Date: October 18, 1999.
Time: 10 a.m. to 12:30 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Administrator, Integrative, Functional & Cognitive Neuroscience & Cognitive Neuroscience Study Section 4, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1255.

Name of Committee: Surgery, Radiology and Bioengineering Initial Review Group, Surgery, Anesthesiology and Trauma Study Section.
Date: October 18–19, 1999.
Time: 1 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW, Washington, DC 20007.
Contact Person: Gerald L. Becker, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 24, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–25955 Filed 10–5–99; 8:45 am]
BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Re-scheduled Meeting on Report on Carcinogens (RoC)

National Toxicology Program Public Meeting to receive comment on the review procedures and listing criteria used in the preparation of the DHHS Report on Carcinogens (RoC); is re-scheduled from September 15 to October 21 and 22, 1999, DoubleTree Hotel Rockville, 1750 Rockville Pike, Rockville, Maryland, beginning at 9 am.

Due to weather conditions posed by Hurricane Floyd, the National Toxicology Program has re-scheduled a public meeting for the purpose of receiving comment on the procedures for reviewing nominations for listing in or delisting from the RoC and the current listing criteria used for evaluation of the nominations to the RoC. The purpose of this public meeting is to obtain input and to provide all interested parties an opportunity to express their views about the review process and/or the evaluation criteria and to comment on the views expressed by others. The purpose of the meeting is not to discuss the evidence for listing or delisting specific substances that are currently in the RoC or proposed for listing or delisting in the 9th or 10th RoC. However, it may be appropriate to use examples from the review of a specific substance to illustrate issues regarding the process.

The meeting will begin at 9 am each day, with on-site registration at 8:30 am on October 21. The meeting will conclude at 5 pm on October 21 and at 5 p.m. October 22 or the conclusion of the public comment and discussion, if sooner. Details regarding registration follow. Attendance at the meeting is limited only by the space available.

Background

The DHHS Report on Carcinogens (RoC) is a public information document prepared for the US Congress by the National Toxicology Program in response to Section 301(b)(4) of the Public Health Service Act, as amended. The intent of the document is to provide a listing of those agents, substances or exposure circumstances which are either ''known'' or ''reasonably anticipated'' to cause cancer in humans, and to which a significant number of people in the United States are exposed. The first edition of the report (then known as the Annual Report on Carcinogens) was published in 1980, and similar criteria and review processes were used to consider nominated substances for listing through preparation of the 7th edition published in 1994. In 1994 Dr. Ken Olden, Director of NTP and NIEHS established an ad hoc working group of the NTP Board of Scientific Counselors and charged them to review and make recommendations on two issues: the adequacy of the existing criteria and the incorporation of mechanistic data as part of the criteria for listing substances in future Reports. In addition Dr. Olden directed that the process used to review nominations for listing in or delisting from the Report be revised to allow more public input throughout the process and to add external review to broaden the scope of scientific review. As a consequence, in 1994 and 1995 the criteria were examined by a panel whose membership included academia, industry, labor, public/environmental organizations, state and local health departments and government who met in public session in public meetings. Recommendations were made for revising the listing criteria and the nomination review process which were approved by the Secretary, HHS on September 13, 1996 [**Federal Register**: September 26, 1996, Volume 61, Number 188, Page 50499–50500]. The substances newly included in the 8th edition of the Report on Carcinogens (1998) and the nominations for listing in or delisting from the 9th edition were evaluated using these revised review process and criteria.

Public Review and Comment Encouraged

NTP staff will briefly summarize the process and the listing criteria from approximately 9:00 am to 10 am. The remainder of the time will be devoted to public comments by all interested parties and discussion of issues raised. Dr. Bernard Goldstein, Director of the Environmental and Occupational Health Sciences Institute of Rutgers and the University of Medicine and Dentistry of New Jersey, will serve as chair and moderator for the day. Dr. Goldstein, with the assistance of NTP Board of Scientific Counselors members, will identify issues raised by speakers and lead discussion sessions on the issues throughout the meeting.

The NTP welcomes the continued and meaningful input from all stakeholders in reviewing the RoC process and the listing criteria as we move forward to the 10th edition of the RoC. The experience and perspectives of all stakeholders are critical to ongoing evaluations of nominations to the RoC.

Oral comments: Speakers will be registered and assigned time on a first-come, first-served basis. Fifty-two speakers were registered for the previously scheduled, September 15, meeting, and the order of these presentations will remain the same. The meeting has been extended for a second day to ensure time for discussion and dialogue and to accommodate any additional speakers. The time allotted for each presentation will be dependent upon the total number of individuals who register to speak; we anticipate that adding a second day to the meeting will permit 10 minutes for each presenter. Each speaker will be asked to identify their supporting organization (if any). When oral comments are read from printed copy, it is requested that 10 copies of the text be provided when registering at the meeting to be distributed to the Chair and NTP Board members and to supplement the record of the meeting.

