



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

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**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.

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### I. Authority

The *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (“Act”),<sup>1</sup> the Final Rule, “*World Trade Center Health Program: Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions*,”<sup>2</sup> and the World Trade Center (WTC) Health Program regulations.<sup>3</sup>

### II. Introduction

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<sup>1</sup> Pub. L. 111-347, as amended by Pub. L. 114-113 and Pub. L. 116-59, codified at 42 U.S.C. § 300mm *et seq.*

<sup>2</sup> 77 Fed. Reg. 56138 (Sept. 12, 2012). See <http://www.gpo.gov/fdsys/pkg/FR-2012-09-12/pdf/2012-22304.pdf>.

<sup>3</sup> 42 C.F.R. Part 88.

The Act provides two pathways to initiate the process to propose adding a health condition, including types of cancer, to the List of WTC-Related Health Conditions (“List”).<sup>4</sup> The Administrator of the WTC Health Program initiates the process either (1) at his own discretion,<sup>5</sup> or (2) after receiving a valid petition<sup>6</sup> from an interested party.<sup>7</sup> Regardless of which pathway is taken, a health condition may only be added to the List by rulemaking.

### **III. Initial Review of Scientific and Medical Information and Administrator Determination on whether to Proceed with Assessment**

Once the process of determining whether to propose adding a type of cancer to the List is initiated, the WTC Health Program’s Science Team reviews the scientific literature to determine if the available scientific information<sup>8</sup> has the potential to provide a basis for a decision on whether to add the type of cancer to the List.

#### **A. Literature Search**

The literature search identifies and gathers information from the following sources for review:

1. Peer-reviewed,<sup>9</sup> published,<sup>10</sup> epidemiologic studies<sup>11</sup> of the cancer in 9/11-

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<sup>4</sup> 42 U.S.C. § 300mm-22(a)(6)(B).

<sup>5</sup> 42 U.S.C. § 300mm-22(a)(6)(A).

<sup>6</sup> When the Administrator receives a submission from an interested party to add a health condition to the List, he follows the steps outlined in the “Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions” (available at: <http://www.cdc.gov/wtc/policies.html>) and determines whether the submission meets the requirements for a petition specified in 42 C.F.R. § 88.16(a)(1).

<sup>7</sup> 42 U.S.C. § 300mm-22(a)(6)(E); 42 C.F.R. § 88.1 (“Interested party means a representative of any organization representing WTC responders, a nationally recognized medical association, a WTC Health Program CCE or Data Center, a State or political subdivision, or any other interested person”).

<sup>8</sup> 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.

<sup>9</sup> The Administrator has determined that articles and reports published in CDC’s *Morbidity and Mortality Weekly Report* (MMWR) are also eligible for review for their potential to provide a basis for deciding whether to propose adding a condition to the List. MMWR publications undergo a review process that has been independently evaluated and found to be similar or equivalent to peer review.

<sup>10</sup> Published studies include those published online ahead of print.

<sup>11</sup> Epidemiologic studies include “descriptive epidemiologic studies” which describe the “what, who, where, when and why/how of a situation,” as well as analytic epidemiologic studies which involve the use of a comparison group. See Centers for Disease Control and Prevention, HHS, *Principles of Epidemiology in Public Health Practice* (3rd ed. 2012), at 1-46. The WTC Health Program reviews these epidemiologic studies to determine if they identify causal

exposed populations;

2. Peer-reviewed, published, epidemiologic studies regarding the potential causal association between a condition already on the List and that cancer; and
3. The most recent classifications of the World Health Organization's International Agency for Research on Cancer (IARC) *Monographs on the Identification of Carcinogenic Hazards to Humans* (Monographs)<sup>12</sup> and the National Toxicology Program (NTP) *Report on Carcinogens* (RoC).<sup>13</sup>

## **B. Literature Review**

The studies found in the literature search<sup>7</sup> are then further reviewed for quantity and quality<sup>14</sup> and their potential to provide a basis for deciding whether to propose adding the type of cancer to the List. In addition, any medical basis provided in the valid petition is included in this review.<sup>15</sup> The findings of this literature review, including any information about IARC classifications and the NTP *RoC*, are documented and discussed with the Administrator.

## **C. Administrator Determination on whether to Proceed with Assessment**

The Administrator determines whether the information gathered in the literature review has the potential to provide a basis for a decision on whether to add the type of cancer and whether to proceed with an assessment of that information.

1. Where the Administrator determines that the information does not provide a sufficient basis for a decision:
  - a. The evaluation is documented and archived according to document management requirements; and
  - b. If the evaluation was initiated by a valid petition, then the Administrator:
    - i. Publishes a determination in the *Federal Register* that the

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associations between exposures and health outcomes with the potential to provide a basis for deciding whether to propose adding a condition to the List.

<sup>12</sup> WHO International Agency for Research on Cancer (IARC) *Monographs on the Identification of Carcinogenic Hazards to Humans* (Monographs). <http://monographs.iarc.fr/>. Accessed October 13, 2021.

