HEALTH AND SENIOR SERVICES

PUBLIC HEALTH SERVICES BRANCH

Communicable Diseases

Readoption with Amendments: N.J.A.C. 8:57

Adopted Repeals: N.J.A.C. 8:57-2.6, 2.11, 3.3, 5.3, 5.15 and 5.16

Adopted New Rules: N.J.A.C. 8:57-1.2, 1.15, 8:57-1 Appendices A and B, 2.2, 2.3, 2.5, 2.8, 2.10, 8:57-2 Appendices A through G, 5.2, 5.7, 5.9, 5.14, 5.18, 8:57-5 Appendices A and B, 6.2, 6.3, 6.9, 8:57-6 Appendix, and 8.2 and 8:58-1.1, 1.2, 1.3, 1.6, 1.7 and 8:58 Appendix

Adopted Repeals and New Rules: N.J.A.C. 8:57-1.1, 2.1, 5.4, 5.5, 5.6, 5.8, 5.10, 5.11 and 5.12

Adopted Recodifications with Amendments: N.J.A.C. 8:57-1.3 as 1.5 and 3.1 and 3.2 as 8:58-1.4 and 1.5

Adopted Amendments: N.J.A.C. 8:36-18.4, 8:39-27.4, 8:43D-15.4, 8:43H-20.2, and 8:52-12.3

Proposed: April 21, 2008 at 40 N.J.R. 1962(a).

Adopted: , 2009 by _____,
Heather Howard, Commissioner, Department of Health and Senior Services (in consultation with the Public Health Council, Herbert Yardley, M.A., Chair).

Filed: , 2009, as R. 2009 d. , <u>with substantive and technical changes</u> not requiring additional public notice and

comment (see N.J.A.C. 1:30-6.3), and with proposed new rules at N.J.A.C. 8:57-1.8 pending.

Authority: N.J.S.A. 17:23A-13; 18A:61D-1 et seq., particularly N.J.S.A. 18A:61D-6, 18A:62-15, 15.1 and 15.2; 26:1A-7; 26:1A-15; 26:2-137.1; 26:4-1 et seq., particularly 26:4-2 and 4-70; 26:5C-1 et seq., particularly 26:5C-6 and 5C-20; and 30:9-57.

Effective Date: , 2009, Readoption;
, 2009, Amendments and New Rules.

Expiration Date: , 2014.

Summary of Hearing Officer Recommendations and Agency Responses:

Pursuant to N.J.S.A. 26:1A-7, the Department of Health and Senior Services (Department) convened a public hearing on the proposed readoption of N.J.A.C. 8:57, Communicable Diseases, with amendments, repeals, new rules, and recodifications. Notice of the public hearing appeared in the New Jersey Register at 40 N.J.R. 1962(a) (April 21, 2008). The Department held the public hearing on May 20, 2008, at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, New Jersey. Dr. John Brook, Managing Physician of the Communicable Disease Service, served as the hearing officer. No persons attended the hearing to comment on the Notice of Proposal. Dr. Brook recommended that the Department readopt N.J.A.C. 8:57, Communicable Diseases, with amendments, repeals, new rules, and

recodifications. Interested persons may review the record of the public hearing according to applicable law by contacting:

Department of Health and Senior Services

Communicable Disease Service

P.O. Box 369

Trenton, NJ 08625-0369.

Summary of Public Comments and Agency Responses:

In this Notice of Adoption, the Department of Health and Senior Services (Department) proceeds with the readoption of the rules at N.J.A.C. 8:57 and the adoption of the proposed amendments, repeals, new rules and recodifications, with the exception of the proposed new rules at N.J.A.C. 8:57-1.8. The Department received written comments prior to the June 20, 2008 close of the 60-day public comment period on the proposed new rules at N.J.A.C. 8:57-1.8, "Reporting of zoonotic diseases and any disease outbreaks in domestic companion animals by veterinarians, certified animal control officers, and animal facility management" from the following four commenters:

1. Richard J. Alampi, Executive Director, New Jersey Veterinary Medical Association, Hillsborough, NJ;

2. Susan Craft, Executive Director, State Agriculture Development Committee, Trenton, NJ;

3. Nancy E. Halpern, D.V.M., Director, Division of Animal Health, Department of Agriculture, Trenton, NJ; and

4. Mark Logan, V.M.D., President, Division of Consumer Affairs, State Board of Veterinary Medical Examiners, Newark, NJ.

In order to prevent N.J.A.C. 8:57 from expiring and to be able to completely consider and respond to the comments on and related to N.J.A.C. 8:57-1.8, it is necessary for the Department to proceed with this Notice of Adoption with N.J.A.C. 8:57-1.8 pending. The Department will respond to the comments on and related to N.J.A.C. 8:57-1.8 from the above commenters in a separate rulemaking that will adopt section 1.8.

