

WTC HEALTH PROGRAM TIMELINE FOR EVALUATING A VALID PETITION TO ADD A CONDITION TO THE LIST OF WTC-RELATED HEALTH CONDITIONS

The timeline below describes the established procedures concerning the WTC Health Program Administrator’s response to a petition to add a condition to the List of WTC-Related Health Conditions (List). It does not address the procedures used when the Administrator initiates the addition of a health condition on his own and/or requests advice of the STAC. **The deadlines and timing of the steps below are approximations** and depend on the amount and complexity of evidence to support the addition of a health condition.

The Zadroga Act severely restricts the amount of time available to the Administrator for handling a petition, including the determination of whether to publish a proposed rule, draft the resulting notice of proposed rulemaking (NPRM) or Federal Register notice, and/or request a recommendation from the STAC. Typical NIOSH rulemakings are not conducted under statutory deadline; NPRMs are generally published 8-12 months after lengthy drafting and clearance processes. Accordingly, the steps described below are established and cannot be changed without compromising the integrity of the rulemaking process.

Time (days)	Activity	Description
1	Petition	Administrator receives submission from interested party
2		Program and OGC review and advise Administrator
3		Administrator determines if valid petition
4		If no: Notify submitter
5		If yes: Notify submitter and direct Science Team to conduct lit search and evaluation AND/OR request advice of STAC
6	Lit Search	
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8		WTCHP Science Team initiates systematic literature search; librarian conducts literature search
9		1-5 days
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11	Assessment	WTCHP Science Team reviews systematic literature search results and identifies relevant references (peer-reviewed, published epidemiology studies of petitioned health condition in 9/11 populations); quality and quantity are evaluated for potential to provide basis for adding the health condition; findings are documented and discussed with Administrator;
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16		1-2 weeks
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19	Decision	Administrator determines if scientific evidence is sufficient to provide a basis for a decision to add a condition to the List
20		If no: Draft and publish FRN that insufficient evidence is available.
21		If yes: Direct Science Team to conduct assessment of the relevant literature AND/OR request advice of STAC
22	Assessment	WTCHP Science Team
23		assesses results, strengths, and limitations of each relevant study
24		assesses body of relevant studies using identified Bradford-Hill criteria;
25		discusses findings with Administrator
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28		1-3 weeks
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35	Decision	Administrator determines whether to conduct rulemaking to add condition or publish FRN
36		If no: Draft and publish FRN finding either insufficient evidence or determination and basis for not proposing rule
37		If yes: Proceed with drafting NPRM proposing to add the condition to the List AND/OR request advice of STAC
38	NPRM DRAFT	
39		Notice of Proposed Rulemaking (NPRM) drafted
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41		• intensive process involving extensive scientific, legal, and economic analysis,
42		and information collection burden (Paperwork Reduction Act) analysis
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45		Typical is 4-5 weeks; show 4 weeks
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Time (days)	Activity	Description
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65	NPRM Clearance	
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73		CDC clearance
74		HHS clearance
75		OMB clearance
76		Clearance is consecutive
77		Clearance includes edits, rewrites, and responses to comments received through the clearance process
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80	• 3 weeks, if expedited	
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86	Publish NPRM	NPRM sent to <i>Federal Register</i> for publication
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91	Comment Period	Public comments (minimum 30 days per Zadroga Act) and peer reviews on the NPRM solicited
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Time (days)	Activity	Description
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Ends from 6-10 months from initiation	Draft Final Rule	<p>final rule drafted, including consideration and response to public comments and peer reviews</p> <ul style="list-style-type: none"> • 2 - 6 months after close of comments and peer review.
Ends from 13-16 months from initiation	Final Rule Clearance	<p>CDC clearance HHS clearance OMB clearance</p> <ul style="list-style-type: none"> • clearance is consecutive • 3 - 6 months after draft Final rule submitted
	Final Rule Published	<p>publication of final rule</p> <ul style="list-style-type: none"> • health condition available for WTCHP coverage typically 30 days after date of publication