

0920-1304 National Outbreak Reporting System (NORS)

(Expiration 09/30/2023)

Non-Substantive Change Request

Program Official/Project Officer

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This is a nonmaterial/non-substantive change request for OMB Control No. 0920-1304, expiration date 9/30/2023. This ICR covers the reporting of foodborne, person-to-person, animal contact, environmental contamination other than food/water, indeterminate/unknown modes of transmission, and waterborne outbreak data from 59 sites (50 US states, the District of Columbia, five US territories, and three Freely Associated States) to the National Outbreak Reporting System (NORS).

CDC requests OMB approval to combine the two forms (Form 52.12 Waterborne Disease Transmission and Form 52.13 Foodborne, Person to Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission mode) previously approved under OMB Control No. 0920-1304 into one form (Form 52.14, Attachment A), as a non-substantive change. This change will streamline the data elements that are collected, by resulting in the utilization of one form for all reportable modes of transmission and eliminating overlapping data collection fields. All data are collected via the NORS online data entry system, and while all possible data elements are detailed in the flat data dictionary (Attachment B), reporters completing the NORS form via the online data entry system will only see applicable questions based on mode of transmission. Form 52.14 is the reference document; no data are submitted to CDC via paper copy.

The requested changes would increase the total number of estimated annualized burden hours for this information collection by 413 hours and increase the estimated cost burden by \$16,557.37. However, this increase is due primarily to updated wage estimates and an increase in the estimated number of reports that are submitted via the NORS form, and do not represent a change in the burden to respondents incurred by the form. The number of reports submitted via the NORS form are a function of outbreak activity in the United States and can fluctuate annually.

Attachments are as follows:

Form 52.14 (Attachment A)

Flat data dictionary (Attachment B)

CDC Form 52.14, National Outbreak Reporting System Form (All Modes) (Attachment A)

Description/Justification of changes: The requested changes will improve clarification and readability of the data collection instrument for outbreaks reportable to NORS, as detailed in the table below. The changes primarily consist of label changes that will improve clarity and accuracy of the data collected. Additionally, existing questions have been re-organized and moved into newly named sub-sections in order to facilitate completion of the form. These label changes and reorganizations should not impact the burden on reporters and should result in improved readability. A few sections have also been added to the form for specific modes of transmission, in order to improve outbreak surveillance by increasing data quality to inform prevention efforts. Existing questions have been moved into these newly proposed sections, and some new questions have been added to improve data collection. Specifically, the following changes are requested:

- Combine the Forms 52.12 and 52.13 into one form (52.14), to streamline data collection for all modes of transmission. This will reduce reporting burden by moving to one comprehensive NORS form for all modes of transmission, allowing for more shared variables across modes and eliminate redundancy.
- Add questions to the General Section in order to collect comprehensive data on the outbreak investigation and case exposures.
- Combine the Etiology and Isolates tables from Forms 52.12 and 52.13, in order to streamline data collection and reduce reporting burden.
- Add sub-sections to the Settings section to collect specific information on outbreaks occurring in long-term care facilities, schools, and correctional or detention facilities. These will provide setting-specific data on outbreaks

affecting vulnerable populations. Data on school outbreaks were previously collected under the Food Section on Form 52.13; these questions are now being moved to the Settings Section and will therefore not increase burden on the reporter.

- Add five questions to the Animal Contact Section. These questions would be already be collected as part of the outbreak investigation and should thus not add burden on the reporter. Additionally, three questions are being removed from this section as they have not shown to be useful.
- Add a Fungal Disease Outbreaks section to the form that includes less than ten questions. This section would provide crucial information regarding fungal disease outbreaks, for which data were not previously collected in a systematic manner. This should not affect the reporting burden as this section would only be filled out specifically for confirmed/suspected fungal disease outbreaks, and questions would be answered by the outbreak investigation.
- Update the contributing factors table within the Food Section by providing descriptions for each contributing factor and updating sources of contamination. This will provide clarification for the data collection elements, thereby eliminating the need for reference to other forms or appendices for completion of these questions, and thus potentially reducing the burden on the reporter.
- Remove the Ground Beef and Eggs sub-sections under the Food Section as these questions have not shown to be useful.
- Add a Legionella and Other Biofilm-Associated Pathogens sub-section to the Water Section. This section would add four questions to the Water Section and would provide useful information for specific biofilm-associated pathogens to prevent future illness.
- Update Waterborne outbreak contributing factors by removing options that have not been reported and replacing with options that were previously reported as write-ins. This will reduce the burden on reporters, as they can now select these options instead of writing them in.

The data collection changes are summarized in the table below. Unless denoted otherwise, questions in the 'Current Question/Item on 52.12 and/or 52.13' column appeared on both Forms 52.12 and 52.13.

