to integrate the new hazard conclusions into the decision-making process. NTP is also re-assessing the number and labels of LoC categories to determine what changes are needed to enhance the framework's transparency in describing how conclusions are reached. This information collection effort is intended to be preliminary and to provide insight into how NTP may improve the LoC framework as a risk communication tool. Outcomes from this study will not directly result in a modified LoC framework intended for implementation.

Forthcoming work will include identifying multiple modalities for visual communication of LoC conclusions and formal evaluation of consumer/public perception and interpretation of the modified LoC framework via cognitive testing or focus group sessions composed of members of the general public as well as experts from other stakeholder sectors. That work is not part of the current study and will occur prior to any formal implementation or communication of an updated LoC framework. NTP will continue to engage experts in risk communication as advisors including Dr. David Budescu, Fordham University, and Dr. Thomas Wallsten, University of Maryland – College Park.

A.2 The Purpose and Use of the Information Collection

Information collected in this study will provide insight into NTP's ongoing effort to update the LoC framework with respect to exploring the number and labels of LoC categories.. NTP scientists at

NIEHS and their collaborators at other institutions will be responsible for carrying out this study and disseminating results through the scientific literature. Results will be published in environmental health journals, posted to the NTP website,[2] presented at scientific meetings, and communicated to users of this information including medical and scientific communities, government health and regulatory agencies, and the public. OMB approval is requested for three years. Results communicated in any presentations, publications, or reports will clearly describe that findings from this collection are preliminary, and that outcomes are not intended to be implemented as an updated LoC framework.

A.3. Use of Information Technology and Burden Reduction

NTP has developed a web-based application with a user interface ("web-based instrument") for participants to use for the LoC card sorting exercises for both Phases 1 and 2. The cards with LoC scenarios will be presented in a standard format for consistency, and both phases of the study will use the same sorting process. A specific website for this study will be set-up, and participants will be able to access the website remotely at any time during the experimental LoC card sorting phases using a variety of Internet browsers. Information collection of participants' responses will be automated and secure, and stored on NIEHS servers. Screenshots of the website are provided in **ATTACHMENT 1 – WEBSITE SCREENSHOTS**.

Both Phase 1 will have two trials (Trial A and B) and Phase 2 will have two trials (Trial C and D). Prior to beginning Phase 1, experts will be trained using an on-line video and help via email will be available to answer questions during the training. Access to the website for each participant will be through a unique Username and PIN-code, everyone will do the card sorting exercises independently, and responses will not be shared among participants.

At enrollment for Phase 1, the following personal identifiable information (PII) will be collected via a web-based registration form: name, affiliation, contact information (telephone number and email), scientific expertise, terminal degree(s), sector (academia, industry, non-government organizations, and federal and state agencies), and self-report of three years' employment working in public health or a risk

[2] *ibid*.

assessment-related activity. Information will be screened to ensure eligibility criteria are met. Name and contact information will not be used in the screening process. PII will be stored encrypted and separately from all other data. In Phase 2, the same PII, as noted above, will be used to screen registrants and identify the new group of eligible participants. A Privacy Impact Assessment was submitted for the LoC information management system on Dec. 15, 2015.

A.4. Efforts to Identify Duplication and Use of Similar Information

The information we will collect is not available from other sources. NTP will collect information to inform its LoC framework due to changes in its literature-based evaluation approach and the hazard conclusion categories .

For 17 years, NTP has prepared in-depth scientific evaluations and used a 5-point LoC framework to communicate NTP's assessment of the degree of concern regarding the potential human health effects of selected substances given what is known about their toxicity, level of human exposure, and pharmacokinetics effects. These evaluations continue to be the only ones of their kind that consider toxicity findings in the context of human exposure to derive "level of concern" conclusions and are a unique environmental resource used by government agencies, medical and scientific communities, and the public.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

