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

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***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 September 11, 2019 Update: This version incorporates non-substantive changes to describe the process by which the Science Team evaluates the quality of scientific evidence, adds descriptions of the select Bradford Hill criteria used by the Science Team to evaluate causality, and provides an additional bibliographic reference.

Note for December 15, 2022 Revision: This version clarifies the evaluation criteria used to assess the likelihood of a causal association between 9/11-related exposures and a health condition in the 9/11-exposed population. This version also clarifies the nature of the rationale that provides the basis for the WTC Health Program Scientific/Technical Advisory Committee (STAC) recommendations.

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I. Authority

The *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* is based on the James Zadroga 9/11 Health and Compensation Act of 2010 ("Act")[1] and the World Trade Center (WTC) Health Program regulations.[2]

II. Initiation of the Process for Adding a Health Condition

A health condition may only be added to the List of WTC-Related Health Conditions (List) by rulemaking.[3] The Act provides two pathways to initiate the process of deciding whether to propose adding a health condition to the List—at the discretion of the Administrator or upon receipt of a petition from an interested party[4] requesting the addition.

A. Administrator's Discretion

The Administrator of the WTC Health Program may initiate the process of promulgating a proposed rule to add a health condition to the List at the Administrator's discretion.[5]

B. Petition Request

Upon receipt of a valid petition[6] requesting that a health condition be added to the List, the Administrator of the WTC Health Program must initiate the process of evaluating whether to add the health condition to the List and take one of the four actions described in Section V of this *Policy and Procedures* within 90 days of receipt of the valid petition.[7]

III. Science Team Identification of Scientific Evidence

A. Petition Review and Identification of Health Condition for Evaluation

Upon direction by the Administrator, the WTC Health Program's Science Team will review the information provided by the petitioner, including the medical basis, to determine the specific health condition that will be the subject of the scientific evaluation.

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[1] Title I of 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*.
[2] 42 C.F.R. Part 88.
[3] *See generally* 42 U.S.C. § 300mm-22(a)(6); 42 C.F.R. § 88.16; the complete List is promulgated at 42 C.F.R. § 88.15.
[4] 42 U.S.C. § 300mm-22(a)(6)(E); 42 C.F.R. § 88.1 (an interested party is 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).
[5] 42 U.S.C. § 300mm-22(a)(6)(A).
[6] When the Administrator receives a written submission from an interested party to add a health condition to the List, the Administrator follows the steps outlined in *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 valid petition specified in 42 C.F.R. § 88.16(a)(1).
[7] 42 U.S.C. § 300mm-22(a)(6); 42 C.F.R. § 88.16(a)(2).

B. Identification of Studies of 9/11-Exposed Populations

Once the health condition being evaluated is identified, the Administrator of the WTC Health Program will direct the Science Team to conduct a search of the scientific literature to identify all peer-reviewed,[8] published,[9] epidemiologic studies[10] of the health condition among 9/11-exposed populations. The Science Team conducts an initial review of each reference identified by the literature search to determine if it identifies any causal association(s) between 9/11 exposure(s) and health outcomes with the potential to provide a basis for deciding whether to propose adding a condition to the List.

C. Evaluation of Quality of Scientific Evidence in Identified Studies

The Science Team will summarize each identified study that has the potential to provide a basis for a decision to propose the addition of the condition and evaluate each study for scientific quality and validity. A high-quality study[11] will demonstrate that potential by exhibiting the following validity[12] indicators:

- Possible confounders are identified and adequately corrected for;
- Recruitment bias is adequately addressed;
- All aspects of exposure are completely considered;
- Blinding of exposure allocation from assessors and other exposure assessment methods lead to reliable classification;
- A control group is used to compare exposures, and inadequacies of the control population(s) are addressed;
- Results are not selectively reported and no evidence of a strong bias may fully explain the results; and
- Any conflicts of interest are identified and reported.

[8] 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 proposeadding 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.

[9] Published studies also include those published online ahead of print.

[10] 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 *NIOSH [2020]. Current Intelligence Bulletin 69: NIOSH Practices in Occupational Risk,* published at: https://www.cdc.gov/niosh/docs/2020-106/pdfs/2020-106revised032020.pdf?id=10.26616/NIOSHPUB2020106.

[11] Studies of low-quality design are unable to be evaluated pursuant to the criteria described in Sec. IV.