| Proposed Form Changes: CDC 52.14 | | |
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| Section | Current Question/Item on 52.12 and/or 52.13 | Requested Change on 52.14 |
| General | Primary Mode of Transmission | Remove descriptive information in parentheses |
| General | Other/Unknown | Change label to 'Indeterminate/unknown' |
| General | Date of report to CDC | Remove question |
| General | | Add question: 'Date outbreak investigation began' [free text field] |
| General | Investigation Methods | Move to question to 'Outbreak Detection & Investigation Methods' |
| General | | Add question: Exposures occurred on any of the following: [Not applicable, National park, Tribal land, Other federal land] |
| General | Number of Primary Cases | Change label to 'Primary Case Counts' |
| General | | Add questions [free text fields, numeric]: For food and animal contact outbreaks, if outbreak occurred during >1 calendar year, # cases per year (by illness onset), for the following: <ul style="list-style-type: none"> • Lab-confirmed primary cases • Probable primary cases • Estimated total primary cases |
| General | Number/percent of cases aged 10-19 years | Change to 10-17 years |
| General | Number/percent of cases aged 20-49 years | Change to 18-49 years |
| General | Number/percent of cases aged 50-74 years | Split into two questions: <ul style="list-style-type: none"> • Number/percent of cases aged 50-64 years • Number/percent of cases aged 65-74 years |
| General | Sign or symptom | Change label from 'Sign or symptom' to 'Commonly reported signs or symptoms'; remove 'HUS' from list |
| General | # cases with signs or symptoms | Change label to '# cases' |
| General | Total # cases for whom information is available | Change label to '# cases with info available' |
| General | | Move questions from 'Primary case outcomes' into newly named 'Healthcare-Seeking Behaviors' section: Number of cases and number of cases with info available who [free text fields, numeric]: <ul style="list-style-type: none"> • Visited health care provider • Visited emergency department • Visited Indian Health Service or tribal facility (new question) |
| General | Primary case outcomes | Change label to 'Case Outcomes' and add 'Disseminated Infection', 'Pregnancy loss', and 'Hemolytic uremic syndrome (HUS)' (formerly in Symptoms list) |
| General | Total # of cases for whom info is available | Change label to '# cases with info available' |
| General | Shigella Questions <ul style="list-style-type: none"> • Were any confirmed, suspected, or probable case-patients immunocompromised (e.g., HIV/AIDS)? | Add new 'Case Characteristics' questions [free text fields, numeric]: Indicate how many primary case-patients who: <ul style="list-style-type: none"> • Attended or worked in a child daycare • Were experiencing homelessness |

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| | Were there any confirmed, suspected, or probable cases among men who have sex with men? | <ul style="list-style-type: none"> • Were exposed in the workplace • Were immunocompromised (from former Shigella section) • Were men who reported sexual contact with another man (MSM) (from former Shigella section) |
| General | Shigella questions: Did any case-patients report travel prior to illness onset? [Yes/No/Unknown]. If yes, was travel international, domestic, or both? [International/Domestic/Both/Unknown] | Move from deleted Shigella section to new "Travel" sub-section and change to: For environmental contamination, person-to-person, water, and indeterminate/unknown outbreaks, did any primary case-patient travel for at least one night away from the primary residence: <ul style="list-style-type: none"> • Domestically [Yes/ No/Unknown/NA] • Internationally [Yes/ No/Unknown/NA] |
| General | | Add question under "Travel": For food outbreaks, was the outbreak associated with the source case-patient (e.g., food worker) traveling internationally? [Yes/ No/Unknown/NA] |
| General | General Remarks | Move to end of form |
| General | | Add question: 'Case characteristics remarks' [free text field] |
| General | Number of secondary cases | Change label to 'Secondary Case Counts' |
| General | | Add 'Secondary Case Outcomes' questions [free text field, numeric] Number of secondary cases and number of secondary cases with info available with the following outcomes: <ul style="list-style-type: none"> • Died • Hospitalized • Hemolytic uremic syndrome (HUS) |
| General | Other CDC System IDs | Move to 'Outbreak Detection & Investigation Methods' section |
| General | Traceback section, Recall section | Combine into 'Traceback and Recall' section |
| General | Reporting Agency | Remove this sub-section and questions from the form |
| Laboratory and Environmental Investigation (newly named section) | <ul style="list-style-type: none"> • How many samples of each type were tested? (from 52.13) • Were clinical diagnostic specimens taken from persons? (from 52.12) | Combine and change to "What types of samples were tested" (no longer asking for number) and add the following questions under "Human" <ul style="list-style-type: none"> • Food Worker? [Yes/No/Unknown] • From how many persons (including food workers)? [free text field, numeric] |
| Laboratory and Environmental Investigation | <ul style="list-style-type: none"> • What were they tested for? (from 52.12) • Tested for (from 52.12) | Distinguish 'Human samples' from 'Animal, food, water, other environmental samples'; add 'Fungus/fungi' as an option. |
| Laboratory and Environmental Investigation | Test types | Change label to 'What test types were used?' and distinguish 'Human samples' from 'Animal, food, water, other environmental samples'; add 'Metagenomics' and 'Antigen or Antibody' as options. |
| Laboratory and Environmental | Was antimicrobial susceptibility testing (AST) performed? If yes, where was AST | Change to 'Did CDC NARMS perform antimicrobial susceptibility testing? [Yes/No/Unknown] |