This study will collect information in two sequential phases. Phase 1 has two trials (Trials A and B) and each participant will do the LoC sorting exercise twice with an intervening interval of ~2-4 weeks. This interval should permit timely scheduling and prevent the need to retrain experts to use the web-based instrument. Once completed, Phase 1 will not be repeated. Phase 2 will have two trials (Trials C and D). Phase 2, Trial C will occur following completion of Phase 1 and analysis of the data to determine the optimal number of LoC categories. Phase 2, Trial D will occur following completion of Trial C and

analysis of data to determine the appropriate labels for LoC categories. Once completed, Phase 2 will not be repeated.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 and the project complies fully.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A 60-day *Federal Register* notice (HHS FRN 80 FR 50298) was published on August 19, 2015. NTP received one public comment (dated October 16, 2015) from Dr. Nancy Beck, American Chemistry Council (see pages 4-10 **ATTACHMENT 2 – PUBLIC COMMENT**). Dr. Beck had previously submitted written comments (dated June 15, 2016) for the NTP Board of Scientific Counselors meeting on June 16, 2015, and provided oral remarks at that meeting; she attached those comments to her October 16 submission. Dr. Beck's comments addressed the proposed collection and methodology and NTP has prepared responses to those issues (see pages 1-2, **ATTACHMENT 2 – PUBLIC COMMENT)**.

In September 2015, NTP sent Dr. Beck via email materials about the LoC research project shared at the Board meeting. Additionally, in response to Dr. Beck's submission for the 60-day *Federal Register* notice, NTP shared information her and another American Chemistry Council staff via a webinar on November 13, 2015. Information in the concept document for the study (http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2015/june/bsc_loc_508.pdf) and information presented in slides at the NTP Board of Scientific Counselors meeting on June 16, 2015 were presented and discussed, and questions from Dr. Beck were addressed. At close of the webinar, Dr. Beck noted having a better understanding of the research project and NTP felt that her concerns and questions had been addressed. One comment from the American Chemistry Council was received in response to the 30-day *Federal Register* notice.

Researchers both within NIH and in the extramural community were consulted during the planning of this study. Early discussions were held with NTP staff, the NTP Board of Scientific Counselors in public session, external technical advisors, and communication staff at the EPA to acquaint them with NTP's plans to re-visit its LoC framework and/or to seek input regarding conduct of the study. Support for this study was overwhelmingly enthusiastic and the majority of comments were favorable. These discussions gave us specific and valuable feedback that was incorporated into our study protocol.

The internal NTP Project Review Committee at NIEHS formally reviewed our study concept on October 30, 2014. This project was mentioned as a research activity to the NTP Board of Scientific Counselors on December 14, 2014, a public meeting. It was presented in more detail to the NTP board at its meeting at NIEHS on June 16, 2015 and they were very supportive of the project. Public comment received at the meeting was also supportive of NTP conducting this project. The project will also be communicated to agencies participating on the NTP Executive Committee through agency points of contact. Membership of the two advisory groups is listed in **ATTACHMENT 3 – ADVISORY COMMITTEE MEMBERSHIP**. We have also convened an internal advisory group for feedback on our proposed study plans and will continue to consult them during the study's execution. This outreach provides opportunities for input from the NIEHS intramural community, NTP advisory board, and externally by federal and academic experts.

A.9. Explanation of Any Payment or Gift to Respondents

Participants will not receive an incentive to complete Phases 1 or 2.

A.10. Assurance of Confidentiality Provided to Respondents

Procedures to protect the confidentiality of the study population and the data collected include the following:

- The data constitute a system of records under the Privacy Act System (#09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), published 9/26/2002, FR 67, pgs. 60742-60784).

- At enrollment, each potential study participant or "registrant" will provide the following personal identifiable information (PII): name, affiliation, contact information (telephone number and email), terminal degree(s), scientific expertise, sector (academia, industry, non-government organizations, and federal and state agencies), and whether they have 3 years' employment working in public health or a risk assessment-related activity.
- All PII will be stored encrypted in a password-protected, restricted-access electronic database at the NIEHS. Each registrant will be assigned a unique Registrant ID.
- Only the following data will be screened for eligibility to select a subset of Registrant IDs to participate in the study: affiliation, terminal degree(s), scientific expertise, sector, and whether employed three or more years working in public health or a risk assessment-related activity.
- Each study participant will be assigned a User ID number. The User ID alone will be used to identify all data from the LoC card-sorting exercises. Only the User ID number will identify study participants in the analysis of data.
- Each participant will also be assigned a unique Username and PIN-code for accessing the website for the LoC card-sorting exercises.
- Employees of NIEHS undergo background checks and take required ethics training.
- Only LoC Categories Study research personnel will have access to study data.
- Shared samples and data will be provided without PII identifiers of name, affiliation, phone, and email.
- The NIH Office of Human Subjects Research Protection designated this proposal exempt on January 13, 2015 (**ATTACHMENT 4 – NIEHS IRB REVIEW**).
- Informed consent form will spell out the steps taken to protect privacy, and this form will be provided electronically at the time of registration (**ATTACHMENT 5 – STUDY CONSENT FORM**).