[12] "Validity is the quality of being logically or factually sound; the extent to which a measure describes that which is being measured; and the degree to which inferences drawn are valid." *See* NIOSH [2020], *supra* note 10 at 152.

D. Study Quality Evaluation Outcomes

1. If the Science Team determines that studies identified in the literature review are of high quality, those studies will be reviewed pursuant to the criteria described in Section IV.A.

2. If the Science Team determines that none of the studies identified in the literature review are of high quality, the Science Team will advise the Administrator that there is an inadequate likelihood of a causal association, pursuant to Section IV.B.3.

IV. Science Team Evaluation of Scientific Evidence

A. Evaluation of Evidence in High-Quality, Peer-Reviewed, Published, Epidemiologic Studies

Only those high-quality studies described above in Section III.D.1. will be further evaluated by the Science Team to determine if they provide a basis to support an addition to the List.[13] The Science Team will evaluate and integrate the information from the studies and then synthesize and interpret the scientific evidence to advise the Administrator on the likelihood of whether the health condition in the 9/11-exposed population is causally associated with 9/11-related exposures (*see* Section IV.B.). This evaluation will include consideration of the following:

1. Bradford Hill Criteria

The Science Team will apply the following select Bradford Hill criteria[14] to describe and evaluate the evidence across the high-quality epidemiologic studies:[15]

[13] Studies that do not fully meet the threshold to be identified as high-quality may be considered at the Science Team's discretion.

[14] *See* NIOSH [2020]*, supra* note 10.

[15] Injury studies are instead evaluated for onsite occurrence, presence of known causative factors, and quality. *See generally* Baker SP, O'Neill, Ginsburg MJ, and Guohua L, [1992], *The Injury Fact Book* 2nd ed. New York: Oxford University Press (regarding causation); *see also* National Academies Press [1985], *Injury in America: A Continuing public health problem.* The injury studies provide information about injuries recorded in contemporaneous medical records and studies which when combined with known hazards and known connections between those hazards and injury may demonstrate concordance of an injury and 9/11 exposures, allowing the Administrator to evaluate whether there is support for a causal association between those exposures and the injury.

- Strength of the association between a 9/11 exposure[16] and the health condition under consideration[17] and precision of the risk estimate;[18]

- Consistency of the association across multiple studies;[19]

- Biological gradient, or exposure-response, relationships between 9/11 exposures and the health condition under consideration;[20] and

- Biological plausibility of the studies and coherence of the study findings with known facts about the biology of the health condition under consideration.[21]

2. Representativeness Assessment

The Science Team will assess whether the studies, taken together, represent both WTC responder and survivor populations or, if only a subgroup of 9/11-exposed populations is represented, whether the results can reasonably be extrapolated to the complete 9/11-exposed population of responders and survivors.

3. Evaluation Outcome

Based on the evaluation of evidence, the Science Team will categorize the evidence of a causal association between 9/11 exposures and the health condition as one of four outcomes described in Section IV.B.: (1) substantial

[16] The term *9/11 exposures* refers to those hazards to which responders, recovery workers, and survivors may have been exposed but which may not have been identified or measured at one of the 9/11 disaster areas. The WTC Health Program considers 9/11 agents to be a subset of 9/11 exposures and has published an inventory of recognized 9/11 agents. *9/11 agents* are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposureassessment 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. *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.

[17] It is generally thought that strong associations are more likely to be causal than weak associations; however, a weak association does not rule out a causal relationship. *See* NIOSH [2020]*, supra* note 10.

[18] Precision of the risk estimate describes the random error inherent in estimating the strength of association (the effect size) between exposure and the health condition. It is often expressed as a confidence interval illustrating a range of plausible values of the effect estimate given sampling error. A narrow confidence interval indicates a more precise measure of the effect and a wider interval indicates greater uncertainty. While precision is not a Bradford Hill criterion, the Science Team takes it into consideration to evaluate the existence of random error in a study. *See* NIOSH [2020]*, supra* note 10.

[19] Consistent findings are demonstrated when they have been repeatedly reported by multiple studies. *See* NIOSH [2020]*, supra* note 10. If only a single study is available for evaluation, the Science Team will place more emphasis on evaluating the strength of the association and precision of the risk estimate.

[20] Studies establish an exposure-response relationship by demonstrating that increases in exposure (i.e., exposures of greater intensity and/or longer duration) are associated with a greater incidence of disease. A thorough evaluation of exposure-response requires analysis of multiple levels of exposure such that the investigator can demonstrate that the risk increases with increasing levels of exposure. *See* NIOSH [2020]*, supra* note 9.

