

adoption and implementation, or impact on health services outcomes. There is a need, then, to collect information from health and health care organizations to understand how and to what extent the *National CLAS Standards* have been

utilized by its intended audiences. *Likely Respondents:* The information to be collected as part of this assessment will come from five categories of respondents: Training and Development Specialists and Managers; Other

Management; Health and Health Care Organization Executives and Managers; Health and Health Care Providers, Managers, and Support Staff; Health Care Practitioners; and Technical Staff.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondent	Number responses per respondent	Average burden per response (hours)	Total burden (hours)
<i>National CLAS Standards</i> Stakeholder Interview.	Training and Development Specialists and Managers; Other Management Occupations (that contributed to development of <i>National CLAS Standards</i>).	21	1	45/60	16
CLAS Stakeholder Interview	Training and Development Specialists and Managers; Other Management Occupations (with subject matter expertise in cultural competence or cultural and linguistic appropriate services).	21	1	1	21
Health and Health Care Organization Leadership Interview.	Health and Health Care Organization Executives and Managers.	140	1	1	140
Health and Health Care Organization Staff Survey.	Health and Health Care Providers, Managers, and Support Staff.	2,500	1	15/60	625
Health and Health Care Organization Screener Survey.	Health and Health Care Organization Executives.	50,000	1	5/60	4,167
<i>National CLAS Standards</i> Experience Form.	Health Care Practitioners and Technical Occupations.	240,000	1	10/60	40,000
Total	44,969

Darius Taylor,

Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of a Workshop and a Request for Public Comment on Questions Regarding Dietary Reference Intakes and Chronic Disease Endpoints

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Dietary Reference Intakes (DRI) Committees of the U.S. and Canadian governments will hold a workshop entitled “Options for Consideration of Chronic Disease Endpoints for Dietary Reference Intakes.” The objective of the workshop is to critically evaluate key scientific issues involved in using chronic disease endpoints for setting DRIs and, in this context, to provide information for future decisions as to whether and/or how chronic disease endpoints can be

incorporated into the setting of DRI values. In preparation for this meeting, the DRI Committees are asking for public comment on the set of questions that the meeting panelists will discuss.

DATES: This meeting will be held on March 10, 2015 from 8:30 a.m. to 5:00 p.m. E.D.T. and on March 11, 2015 from 8:30 a.m. to 12:30 p.m. E.D.T.

ADDRESSES: The workshop will be held at the Lister Hill Auditorium, National Institutes of Health, in Bethesda, Maryland, USA. The workshop will be open to the public either in-person (seating is limited) or by videocast on the Internet.

FOR FURTHER INFORMATION CONTACT: Additional information about this workshop and the agenda will be made available on the Internet at <http://www.health.gov/dri/as-the-meeting-approaches>. You may also send emails to DRI@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background Information

The current DRI approaches for selecting indicators of adequacy and toxicity and for estimating dose-response relationships between nutrient intakes and selected outcomes derive from several Food and Nutrition Board committee reports published by the

Institute of Medicine (IOM) in 1994¹ and 1998.² These committees recommended that DRIs for adequacy be expressed as Estimated Average Requirements (EARs) and Recommended Dietary Allowances (RDAs, representing 97.5% of population requirements). They also recommended that reference values for Tolerable Upper Intake Levels (ULs) be included in future DRI evaluations. Additionally, the 1994 IOM committee concluded that future RDA processes (now called DRIs) should include the concept of chronic disease risk reduction in addition to the classical nutrient deficiency endpoints. The approaches recommended by the 1994 and 1998 committees were applied, with a few additions (*e.g.*, Adequate Intakes, Acceptable Macronutrient Distribution Ranges), for all seven of the DRI reviews published from 1997 to 2011. These reports can be accessed at the following Web site: <http://>

¹ Food and Nutrition Board, Institute of Medicine. 1994. *How Should the Recommended Dietary Allowances Be Revised?* National Academy Press, Washington, DC.

² *Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients.* National Academy Press, Washington, DC.

fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes/dri-reports.

It has become apparent that a number of unanticipated challenges were encountered when chronic disease endpoints were considered as indicators for setting DRI reference values. Many of these challenges were discussed in a 2007 “lessons learned” workshop conducted by the IOM after the first six DRI reports were published.³ Other scientific publications have also discussed the challenges, but approaches for addressing the identified challenges have not yet been adequately explored.

Recently, the DRI Committees of the U.S. and Canadian governments called for nominations for nutrients to be considered for future DRI reviews. Many of the nominated nutrients cited new data on chronic disease relationships as the justification for new DRI reviews, including three of the four nutrients selected by the DRI Committees for further consideration based on the availability of sufficient new and relevant evidence. Given the clear need for more in-depth evaluation of the challenges involved in incorporating chronic disease endpoints into DRI processes prior to initiating a new DRI review, the two government committees announced plans to sponsor a workshop to be held in 2015 to address whether, and how, chronic disease outcomes can be incorporated into the process of setting DRI values.

The limited time available for the workshop may preclude consideration of all issues relevant to the incorporation of chronic disease endpoints into DRI processes. As warranted, subsequent activities will address issues that arise in the workshop or that have been identified in other activities but not covered in workshop discussions.

Written Public Comments

The key questions for the workshop, on which the committees would like public comments, are derived from prior discussions of the major challenges in incorporating chronic disease endpoints into DRI considerations:

1. What dose-response models can be considered for future DRI reviews when chronic disease endpoints are used?
 - a. What are the scientific issues?
 - b. What are the options for addressing these issues?

c. What are the advantages and disadvantages of the various options?

2. What are the evidentiary challenges important in selecting and using chronic disease endpoints in future DRI reviews?

- a. What are the scientific issues?
- b. What are the options for addressing these issues?

c. What are the advantages and disadvantages of the various options?

3. What arguments can be made for and against continuing to include chronic disease endpoints in future DRI reviews?

- a. What are the scientific issues?
- b. What are the options for addressing these issues?
- c. What are the advantages and disadvantages of the various options?

Public comments are to be submitted via email to DRI@hhs.gov. Provide a brief summary (approx. 250 words) of the points or issues. If providing literature or other resources, one of the following forms is preferred:

- Complete citation, as in a bibliographic entry
- Abstract
- Electronic link to full article or report

Please provide comments as early as possible in order to increase the likelihood of having a meaningful impact, as the workshop panelists will be considering them prior to the workshop. The deadline for comment submission is Friday, January 30, 2015. Comments received later than January 30, 2015 will not be considered.

Meeting Registration: The meeting will be publicly accessible both in-person and by videocast on the Internet. Due to limited seating capacity, registration will be required for in-person attendance. Notice of registration will be available on <http://www.health.gov/dri/prior> to the workshop; registration is expected to open on or about February 15, 2015.

Dated: December 16, 2014.

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Office of Disease Prevention and Health Promotion,
Office of the Assistant Secretary for Health,
U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-14AQA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Enhanced STD Surveillance Network (eSSuN)—NEW—Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

³ The Development of DRIs 1994–2004: Lessons Learned and New Challenges, Workshop Summary, November 30, 2007. Available from: <http://www.iom.edu/Reports/2007/The-Development-of-DRIs-1994-2004-Lessons-Learned-and-New-Challenges-Workshop-Summary.aspx>.