

#I# #a#g#r#e#e# #t#h#a#t# #t#h#e#s#e# #a#c#t#i#v#i#t#i#e#s# #a#r#e# #s#t#i#l#l#
#w#i#t#h#i#n# #t#h#e# #s#c#o#p#e# #o#f# #r#o#u#t#i#n#e# #n#o#n#-
#r#e#s#e#a#r#c#h# #p#u#b#l#i#c# #h#e#a#l#t#h# #s#u#r#v#e#i#l#l#a#n#c#e#.###

#H#o#w#e#v#e#r#,# #I# #n#o#t#e#d# #s#o#m#e# #r#e#s#e#a#r#c#h#y#
#l#a#n#g#u#a#g#e# #i#n# #t#h#e# #s#u#p#p#o#r#t#i#n#g# #s#t#a#t#e#m#e#n#t#s# ##
#p#l#e#a#s#e# #s#e#e# #a#t#t#a#c#h#e#d# #v#e#r#s#i#o#n#s# #f#o#r# #m#y#
#i#n#s#e#r#t#e#d# #c#o#m#m#e#n#t#s# #a#n#d# #s#u#g#g#e#s#t#i#o#n#s# #f#o#r#
#r#e#p#h#r#a#s#i#n#g#.###

#L#a#u#r#a# #Y#o#u#n#g#b#l#o#o#d#,# #M#P#H#,# #C#I#P# ##
#H#u#m#a#n# #S#u#b#j#e#c#t#s# #A#d#v#i#s#o#r# #|# #N#C#E#Z#I#D# #|# #
#<#m#a#i#l#t#o#:#l#y#o#u#n#g#b#l#o#o#d#@#c#d#c#.#g#o#v#>#
#l#y#o#u#n#g#b#l#o#o#d#@#c#d#c#.#g#o#v# #|# #0#f#f#i#c#e#:# #(#4#0#4#)#
#6#3#9#-#6#3#9#4# #|# #M#o#b#i#l#e#:# #(#4#0#4#)# #5#1#0#-#0#0#9#3# ##

#F#r#o#m#:# #H#y#n#e#s#,# #A#n#s#l#e#y# #(#C#D#C#/#0#I#D#/#N#C#I#R#D#)#
#(#C#T#R#)# ##
#S#e#n#t#:# #W#e#d#n#e#s#d#a#y#,# #M#a#y# #2#7#,# #2#0#1#5# #1#0#:#2#9# #A#M##
#T#o#:# #Y#u#,# #J#o#a#n#a# #(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)# #(#C#T#R#)#;#
#Y#o#u#n#g#b#l#o#o#d#,# #L#a#u#r#a# #(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)##
#C#c#:# #R#o#b#e#r#t#s#,# #V#i#r#g#i#n#i#a# #(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)##
#S#u#b#j#e#c#t#:# #R#E#:# #I#R#B# #a#p#p#r#o#v#a#l# #f#o#r# #n#e#w# #H#A#B#s#
#s#u#r#v#e#i#l#l#a#n#c#e# #s#y#s#t#e#m##

#L#a#u#r#a#,###

#G#r#e#a#t# #t#o# #t#a#l#k# #t#o# #y#o#u#.# # #I# #h#a#v#e# #a#t#t#a#c#h#e#d#
#t#h#e# #v#a#r#i#a#b#l#e#s# #f#o#r# #t#h#e# #H#A#B# #c#o#l#l#e#c#t#i#o#n# #a#s#
#w#e#l#l# #a#s# #t#h#e# #d#r#a#f#t# #v#e#r#s#i#o#n# #o#f# #s#u#p#p#o#r#t#i#n#g#
#s#t#a#t#e#m#e#n#t# #A# #a#n#d# #B#.# #P#l#e#a#s#e# #l#e#t# #m#e# #k#n#o#w#
#i#f# #y#o#u# #r#e#q#u#i#r#e# #a#d#d#i#t#i#o#n#a#l# #i#n#f#o#r#m#a#t#i#o#n#.###

#R#e#g#a#r#d#s#,###

#A#n#s#l#e#y##

#F#r#o#m#:# #Y#u#,# #J#o#a#n#a# #(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)# #(#C#T#R#)# ##
#S#e#n#t#:# #T#u#e#s#d#a#y#,# #M#a#y# #2#6#,# #2#0#1#5# #9#:#0#5# #A#M##
#T#o#:# #Y#o#u#n#g#b#l#o#o#d#,# #L#a#u#r#a# #(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)##
#C#c#:# #H#y#n#e#s#,# #A#n#s#l#e#y# #(#C#D#C#/#0#I#D#/#N#C#I#R#D#)#
#(#C#T#R#)#;# #R#o#b#e#r#t#s#,# #V#i#r#g#i#n#i#a#
#(#C#D#C#/#0#I#D#/#N#C#E#Z#I#D#)##
#S#u#b#j#e#c#t#:# #I#R#B# #a#p#p#r#o#v#a#l# #f#o#r# #n#e#w# #H#A#B#s#
#s#u#r#v#e#i#l#l#a#n#c#e# #s#y#s#t#e#m##

#H#i# #L#a#u#r#a#,###

#I# #a#m# #w#o#r#k#i#n#g# #w#i#t#h# #A#n#s#l#e#y# #t#o# #s#u#b#m#i#t# #0#M#B#
#a#p#p#r#o#v#a#l# #d#o#c#u#m#e#n#t#s# #f#o#r# #t#h#e# #h#a#r#m#f#u#l#
#a#l#g#a#l# #b#l#o#o#m#s# (#H#A#B#s#)# #s#u#r#v#e#i#l#l#a#n#c#e#
#s#y#s#t#e#m#,# #f#o#r#m#e#r#l#y# #k#n#o#w#n# #a#s# #H#A#B#I#S#S#.# # #0#u#r#
#n#e#w# #s#y#s#t#e#m# #w#i#l#l# #b#e# #i#n#c#o#r#p#o#r#a#t#i#n#g# #t#h#e#
#d#a#t#a# #e#l#e#m#e#n#t#s# #o#f# #H#A#B#I#S#S# #b#u#t# #w#i#l#l# #b#e#
#o#p#e#r#a#t#e#d# #u#n#d#e#r# #N#O#R#S#.# # #N#o# #p#e#r#s#o#n#a#l#l#y#
#i#d#e#n#t#i#f#i#a#b#l#e# #i#n#f#o#r#m#a#t#i#o#n# #w#i#l#l# #b#e#
#c#o#l#l#e#c#t#e#d# #f#r#o#m# #C#D#C# #a#n#d# #w#i#l#l# #i#n#c#l#u#d#e#
#e#x#p#o#s#u#r#e#,# #s#y#m#p#t#o#m#,# #c#l#i#n#i#c#a#l#,# #a#n#d#
#l#a#b#o#r#a#t#o#r#y# #d#a#t#a# #f#o#r# #s#i#n#g#l#e# #h#u#m#a#n# #c#a#s#e#s#,#
#s#i#n#g#l#e# #a#n#i#m#a#l# #c#a#s#e#s#,# #a#n#d# #e#n#v#i#r#o#n#m#e#n#t#a#l#
#e#v#e#n#t#s# #a#s#s#o#c#i#a#t#e#d# #w#i#t#h# #H#A#B#s#.# # #F#o#r# #h#u#m#a#n#
#c#a#s#e#s#,# #a#g#e# #w#i#l#l# #b#e# #c#o#l#l#e#c#t#e#d# #(#i#n# #y#e#a#r#s#)#
#a#n#d# #t#h#e# #s#t#a#t#e# #o#f# #t#h#e# #e#x#p#o#s#u#r#e# #w#i#l#l# #b#e#
#c#o#l#l#e#c#t#e#d#.# # ##