Participants may elect to leave the study at any time. As explained in the Informed consent form, no new data will be collected from participants who elect to drop out, and the data already provided will continue to be used in some analyses unless a written request to destroy the data is received.

A.11. Justification for Sensitive Questions

No questions addressing sensitive and personal issues will be asked.

A.12.1 Estimated Annualized Burden Hours

It is anticipated to take 6 minutes to read the LoC Study Consent Form **(ATTACHMENT 5 – STUDY CONSENT FORM)**. The LoC card-sorting exercises in Phases 1, Trials A and B and Phase 2, Trials C and D will be self-administered and it is anticipated to take 1.5 hours for participants to complete per phase per trial.

The annual reporting burden is as follows: *Estimated Number of Participants:* 200 study participants.

Estimated Number of Responses per Participant: See annualized table below:

A.12-1 Estimated Annualized Burden Hours

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Study Consent	Experts	200	1	6/60	20
LoC "Cards"	Experts	200	2	90/60	600
Total		200	600		620

A.12-2 Annualized Cost to Respondents

The estimated total annualized cost to respondents is $34,360.40 (assuming $55.42 hourly wage X 620 hours). There are no capital, operating, or maintenance costs.

A.12-2 Annualized Cost to the Respondents

Type of respondent	Number of respondents	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
Experts	200	620	$55.42	$34,360.40

*Hourly wage rates for 19-1029 Biologic Scientist, (experienced, 90 percentile) is $55.42 (based on http://www.bls.gov/oes/current/oes191029.htm).

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There is no other total annual cost burden to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal government is $156,606 with Federal salary (including benefits) support of $93,193 per year. The estimated cost of the study is $233,503 (start-up costs plus implementation costs). The start-up costs to plan and develop the project were $76,897 over a 10-month period, including $69,179 for Federal salary support.

Start-up Cost (10 months)

Staff	Grade/Step	Salary	% of Effort	Fringe	Travel	Total Cost to Gov't
Federal Oversight						
Deputy Division Director for Policy	GS 15/9	$149,427.00	7.2%	$3,987.11		$14,763.10
Deputy Division Director for Policy	GS 15/9	$150,925.00	6.3%	$3,490.14		$12,922.95
Deputy Division Director for Analysis	T42	$185,120.00	6.3%	$4,280.90		$15,850.90
Deputy Division Director for Analysis	GS 15/5	$133,702.00	7.2%	$3,567.53		$13,209.50
Health Scientist	GS 12/3	$76,897.60	1.9%	$547.16		$2,025.96
Health Scientist	GS 12/3	$76,128.00	1.9%	$541.68		$2,005.68
Data Scientist	GS 11/10	$78,187.00	6.4%	$1,863.71		$6,900.75
Staff Scientist	T42	$151,840.00	0.7%	$405.15		$1,500.15
Federal Oversight Total						**$69,178.99**
Contractor Cost						
Consultant	Independent Contractor	$312,000.00	0.5%		$288.00	$1,788.00
Consultant	Independent Contractor	$312,000.00	0.5%		$322.00	$1,822.00
Consultant	Independent Contractor	$187,200.00	2.2%			$4,108.00
Contractor Cost Total						**$7,718.00**
TOTAL						**$76,896.99**

Annualized Implementation Cost (3 years)

Staff	Grade/ Step	Salary	% of Effort	Fringe	Travel	Total Cost to Gov't
Federal Oversight						
Deputy Division Director for Policy	GS 15/10	$155,428.00	13.5%	$7,741.51		$28,664.51
Deputy Division Director for Analysis	T42	$185,120.00	13.5%	$9,220.40		$34,140.40
Health Scientist	GS 12/3	$76,897.60	15.4%	$4,377.25		$16,207.65
Data Scientist	GS 11/10	$78,187.00	5.8%	$1,668.99		$6,179.78
Staff Scientist	T42	$151,840.00	3.8%	$2,160.80		$8,000.80
Federal Oversight Total						**$93,193.14**
Contractor Cost						
Science Communications Editor	Kelly Government Solutions	$59,488.00	60.0%			$35,692.80
Computer Programmer	Kelly Government Solutions	$68,640.00	19.2%			$13,200.00
Consultant	Independent Contractor	$312,000.00	1.9%			$6,000.00
Consultant	Independent Contractor	$312,000.00	1.9%			$6,000.00
Consultant	Independent Contractor	$158,080.00	1.0%			$1,520.00
Contractor Cost Total						**$62,412.80**
Other Cost						**$1,000.00**
TOTAL						**$156,605.94**