[21] Study findings demonstrate a basis in scientific theory that supports the relationship between the exposure and the health effect, and do not conflict with known facts about the biology of the health condition. *See* NIOSH [2020]*, supra* note 9.

likelihood, (2) high likelihood, (3) limited or inadequate likelihood, and (4) no likelihood.

B. Science Team Evaluation Outcome and Advice to Administrator

Based on the evaluation of the totality of the scientific evidence described in Section III.B., the Science Team will assess the degree to which the evidence supports a causal association between 9/11 exposures and the health condition and advise the Administrator.

The causal association will be described as meeting one of the following standards of causal association: (1) substantial likelihood, (2) high likelihood, (3) limited or inadequate likelihood, and (4) no likelihood. If the Science Team determines there is a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition, the Administrator may direct the Science Team to evaluate additional scientific evidence as outlined below. After receipt of the Science Team's assessment, the Administrator will take one of four actions described in Section V.

1. Evidence Supports Substantial Likelihood of a Causal Association

a. Substantial Likelihood Standard

Substantial likelihood of causal association means that the scientific evidence demonstrates that a causal association exists and there is high confidence that the association cannot be explained by chance, bias, confounding, or any other alternative explanation. The scientific evidence demonstrating that a causal association is *substantially likely* includes the following:

- Evidence supporting a causal association from more than one high-quality epidemiologic study;
- Available epidemiologic studies as a whole must have examined both groups of the 9/11-exposed population (e.g., responders and survivors); and
- Available epidemiologic studies as a whole consistently and precisely report increasing risk of the health condition with increased 9/11 exposures.[22]

b. Science Team Evaluation Conclusion

If the Science Team concludes that the scientific evidence, taken as a whole, demonstrates a substantial likelihood of a causal association between 9/11 exposures and the health condition, the Science Team will advise the Administrator of their conclusion.

[22] *See supra* note 18.

2. Evidence Supports High Likelihood of Causal Association

a. High Likelihood Standard

High likelihood of causal association means that the scientific evidence, taken as a whole, demonstrates that a causal association is likely to exist, but there is some possibility that the association can be explained by chance, bias, confounding, or another alternative explanation. The scientific evidence supporting that a causal association is *highly likely* includes the following:

- Evidence supporting a causal association from more than one high-quality epidemiologic study;

- Available epidemiologic studies as a whole must have examined at least one group of the 9/11-exposed population (e.g., responders or survivors); and

- Available epidemiologic studies as a whole mainly report increasing risk of the health condition with increased 9/11 exposures; however, the uncertainty in findings precludes the determination of "substantial likelihood" because there is some possibility that the association can be explained by chance, bias, confounding or any other alternative explanation.

b. Science Team Evaluation Conclusion

If the Science Team concludes that the scientific evidence, taken as a whole and after considering all sources of uncertainty, demonstrates that the likelihood of a causal association between 9/11 exposures and the health condition is less than substantial, but definitively more than "more likely than not," the Science Team will so advise the Administrator that the causal association is highly likely.

c. Discretionary Second-Level Review of Additional Scientific Evidence in Non-9/11-Exposed Populations

If the Science Team evaluation concludes that the available high-quality, peer-reviewed, published epidemiologic studies of the health condition in 9/11-exposed populations demonstrate a high, but not substantial, likelihood of causal association between 9/11 exposures and the health condition, the Administrator may, at their discretion, request further input from the Science Team.

If the Administrator elects to seek further input, the Science Team will be directed to evaluate additional highly relevant scientific evidence

regarding exposures to known 9/11 agents[23] in non-9/11-exposed populations. The Administrator considers "highly-relevant" evidence to be found in authoritative scientific sources published by the U.S. government, as described below.

(1) Sources of Highly-Relevant Scientific Information in Non-9/11-Exposed Populations

The Science Team will identify and review additional peer-reviewed, scientific information on exposures to known 9/11 agents in non-9/11-exposed populations that is obtained from authoritative scientific sources published by the U.S. government, such as:

- *Toxicological Profiles* published by the Agency for ToxicSubstances and Disease Registry (ATSDR); [24]
- *Monographs* published by the National Toxicology Program (NTP); [25] and
- *Human Health Risk Assessments* published by the Environmental Protection Agency (EPA). [26]

(2) Second-Level Review of Scientific Evidence

- The review of the evidence from the additional scientific sources will include, but not be limited to, an evaluation of the following:
  - Whether the information provides evidence that exposure to 9/11 agents is substantially likely to cause the health condition;
  - Whether the evidence fills an important gap in establishing a causal association between exposure to 9/11 agents and the health condition;
  - Whether the evidence mitigates the quality limitations found in peer-reviewed, published, epidemiologic studies of the health condition among 9/11-exposed populations; and
  - Whether the information is inconclusive or outdated.