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| Investigation | performed? If yes, were any antimicrobial resistant isolates associated with the outbreak? | |
| Laboratory and Environmental Investigation | | Add 'Waterborne Disease Outbreak Environmental Investigation' sub-section |
| Laboratory and Environmental Investigation | | Add question: Which of the following sampling locations were tested? [Select all that apply from list in Appendix E] |
| Laboratory and Environmental Investigation | | Add questions: <ul style="list-style-type: none"> • Did environmental sampling results implicate water as the primary mode of transmission? [Yes/No/Unknown] • Did the results implicate the vehicle(s) of transmission? [Yes/No/Unknown] • Did historical or other environmental health evidence implicate water as the primary mode of transmission? [Yes/No/Unknown]. If yes, please describe. [free text field] • Would you like to attach environmental sampling results to this report? [Yes/No] |
| Laboratory and Environmental Investigation | Water Testing Results, Water Quality Indicators, and Microbiology or Chemical/Toxin Analysis tables (all only on 52.12) | Combine into 'Environmental sampling results' table |
| Etiology and Isolates | | Rename 'Etiology Section' to 'Etiology and Isolates'. Etiology and Isolates tables from Forms 52.12 and 52.13 have been combined into one 'Etiology' table and one 'Isolates or Strains' table for all modes of transmission. |
| Etiology and Isolates | Serotype/genotype | Change label to 'Subtype' |
| Etiology and Isolates | Etiology confirmed or suspected | Change label to 'Outbreak etiology confirmed or suspected' |
| Etiology and Isolates | # of lab-confirmed cases | Change to 'Total # positive primary cases' and distinguish between 'Total #', '# culture-confirmed', and '# C1DT-positive only' |
| Etiology and Isolates | State lab ID/Accession ID/CaliciNet key/ PulseNet key | Separate into two questions <ul style="list-style-type: none"> • State lab: sample ID • CDC lab: sample ID |
| Etiology and Isolates | CDC PulseNet cluster code or CaliciNet outbreak number | Change label to 'CDC lab: outbreak ID' |
| Etiology and Isolates | <ul style="list-style-type: none"> • CDC PulseNet pattern designation for enzyme 1 • CDC PulseNet pattern designation for enzyme 2 | Combine questions and change label to 'PFGE pattern' |
| Etiology and Isolates | <ul style="list-style-type: none"> • CaliciNet sequenced region/whole genome sequencing ID • CaliciNet genotype/other molecular designation | Remove from Isolates table and replace with 'Sequencing information' |

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| Etiology and Isolates | Specimen type | Change label to 'Source/sample type' |
| Etiology and Isolates | Specimen subtype | Change label to 'Subtype information' |
| Settings | <ul style="list-style-type: none"> Major Setting of Exposure Other settings of Exposure | Combine into 'Setting(s) of Exposure: Animal Contact, Environmental Contamination, Food, Person-to-Person, and Indeterminate/Unknown' and 'Setting(s) of Preparation: Food' with the following questions [dropdown fields]: <ul style="list-style-type: none"> Setting 1/Major Setting Setting 2 Setting 3 Setting 4 Other (specify) Remove check box options on paper form (will appear as dropdown in online data entry portal) |
| Settings | | Add questions [free text fields]: Setting of exposure remarks, Setting of preparation remarks |
| Settings | Attack Rates for Major Setting of Exposure | Change label to 'Attack Rates' |
| Settings | Estimated exposed in major setting | Change label to 'Estimated # exposed' in Attack Rates table |
| Settings | Estimated ill in major setting | Change label to 'Estimated # ill' in Attack Rates table |
| Settings | Type of Water Exposure (only 52.12) | Change labels: 'Other water' to 'Other exposures to water, including other environmental exposures to water' and change 'Unknown water uses' to 'Undetermined exposures to water' |
| Settings | USUAL water treatment provided at venue (only on 52.12) | Change label to 'How was the water in the venue treated?' [free text field] |
| Settings | <ul style="list-style-type: none"> Venue treatment subtype (only 52.12) Water treatment subtype (only 52.12) | Combine and change label to 'Treatment description' [free text field] |
| Settings | Chlorination subtype (only 52.12) | Change label to 'What were chlorine stabilizer levels at the time of the outbreak?' [free text field] |
| Settings | <ul style="list-style-type: none"> Venue number Fill water type If public water supply, USUAL water treatment provided before coming to the venue If public water supply, fill water treatment subtype If outbreak occurred during a defined event, dates of event (all above questions only on 52.12) | Remove questions |
| Settings | | Add questions: <ul style="list-style-type: none"> System or source of the water [free text field] Was the water system/source treated to reduce or prevent the risk of disease transmission?' [free text field] If yes, how was the water in the system/source treated?' [free text field] Water setting of exposure remarks [free text |

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| Settings | | Add 'Long-term Care Outbreaks' as a sub-section with the question 'Types of care affected' [check boxes] [Nursing home/skilled nursing, Assisted living, Independent living, Intermediate care, Memory care, Other (specify)] |
| Settings | School Questions sub-section (only on 52.13) | Move to Settings (on 52.14) and change label to 'School Outbreaks' |
| Settings | School characteristics 'Total possible enrollment' | Remove question |
| Settings | Primary funding of involved schools: Public Private Unknown | Change label to 'Number of schools with public or private funding: [Public #, Private #, Unknown or undetermined #] |
| Settings | | <p>Add 'Correctional or Detention Facility Outbreaks' sub-section and the following questions:</p> <ul style="list-style-type: none"> • What was the name of the correctional/detention facility? [free text field] • Is the facility run by the government or by a privately contracted business? [Government, Private, Unknown] • What was the type of facility? [Federal prison, State prison, State/local jail, Juvenile detention center, Immigration detention center, Unknown, Other (specify)] • Who is involved in food preparation at this facility? <ul style="list-style-type: none"> o Inmate food workers [Yes/No/Unknown] o Other food workers [Yes/No/Unknown] • If contamination from a food worker was a contributing factor (also answer yes in the Food Contributing Factors section) were any of the following types of food workers implicated? <ul style="list-style-type: none"> o Inmate food workers [Yes/No/Unknown] o Other food workers [Yes/No/Unknown] |
| Animal Contact | <ul style="list-style-type: none"> • Animal Type (specify) • Settings of exposure (animal contact) • What prevention measures or recommendations were used to stop the outbreak and prevent additional infections? | Remove questions |
| Animal Contact | Did any cases have exposure to livestock or household pets that were experiencing diarrhea? | Change to 'Animals experienced diarrhea or illness that could be related to outbreak illnesses? [Yes/No/Unknown] |
| Animal Contact | | <p>Add questions:</p> <ul style="list-style-type: none"> • Animals imported to US? [Yes, country: (free text), Yes country unknown, No, Unknown] • Did the animals implicated in the outbreak meet any of the following criteria? • [Backyard/residential livestock or poultry, Commercial livestock or poultry, |