#I# #j#u#s#t# #w#a#n#t#e#d# #t#o# #d#o#u#b#l#e# #c#h#e#c#k# #w#i#t#h# #y#o#u#
#t#h#a#t# #o#u#r# #s#y#s#t#e#m# #w#i#l#l# #n#o#t# #r#e#q#u#i#r#e# #I#R#B#
#a#p#p#r#o#v#a#l# #a#n#d# #i#s# #c#o#n#s#i#d#e#r#e#d# #r#o#u#t#i#n#e#
#s#u#r#v#e#i#l#l#a#n#c#e#.# # ##

#T#h#a#n#k# #y#o#u# #f#o#r# #y#o#u#r# #h#e#l#p#.###

#A#l#l# #t#h#e# #b#e#s#t#,###

#J#o#a#n#a##

#-#-#-#-##

#J#o#a#n#a# #Y#u#,# #M#P#H##

#E#p#i#d#e#m#i#o#l#o#g#i#s#t# #,# #K#a#r#n#a# #L#L#C##

#C#e#n#t#e#r#s# #f#o#r# #D#i#s#e#a#s#e# #C#o#n#t#r#o#l# #a#n#d#
#P#r#e#v#e#n#t#i#o#n##

#O#I#D#/#N#C#E#Z#I#D#/#D#F#W#E#D#/#W#D#P#B##

#1#6#0#0# #C#l#i#f#t#o#n# #A#v#e#,# #N#E#;# #M#a#i#l#s#t#o#p# #C#-#0#9##

#A#t#l#a#n#t#a#,# #G#A# #3#0#3#3#3##

#P#h#o#n#e#:# #+1#(#4#0#4#)# #6#3#9#-#0#2#3#1##

#E#m#a#i#l#:# #<#m#a#i#l#t#o#:#y#j#o#3#@#c#d#c#.#g#o#v#>#
#y#j#o#3#@#c#d#c#.#g#o#v##

#####E#C#A#S#H#U#B#-

#C#L#F#T#3#.#c#d#c#.#g#o#v#####0#4#####
#####<#5#8#4#F#C#F#8#9#2#B#2#2#7#9#4#2#9#9#5#9#D#C#6
#0#D#4#C#6#B#9#2#4#1#4#4#6#2#8#3#F#@#E#M#B#X#-
#C#L#F#T#4#.#c#d#c#.#g#o#v#>#####B#T#=#2#;#I#I#=#0#1#D#0#9#4#C#7#4#B#4#C#C#2#2
#2#9#B#9#F#3#1#A#0#4#7#0#A#B#6#B#3#0#7#E#2#E#1#C#2#0#2#3#1#0#0#F#0#4#C#4#0#B#0#0
#0#0#1#6#0#A#3#B#0#0#0#0#3#A#D#F#8#D#0#0#E#E#7#E#C#1#5#4#0#;#S#B#M#I#D#=#2#1#;#S
#B#T#=#7#9#;#S#2#=#<#2#E#7#9#8#B#4#5#2#8#C#1#A#A#4#7#B#D#8#F#E#0#E#A#F#B#B#9#0#7
#0#1#2#2#1#3#C#D#5#3#@#E#M#B#X#-
#C#L#F#T#2#.#c#d#c#.#g#o#v#>;#F#I#X#U#P#=#1#0#4#.#3#0#6#3#;#V#e#r#s#i#o#n#=#V#e
#r#s#i#o#n# #1#4#.#3# #(#B#u#i#l#d# #2#2#4#.#0#)#,#
#S#t#a#g#e#=#H#5#####e#n#-
#U#S#####I#P#M#.#N#o#t#e#####
#####0#0#0#0#0#0#0#1###o#u#t#l#o#o#k#.#c#d
#c#.#g#o#v#/#o#=#C#D#C#/#o#u#=#E#x#c#h#a#n#g#e# #A#d#m#i#n#i#s#t#r#a#t#i#v#e#
#G#r#o#u#p#
#(#F#Y#D#I#B#O#H#F#2#3#S#P#D#L#T#)#/#c#n#=#R#e#c#i#p#i#e#n#t#s#/#c#n#=#v#h#r#4##
#####v#h#r#4#####
#####s#i#p#:#y#j#o#3#@#c#d#c#.#g#o#v#####
#####y#j#o#3#@#c#d#c#.#g#o#v#####
#a#u#h#1#@#c#d#c#.#g#o#v#####a#u#h#1#@#c#d#c
#.#g#o#v#####y#j#o#3#@#c#d#c#.#g#o#v#####
#####y#j#o#3#@#c#d#c#.#g#o#v#####
#####/#o#=#C#D#C#/#o#u#=#E#x#c#h#a#n#g#e#
#A#d#m#i#n#i#s#t#r#a#t#i#v#e# #G#r#o#u#p#
#(#F#Y#D#I#B#O#H#F#2#3#S#P#D#L#T#)#/#c#n#=#R#e#c#i#p#i#e#n#t#s#/#c#n#=#Y#u#,#
#J#o#a#n#a#d#2#e#####E#X#####
#####Û@ÈÀB##´¹##+/á#####/O=CDC/OU=EXCHANGE ADMINISTRATIVE
GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=YU,
JOANAD2E#####a#u#h#1#@#c#d#c#.#g#o#v#####
#####Û@ÈÀB##´¹##+/á#####/O=CDC/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=YU, JOANAD2E#####Y#u#,# #J#o#a#n#a#
#(#C#D#C#/#O#I#D#/#N#C#E#Z#I#D#)# #(#C#T#R#)#s###
□8iDÑ#####©]«anÁ×F¨>Â!
4Ée}#####<#2#E#7#9#8#B#4#5#2#8#C#1#A#
A#4#7#B#D#8#F#E#0#E#A#F#B#B#9#0#7#0#1#2#2#0#A#1#7#1#8#@#E#M#B#X#-
#C#L#F#T#2#.#c#d#c#.#g#o#v#>#####<#5#8#4#F#C#F#8#9#2#B#2#2#7#9#4#2#9#9#5#9#D#C
#6#0#D#4#C#6#B#9#2#4#1#4#4#3#2#1#4#D#@#E#M#B#X#-#C#L#F#T#4#.#c#d#c#.#g#o#v#>#
#<#B#0#7#6#E#8#4#5#6#6#6#5#4#9#4#B#9#6#0#9#C#3#4#8#B#D#2#2#3#9#E#0#3#6#C#C#8#B#5
#8#@#E#M#B#X#-#C#L#F#T#4#.#c#d#c#.#g#o#v#># #
#<#2#E#7#9#8#B#4#5#2#8#C#1#A#A#4#7#B#D#8#F#E#0#E#A#F#B#B#9#0#7#0#1#2#2#0#A#1#7#1
#8#@#E#M#B#X#-
#C#L#F#T#2#.#c#d#c#.#g#o#v#>#####<#5#8#4#F#C#F#8#9#2#B#2#2#7#9#4#2#9#9#5#9#D#C
#9#D#C#6#0#D#4#C#6#B#9#2#4#1#4#4#6#2#8#3#F#@#E#M#B#X#-
#C#L#F#T#4#.#c#d#c#.#g#o#v#>#####/#0#=#C#D#C#/#0#U#=#E#X#C#H#A#N#G#E#
#A#D#M#I#N#I#S#T#R#A#T#I#V#□####_#LZF#□è□##
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Àseøt0 ###□#□#P#V¿#U#²#U#Q###W2##;#Ã#U3#F#Y#of4μ#□W#□g#P#ðs#U#5#Æ"Bradl#ey H#pd
IhTC"#U6#i#PC{##
Àa#q#c#i ÷; '#C#D Ä99
#19v3#R