Written comments are welcome and can be sent to the address given below. All comments previously submitted for the September 15 meeting will be considered. Written comments must

include name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any).

RoC Listing/Delisting Procedures and Listing Criteria

Revised criteria were announced first in the **Federal Register** and other publications in 1996 [**Federal Register**: September 26, 1996, Volume 61, Number 188, Page 50499–50500] and clarified in the FR and other publications in April 1999 (FR Vol. 64, No. 63 pp 15983–15984 and Vol. 64, No. 74; pp 19188–19189). The procedures and criteria can be found on the NTP website located at *www.ntp-server.niehs.nih.gov*

Registration for Meeting

Pre-registration to attend this meeting can be made by notifying Ms. Angie Wilson by mail at NIEHS, Building 101, Room A328, P.O. Box 12233, Research Triangle Park NC 27709, by phone at (919) 541–3971, by FAX at (919) 541–0295, or by e-mail at *wilson9@niehs.nih.gov*. Please indicate if you wish to make an oral presentation. Those pre-registered for the September 15 meeting are asked to re-confirm their participation for October 21–22. On site registration will be available the morning of October 21, 1999 from 8:30 am to 9:00 am. If possible, those wishing to speak should provide a written copy of their statement or talking points before the October 21 meeting, to assist the Chair and Board Members in identifying issues for discussion and to supplement the record of the meeting. Those registering on site are requested to bring 10 copies of their statement or talking points. Written statements should supplement and may expand on the oral presentation, or may be submitted in lieu of an oral presentation. When registering to comment, please provide your name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any).

Report on Carcinogens; Listing/Delisting Procedures

Petitions for listing or delisting an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) should be submitted to the National Toxicology Program (NTP).[1] Petitions must contain a rationale for listing or delisting as either a ''known human carcinogen'' or a ''reasonably anticipated human carcinogen.'' Appropriate background information and relevant data (e.g. journal articles, NTP Technical Reports, IARC listings, exposure surveys, release inventories, etc.) which support a petition should be provided or referenced.

An agent, substance, mixture, or exposure circumstance petitioned for listing or delisting will be announced in the **Federal Register**, trade journals, and NTP publications to solicit public comment. The original petition and all comments received will be evaluated by a National Institute of Environmental Health Sciences (NIEHS/NTP) Report on Carcinogens Review Committee (RG1), composed of scientists from the NIEHS/NTP, to determine if the information provided is sufficient to merit further consideration. If it is determined the petition warrants formal consideration, the NTP may initiate an independent search of the literature and prepare a draft review document for the substance under consideration. Draft documents will be prepared according to the following general format:

1.0 Introduction
- 1.1 Chemical Information—synonyms, trade names, CAS #'s, molecular formula, molecular structure, etc.
- 1.2 Physical-Chemical Properties
- 1.3 Identification of Structural Analogs

2.0 Exposure Assessment
- 2.1 Production
- 2.2 Use
- 2.3 Environmental Exposure—environmental occurrence, environmental release, drinking water and food content, consumer products, occupational exposures, biomarkers of exposure
- 2.4 Regulations—Occupational Exposure Limits (standards and criteria), ''other'' standards and criteria

3.0 Human Studies
- 3.1 Epidemiology Studies—occupational studies, clinical trials, consumer exposure, other ''non-occupational'' exposures
- 3.2 Laboratory Studies—controlled exposures
- 3.3 Poisonings—case reports, accidents, symptoms and clinical signs

4.0 Animal Carcinogenicity Studies—subdivided by species

5.0 Genotoxicity

6.0 Mechanistic and Other Relevant Studies

Data used in the preparation of Sections 3 through 6 of the draft document must come from publicly available, peer reviewed sources.

If it is determined that the petition contains insufficient information to warrant consideration by the NTP, it will be returned to the original petitioner who will be invited to resubmit the petition with additional justification, which may include new data, exposure information, etc. A notice, stating the action taken for a petitioned substance found to contain insufficient justification for consideration, will be published in the **Federal Register**, trade journals, and NTP publications, and included in subsequent editions of the RoC with the reason(s) why it was not considered further. This decision will also be forwarded to the NTP Executive Committee and Board of Scientific Counselors.

Formal Review Steps

The following describes the review process for petitions that are considered by the NTP for listing in or delisting from the Report on Carcinogens.

NIEHS/NTP Review Committee for the Report on Carcinogens (RG1)

The original petition and all public comments received in response to a petition will be reviewed by RG1. Assignment of a primary and secondary reviewer will be made upon receipt of a petition. Reviewers will lead discussions concerning the adequacy of the petition. If the petition warrants formal consideration, a search of pertinent databases will be performed and available citations will be reviewed by the primary reviewer. The primary reviewer will identify the relevant articles. After consultation with the secondary reviewer, the identified literature will be obtained and a draft summary of all available information from the original petition and the literature search will be prepared. The primary and secondary reviewers will examine the petition, the literature citations, and the draft document for completeness and adequacy. The draft document will be revised if necessary and presented by the primary reviewer to the RG1. Public comments received in response to announcements of petitions will also be considered. The RG1 will make a formal recommendation for those petitions determined to contain sufficient information for listing or delisting in the RoC. The petition then continues through the review process.