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| | | <p>Pet/companion animal, Interactive exhibit animal, Wild animal/wild game, Other (specify), Unknown]</p> <ul style="list-style-type: none"> • How many animals were involved in the outbreak? [# or Unknown] • 'How many animals died during the outbreak period of interest? [# or Unknown] • 'How many animal deaths were presumed to be the result of outbreak-associated illness? [# or Unknown] • Was the animal's living environment implicated as a source of the outbreak? [Yes/No/Unknown] • If any outbreak-associated case-patients were exposed in the workplace, specify the occupation(s) of primary cases exposed in the workplace: [Farm/dairy worker, Pet store worker, Agricultural store worker, Processing plant/slaughterhouse worker, Other (specify)] |
| Fungal Disease Outbreaks (new section) | | <p>Add 'Treatments' sub-section with the following questions [free text fields, numeric]: Number of cases and number of cases with info available (who were):</p> <ul style="list-style-type: none"> • Treated with systemic antibacterial medication before fungal infection was diagnosed • Treated with systemic antifungal medication |
| Fungal Disease Outbreaks | | <p>Add questions: Environmental samples collected [Yes/No/Unknown] and Results [free text field]</p> |
| Fungal Disease Outbreaks | | <p>Add question: 'Contributing Factors' with the following check boxes:</p> <ul style="list-style-type: none"> • Demolition, construction, or renovation • Disruption of bat droppings • Disruption of bird droppings • Disruption of plant matter • Disruption of soil • Natural disaster or phenomenon • Bats (specify) • Birds (specify) • Other (specify) • Unknown |
| Fungal Disease Outbreaks | | <p>Add 'Occupational Exposures' sub-section with the following questions:</p> <ul style="list-style-type: none"> • Specify major industry/industries [free text field] • Specify major occupations [free text field] |
| Fungal Disease Outbreaks | | <p>Add 'Personal Protective Equipment (PPE)' sub-section and questions:</p> <ul style="list-style-type: none"> • Number of cases and number of cases with info available (who) wore PPE at any time during the suspected exposure [free text fields, numeric] |

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| | | <ul style="list-style-type: none"> Specify type(s) of PPE [free text field] |
| Food | Total # of cases exposed to implicated food | Remove question |
| Food | | Add question: Type of packaging [free text field] |
| Food | Was product both produced under domestic regulatory oversight and sold? | Split into two questions: <ul style="list-style-type: none"> Was the product produced under U.S. domestic regulatory oversight? [Yes, federal, Yes, state only, No, Unknown] Was product sold under U.S. domestic regulatory oversight? [Yes, federal, Yes, state only, No, Unknown] |
| Food | Was there a kitchen manager certified in food safety at the location of preparation? | Change label to: Does the location of preparation have a certified food protection manager? [Yes/No/Unknown] <ul style="list-style-type: none"> If yes, is the certified manager on-site during all hours of operation for the location of preparation? [Yes/No/Unknown] |
| Food | <ul style="list-style-type: none"> Location where food was prepared Location of exposure Where prepared remarks Where eaten remarks | Move questions to Settings section |
| Food | <ul style="list-style-type: none"> Location where food was prepared Location of exposure (where food was eaten) | Remove check box options on paper form (will appear as dropdown in online data entry portal) |
| Food | Was food-worker implicated as the source of contamination? | Change label to: Was an infectious food worker implicated as the source of contamination?' |
| Food | Contributing Factors sub-section | Change label to 'Food Contributing Factors' |
| Food | <ul style="list-style-type: none"> Confirmed or Suspected Point of Contamination Reason suspected | Remove questions |
| Food | Contamination Factor (C1 – C15) | Change to table with questions: <ul style="list-style-type: none"> Factor code (C1 – C13) Factor (provides definition for each factor code) Source(s) [check boxes]: [Point of Final Prep/Sale, Before POS Post-Harvest, Unknown location, Before POS Pre-Harvest, Before POS Unknown Pre or Post Harvest] If no contamination source available to enter, please select reason: [N/A, Unknown, None identified] |
| Food | Proliferation/amplification factor (P1 – P12) | Change to table with questions: <ul style="list-style-type: none"> Factor code (P1 – P11) Factor (provides definition for each factor code) Source(s) [check boxes]: [Point of Final Prep/Sale, Before POS Post-Harvest, Unknown location, Before POS Pre-Harvest, Before POS Unknown Pre or Post Harvest] If no proliferation factor available to enter, select reason: [N/A, Unknown, None identified] |
| Food | Survival factor (S1 – S5) | Change to table with questions: <ul style="list-style-type: none"> Factor code (S1 – C6) |