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òm&@#D"%åo&o'yµ' fàe*□(Vw(ìx)ÿ+à#°d(Vm,##° tp://,e.'G*.'á/*□/#D04¶/# 0àm(7/#w3
#.w3.#°g/T@R/REC-#²400">#c\$×3\$P%□!e#□4½16#ð<#□□#□ na#□=G ðy#□at#±# #0
ðt#,#M'V#À.A 15¼ (*À% #□ □#□q#Pum)4@\$`71s#ty#°;□71!--!
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£@##-f#De7
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°n'□e-¼1::0#àD□ À}@/□A?BC#!#D#!#D8Ph¿#pC?
D@#p\$p:03J□ý\$p6J;JQE□F`B##0üliHqI#J#::!0#pýPB\$P#K?LOM]#SN□0□yJr#pJ°UòPcQ#R/
G.ì#□T/D1J°7Ja#pJ□iUòUÑV!>ÁS<Â??
Áhp.M'□N#°#ÀlÜ,
N@_*#Pv_(wÊç#À3 #□:0#□ZibT.-#à#@'ñ.1p01/#0ZiW3#□z*ð11□d□dßG¹NC",s#q'eà#rV!a:N@nk
□_ÀsCÑ_"Hyp#□□iòa□'□eà<Â-p##?#°?□Bp!□Zi##:#À0563C1Zi8D□x'À#□8P?±:u##ðk#eiXv##?□
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kolám□954F#Àny#;q#rcE#À##]□17isÿu#<Àjð:jñ'□7°ÿ#pf¿gİh0m#ð##s°÷x2yİz08{_|
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°g]À90##`c?Ç□;e68.5ÿ#□:#fQbβb□^a□:#~#ÿV|`Â`_X#`#B□@IV!;□>P=#%q/□<İ=Ø[## g8Đ:à'□
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£<0, Pβ#□jđ##£"# v¥#9#½;#t(Pr`#@#Àx, #©§#26(P/μ¥/μrÍ>0[đ#Pf]
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B½Àÿs°ÿÖ,□ZÀp##°#□ÿ□æLE Y` Y#`#ð#□|o# #□#8□
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ÿo#:n°oq f4o o#p¶ sçç #E1oh#~RŞQ£pdÃp# :ú3Ş2 ~"iÅSod#MïoNÿk?V`Æpn#tqn×Fù
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#####Harmful Algal Bloom-related Illness Surveillance System (HABISS)NEWJuly 21, 2015Point of Contact: Amy McMillen # HYPERLINK "mailto:auh1@cdc.gov" #auh1@cdc.gov#Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases1600 Clifton Road, NE, Mailstop D76Atlanta, GA 30333Table of Contents AbstractA. Justification1. Circumstances Making Case Notification Necessary 2. Purpose and Use of Submitted Information 3. Use of Improved Information Technology and Burden Reduction4. Efforts to Identify Duplication and Use of Similar Information 5. Impact on Small Businesses or Other Small Entities6. Consequences of Less Frequent Case Notification 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 9. Explanation of Any Payment or Gift to Respondents 10. Assurance of Confidentiality Provided to Respondents11. Justification for Sensitive Questions 12. Estimates of Annualized Burden Hours and Costs 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers 14. Annualized Cost to the Government 15. Explanation for Program Changes or Adjustments 16. Plans for Tabulation and Publication and Project Time Schedule 17. Reason(s) Display of OMB Expiration Date is Inappropriate18. Exceptions to Certification for Paperwork Reduction Act Submissions# The Centers for Disease Control and Prevention (CDC) requests a three year approval for Harmful Algal Bloom-related Illness Surveillance System (HABISS). The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) is requesting 3 year approval for surveillance activities through Harmful Algal Bloom-related Illness Surveillance System (HABISS). HABISS was previously covered under OMB Control No. 0920-0004 through the National Center for Environmental Health (NCEH). Previous Harmful Algal Bloom (HAB) surveillance under HABISS ceased due to defunding. NCEZID is now managing HAB surveillance. This surveillance is now a priority under NCEZID due to the Great Lakes Restorative Initiative. A. JUSTIFICATION1.