Petitions reviewed by RG1 for which sufficient information could *not* be obtained will not proceed further. The other RoC review groups, as well as the

[1] National Toxicology Program, Report on Carcinogens, P.O. Box 12233, 79 Alexander Drive, Bldg. 4401, Room 3127, MD–EC–14, Research Triangle Park, NC 27709

For information contact: Dr. C.W. Jameson, phone: (919) 541–4096, fax: (919) 541–2242, email:jameson@niehs.nih.gov

NTP Executive Committee, will be informed of this action. The original petitioner will be notified of the RG1 action and invited to resubmit the petition with additional justification. All petitioned agents, substances, or mixtures reviewed by RG1 but not selected for listing or delisting will be included in the subsequent edition of the RoC with the reason(s) why they were not considered further.

NTP Executive Committee's Interagency Working Group for the Report on Carcinogens (RG2)

The second review phase of petitions will be done by the NTP Executive Committee's Interagency Working Group for the Report on Carcinogens (RG2). RG2 is a Governmental interagency group that assesses whether relevant information on the petitioned agent, substance, or mixture is available and sufficient for listing in or delisting from the RoC. A reviewer for each petition will be assigned from the RG2 who will be responsible for reviewing the draft document and for leading the Working Group's discussion of the petition. Public comments received in response to announcements of petitions will also be considered by RG2 during the review. Upon completion of its review, RG2 will provide comments and recommendations for any changes and/or additions to the draft document and also make its recommendation for listing or delisting. The petition then continues through the review process.

Board of Scientific Counselors RoC Subcommittee (External Peer Review)

The third review phase for petitions will be performed by a subcommittee of the NTP Board of Scientific Counselors. This subcommittee serves as another independent peer review group that assesses whether the relevant information available is sufficient for listing in or delisting. The NTP Board RoC Subcommittee will review petitions in a public meeting. Prior to public review, a notice will be published in the **Federal Register**, trade journals, and NTP publications, soliciting public comment. The notice will also invite interested groups or individuals to submit written comments and/or to address the NTP Board RoC Subcommittee during the review meeting. Reviewers for each petition will be assigned from the NTP Board RoC Subcommittee who will be responsible for reviewing the draft document and leading the subcommittee's discussion of the petition. Upon completion of its review, NTP Board RoC Subcommittee will provide comments and recommendations for any changes and/or additions to the draft document and also make its formal recommendation for listing or delisting the petitioned agent, substance, or mixture.

Upon completion of the reviews by RG1, RG2, and NTP Board RoC Subcommittee, those petitioned agents, substances, mixtures, or exposure circumstance which are recommended for listing in or delisting from the RoC, will be published in the **Federal Register**, trade journals, and NTP publications, and public comment and input on the recommendations will be solicited.

NTP Executive Committee

The independent recommendations of RG1, RG2, and NTP Board RoC Subcommittee and all public comment will be presented to the NTP Executive Committee [2] for review and comment.

NTP Director

The Director, NTP receives the four independent recommendations from RG1, RG2, NTP Board RoC Subcommittee, and the NTP Executive Committee and makes the final decision regarding the proposed listing and/or delisting and submits the RoC to the Office of the Secretary, DHHS. Upon review and approval by the Secretary, DHHS and submission to Congress, a notice of the RoC publication, indicating all newly listed or delisted agents, substances, mixtures, or exposure circumstance will be published in the **Federal Register**, trade journals, and NTP publications.

Report on Carcinogens; Criteria for Listing Agents, Substances or Mixtures

1. Known To Be Human Carcinogens

There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance or mixture and human cancer.

2. Reasonably Anticipated To Be Human Carcinogens

There is limited evidence of carcinogenicity from studies in humans which indicates that causal interpretation is credible but that alternative explanations such as chance, bias or confounding factors could not adequately be excluded; *or*

There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors: (1) In multiple species, or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site or type of tumor or age at onset; *or*

There is less than sufficient evidence of carcinogenicity in humans or laboratory animals, however; the agent, substance or mixture belongs to a well defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either a known to be human carcinogen, or reasonably anticipated to be human carcinogen or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Dated: September 29, 1999.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 99–25940 Filed 10–5–99; 8:45 am]

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[2] Agencies represented on the NTP Executive Committee include: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Cancer Institute (NCI), National Library of Medicine (NLM), and National Institute of Environmental Health Sciences/NTP (NIEHS/NTP).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on