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| | | <ul style="list-style-type: none"> Factor (provides definition for each factor code) Source(s) [check boxes]: [Point of Final Prep/Sale, Before POS Post-Harvest, Unknown location, Before POS Pre-Harvest, Before POS Unknown Pre or Post Harvest] If no survival factor available to enter, select reason: [N/A, Unknown, None identified] |
| Food | | Add question: Food Contributing Factor Remarks [free text field] |
| Food | <ul style="list-style-type: none"> Describe the preparation of the implicated item How many times has the state, county, or local health department inspected this school cafeteria or kitchen in the 12 months before the outbreak? Does the school have a HACCP plan in place for the school feeding program? Was implicated food item provided to the school through the National School Lunch/Breakfast Program? <p>(all questions formerly on 52.13 in school sub-section)</p> | Remove questions |
| Food | Ground Beef sub-section | Removed entire sub-section and all questions |
| Food | Eggs sub-section | Removed entire sub-section and all questions |
| Traceback & Recall (new section) | Source name (from General Section on 52.13) | Change label to 'Company name' |
| Traceback & Recall | Source type (from General Section on 52.13) | Change label to 'Company type' |
| Traceback & Recall | Traceback comments (from General Section on 52.13) | Change label to 'Traceback findings' |
| Traceback & Recall | | Add questions: <ul style="list-style-type: none"> What federal agencies were involved in the traceback investigation? [CDC, FDA, USDA/APHIS, USDA/FSIS, Other (specify), None] Link to official recall announcement(s) [free text field] |
| Traceback & Recall | Please check if any food or bottled water product was recalled (from General Section on 52.13) | Change label to 'Food product was recalled' [checkbox] |
| Traceback & Recall | Type of item recalled (from General Section on 52.13) | Change label to 'Exact item(s) recalled' |
| Water | | Add question: What evidence implicated the water exposure(s)? [Epidemiologic data, Clinical laboratory data, Environmental health data, Prior experience makes this a likely source] |
| Water | Were data collected from comparison groups to estimate risk? (only 52.12) | Change label to: <ul style="list-style-type: none"> Were data collected to estimate association? Add question: If yes, please provide the epidemiologic data that implicates the water exposure: [free text fields] |

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| Water | Exposure in epidemiologic investigation (only 52.12) | Change label to 'Exposure description' |
| Water | | Add questions: 'Effect measure' and 'Type of effect measure' under Supporting evidence |
| Water | <ul style="list-style-type: none"> Total # exposed, # ill exposed Total # not exposed, # ill not exposed, Odds ratio Attack rate for residents of reporting state, Attack rate for non-residents of reporting state Route of Entry Relative risk (all formerly only 52.12) | Remove questions |
| Water | 'Epidemiologic Data' sub-section (only 52.12) | Change label to 'Supporting evidence' sub-section |
| Water | | Add 'Water remarks' to Supporting evidence sub-section |
| Water | Geographic Location, Associated Events (sub-sections on 52.12) | Remove questions – questions captured in Settings section |
| Water | | Add 'Legionella and Other Biofilm-Associated Pathogens' sub-section |
| Water | | Add question: Did the outbreak occur in a facility with an of the following characteristics? [>10 stories, "Green" components, Construction in building within the last six months, Construction nearby within the last six months, Associated cooling towers, Other associated aerosolizing devices, Supplemental building disinfection system, Centralized hot water system, Other, Unknown, None] |
| Water | | <p>Add questions: Did the facility have a water management program in place at the time of the outbreak? [Yes/No/Unknown]</p> <ul style="list-style-type: none"> If yes, which of these elements did the plan include: [Multi-disciplinary water management program team, Diagram of the building's water system, Identification of control points/locations, Established control limits, Regular water parameter testing, Plan for implementing corrective action, Method of plan verification, Documentation of water management program performance and activities, Unknown, None] If yes, who designed the water management program: [Facility, Outside contractor, Public health department, Other (specify), Unknown] |
| Water | | Add questions: After the outbreak were recommendations provided to the facility to decrease the risk of Legionella or other biofilm-associated pathogen exposure? [Yes/No/Unknown/Not applicable] |

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| | | <ul style="list-style-type: none"> If yes, please select all that apply:[Flushing potable water system, Superheat potable water system, Implement secondary potable water disinfection system, Implement point of use filter(s), Hyperchlorination of potable water system, Hyperchlorination of recreational water system, Low level chlorination of potable water system, Water restrictions, Closure of an associated device, Other] |
| Water | | Add question: Were samples tested for Legionella at a laboratory participating in a national proficiency program? [Yes/No/Unknown/Not applicable] |
| Water | | Add question: Was water venue(s) inspected in the 6 months before the outbreak? [Yes/No/Unknown/Not applicable] |
| Water | | Add questions [free text fields]: Treated recreational water remarks, Untreated recreational remarks, Facility characteristic remarks, Biofilm-associated pathogen remarks, Drinking water remarks [free text field] |
| Water | Implicated Water – Recreational Water Venue Description sub-section and table (only 52.12) | Combined into “Settings of Exposure and Implicated Vehicle Description: Water” table |
| Water | <ul style="list-style-type: none"> Did the venue meet state or local recreational water quality regulations? (only 52.12) Did the venue meet Environmental Protection Agency (EPA) recreational water quality standards? (only 52.12) | Combine and change label to ‘Did the venue meet recreational water quality standards at the time of the outbreak?’ |
| Water | | Add question: Do you have microbiological water quality testing results collected in the 3 months before the outbreak? [Yes/No/Unknown] |
| Water | Was there a pool operator on the payroll with state-approved training or certification? (only 52.12) | Remove question |
| Water | Contributing factor: Primary intended use of water is by diaper/toddler-aged children (only 52.12) | Change label to ‘Water venue(s) primarily used by children ages <5 years’ |
| Water | Contributing factors (People): Heavy use by child care center groups, Operator error, Intentional contamination (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | Contributing factor: Fecal/vomit accident (only 52.12) | Change label to ‘Fecal/vomit incident in water’ |
| Water | | Add contributing factor options (Facility Design) [checkboxes]: Ventilation insufficient in indoor aquatic facility, New construction or alteration of water venue or indoor facility |
| Water | Contributing factors (Facility Design): Combined pool filtration/recirculation | Remove these contributing factor options [checkboxes] |