Circumstances Making the Collection of Information NecessaryAlgal toxins from HABs include some of the most potent natural chemicals; these toxins can contaminate surface water used for recreation and drinking, as well as food sources. HABs pose a threat to both humans and animals. Human and animal illnesses from environmental exposures to HABs in fresh and marine waters have been documented in the United States. Animal illness may be an indicator of bloom toxicity; thus, it is necessary to provide a One Health approach for reporting HAB-related illnesses and events. Harmful algal blooms (HABs) are an emerging public health concern. Several outbreaks related to HABs in freshwater settings have occurred in the United States. In 2009-2010, 11 HAB-related outbreaks in fresh water settings were reported to the CDC Waterborne Disease and Outbreak Surveillance System (WBD OSS). These 11 outbreaks represent 46% of the outbreaks associated with untreated recreational water reported in 2009-2010 and 79% of HAB-related outbreaks reported to WBD OSS since 1978. At least 61 persons experienced health effects such as dermatologic, gastrointestinal, respiratory, or neurologic symptoms. In August 2014, detectable levels of microcystin, a potent HAB toxin, were detected in drinking water supply in Toledo, Ohio, resulting in a "do not drink" water advisory and an extensive emergency response. Known adverse health effects from HABs in marine waters include respiratory illness and seafood poisoning. In 2007, 15 persons were affected with respiratory illness from exposures to brevetoxins, an algal toxin, during a Florida red tide. From 2007-2011, HAB-related foodborne exposures were identified for 273 case reports of human illness through the former HABISS. Of these reports, 248 reported ciguatera fish poisoning or poisoning by other toxins in seafood, including saxitoxin and brevetoxin. Domestic animal and wildlife HAB-related illnesses have also been documented in the United States. Between 2007 and 2011, 67 cases of canine intoxication related to HAB exposure were reported to CDC as part of a 5-year project that conducted enhanced

surveillance for HABs and related illnesses in 10 states. Of the 67 canine cases, 87% of the cases reported exposure to fresh water and resulted in gastrointestinal illness, lethargy, neurological signs, or death. In 1998 a marine algal bloom along the Californian coast in Monterey Bay affected mussels, anchovies, sardines, birds, and sea lions. Over 400 sea lions died and displayed neurologic dysfunction due to poisoning of an algal toxin, domoic acid. Factors that influence the occurrence of HABs include water temperature and nutrient levels. Warm waters with abundant phosphorus and nitrogen content (e.g., from urban or agricultural run-off) are more likely to form HABs. These environments promote the growth of phytoplankton or algae that can produce toxins or otherwise cause illness in animals, people, and negatively impact the local ecology (e.g., reduced oxygen and light available for aquatic organisms) and economy (e.g., beach closures, shellfish bed closures). There is evidence that the frequency and geographic distribution of HABs is increasing as a consequence of climate change. HABISS will provide a centralized data source for public health surveillance of HAB events and HAB-related illnesses using a One Health approach. Outbreaks of human illness related to HABs may already be reported to CDC by state and territorial public health agencies within the electronic National Outbreak Reporting System (NORS) under OMB 0920-0004. However, there is currently no national surveillance for single cases of HAB-related human or animal illness. A standardized surveillance system for HABs and HAB-related illnesses is necessary to quantify and characterize HAB-related illnesses, refine case definitions, and inform One Health prevention efforts. CDC has organized a Working Group comprised of state and federal partners with expertise in HABs and illness surveillance. This Working Group has reviewed the case definitions and data elements used previously and revised them to meet current surveillance objectives. CDC is authorized to collect this data under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

2. Purpose and Use of Information Collection HABISS data elements (electronic, year-round collection) will include questions about HAB-related human cases, animal cases, and environmental events. State and territorial health department participation will be voluntary. Participating states and territories will be responsible for the collection and interpretation of these data elements at the state level and will voluntarily submit them to CDC. CDC will tabulate, analyze, and publish these data. HABISS will serve to identify and address knowledge gaps, such as a need for improved HAB-related human and animal case definitions and HAB event definitions. HABISS data will provide information about temporal and spatial trends of HAB-related illness, health risks from HABs, and will improve public health prevention and response in the United States. HABISS will also help inform existing initiatives. The Great Lakes Restoration Initiative (GLRI) will use HABISS data to inform and evaluate its work to restore and protect the Great Lakes ecosystem.

3. Use of Improved Information Technology and Burden Reduction HABISS will collect data through NORS, a password-protected, web-based surveillance platform hosted at CDC (ITSO/AHB) that is designed to support reporting to CDC from state and territorial public health departments. NORS is a shared access point for foodborne and waterborne disease outbreaks and enteric disease outbreaks involving person-to-person, animal contact, environmental contamination, and indeterminate modes of transmission (# [HYPERLINK "http://www.cdc.gov/nors/about.html"](http://www.cdc.gov/nors/about.html) #<http://www.cdc.gov/nors/about.html>).

HAB-related illnesses are primarily foodborne or waterborne and can affect individual to multiple human or animal cases. HABISS data elements will be collected within NORS as a linked system. No other such regional or national case-based system exists in the United States for reporting of HAB-related human and animal illnesses. HABISS reporting will be web-based to enable state and territorial health departments to electronically report, maintain, and have direct access to their records for HAB-related human and animal cases and HAB events. Users will have the flexibility to report cases or events, starting with the category for which they have the most information. Minimal data elements will be required (e.g. date of illness onset, state of exposure) for a record to be created. Access for reporting to HABISS will be limited to NORS account holders who have been granted access to HABISS. Similar to NORS, user access at state and territorial levels will include read-only, read-write, and administrative user accounts within their states/territories. CDC administrators

will be granted full access to manage all user accounts and records. CDC will provide user