<sup>13</sup> NTP Report on Carcinogens (RoC). <https://ntp.niehs.nih.gov/go/roc14>. Accessed October 13, 2021.

<sup>14</sup> The evaluation of quantity and quality includes consideration of any limitations, such as bias or confounding, of the reviewed studies.

<sup>15</sup> See 42 C.F.R. § 88.16(a)(1)(iv); see also "Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions" (available at: <http://www.cdc.gov/wtc/policies.html>).

available information is insufficient to take action;<sup>16</sup> and

- ii. Notifies the petitioner in writing of the decision concurrently with the publication of the determination in the *Federal Register*.
2. Where the Administrator determines that the available information has the potential to provide a basis for a decision, the Administrator may:
    - a. Direct the Science Team to conduct a full assessment of the scientific and medical information and provide input on whether the available information supports a causal association between 9/11 exposures and the type of cancer [see Section IV.A.1.], and
    - b. In addition, the Administrator may request advice from the WTC Health Program Scientific/Technical Advisory Committee (STAC) [see Sections IV.A.1. Method 4 and V.A.].

#### **IV. Assessment of Scientific and Medical Information**

##### **A. Assessment Process**

##### **1. Administrator's Review Criteria**

The Administrator of the WTC Health Program has developed four methods for determining whether to add a type of cancer to the List. In order to propose adding a type of a cancer to the List, the Administrator's review of the information must demonstrate fulfillment of at least one of the four methods.

The Administrator will direct the Science Team to assess the available information under Methods 1 through 3. If the Administrator requests a recommendation from the STAC, Method 4 may be used to determine whether to add a type of cancer to the List.

##### ***Method 1. Epidemiologic Studies of September 11, 2001 Exposed Populations.***

The peer-reviewed, published, epidemiologic studies of 9/11-exposed populations are assessed by applying the following criteria extrapolated from the Bradford Hill criteria,<sup>17</sup> as appropriate:

- a. Strength of the association between a 9/11 exposure and a type of cancer (including the precision of the risk estimate<sup>18</sup>);

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<sup>16</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

<sup>17</sup> See Hill AB [1965]. The environment and disease: association or causation? Proc R Soc Med 58:295–300.

<sup>18</sup> A precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is often expressed as a confidence

- b. Consistency of the findings across multiple studies. If only a single published epidemiologic study is available for assessment, the consistency of findings cannot be evaluated and more emphasis will be placed on evaluating the strength of the association and the precision of the risk estimate;
- c. Biological gradient, or dose-response relationships between 9/11 exposures and the type of cancer; and
- d. Plausibility and coherence with known facts about the biology of the type of cancer.

**Method 2. Established Causal Associations.**

A type of cancer may be added to the List if there is well-established scientific support published in multiple peer-reviewed epidemiologic studies for a causal association between a condition already on the List and that cancer.

**Method 3. Review of Evaluations of Carcinogenicity in Humans.**

A type of cancer may be added to the List under Method 3 only if both of the following criteria are satisfied:

**3A. Published Exposure Assessment Information.** A 9/11 agent<sup>19</sup> included in the Inventory of 9/11 Agents<sup>20</sup> is identified; and

**3B. Evaluation of Carcinogenicity in Humans from Scientific Studies.** NTP has determined that the 9/11 agent is *known to be a human carcinogen* or is *reasonably anticipated to be a human carcinogen*, and IARC has determined there is *sufficient* or *limited* evidence in humans that the 9/11 agent causes the type of cancer.

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interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty.

<sup>19</sup> Chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 C.F.R. § 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. WTC Health Program, “Development of the Inventory of 9/11 Agents,” published July 17, 2018, available at: [https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf).

<sup>20</sup> The Inventory of 9/11 Agents is composed of those agents identified in Tables 1-4 of the document, “Development of the Inventory of 9/11 Agents.” See WTC Health Program, “Development of the Inventory of 9/11 Agents,” published July 17, 2018, available at: [https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf).

#### **Method 4. Review of Information by the WTC Health Program Scientific/Technical Advisory Committee (STAC).**

A type of cancer may be added to the List if the STAC recommends the addition and provides a reasonable basis for the recommendation.<sup>21</sup> To assist the Administrator in understanding whether the STAC's recommendation has a reasonable basis, the STAC must describe in detail the basis for its recommendation and, if applicable, any evidentiary sources it has used to support its recommendation.

#### **2. Administrator's Consideration**

The Science Team ensures that the results of their assessment are documented and provided to the Administrator (additional discussion between the Science Team and the Administrator may occur). If applicable, the Designated Federal Officer for the STAC ensures that the STAC's recommendation and basis are documented and provided to the Administrator. The Administrator will review the findings and determine whether one or more of the four methods have been met.