The Department received written comments, about sections other than and not related to N.J.A.C. 8:57-1.8, prior to the June 20, 2008 close of the 60-day public comment period from the following:

1. Richard J. Alampi, Executive Director, New Jersey Veterinary Medical Association, Hillsborough, NJ;

2. Steven M. Marcus, M.D., Executive and Medical Director, New Jersey Poison Information and Education System, Newark, NJ;

3. Nancy E. Halpern, D.V.M., Director, Division of Animal Health, Department of Agriculture, Trenton, NJ;

4. John Sarnas, M.A., H.O., Chairman, Department of Environmental Protection, State Mosquito Control Commission, Trenton, NJ; and

5. Andrea J. Wollock, Director, State Government Affairs, Quest Diagnostics, Washington, DC.

A summary of the comments and the Department's responses follows. The number(s) in parentheses after each comment identifies the respective commenter(s) listed above that submitted comments, about sections other than and not related to N.J.A.C. 8:57-1.8.

N.J.A.C. 8:57-1.3

1. COMMENT: The commenter quotes the Department's definition of "Outbreak" and asks "what are the endemic levels of these diseases in DCA's in New Jersey?" (3)

RESPONSE: Since this is the first time that this data is being collected from veterinarians, there are no official State-wide data on current endemic levels of these diseases in New Jersey domestic companion animals (DCAs). However, the majority of the listed diseases are generally understood by veterinary public health experts to be of low to rare incidence in those species. Also, some veterinarians already report these diseases to the Department, although not required by law, and the number of reports for all the listed diseases has been less than 20 per year.

N.J.A.C. 8:57-1.5(b)

2. COMMENT: The commenter states that with global warming, Dengue could become established within the continental United States, and that the removal of Dengue from the list of reportable diseases could establish "a precedent that other, similarly quiescent but potentially fatal, vector-borne diseases" could also be removed from the list. The

commenter states that transmission of Dengue could occur in the United States without warning and in the recent past, there has been “imported human cases in the United States.” The commenter asks the Department to maintain Dengue as a reportable disease at N.J.A.C. 8:57. (4)

RESPONSE: The Department appreciates the commenter’s statements. The proposed amendments at N.J.A.C. 8:57-1.5(b) do include removing Dengue as a distinct category from the list of reportable diseases, however, Dengue would still remain reportable under the existing broader category of "arboviral diseases." N.J.A.C. 8:57-1.5(b) requires health care providers and administrators to report within 24 hours confirmed cases of the specified communicable diseases. One category of communicable diseases that must be reported is “arboviral diseases,” which includes, but is not limited to, West Nile virus, Eastern equine encephalitis, St. Louis encephalitis, Powassan encephalitis, Chikungunya, and Dengue. This broader category allows for the reporting of, and a public health response to, existing arboviruses and emerging arboviral pathogens that may become established in New Jersey in the future. It would be repetitive to keep Dengue on the list of reportable diseases as a separate category and the Department declines to make any changes on adoption.

N.J.A.C. 8:57-1.7(a)

3. COMMENT: The commenter states that her organization is “the nation’s largest independent clinical laboratory” and that her statements

are on behalf of three Quest laboratories that provide communicable disease reporting to the Department. The commenter recommends that the Department, at N.J.A.C. 8:57-1.7(a), add the following language after "health officer" to provide additional clarity, "of the jurisdiction where the person lives, or if unknown, to the local health officer in whose jurisdiction the health care provider or health care facility requesting the laboratory examination is located." (5)

RESPONSE: The Department agrees with the commenter's recommendation. In the Notice of Proposal published on April 21, 2008. at 40 N.J.R. 1962(a), the Department proposed amendments at N.J.A.C. 8:57-1.7(b) to add language that is identical to the language recommended by the commenter for addition to N.J.A.C. 8:57-1.7(a). The Department erroneously omitted the recommended language from the Notice of Proposal at N.J.A.C. 8:57-1.7(a) and will add the recommended language on adoption. This change on adoption would not increase the reporting burden of the regulated community, instead it would provide better guidance on how to determine the correct local health officer to which reports should be made, consistency in reporting, and added public health protection.