support and training, including guidance documents that will be available electronically. Efforts to Identify Duplication and Use of Similar Information CDC staff along with the HAB Working Group (16 voluntary state partners and 7 federal partners) did not identify a similar regional or national surveillance effort in operation in the United States. Additionally, CDC is coordinating with other federal agencies to ensure that there is no duplication of data collection and plans to optimize data use through future data linkages with other federal environmental data systems. 5. Impact on Small Businesses and Other Small Entities This collection of information does not involve small businesses or other small entities. 6. Consequences of Collecting Information Less Frequently HABISS data will be collected electronically throughout the year; if data were collected less frequently, there may be missed opportunities for response and prevention efforts. Ongoing surveillance of HAB-related illnesses is expected to aid in the timely detection of events and illnesses and improve data quality. These data will also be used to determine trends across geographical boundaries, to assess morbidity and mortality, and to improve existing human and animal case definitions. 7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5 This request fully complies with the regulation 5 CFR 1320.5. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency A 60-day Federal Register Notice was published in the Federal Register on 07/21/2015, Vol 80, No. 139, pp. 43090-43091. No comments were received. Consultation outside the Agency with Federal partners has included the Agency for Toxic Substances and Disease Registry (ATSDR), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the National Oceanic and Atmospheric Administration (NOAA), the United States Geological Service (USGS), the National Park Service (NPS), and the International Joint Commission (IJC). With state public health departments, consultation has included Florida, Illinois, Indiana, Iowa, Kansas, Maryland, Massachusetts, Michigan, Minnesota, New York, Ohio, Oregon, South Carolina, Virginia, Washington, and Wisconsin. 9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents. 10. Assurance of Confidentiality Provided to Respondents HABISS will collect data on HAB-related illnesses including single human case reports, single animal case reports, and HAB environmental events from state and territorial health departments that conduct HAB surveillance and voluntarily report to HABISS. Personally identifiable information will not be collected; state and territorial health departments may collect personally identifiable information to support local or state public health activities but this information is not included in HABISS data elements. State and territorial health departments that participate in HABISS will submit electronic reports to CDC. An electronic link to HABISS-specific questions will be available within NORS, a password-protected, web-based reporting system. Access will be limited to users with an account and may be further restricted by user account type. Individual states and territories will have access to HABISS data in accordance with established data-use guidelines and the electronic user account permissions; CDC staff will have access to data according to user account permissions. System users will be required to agree to terms of use, also referred to as "Rules of Behavior." States and territories may create and manage records and enter HABISS data elements including information such as age (in years), gender, and state of exposure, county of exposure (but not county of residence), case health history, and types of clinical testing performed. Exposure activities, exposure settings, algal bloom descriptions, and signs and symptoms of illness will also be collected. These data have no personal identifiers and cannot be used to distinguish individuals. Privacy Impact Assessment Information State participation in the surveillance collection is voluntary. Personally identifiable information is not submitted to CDC; however, state and local health departments might collect and store personally identifiable information locally to support local disease control activities related to HABs. HABISS data elements will include age (in years), gender, state of exposure, county of exposure (but not county of residence), case health history, and types of clinical testing performed. Data elements related to exposure settings, exposure activities, description of blooms, and signs and symptoms will also be

collected. These data are not personally identifiable and cannot be used to recognize individuals. Data entry and data management guidance will be developed for scenarios where the county of exposure is also the county of residence. HABISS will collect data electronically from state and local government health departments. Paper forms will neither be distributed nor collected by CDC. State and territorial health departments may submit HABISS data to CDC by logging into the NORS, a secure password-protected, web-based reporting system. A link to HABISS-specific questions will be available within NORS. Access to HABISS data will be limited to users on a permission-only basis. All contractor staff working on the project at CDC will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes including the Privacy Act. IRB Approval A CDC human subjects advisor has determined that the activities considered routine surveillance activities. Consistent with current CDC policy, routine surveillance activities do not meet the regulatory definition of research, and are therefore outside the scope of IRB review requirements.¹¹ Justification for Sensitive Questions Questions regarding highly sensitive information including social security numbers and photographic identifiers will not be asked. Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. These questions will be asked in a general format, e.g., age (in years) rather than date of birth is collected. Clinical laboratory data and health illness information (signs and symptoms) are essential to proper identification and control of HAB-related illnesses and will be collected without laboratory or clinical identifiers for human cases of illness.¹² Estimates of Annualized Burden Hours and Costs A. The total burden estimate for the collection of data elements is shown in Table 1. State Epidemiologists will complete the forms. There are 57 of them and we estimate they will need to complete the forms approximately 3 times per year. Burden estimates are based on previous experience with these instruments. The total burden estimate is 57 hours. (Table 1) Table 1 □ Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State Epidemiologists	Harmful Algal Bloom-related Illness Surveillance System (HABISS) data elements (electronic, year-round)	57	3	20/60	57

Total ##### B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations □ medical and health services managers in state government (# HYPERLINK "<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>" #<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>#). Based on DOL data, an average hourly wage of \$42 is estimated. Type of Respondent # Form Name # Total Burden Hours # Hourly Wage Rate # Total Respondent Cost ## State Epidemiologist # Harmful Algal Bloom-related Illness Surveillance System (HABISS) data elements (electronic, year-round) # 57 # \$42 # \$2394 ##### 13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers There are no capital and maintenance costs incurred by respondents.¹⁴ Annualized Cost to the Government Table 14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)	Total Costs to the Federal Government
Personnel- Software development, support, and management		\$90,578	

15. Explanation for Program Changes or Adjustments This is new data collection. It previously existed in 0920-0004 but was discontinued due to funding.¹⁶

Plan for Tabulation and Publication and Project Time Schedule

Data collected through HABISS will be compiled and analyzed on an annual or biennial basis. Summary reports will be distributed within the public health community and to state and federal partners. 17.

Reason(s) Display of OMB Expiration Date is Inappropriate HABISS is considered ongoing routine surveillance through an electronic system and will perform continuous collection of data. The OMB control number for HABISS will be available to the states but not expiration dates. 18. Exceptions to Certification for Paperwork Reduction Act Submission There are no exceptions to the certification. List of Attachments Attachment A, Section 301 of the Public Health Service Act (42 USC 241) Attachment B, 60 Day Federal Register Notice Attachment C, Harmful Algal Bloom-related Illness Surveillance System (HABISS) data elements (electronic, year-round) Attachment D, IRB determination ##### PAGE

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##theme/theme/_rels/themeManager.xml.relsPK#####]###Ë
####<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<a:clrMap xmlns:a="http://schemas.openxmlformats.org/drawingml/2006/main"
bg1="lt1" tx1="dk1" bg2="lt2" tx2="dk2" accent1="accent1" accent2="accent2"
accent3="accent3" accent4="accent4" accent5="accent5" accent6="accent6"
hlink="hlink"
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#####Attachment A_ Authorizing LegislationFrom the U.S. Code
Online via GPO Access[wais.access.gpo.gov][Laws in effect as of January 3, 2005]
[Document not affected by Public Laws enacted between January 3, 2005 and
January 18, 2007][CITE: 42USC241] TITLE 42--THE PUBLIC HEALTH
AND WELFARE CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER II--GENERAL POWERS AND DUTIES Part A--Research and