### **B. Administrator Actions**

1. If the assessment was performed in response to a valid petition, the Administrator takes one of the following actions:<sup>22</sup>
  - a. If a review of the information demonstrates fulfillment of at least one of the four methods described in IV.A.1. above, the Administrator publishes in the *Federal Register* a notice of proposed rulemaking (NPRM) to add the type of cancer to the List;<sup>23</sup> or
  - b. If a review of the information does not demonstrate fulfillment of at least one of the four methods described in IV.A.1. above and does demonstrate that 9/11 exposures are not causally related to the type of cancer, the Administrator publishes in the *Federal Register* a determination not to propose a rule and the basis for such determination;<sup>24</sup> or
  - c. If a review of the information indicates the information is insufficient to take either of the actions in IV.B.1.a. or b. above, then the Administrator

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<sup>21</sup> The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Methods 1-3.

<sup>22</sup> If the Administrator exercises his discretion to request review and recommendation from the STAC, he will also take the STAC's recommendation into consideration in determining which of the actions described in Section IV.B.1. to take [see Section V].

<sup>23</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(ii).

<sup>24</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iii).

publishes that determination in the *Federal Register*.<sup>25</sup>

2. If the assessment was initiated by the Administrator, the Administrator may take one of the actions described in Section IV.B.1. above.

## V. WTC Health Program Scientific/Technical Advisory Committee (STAC)

### A. Convening the STAC

The Administrator may convene the STAC to request a recommendation on whether to add a type of cancer to the List [see Section IV.A.1. Method 4].

### B. Meeting Procedures

If the Administrator decides to request a recommendation from the STAC regarding a type of cancer, the Designated Federal Officer (DFO) works with the STAC to schedule meetings and assemble information needed to develop recommendations on whether there is a reasonable basis to support adding the type of cancer to the List. The Administrator provides a charge to the STAC and all proceedings are conducted in accordance with the Federal Advisory Committee Act.<sup>26</sup>

### C. Time Limits

1. If a valid petition to add a type of cancer to the List has been received and the Administrator decides to exercise his discretion to convene the STAC, then the Administrator must make his request for a STAC recommendation within 90 days of receipt of the petition.
2. If the Administrator requests a recommendation from the STAC, whether following the receipt of a valid petition or as part of an Administrator-initiated review, the Administrator will send a letter to the STAC Chair requesting advice on whether to add the type of cancer and establishing a period of 90 days, with potential extension up to 180 days, for the committee to provide recommendations and their reasonable basis for those recommendations.
3. After receiving the recommendations from the STAC, the Administrator evaluates the STAC's recommendation and takes appropriate action under Section IV.B. not later than 90 days after receipt of the recommendation.

**Exception:** The option found in Section IV.B.1.c. above is not an option for the Administrator when advice has been requested from the STAC in response to a valid petition.

## VI. Rulemaking

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<sup>25</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

<sup>26</sup> 5 U.S.C. App.

## A. Notice of Proposed Rulemaking (NPRM)

If the Administrator decides to propose adding the health condition to the List, he publishes an NPRM in the *Federal Register* to that effect. The NPRM solicits public comments. The Administrator also conducts an independent peer review of the Program's evaluation of the scientific and technical evidence supporting the addition of the condition.<sup>27</sup>

1. Public comments. All public comments received are considered and responded to, as appropriate, in the final rule preamble. The public comment period will remain open no less than 45 days after publication of the NPRM in the Federal Register to allow the public an additional 15 days to comment after peer reviewers' comments are posted. The public comments are posted to the rulemaking docket.
2. Independent Peer Review. The Program requests peer review from three subject matter experts for the health condition to be added.
  - a. Identification of peer reviewers. The Administrator identifies qualified peer reviewers who are outside of NIOSH, with input provided by the STAC.<sup>28</sup>
  - b. Charge to peer reviewers. Peer reviewers are asked to review the evaluation of the evidence for adding the health condition to the List within the context of this policy, and provide a brief written report answering the following questions:<sup>29</sup>
    - i. Are you aware of any other studies which should be considered? If so, please identify them.
    - ii. Have the requirements of this *Policy and Procedures* been fulfilled? If not, please explain which requirements are missing or deficient.
    - iii. Is the interpretation of the available information appropriate, and does it support the conclusion to add the health condition, as described in the regulatory text, to the List? If not, please explain why.
  - c. All peer reviewers' comments are considered and responded to in the final rule preamble. The peer reviews are compiled without attribution and posted to the rulemaking docket at the end of 30 days.

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<sup>27</sup> 42 U.S.C. § 300mm-22(a)(6)(F).

<sup>28</sup> 42 U.S.C. § 300mm-22(a)(6)(G)(ii).

<sup>29</sup> The questions given to the peer reviewers may be modified by the Administrator, as necessary, for the specific health condition being considered.



**B. Final Rule**

After reviewing the public comments and peer reviews, the Administrator determines whether the rationale discussed in the NPRM is changed by the information supplied by commenters. If the evidence continues to support the addition of the type of cancer:

1. A final rule is developed and published in the *Federal Register*;
2. The condition is added to the List; and
3. Implementation procedures are developed, which may include:
  - a. Exposure qualifications;
  - b. Time intervals/latency; and
  - c. Other procedures as appropriate to the type of cancer.

**November 18, 2021**