[23] *See supra* note 17.
[24] For available ATSDR Toxicological Profiles, *see* http://www.atsdr.cdc.gov/toxprofiles/index.asp.
[25] For available NTP Monographs, *see* http://ntp.niehs.nih.gov/pubhealth/hat/noms/index.html.
[26] For EPA Human Health Risk Assessment Products and Publications, *see* https://cfpub.epa.gov/ncea/risk/hhra/advSearch.cfm.

- The review of scientific evidence from additional sources will include an evaluation of the similarity of the exposure characteristics to 9/11 exposure characteristics including, but not limited to, the following:

    - The amount of exposure;

    - Route of exposure;

    - Physical form of the exposure to the 9/11 agent, *e.g.*, particulate, gas, fume, vapor, or solute;

    - Duration and consistency of the exposure; and

    - Whether the adverse health outcome arises from acute, sub-chronic, or chronic exposure.

(3) Summary of Second-Level Review

The Science Team will summarize its review of the scientific evidence on exposures to known 9/11 agents and the health condition in non-9/11-exposed populations. The Science Team will advise the Administrator regarding whether, based on the additional evidence from the sources using non-9/11-exposed populations, there is now sufficient evidence to support the conclusion that a causal association between 9/11 exposures and the health condition is substantially likely to be causal, i.e., unlikely to be explained by chance, bias, confounding, or any other alternative explanation.

3. Evidence Supports Limited or Inadequate Causal Association

a. Limited or Inadequate Likelihood Standard

Limited likelihood of causal association means the scientific evidence demonstrates that there is some evidence of a causal association between 9/11 exposures and the health condition, i.e., a causal association might exist but alternative explanations of the association such as bias, confounding, chance, or other alternative explanation, are also likely. The scientific evidence supporting *limited likelihood* of a causal association includes the following:

- Evidence supporting a causal association from at least one epidemiologic study of a 9/11-exposed population;

- Available body of evidence must have examined at least one group of the 9/11-exposed population, e.g., responders or survivors; and

- Available body of evidence reports increasing risk of the health condition with increased 9/11 exposures; however, the evidence lacks sufficient consistency and precision to eliminate alternative explanations of the association, such as bias, confounding, chance, or any other alternative explanation.

Inadequate likelihood of causal association means the scientific evidence fails to meet the criteria above and is inconclusive with regard to a causal association between 9/11 exposures and the health condition.

b. Science Team Evaluation Conclusion

If the Science Team concludes that the scientific evidence, taken as a whole, demonstrates that there is limited or inadequate likelihood of a causal association between the 9/11 exposures and the health condition, but not sufficient evidence to establish a high likelihood, the Science Team will advise the Administrator of their conclusion.

4. Evidence Does Not Support Causal Association

a. No Likelihood Standard

No likelihood means that the scientific evidence demonstrates that the health condition is substantially unlikely to be causally associated with 9/11 exposures. The scientific evidence of no likely causal association must include the following:

- Evidence supporting no causal association from more than one high-quality epidemiologic study;

- Available epidemiologic studies as a whole must have examined both groups of the 9/11-exposed population (e.g., responders and survivors);

- Available epidemiologic studies as a whole consistently and precisely report no increased risk of the health condition with increased 9/11 exposures;

- The evidence of biological plausibility is absent or is of low quality; and

- There is high confidence that the evidence against a causal association is not explained by chance, bias, confounding, or any other alternative explanation.

b. Science Team Evaluation Conclusion

If the Science Team concludes that the scientific evidence, taken as a whole, demonstrates no likelihood that the health condition is causally associated with 9/11 exposures, the Science Team will advise the Administrator of their conclusion.

V. Administrator Actions

At the conclusion of its evaluation, the Science Team will provide the Administrator with its advice and findings regarding the potential causal association between 9/11 exposures and the health condition. The causal association will be described as meeting one of the following standards of causal association: (1) substantial likelihood; (2) high likelihood; (3) limited or inadequate likelihood; or (4) no likelihood. If the Administrator directed the Science Team to evaluate additional scientific evidence in non-9/11 exposed populations, the Science Team will also provide those findings.