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| | systems led to cross-contamination, Some spray feature water bypasses filtration/treatment system and returns to feature unfiltered/untreated, No supplemental disinfection installed that would have inactivated pathogen, Water temperature >30 degrees C (only 52.12) | |
| Water | Remarks (only 52.12) | Change label to 'Other contributing factors' |
| Water | | Add the following contributing factor options (Maintenance) [checkboxes]: Chemical feed continues when no or low water in recirculation system, Disinfection inadequate or absent, Disinfection excessive, Chloramine concentration >0.4ppm, No regular scrubbing to remove slime/biofilm, No regular hot tub/spa draining, Stagnant water in hot tub/spa piping |
| Water | Contributing factors (Maintenance): Disinfectant control system malfunctioning, inadequate, or lacking, Incorrect settings on disinfectant control system, pH control system malfunctioning, inadequate, or lacking, Incorrect settings on pH control system, Supplemental disinfection system malfunctioning or inadequate, Insufficient system checks so breakdown detection delayed, No preventive equipment maintenance programs to reduce breakdowns, Ventilation insufficient for indoor aquatic facilities, Chemical handling error, Maintenance chemicals not flushed from system before opening to swimmers, Low or zero water flow combined with continuous feed of chemicals resulted in excess chemicals in water, Extensive slime/biofilm formation, Recent construction, Cyanurate level excessive, Lack of draining/cleaning, Stagnant water in spa piping was aerosolized (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | | Add the following contributing factor options (Policy and Management)[checkboxes]: No qualified operator on payroll or under contract, No qualified operator or responsible supervisor on duty during outbreak, Record keeping inadequate or absent, Water venue(s) not regulated as recreational water venue(s) |
| Water | Contributing factors (Policy and Management): No aquatics operators on payroll who have completed state/local training, Untrained/inadequately trained staff on duty, Remote monitoring system replaces on-site water quality testing, | Remove these contributing factor options [checkboxes] |

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| | Unclear communication chain for reporting problems, No or inadequate policies on good chemical handling and storage practices, No operator on duty at the time of incident, Facility falls outside aquatic health code, No shock/hyperchlorination policy (only 52.12) | |
| Water | Contributing factor (People): Staff error (only 52.12) | Remove contributing factor option [checkbox] |
| Water | Contributing factors (Swim Area Design): Malfunctioning or inadequate on-site wastewater treatment system, Poor siting/design of on-site wastewater treatment system, Sanitary sewer overflow impact, Combined sewer overflow impact, Wildlife contamination – Fish kill, Wastewater treatment plant effluent flows past swim area, Wastewater treatment plant malfunction, Sewer line break, Nearby biosolid/land application site, Contamination from agricultural chemical application, Contamination from chemical pollution not related to agricultural application, Dumping of ballast water, Tidal wash (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | Contributing factor: Wildlife contamination – Birds (only 52.12) | Change label to ‘Animal contamination: Wildlife: birds’ |
| Water | Contributing factor: Domestic animal contamination (only 52.12) | Change label to ‘Animal contamination: Domestic: Pet’ and ‘Animal contamination: Domestic: livestock’ |
| Water | Contributing factor: Wildlife contamination – Mammals (only 52.12) | Change label to ‘Animal contamination: Wildlife: Other’ and ‘Animal contamination: Other’ |
| Water | | Add the following contributing factor options (Environment)[checkboxes]: Sewage contamination: Wastewater treatment plant, sewer system, Sewage contamination: Septic tanks, Application or release of chemical |
| Water | | Add the following contributing factor options (Policy and Management)[checkboxes]: No trained beach manager on payroll or under contract, No trained beach manager on duty when initial outbreak exposure, Water venue(s) not designated and managed by state/local jurisdictions as recreational water venue(s) |
| Water | Contributing factor: No or inadequate monitoring of water quality (only 52.12) | Change label to ‘Monitoring of microbiological water quality inadequate or absent’ |
| Water | Contributing factor: Unclear communication chain for reporting problems (only 52.12) | Change label to ‘Inadequate communication to patrons of poor recreational water quality or closures’ |
| Water | Policy and Management contributing factors: No managers have completed | Remove these contributing factor options [checkboxes] |

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| | state/local required training, Untrained/inadequately trained staff on duty, Employee illness policies absent or not enforced (only 52.12) | |
| Water | Drinking Water Quality sub-section (only 52.12) | Change label to 'Drinking Water System' sub-section |
| Water | Did a problem with the source water contribute to the disease or outbreak? (only 52.12) | Change label to 'Was there a problem with the quality of the source water? [Yes/No/Unknown]' |
| Water | Source water contributing factors (only 52.12) | Change label to 'Drinking water contributing factors' |
| Water | Did a problem with the water treatment prior to entry into a house or building contribute to the disease or outbreak? (only 52.12) | Remove question |
| Water | Did a problem with the distribution system contribute to the disease or outbreak? (only 52.12) | Change label to 'Was water quality affected by a problem occurring with the water treatment or within the distribution system before entry into a building or house? [Yes/No/Unknown]' |
| Water | Did a problem occur after the water meter or outside the jurisdiction of a water utility that contributed to the disease or outbreak? (only 52.12) | Change label to 'Was water quality affected by a problem occurring after the water meter or outside the jurisdiction of a water utility? [Yes/No/Unknown]' |
| Water | Contributing factors: 'Treatment contributing factors' and 'Distribution and storage contributing factors' (only 52.12) | Combine and change label to 'Water treatment/distribution system' |
| Water | Contributing factors: Factors not under the jurisdiction of a water utility or contributing factors at the point of use (only 52.12) | Change label to 'Outside water utility jurisdiction or at point of use' |
| Water | Source water contributing factors: Sanitary sewer overflow, Combined sewer overflow, Malfunctioning on-site wastewater treatment system, Sewage treatment plant malfunction, Sewer line break, Poor siting/design of on-site wastewater treatment system, Nearby biosolid/land application site, Contamination by a chemical that the current treatment methods were not designed to remove, Seasonal variation in water quality, Low water table, Contaminated recharge water, Use of an alternate source of water by a water utility, Mixing of raw water from different sources, Water system intake failure, Intentional contamination (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | | Add contributing factor option: Wastewater contamination of drinking water source [checkbox] |
| Water | Contributing factors: Wildlife contamination – Birds Wildlife contamination – Mammals | Combine options and change label to: Wildlife contamination [checkbox] |