Investigations Sec. 241. Research and investigations generally(a) Authority of
Secretary The Secretary shall conduct in the Service, and encourage,
cooperate with, and render assistance to other appropriate public authorities,
scientific institutions, and scientists in the conduct of, and promote the
coordination of, research, investigations, experiments, demonstrations, and
studies relating to the causes, diagnosis, treatment, control, and prevention of
physical and mental diseases and impairments of man, including water

purification, sewage treatment, and pollution of lakes and streams. In carrying
out the foregoing the Secretary is authorized to-- (1) collect and make
available through publications and other appropriate means, information as
to, and the practical application of, such research and other activities;
(2) make available research facilities of the Service to appropriate public
authorities, and to health officials and scientists engaged in special
study; (3) make grants-in-aid to universities, hospitals, laboratories,
and other public or private institutions, and to individuals for such
research projects as are recommended by the advisory council to the entity
of the Department supporting such projects and make, upon recommendation of
the advisory council to the appropriate entity of the Department, grants-in-
aid to public or nonprofit universities, hospitals, laboratories, and other
institutions for the general support of their research; (4) secure

from time to time and for such periods as he deems advisable, the assistance
and advice of experts, scholars, and consultants from the United States or
abroad; (5) for purposes of study, admit and treat at institutions,
hospitals, and stations of the Service, persons not otherwise eligible for
such treatment; (6) make available, to health officials, scientists, and
appropriate public and other nonprofit institutions and organizations,
technical advice and assistance on the application of statistical methods to
experiments, studies, and surveys in health and medical fields; (7)

enter into contracts, including contracts for research in accordance with
and subject to the provisions of law applicable to contracts entered into by
the military departments under sections 2353 and 2354 of title 10, except
that determination, approval, and certification required thereby shall be by
the Secretary of Health and Human Services; and (8) adopt, upon
recommendations of the advisory councils to the appropriate entities of the
Department or, with respect to mental health, the National Advisory Mental
Health Council, such additional means as the Secretary considers necessary
or appropriate to carry out the purposes of this section.

The Secretary may
make available to individuals and entities, for biomedical and behavioral
research, substances and living organisms. Such substances and organisms shall
be made available under such terms and conditions (including payment for them)
as the Secretary determines appropriate.(b) Testing for carcinogenicity,
teratogenicity, mutagenicity, and other harmful biological effects;
consultation (1) The Secretary shall conduct and may support through grants
and contracts studies and testing of substances for carcinogenicity,
teratogenicity, mutagenicity, and other harmful biological effects. In carrying
out this paragraph, the Secretary shall consult with entities of the Federal
Government, outside of the Department of Health and Human Services, engaged in
comparable activities. The Secretary, upon request of such an entity and under
appropriate arrangements for the payment of expenses, may conduct for such
entity studies and testing of substances for carcinogenicity, teratogenicity,
mutagenicity, and other harmful biological effects. (2)(A) The Secretary

shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts. (B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation. (3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity. (4) The Secretary shall publish a biennial report which contains-- (A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed; (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances; (C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and (D) a description of (i) each request received during the year involved-- (I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or (II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request. (5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts. (c) Diseases not significantly occurring in United States The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States. (d) Protection of privacy of individuals who are research subjects The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. (July 1, 1944, ch. 373, title III, Sec. 301, 58 Stat. 691; July 3, 1946, ch. 538, Sec. 7(a), (b), 60 Stat. 423; June 16, 1948, ch. 481, Sec. 4(e), (f), 62 Stat. 467; June 24, 1948, ch. 621, Sec. 4(e), (f), 62 Stat. 601; June 25, 1948, ch. 654, Sec. 1, 62 Stat. 1017; July 3, 1956, ch. 510, Sec. 4, 70 Stat. 490; Pub. L. 86-798, Sept. 15, 1960, 74 Stat. 1053; Pub. L. 87-838, Sec. 2, Oct. 17, 1962, 76 Stat. 1073; Pub. L. 89-115, Sec. 3, Aug. 9, 1965, 79 Stat. 448; Pub. L. 90-174, Sec. 9, Dec. 5, 1967, 81 Stat. 540; Pub. L. 91-513, title I, Sec. 3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91-515, title II, Sec. 292, Oct. 30, 1970, 84

Stat. 1308; Pub. L. 92-218, Sec. 6(a)(2), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92-423, Sec. 7(b), Sept. 19, 1972, 86 Stat. 687; Pub. L. 93-282, title I, Sec. 122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93-348, title I, Sec. 104(a)(1), July 12, 1974, 88 Stat. 346; Pub. L. 93-352, title I, Sec. 111, July 23, 1974, 88 Stat. 360; Pub. L. 94-278, title I, Sec. 111, Apr. 22, 1976, 90 Stat. 405; Pub. L. 95-622, title II, Secs. 261, 262, Nov. 9, 1978, 92 Stat. 3434; Pub. L. 96-88, title V, Sec. 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99-158, Sec. 3(a)(5), Nov. 20, 1985, 99 Stat. 879; Pub. L. 99-570, title IV, Sec. 4021(b)(2), Oct. 27, 1986, 100 Stat. 3207-124; Pub. L. 99-660, title I, Sec. 104, Nov. 14, 1986, 100 Stat. 3751; Pub. L. 100-607, title I, Sec. 163(1), (2), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 103-43, title XX, Sec. 2009, June 10, 1993, 107 Stat. 213.)