Upon receipt of the Science Team's assessment, the Administrator will take one of the following actions:[27]

A. Request a Recommendation of the STAC

The Administrator may request a recommendation from the STAC on whether to propose the addition of a health condition to the List.[28] The Administrator may request a recommendation of the STAC at any time, including when the Science Team evaluation concludes that the evidence supports a high, but not substantial, likelihood of causal association between 9/11 exposures and a health condition.

A health condition may be added to the List if the STAC recommends the addition and provides a reasonable basis for the recommendation.[29] 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 used to support the recommendation.

B. Publish a Notice of Proposed Rulemaking to Add the Health Condition

The Administrator will publish in the *Federal Register* a notice of proposed rulemaking (NPRM) to add the health condition to the List of WTC-Related Health Conditions[30] if the Administrator determines that there is sufficient evidence that 9/11 exposures are causally associated with the health condition. Such a determination may be based on any of the following:

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[27] Where the evaluation by the Science Team is in response to a valid petition, one of these actions must be taken within 90 days of receipt of the petition. *See* 42 U.S.C. § 300mm-22(a)(6)(B); 42 C.F.R. § 88.16(a)(2). The statutory deadlines do not apply where the evaluation is conducted at the discretion of the Administrator.

[28] 42 U.S.C. § 300mm-22(a)(6)(B)(i); 42 C.F.R. § 88.16(a)(2)(i).

[29] The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Section IV.A.

[30] 42 U.S.C. § 300mm-22(a)(6)(B)(ii); 42 C.F.R. § 88.16(a)(2)(ii).

The Science Team advises that the evaluation of the scientific evidence supports a finding that the health condition is substantially likely to be causally associated with 9/11 exposures (*see* Section IV.B.1.);

The Science Team advises that evaluation of the scientific evidence supports that there is a high likelihood that 9/11 exposures are causally associated with the health condition and, if applicable, upon review of additional highly-relevant scientific information on non-9/11-exposed populations, there is sufficient evidence to support the conclusion that this causal association is unlikely to be explained by chance, bias, confounding, or any other alternative explanation (*see* Section IV.B.2.); or

The Administrator finds that the STAC has provided a reasonable basis for adding the health condition to the List of WTC-Related Health Conditions.

C. Publish a Notice of Determination Not to Propose a Rule to Add a Condition

If the Science Team advises that the evidence supports that the health condition is not causally associated with 9/11 exposures, then the Administrator will publish in the *Federal Register* a determination not to propose a rule and the basis for such determination (*see* Section IV.B.4.).[31]

D. Publish a Notice of Insufficient Evidence

The Administrator will publish in the *Federal Register* a determination of insufficient evidence if the Administrator determines that there is insufficient evidence to take either of the actions in Sec. V.B. or C.[32] Such a determination may be based on any of the following:

1. The Science Team advises that peer-reviewed, published, epidemiologic studies of the health condition in 9/11-exposed populations were not identified by the literature review (*see* Section III.B.);

2. The Science Team advises that peer-reviewed, published, epidemiologic studies were identified by the literature review but are not considered to be high-quality (*see* Section III.C.);

3. The Science Team advises that the evaluation of the scientific evidence supports a high likelihood of a causal association between the health condition and 9/11 exposures (*see* Section IV.B.2.), and either:

    - The Administrator does not direct the Science Team to conduct a second-level review (*see* Section IV.B.2.c.);

    or

[31] 42 U.S.C. § 300mm-22(a)(6)(B)(iii); 42 C.F.R. § 88.16(a)(2)(iii).
[32] 42 U.S.C. § 300mm-22(a)(6)(B)(iv); 42 C.F.R. § 88.16(a)(2)(iv).

- The second-level review finds that any causal association between 9/11 agents and the health condition may still be explained by chance, bias, confounding, or any other alternative explanation (*see* Section IV.B.2.c.(3)); or

4. The Science Team advises that the evaluation of the scientific evidence supports a limited or inadequate causal association between the health condition and 9/11 exposures (*see* Section IV.B.4.).

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

A. Convening the STAC

The Administrator may send a letter to the STAC Chair requesting a recommendation from the STAC on whether to add a health condition, including the scientific and medical basis for the recommendation.[33]

B. STAC Meeting Procedures

The Designated Federal Official will work with the STAC to schedule meetings and assemble information needed to develop recommendations on whether 9/11 exposures are causally associated with the health condition.