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| | Wildlife contamination – Fish kill (only 52.12) | |
| Water | Contributing factor: Improper construction or location of a well or spring (only 52.12) | Change label to 'Improper construction, location, or maintenance of a well or spring' |
| Water | Contributing factor: Flooding/heavy rains (only 52.12) | Change label to 'Extreme weather in area' |
| Water | Contributing factor: Inadequate filtration (only 52.12) | Change label to 'Filtration inadequate or absent in drinking water system' |
| Water | | Add contributing factor: Disinfection inadequate or absent in drinking water system [checkbox] |
| Water | Contributing factor: Aging water distribution components (only 52.12) | Change label to 'Aging or corroded water distribution components' |
| Water | Contributing factor: Low pressure or change in water pressure in the distribution system (only 52.12) | Change label to 'Low water pressure event in the distribution system' |
| Water | | Add contributing factor: Wastewater contamination after treatment [checkbox] |
| Water | Treatment contributing factors: Change in treatment process, No disinfection, Temporary interruption of disinfection, Chronically inadequate disinfection, No filtration, Deficiencies in other treatment processes, Corrosion in or leaching from pipes or storage tanks, Pipe/component failure or break, Contamination during construction or repair of pipes/components, Construction or repair of pipes/components without evidence of contamination, Operator error (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | Distribution and storage contributing factors: Cross-connection of potable and nonpotable water pipes resulting in backflow, Change in water flow direction in the distribution system, Mixing of treated water from different sources, Pipe/component failure or break, Contamination of mains during construction or repair, Construction or repair of mains without evidence of contamination, Scheduled flushing of the distribution system, Contamination of storage facility, Water temperature $\geq 30^{\circ}\text{C}$, Intentional contamination (only 52.12) | Remove these contributing factor options [checkboxes] |
| Water | Contributing factors (Not under the jurisdiction of a water utility): Legionella species in water system, Lack of backflow prevention in plumbing, Low pressure or change in water pressure in the plumbing, Change in water flow direction in the plumbing, Contamination of plumbing during construction or repair, Construction | Remove these contributing factor options [checkboxes] |

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| | or repair of plumbing without evidence of contamination, Deficiency in building/home-specific water treatment after the water meter or property line, Deficiency or contamination of equipment/devices using or distributing water, Contamination during commercial bottling, Contamination during shipping, hauling, or storage, Contamination at point of use – Tap, Contamination at point of use – Hose, Contamination at point of use – Container, bottle, or pitcher, Contamination at point of use – Unknown (only 52.12) | |
| Water | | Add the following contributing factors [checkboxes] (Outside water utility jurisdiction): Temperatures in optimal range for opportunistic plumbing pathogen growth, Disinfectant inadequate or absent in building water system, Stagnation of water in building water system, Construction in or around building, Water system components not functioning as designed, Equipment/device contamination failure, Missing or poor adherence to industry compliant water management programs |
| Water | Contamination at point of use – Commercially-bottled water (only 52.12) | Change label to ‘Contamination of commercially-bottled water at point of use’ |
| Water | | Add questions [free text fields]: <ul style="list-style-type: none"> • How did the exposure(s) to the water system/source occur? • Other exposures to water remarks |
| Water | What was the intended use for the implicated water? (only 52.12) | Remove question |
| Water | Other or Unknown Water section (only 52.12) | Change to ‘Other Exposures to Water, Including Other Environmental Exposures to Water’ and ‘Undetermined Exposures to Water’ sub-sections |
| Water | Factors Contributing to Contamination and/or Increased Exposure to Contaminated Water table | Change contributing factor types to: ‘Unknown’ ‘Cross cutting’ and ‘Other’ |
| Water | | Add the following contributing factor options under ‘Cross cutting’ [check boxes]: Missing or poor adherence to industry compliant water management programs, Presence of dirt, organic matter, or other debris in the basin or fill, Construction in or around the building, Missing or inadequate disinfectant, Lack of a written cleaning and maintenance plan/program, Temperatures in optimal range for opportunistic plumbing pathogen growth, Broken/damaged sewer pipe, Recycling of water |
| Water | | Add the following contributing factor options under ‘Other’ [check boxes]: Improper start-up or shutdown procedures, Presence of scale or |

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| | | corrosion, Damaged or missing drift eliminators, Missing or inadequate scale and corrosion inhibitors, History of recent repairs to the device, Location of device near high risk area, Intended as an ornamental fountain but utilized as an interactive fountain, Inadequate disinfection for recreational use, Inadequate filtration for recreational use, Presence of submerged lighting |
| Water | | Add question: Which water exposure(s) were suspected in the outbreak? [Treated recreational water, Untreated recreational water, Drinking water in public or individual water systems, Other exposures to water including environmental exposure to water, Specific water exposure(s) could not be identified] |
| Water | | Add question: Undetermined exposure to water remarks [free text field] |
| Water | | Add questions: Were any contributing factors documented or suspected in this outbreak investigation [Yes/No/Unknown] <ul style="list-style-type: none"> If yes, please describe the contributing factors below. [free text field] |
| Outbreak Detection & Investigation Methods (new section) | Investigation Methods sub-section | Move this sub-section to the Outbreak Detection & Investigation Methods section |
| Outbreak Detection & Investigation Methods | | Add question: Outbreak Detection – How was the outbreak initially detected? [Public complaint to health department, Routine public health surveillance interview, Notification from facility, Healthcare provider report, Notification from CDC lab system, Notification from other CDC group, Notification from other public health lab, Website or social media, Media report from news outlet, Other (specify)] |
| Outbreak Detection & Investigation Methods | Investigation Methods | Add the following options to Investigation Methods: Binomial probability assessment, Food, animal, or water investigation, Consumer purchase records [check boxes] |
| Outbreak Detection & Investigation Methods | Investigation Methods: Investigation at factory/production/treatment plant | Change label to 'Investigation at distributor, supplier, or production facilities' |
| Outbreak Detection & Investigation Methods | Investigation Methods: Environment/food/water sample testing | Change label to 'Environmental, food, water, animal, or sample testing' |
| Outbreak Detection & Investigation | Investigation Methods Food product or bottled water traceback | Remove option from Investigation Methods |