Amendments 1993--Subsec. (b)(4). Pub. L. 103-43 substituted ``a biennial report'' for ``an annual report'' in introductory provisions. 1988--Subsec. (d). Pub. L. 100-607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted ``biomedical, behavioral, clinical, or other research (including research on mental health, including'' for ``research on mental health, including'', and substituted ``drugs'' for ``drugs,''. 1986--Subsec. (a)(3). Pub. L. 99-570 struck out ``or, in the case of mental health projects, by the National Advisory Mental Health Council;'' after ``Department supporting such projects'' and struck out ``or the National Advisory Mental Health Council'' after ``appropriate entity of the Department''. Subsec. (c). Pub. L. 99-660 added subsec. (c). 1985--Subsec. (a)(3). Pub. L. 99-158, Sec. 3(a)(5)(A), substituted ``as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research'' for ``as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: Provided, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year''. Subsec. (a)(8). Pub. L. 99-158, Sec. 3(a)(5)(B), substituted ``recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers'' for ``recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems''. 1978--Pub. L. 95-622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted ``Secretary'' for ``Surgeon General'' wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b). 1976--Subsecs. (c), (h). Pub. L. 94-278 substituted ``heart, blood vessel, lung, and blood diseases and blood resources'' for ``heart diseases'' and ``National Heart, Lung and

Blood Advisory Council'' for ``National Heart and Lung Advisory Council''. 1974--Subsec. (c). Pub. L. 93-348, Sec. 104(a)(1), redesignated subsec. (d) as (c) and substituted ``research projects'' for ``research or research training projects'' in two places, ``general support of their research'' for ``general support of their research and research training programs'' and ``research grants-in-aid'' for ``research and research training program grants-in-aid''. Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out. Subsec. (d). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (e) as (d). Pub. L. 93-282 substituted ``mental health, including research on the use and effect of alcohol and other psychoactive drugs'' for ``the use and effect of drugs'' in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above. Subsecs. (e), (f). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d). Subsec. (g). Pub. L. 93-352 struck out ``during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years'' after ``Enter into contracts''. Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93-348. Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f). Subsecs. (h), (i). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively. 1972--Subsecs. (d), (i). Pub. L. 92-423 substituted ``National Heart and Lung Advisory Council'' for ``National Advisory Heart Council''. 1971--Subsecs. (d), (i). Pub. L. 92-218 substituted ``National Cancer Advisory Board'' for ``National Advisory Cancer Council''. 1970--Subsec. (d). Pub. L. 91-513 added subsec. (d). See 1988 Amendment note above. Subsec. (h). Pub. L. 91-515 substituted ``eight'' for ``five'' succeeding fiscal years. 1967--Subsec. (h). Pub. L. 90-174 substituted ``five'' for ``two'' succeeding fiscal years. 1965--Subsecs. (h), (i). Pub. L. 89-115 added subsec. (h) and redesignated former subsec. (h) as (i). 1962--Subsec. (d). Pub. L. 87-838 inserted ``or research training'' in two places. 1960--Subsec. (d). Pub. L. 86-798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health. 1956--Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h). 1948--Subsec. (d). Acts June 16, 1948, Sec. 4(e), and June 24, 1948, Sec. 4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively. Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects. Subsec. (g). Acts June 16, 1948, Sec. 4(f), and June 24, 1948, Sec. 4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively. 1946--Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health. Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.

Change of Name ``Secretary of Health and Human Services'' substituted for ``Secretary of Health, Education, and Welfare'' in subsec. (a)(7), and ``Department of Health and Human Services'' substituted for ``Department of Health, Education, and Welfare'' in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education. Effective

Date of 1978 Amendment Sections 261 and 262 of Pub. L. 95-622 provided that the amendments made by those sections are effective Oct. 1, 1978.

Effective Date of 1974 Amendment Section 104(b) of Pub. L. 93-348 provided

that: ``The amendments made by subsection (a) [amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c-1, 289g, 289k, and heading preceding section 289l of this title] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a).''

Effective Date of 1972

Amendment Amendment by Pub. L. 92-423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92-423, set out as a note under section 218 of this title.

Effective Date of 1971

Amendment Amendment by Pub. L. 92-218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92-218, set out as a note under section 218 of this title.

Coordination of Data

Surveys and Reports Pub. L. 106-113, div. B, Sec. 1000(a)(6) [title VII, Sec. 703(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A-402, provided that: ``The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health.''

Female Genital Mutilation Pub. L. 104-134,

title I, Sec. 101(d) [title V, Sec. 520], Apr. 26, 1996, 110 Stat. 1321-211, 1321-250; renumbered title I, Pub. L. 104-140, Sec. 1(a), May 2, 1996, 110 Stat. 1327, provided that: ``(a) Congress finds that-- ``(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and ``(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved. ``(b) The Secretary of Health and Human Services shall do the following: ``(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation. ``(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice. ``(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools. ``(c) For purposes of this section the term `female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major. ``(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996].''

Sentinel Disease Concept Study Section 1910 of Pub. L. 103-43 directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project. Study of Thyroid Morbidity for Hanford, Washington Section 161 of Pub. L. 100-607, as amended by Pub. L. 102-531, title III, Sec. 312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study,

to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

National Commission on Sleep Disorders Research Section 162 of Pub. L. 100-607 directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

Research With Respect to Health Resources and Services Administration Section 632 of Pub. L. 100-607 provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

Continuing Care for Psychiatric Patients in Former Clinical Research Center at National Institute on Drug Abuse Pub. L. 99-117, Sec. 10, Oct. 7, 1985, 99 Stat. 494, provided that: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [this section] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations." Analysis of Thyroid Cancer; Creation and Publication of Radioepidemiological Tables Pub. L. 97-414, Sec. 7, Jan. 4, 1983, 96 Stat. 2059, provided that: "(a) In carrying out section 301 of the Public Health Service Act [this section], the Secretary of Health and Human Services shall--

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

(4) prepare and transmit to the Congress within one year after the date of enactment of this Act [Jan. 4, 1983] a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish--

(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas

shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose. (3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.'

Termination of Advisory Committees Pub. L. 93-641, Sec. 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

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<xsd:import namespace="http://purl.org/dc/elements/1.1/"
schemaLocation="http://dublincore.org/schemas/xmls/qdc/2003/04/02/dc.xsd"/>
<xsd:import namespace="http://purl.org/dc/terms/"
schemaLocation="http://dublincore.org/schemas/xmls/qdc/2003/04/02/dcterms.xsd"/>
<xsd:element name="coreProperties" type="CT_coreProperties"/>
<xsd:complexType name="CT_coreProperties">
<xsd:all>
<xsd:element ref="dc:creator" minOccurs="0" maxOccurs="1"/>
<xsd:element ref="dcterms:created" minOccurs="0" maxOccurs="1"/>
<xsd:element ref="dc:identifier" minOccurs="0" maxOccurs="1"/>
<xsd:element name="contentType" minOccurs="0" maxOccurs="1" type="xsd:string"
ma:index="0" ma:displayName="Content Type"/>
<xsd:element ref="dc:title" minOccurs="0" maxOccurs="1" ma:index="4"
ma:displayName="Title"/>
<xsd:element ref="dc:subject" minOccurs="0" maxOccurs="1"/>
<xsd:element ref="dc:description" minOccurs="0" maxOccurs="1"/>
<xsd:element name="keywords" minOccurs="0" maxOccurs="1" type="xsd:string"/>
<xsd:element ref="dc:language" minOccurs="0" maxOccurs="1"/>
<xsd:element name="category" minOccurs="0" maxOccurs="1" type="xsd:string"/>
<xsd:element name="version" minOccurs="0" maxOccurs="1" type="xsd:string"/>
<xsd:element name="revision" minOccurs="0" maxOccurs="1" type="xsd:string">
<xsd:annotation>
<xsd:documentation>
This value indicates the number of saves or revisions.
The application is responsible for updating this value after each revision.
</xsd:documentation>
</xsd:annotation>

