



Shanksville



New York City



Pentagon

Revisions to the P&P for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

**World Trade Center (WTC) Health Program
Meeting of the Scientific/Technical Advisory Committee (STAC)
February 9, 2023**

Purpose of the Revision:

- To align the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions* with the *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* and clarify the nature of the rationale for STAC recommendations.
 - Allows for a health condition to be added to the List based on STAC recommendations that include a reasonable basis for the addition.
- To clarify criteria used by the Science Team to assess the likelihood of a causal association between 9/11-related exposures and a health condition.

Location of Key Revisions:

- I. Authority
- II. Initiation of the Process for Adding a Health Condition
 - A. Administrator's Discretion
 - B. Petition Request
- III. Science Team Identification of Scientific Evidence
 - A. Petition Review and Identification of Health Condition for Evaluation
 - B. Identification of Studies of 9/11-Exposed Populations
 - C. Evaluation of Quality of Scientific Evidence in Identified Studies
 - D. Study Quality Evaluation Outcomes
- IV. Science Team Evaluation of Scientific Evidence**
 - A. Evaluation of Evidence in High-Quality, Peer-Reviewed, Published, Epidemiologic Studies
 - B. Science Team Evaluation Outcome and Advice to Administrator**
- V. Administrator Actions**
 - A. Request a Recommendation of the STAC**
 - B. Publish a Notice of Proposed Rulemaking to Add the Health Condition**
 - C. Publish a Notice of Determination Not to Propose a Rule to Add a Condition
 - D. Publish a Notice of Insufficient Evidence
- VI. WTC Health Program Scientific/Technical Advisory Committee (STAC)
 - A. Convening the STAC
 - B. STAC Meeting Procedures
 - C. Time Limits
- VII. Rulemaking and Peer Review
 - A. Notice of Proposed Rulemaking (NPRM)
 - B. Independent Peer Review
 - C. Public Comments
 - D. Final Rule

***Science Team Evaluation:* Characterizes the weight of evidence by assigning it to one of five evidentiary categories (Section IV B.)**

- The revision provides clarity on the five existing evidentiary categories:
 - The evidence supports that the causal association is *substantially likely*,
 - The evidence supports a *high likelihood* of a causal association,
 - There is *limited evidence* of a causal association,
 - The evidence is *inadequate* to draw any conclusion on a causal association, or
 - There is substantial evidence *against* a causal association.

Science Team Evaluation: Provides support for Administrator actions

Section IV B.2.c:

- The Administrator may request a discretionary second-level review by the Science Team when there is a finding of a high, but not substantial, likelihood of causal association.

Section V:

- A. Request a Recommendation of the STAC (always available to the Administrator)
 - Supported by a finding of a high likelihood of causal association.
- B. Publish a Notice of Proposed Rulemaking to Add the Health Condition
 - Supported by a finding of substantially likely to be causally associated.
- C. Publish a Notice of Determination Not to Propose a Rule to Add a Condition
 - Supported by a finding of no likelihood of a causal association
- D. Publish a Notice of Insufficient Evidence
 - Supported by a finding of limited or inadequate evidence of a causal association

Questions for the STAC:

- Does the revised language adequately clarify the five weight-of-evidence categories used for grading a causal association by the Science Team: (i.e., substantial likelihood, high likelihood, limited or inadequate likelihood; and no likelihood)?
- Are the evaluation criteria established for each weight-of-evidence category clearly defined, reasonable, and appropriately linked to an action?