Cost Calculations

- Costs for federal staff were calculated based upon hourly rate and estimated hours for project.
- Consultant costs were calculated based upon hourly rate (including fees) and estimated hours for project.
- Total Cost is calculated as sum of all individual cost categories.
- Total Annual Cost Burden for start-up is the same as the 10-month cost since the start-up period is less than one year. Total Annualized Cost Burden for implementation is calculated as total cost divided by 3 years.

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information. Currently, this work is anticipated to take almost two years. The projected time schedule is provided below in Table A.16. Because the project time schedules for various activities are estimates, it is possible that some activities may take longer than anticipated. Conduct of Phase 2 cannot occur until Phase 1 is completed and the data analyzed. Therefore, we are asking for OMB approval for 3 years. If the work is completed sooner, NIH will notify OMB and submit a request for discontinuation of the ICR.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Activity	**Time Schedule**
Project concept and development	September 2014 – June 2015
Begin enrollment for Phase 1	1 month after OMB approval
Complete Phase 1 enrollment	3-4 months after enrollment begins
Conduct Phase 1, Trials A and B	Start 1-2 months after Phase 1 enrollment is completed
Begin enrollment for Phase 2	8-9 months after OMB approval
Analyze Phase 1 data	Start 1 month after completing Phase 1, Trial B
Complete Phase 2 enrollment	3-4 months after enrollment begins
Conduct Phase 2, Trial C	Start 1-2 months after Phase 2 enrollment and data analysis for Phase 1 are completed

Analyze Phase 2, Trial C data	Start 1 month after Phase 2, Trial C is completed
Conduct Phase 2, Trial D	Start 1-2 months after Phase 2, Trial C data analysis is completed
Analyze Phase 2, Trial D data	Start 1 month after Phase 2, Trial D is completed
Publication	Start manuscript preparation 1-2 months after all data analysis is completed

The primary goal of this study is to explore alternate LoC frameworks that seek to integrate the new hazard conclusions into the decision-making process and to re-assess the number and labels of LoC categories. This study will serve as a preliminary step in the larger effort toward modifying the LoC framework to enhance its transparency and use as a communication tool—which will be tested in the future using cognitive testing of focus groups composed of experts from the five stakeholder sectors and members of the general public. In particular, the study results will help determine the number of categories and potential category labels according to a sorting tasking using a sample of hypothetical LoC scenarios. Future testing will review and refine these results to ensure clarity and facilitate risk communication. Results communicated in any presentations, publications, or reports will clearly describe that findings from this exploratory study are preliminary and based on a convenience sample of respondents examining hazard situations that may not be representative of the universe of hazard and exposure scenarios for all substances. All communications and reports will detail that outcomes are not intended to be implemented as an updated Level of Concern framework. Future cognitive testing of any alternate LoC models will be conducted using respondents from the general public as well as experts from the five stakeholder sectors prior to any formal implementation or communication of an updated LoC framework.

There are several limitations to this exploratory study. Because a complete sampling frame (list of all possible participants) is not readily available, an approximate sampling frame will be formed through communications with federal and state agencies, non-government organizations, and professional

societies, as well as NTP listserv and advisory groups. Using this list, participants will be selected from each of the five stakeholder sectors. It is possible that this approximate sampling frame may not adequately represent the stakeholders, although every effort will be made to include as many potential participants in this list as feasible. In addition, the 40 LoC scenario cards are, by necessity, brief and may not span the entire range of possible scenarios; however, these cards have been reviewed by scientists with expertise in toxicology, epidemiology, and risk assessment to ensure that they adequately cover the scenarios typically encountered in NTP hazard assessment activities. Although the general public is an important stakeholder sector, this sector's opinions are not being solicited in this exploratory study. Instead, the outcomes of this study will be used to formulate potential updates to the LoC framework, which would then be evaluated in a separate forthcoming study that includes the general public. The results from the proposed exploratory study will not be used to directly update the LoC framework. Rather, it will provide data on potential changes to the LoC framework that can be used to plan a focused evaluation of consumer/public perception and interpretation of the framework that involves all stakeholder sectors, including the general public.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. We anticipate completion of this study prior to the expiration date of the OMB control number.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for this submission.

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