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</xsd:element>
<xsd:element name="lastModifiedBy" minOccurs="0" maxOccurs="1"
type="xsd:string"/>
<xsd:element ref="dcterms:modified" minOccurs="0" maxOccurs="1"/>
<xsd:element name="contentStatus" minOccurs="0" maxOccurs="1"
type="xsd:string"/>
</xsd:all>
</xsd:complexType>
</xsd:schema>
<xs:schema targetNamespace="http://schemas.microsoft.com/office/infopath/2007/
PartnerControls" elementFormDefault="qualified"
attributeFormDefault="unqualified"
xmlns:pc="http://schemas.microsoft.com/office/infopath/2007/PartnerControls"
xmlns:xs="http://www.w3.org/2001/XMLSchema">
<xs:element name="Person">
<xs:complexType>
<xs:sequence>
<xs:element ref="pc:DisplayName" minOccurs="0"/></xs:element>
<xs:element ref="pc:AccountId" minOccurs="0"/></xs:element>
<xs:element ref="pc:AccountType" minOccurs="0"/></xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="DisplayName" type="xs:string"></xs:element>
<xs:element name="AccountId" type="xs:string"></xs:element>
<xs:element name="AccountType" type="xs:string"></xs:element>
<xs:element name="BDCAssociatedEntity">
<xs:complexType>
<xs:sequence>
<xs:element ref="pc:BDCEntity" minOccurs="0" maxOccurs="unbounded"/></xs:element>
</xs:sequence>
<xs:attribute ref="pc:EntityNamespace"/></xs:attribute>
<xs:attribute ref="pc:EntityName"/></xs:attribute>
<xs:attribute ref="pc:SystemInstanceName"/></xs:attribute>
<xs:attribute ref="pc:AssociationName"/></xs:attribute>
</xs:complexType>
</xs:element>
<xs:attribute name="EntityNamespace" type="xs:string"></xs:attribute>
<xs:attribute name="EntityName" type="xs:string"></xs:attribute>
<xs:attribute name="SystemInstanceName" type="xs:string"></xs:attribute>
<xs:attribute name="AssociationName" type="xs:string"></xs:attribute>
<xs:element name="BDCEntity">
<xs:complexType>
<xs:sequence>
<xs:element ref="pc:EntityDisplayName" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityInstanceReference" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityId1" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityId2" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityId3" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityId4" minOccurs="0"/></xs:element>
<xs:element ref="pc:EntityId5" minOccurs="0"/></xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="EntityDisplayName" type="xs:string"></xs:element>
<xs:element name="EntityInstanceReference" type="xs:string"></xs:element>
<xs:element name="EntityId1" type="xs:string"></xs:element>
<xs:element name="EntityId2" type="xs:string"></xs:element>
<xs:element name="EntityId3" type="xs:string"></xs:element>
<xs:element name="EntityId4" type="xs:string"></xs:element>
<xs:element name="EntityId5" type="xs:string"></xs:element>
<xs:element name="Terms">
<xs:complexType>
<xs:sequence>

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<xs:element ref="pc:TermInfo" minOccurs="0" maxOccurs="unbounded"></xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="TermInfo">
<xs:complexType>
<xs:sequence>
<xs:element ref="pc:TermName" minOccurs="0"></xs:element>
<xs:element ref="pc:TermId" minOccurs="0"></xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="TermName" type="xs:string"></xs:element>
<xs:element name="TermId" type="xs:string"></xs:element>
</xs:schema>
</
ct:contentTypeSchema>#####
#####
#####
#####
##### ###
#####
```



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spe:Receivers>#####<?xml version="1.0" encoding="UTF-8"
standalone="no"?>
<ds:datastoreItem ds:itemID="{26B75F9F-A2F3-489F-B074-7EDBBD1D0AFF}"
xmlns:ds="http://schemas.openxmlformats.org/officeDocument/2006/customXml"><ds:s
chemaRefs><ds:schemaRef
ds:uri="http://schemas.microsoft.com/sharepoint/events"/></ds:schemaRefs></
ds:datastoreItem>#####
<?mso-contentType?><FormTemplates
xmlns="http://schemas.microsoft.com/sharepoint/v3/contenttype/forms"><Display>Do
cumentLibraryForm</Display><Edit>DocumentLibraryForm</
Edit><New>DocumentLibraryForm</New></
FormTemplates>#####<?xml version="1.0"
encoding="UTF-8" standalone="no"?>
<ds:datastoreItem ds:itemID="{AEF6E2AE-87BF-485F-9E1A-C43226E91A64}"
xmlns:ds="http://schemas.openxmlformats.org/officeDocument/2006/customXml"><ds:s
chemaRefs><ds:schemaRef
ds:uri="http://schemas.microsoft.com/sharepoint/v3/contenttype/forms"/></
ds:schemaRefs></
ds:datastoreItem>#####pÿ#
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#R#_#R#I#M#_#I#N#T#E#R#N#E#T#_#M#E#S#S#A#G#E#_#I#D#####I#s#R#e#a#d#R#e#c#e#i#p#t
#####I#s#S#i#g#n#e#d#####PR_RIM_MSG_FOLDER_IDP###x#-#m#s#-#e#x#c#h#a#n#g#e#-
#o#r#g#a#n#i#z#a#t#i#o#n#-#a#u#t#h#m#e#c#h#a#n#i#s#m#J###x#-#m#s#-
#e#x#c#h#a#n#g#e#-#o#r#g#a#n#i#z#a#t#i#o#n#-
#a#u#t#h#s#o#u#r#c#e#####PR_RIM_MESSAGE_SUBMISSION_ID ###x#-
#o#r#i#g#i#n#a#t#i#n#g#-
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