C. Time Limits

1. STAC Recommendation

The STAC will submit its recommendation on whether to add the health condition to the Administrator no later than 90 days after the date of the Administrator's request or by such date (not to exceed 180 days from the date of the request) as specified by the Administrator.[34]

2. Administrator Actions after Receipt of a STAC Recommendation

Where the Administrator is reviewing a potential addition of a health condition to the List, whether at the Administrator's own discretion or in response to a petition, and has requested a recommendation from the STAC, the Administrator will evaluate the STAC's recommendation(s) and take one of the following actions within 90 days after receipt:

a. Publish an NPRM in the *Federal Register* to propose the addition of a health condition (*see* Section V.B.); or

[33] 42 U.S.C. § 300mm-22(a)(6)(B)(i) and (C).
[34] 42 U.S.C. § 300mm-22(a)(6)(C); 42 C.F.R. § 88.16(b)(1).

b. Publish a notice in the *Federal Register* of the determination not to propose a rule to add a condition and the basis for such a determination (*see* Section V.C.).

VII. Rulemaking and Peer Review

A. Notice of Proposed Rulemaking (NPRM)

If the Administrator decides to propose adding the health condition to the List, the Administrator will publish an NPRM in the *Federal Register*. The Administrator will solicit written public comments on the NPRM.[35]

B. Independent Peer Review

As required by the James Zadroga 9/11 Health and Compensation Reauthorization Act, the Administrator will conduct an independent peer review of the WTC Health Program's evaluation of the scientific and technical evidence supporting the addition of the health condition prior to issuing a final rule.[36]

1. Selection of Peer Reviewers

a. At least every two years, the Administrator will request recommendations from the STAC regarding the identification of potential independent peer reviewers with medical and/or scientific expertise.[37]

b. Prior to issuing a final rule adding a condition to the List, the Administrator will select three subject matter experts for each health condition being proposed for addition to review the proposed rulemaking.[38] In selecting peer reviewers to review the Program's evaluation of evidence regarding a specific health condition, the Administrator will balance the following factors:

(1) Medical and/or scientific expertise needed to evaluate the evidence relied on to propose adding the health condition, including the authorship of publication(s) concerning the respective health condition;

(2) Independence from the National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC); and

(3) Previous service as a peer reviewer (rotation of peer reviewers).

[35] 42 U.S.C. § 300mm-22(a)(6)(D); 42 C.F.R. § 88.16(b).
[36] 42 U.S.C. § 300mm-22(a)(6)(F); 42 C.F.R. § 88.16(b)(2).
[37] 42 U.S.C. § 300mm-22(a)(6)(G)(ii).
[38] 42 C.F.R. § 88.15.

c. The Administrator will apply Federal science agency conflict or bias prevention methods to:

(1) Limit potential conflicts of interest;

(2) Ensure that bias is minimized in the peer review process;

(3) Achieve a high level of credibility; and

(4) Balance extremes in scientific perspectives.

2. Charge to Peer Reviewers

a. Peer reviewers will be asked to review the evidence assessment for adding the health condition to the List within the context of this policy. Within 30 days of when the NPRM is published in the *Federal Register*, reviewers will be expected to provide a brief written report answering the following questions:[39]

(1) Are you aware of any other studies which should be considered? If so, please identify them.

(2) Have the requirements of this *Policy and Procedures* been fulfilled? If not, please explain which elements are missing or deficient.

(3) Is the interpretation of the available evidence appropriate, and does it support the conclusion to add the health condition, as described in the proposed regulatory text, to the List? If not, please explain why.

b. The peer reviews will be compiled and posted to the NIOSH rulemaking docket at the end of 30 days. Peer reviewers will be identified without individual attribution of their comments.

C. Public Comments

All public comments and peer reviews will be 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 will be posted to the rulemaking docket.

[39] The questions given to the peer reviewers may be modified by the Administrator, as necessary, for the specific health condition being considered.

D. Final Rule

After reviewing the public comments and peer reviews, the Administrator will determine 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 health condition:

1. A final rule will be developed and published in the *Federal Register*;

2. The condition will be added to the List on the final rule's effective date; and

3. Implementation procedures will be developed, which may include:

a. Exposure qualifications;

b. Time intervals for diagnosis and/or symptom onset; and

c. Other procedures as appropriate to the particular health condition.

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