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Pentagon

Updates to the Policy and Procedures to Add Cancer Conditions

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Updates to the Policy and Procedures



Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions

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May 14, 2014

Revised May 11, 2016

Updated May 1, 2019

Updated November 18, 2021

Note for May 11, 2016 Revision: This version (1) clarifies that a type of cancer can be added if the criteria of *any* of the four methods are met; and (2) adds peer review procedures when the Administrator proposes to add a type of cancer to the List of WTC-Related Health Conditions.

Note for May 1, 2019 Update: This version incorporates non-substantive changes to update the definition of “9/11 agents” and describe the Inventory of 9/11 agents as established in the “Development of the Inventory of 9/11 Agents,” published July 17, 2018.

Note for November 18, 2021 Update: This version clarifies the role of the WTC Health Program in the application of Methods 1-3 versus the role of the Scientific/Technical Advisory Committee (STAC) in Method 4, the Review of Information by the STAC.

Categories of Updates to the Policy

- Identification of peer-reviewed, published, epidemiologic studies
- Consistency and alignment with the policy for adding a non-cancer condition to the List of WTC-Related Health Conditions (List)
- Clarification of the four Methods and roles

Identification of Studies Updates

- **May 2019 Policy**
 - **Section III.A. and B.**
 - **First step: Literature search**
 - Studies regarding the type of cancer among 9/11-exposed populations
 - Studies regarding potential causal association between a condition already on the List and that cancer
 - The most recent classifications of the World Health Organization's International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) Report on Carcinogens
 - **Second step: Literature review**
 - Identify peer-reviewed, published, epidemiologic studies found among the results of the above literature search
 - Evaluate peer-reviewed, published, epidemiologic studies for quantity and quality

Identification of Studies Updates (continued)

- **November 2021 Policy**
 - Section III.A. and B.
 - **First step: Literature search**
 - Peer-reviewed, published, epidemiologic studies regarding the type of cancer among 9/11-exposed populations
 - Peer-reviewed, published, epidemiologic studies regarding potential causal association between a condition already on the List and that cancer
 - The most recent classifications of the IARC and NTP Report on Carcinogens
 - **Second step: Literature review**
 - Evaluate peer-reviewed, published, epidemiologic studies for quantity and quality

Consistency and Alignment Updates

- Specified IARC's *Monographs on the Identification of Carcinogenic Hazards to Humans* and **added citations** in footnotes for both IARC's Monographs and NTP's *Report on Carcinogens*
- “Information” and “Evidence” – both used throughout May 2019 policy
 - Updated to **“Information”** in November 2021 policy and defined the term in a footnote:

“Information may be gathered by the Program in a search of the peer-reviewed, published scientific literature of epidemiologic studies of 9/11 populations or supplied to the Administrator by a petitioner. The Program then evaluates the information to determine whether it meets the standard of scientific evidence necessary for the Administrator to make a determination. Scientific evidence is a subtype of information that supports, refutes, or has no impact on a determination whether an association exists between a specified exposure and a specific health effect.”

Consistency and Alignment Updates (continued)

- Updated section references from prior versions
- Specified public comment period and timing of posting of peer reviewers' comments, in event of Notice of Proposed Rulemaking (NPRM)
(45 days total with peer reviewers' comments posted after 30 days)

Clarification of Methods and Roles Updates

- **Method 1:** Peer-reviewed, published, epidemiologic studies of the cancer in 9/11-exposed populations;
- **Method 2:** Peer-reviewed, published, epidemiologic studies of causal associations between a health condition already on the List of WTC-Related Health Conditions (List) and the cancer;
- **Method 3:** Review of evaluations of carcinogenicity in humans based on classifications from National Toxicology Program (NTP) and International Agency for Research on Cancer (IARC); and
- **Method 4:** Review of information provided by the Scientific/Technical Advisory Committee (STAC).

Clarification of Methods and Roles Updates (continued)

- **Section IV.A.1.**
- **Methods 1 – 3**
 - Administrator directs Science Team to assess information
- **Method 4**
 - STAC recommends addition and provides reasonable basis
 - Added “recommendation,” and clarified the details that should be provided regarding the STAC’s reasonable basis. Added the following footnote:
 - The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Methods 1 – 3.
- Administrator reviews findings from Methods 1 – 4 and determines whether one or more of the Methods have been met

Questions?

