



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request

National Toxicology Program (NTP) Level of Concern Categories Study (NIEHS)

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the

burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kristina Thayer, Director of the Office of Health Assessment and Translation, Division of National Toxicology Program, NIEHS, P.O. Box 12233, Mail Drop K2-04, Research Triangle Park, NC 27709, or call non-toll-free number (919) 541-5021, or Email your request, including your address to: [thayer@niehs.nih.gov](mailto:thayer@niehs.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: National Toxicology Program Level of Concern Categories, 0925-NEW, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Toxicology Program (NTP) has used a 5-point level of concern (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. As part of its systematic review methodologies, the NTP is updating its LoC framework to enhance transparency in what the LoC categories mean, describing the factors considered in reaching conclusions and identifying strategies for improving their use as a risk communication tool. This study will use expert solicitation from five NTP stakeholder sectors (academia, industry, non-government organizations, and federal and state agencies) to aid in determining the optimal number of LoC categories for an updated LoC framework.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 300.

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
LoC “Cards”	Experts	200	2	90/60	600

Dated: August 11, 2015

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NIEHS, NIH

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