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| Methods | | |
| Outbreak Detection & Investigation Methods | | Add question: Investigation methods comments [free text field] |
| Outbreak Detection & Investigation Methods | 'Other CDC System IDs' sub-section | Change label to 'Other Linked CDC Systems' |
| Interventions (new section) | | <p>Add questions: Were any interventions recommended or implemented to help stop the outbreak? [Yes/No/Unknown]</p> <ul style="list-style-type: none"> • If no, explain why none were recommended or implemented. [free text field] • If yes, what type(s) of interventions were recommended or implemented to help stop the outbreak? [free text field] |
| Interventions | | <p>Add table for Interventions entitled 'Facility/site/venue and equipment' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> • Intervention type 'Facility/site/venue closed, Facility/site/venue closed <1 day or partially closed, Cleaning protocol modified, Facility/site/venue deep cleaned, Equipment deep cleaned, Equipment acquired adjusted repaired replaced or discarded, Facility/site/venue physically or structurally modified, Health promotion signage posted, Personal protective equipment provided by facility] • Any Point of Intervention OR Point of Exposure • Point of distribution • Point of Processing • Source |
| Interventions | | <p>Add table for Interventions entitled 'People' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> • Intervention type [Ill workers excluded, Ill workers restricted, Ill children or persons excluded, Ward(s) closed to new admissions, Visitors excluded, Asymptomatic persons' stools screened, Ill persons' stools screened, Vaccination or prophylaxis, Isolation/quarantine/cohorting, Education/training] • Any Point of Intervention OR Point of Exposure • Point of distribution • Point of Processing • Source |
| Interventions | | <p>Add table for Interventions entitled 'Animals' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> • Intervention type [Animal(s) quarantined or |

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| | | <p>movement stopped, Animal(s) relocated, Herd culled, Vaccination or prophylaxis]</p> <ul style="list-style-type: none"> Any Point of Intervention OR Point of Exposure Point of distribution Point of Processing Source |
| Interventions | | <p>Add table for Interventions entitled 'Food' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> Intervention type [Menu modified, Food preparation processes modified, Self-service discontinued, Food withdrawn (before recall), Food discarded, Food embargoed, Food source modified] Any Point of Intervention OR Point of Exposure Point of distribution Point of Processing Source |
| Interventions | | <p>Add table for Interventions entitled 'Water' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> Intervention type [Water restrictions issued, Water advisory issued, Water chemically treated, Water filtered, Water system superheated, Water system flushed] Any Point of Intervention OR Point of Exposure Point of distribution Point of Processing Source |
| Interventions | | <p>Add table for Interventions entitled 'Other' with the following questions [free text fields]:</p> <ul style="list-style-type: none"> Intervention type [Other (specify), Other (specify), Other (specify)] Any Point of Intervention OR Point of Exposure Point of distribution Point of Processing Source |
| Interventions | | <p>Add questions: Were any public communications released for this outbreak? [Yes/No/Unknown]</p> <ul style="list-style-type: none"> If yes, by what group(s)? [State/local/territorial health department, Other state/local/territorial government agency (specify), Federal government, Industry, Facility, Other (specify)] |
| Interventions | | <p>Add question: Remarks about interventions [free text field]</p> |

Burden

The estimated number of annualized burden hours is expected to increase by 413 hours, from 747 hours to 1,160 hours. This change is due to an increase in the median number of reports submitted by respondents, as estimated based on reports submitted for 2019. The frequency of response for the NORS form is dependent on outbreak activity in the United States, varies depending on the pathogen and surveillance need, and often fluctuates each year. The proposed

changes do not affect the burden per response, which was estimated based on the average time to complete the common data collection fields by multiple team members.

The proposed estimated annual cost for the NORS form is \$41,574.40. This is based on the 2020 median hourly wage of \$35.84 for an epidemiologist, as indicated on the Bureau of Labor Statistics website (<https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>). This reflects an increase of \$16,557.37 from the approved respondent cost of \$25,017.03. The increase in cost is due to the increase in median hourly wage for an epidemiologist (previously reported as \$33.49 based on 2018 data), as well as the increase in burden hours due to an estimated increase in the median number of submitted reports.

Estimates of Annualized Burden Hours

| Respondents | Form name | Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Approved burden (in hours) | Requested Burden (in hours) |
|----------------|------------|-----------------------|------------------------------------|--|----------------------------|-----------------------------|
| Epidemiologist | Form 52.14 | 59 | 59 | 20/60 | 747 | 1,160 |

Estimates of Annualized Cost Burden

| Respondents | Total Burden Hours | Hourly Wage Rate | Approved cost to respondents | Requested Respondent Cost |
|----------------|--------------------|------------------|------------------------------|---------------------------|
| Epidemiologist | 1,160 | \$35.84 | \$25,017.03 | \$41,574.40 |