N.J.A.C. 8:57-1.7(c)

4. COMMENT: The commenter states that a laboratory does not always receive from the ordering physician all the demographic information about the patient which is mandated for inclusion in the

laboratory's report under N.J.A.C. 8:57-1.7(c). The commenter believes that the laboratory could "report on a more timely basis" if the Department revised the rule to allow the laboratory to report the demographic information only when that information is provided to the laboratory by the ordering physician. (5)

RESPONSE: The Department disagrees with the commenter's suggestion and makes no change on adoption. This requirement has been in effect for well over 30 years, and the Department believes this information is essential to ensure prompt public health follow-up to an identified communicable disease. The Department recognizes that if the physician does not initially provide the patient's demographic information when the laboratory test is ordered, the laboratory must contact the physician to obtain the information. However, the implementation of electronic recordkeeping and electronic data exchange will alleviate difficulty to the laboratory in obtaining this information and reporting it in a timely fashion to the required public health agency.

5. COMMENT: The commenter states that source of the specimen tested should only be required in the report set forth at N.J.A.C. 8:57-1.7(c) "when appropriate," based on whether the test performed can be derived from multiple body sources, such as a culture. (5)

RESPONSE: The Department disagrees with the commenter's suggestion and makes no change on adoption. Reporting the source of the laboratory specimen only when the source could be derived from more

than one source type would require the reader of the report to “guess” what the true source is when it is not reported. Laboratory tests, procedures, and specimens tested change over time, and the Department believes that it is a better standard to report the specimen source in order to ensure that there is no confusion.

N.J.A.C. 8:57-1.7(g)

6. COMMENT: The commenter recommends that the Department delete the proposed language regarding antibiogram reporting. The commenter states that the “antibiogram requirement is beyond the capability of a reference laboratory because of the high volume of cultures performed annually.” The commenter expresses concern about having to hire additional staff in order to compile and review data and complete the report, and having to upgrade computer systems to automate collection and sorting of that type of data. The commenter suggests that the Department can create its own antibiograms based on laboratory reports on reportable organisms. (5)

RESPONSE: The Department intended N.J.A.C. 8:57-1.7(g) to apply only to clinical laboratories operated by or located within hospitals licensed under N.J.A.C. 8:43G. N.J.A.C. 8:43G-14 requires each hospital to have an infection prevention program. N.J.A.C. 8:43G-14.1(b) specifies that the hospital must conduct on-going surveillance for antimicrobial resistance. The Joint Commission on Accreditation of Health Care Organizations (JCHO) recognizes the antibiogram document as a quality

assurance measure for clinical laboratories fulfilling JCHO Standard IM.8. The intended effect of N.J.A.C. 8:57-1.7(g) is to require that hospital clinical laboratories provide the Department with a copy of a document they are already creating. On adoption, the Department will amend the rule to read "A clinical laboratory director for a clinical laboratory operated by, or located within, a hospital licensed under N.J.A.C. 8:43G performing culture and sensitivity testing on isolates from human specimens shall annually report …." With this change, a "reference laboratory" would not be subject to the required reporting and would not need to hire additional staff nor upgrade computers systems to automate collection and sorting of that type of data unless the "reference laboratory" chooses to perform such testing on behalf of a hospital licensed under N.J.A.C. 8:43G and accepts the reporting responsibility as described at N.J.A.C. 8:57-1.7(g). This change, on adoption would not increase the reporting burden of the regulated community nor decrease a protection of the public, instead it would provide better guidance on which laboratories are required to submit reports that are already being created.

N.J.A.C. 8:57-1.11

7. COMMENT: The commenter states that N.J.A.C. 8:57-1.11 is completely oriented to human disease outbreaks. The commenter points to references in the rules that are "unrelated to veterinary medicine" and which indicate that this section applies to humans, such as a reference to hospitalization of the "ill person" and a reference that a health officer may

use Appendix B as guidance for isolation and quarantine procedures, which then references patient social security number, ethnicity and race. The commenter states that “NJVMA is strongly opposed to a model that would permit health officers to determine isolation and quarantine requirements on animals without the input of a veterinarian” because “health officers do not have adequate training or knowledge of domestic companion animal diseases to make such determinations without veterinary input.” The commenter believes that “this is particularly critical, as the health officer has the right to close down a facility where a zoonotic disease listed in section N.J.A.C. 8:57-1.8(a) is reported.” The commenter believes that there is a “lack of veterinary-specific approaches to isolation and quarantine” because there is a reference for health officers to view the Department’s website for model rules in establishing isolation and quarantine. The commenter asks the Department to add mandatory veterinary input to this section and to develop separate protocols for isolation and quarantine in animal facilities. (1)

8. COMMENT: The commenter states that “these guidelines are merely recommendations and are only applicable to those jurisdictions that expressly adopt them.” The commenter asks whether the Department can require a local health agency to reverse the quarantine of a veterinary hospital, when that quarantine was not recommended by the Department. (3)

references the Quarantine and Isolation Model Rules for Local Boards of Health, which as commenter three states is not required but rather is made available as guidance for local boards of health if they choose to use them. N.J.A.C. 8:57-11 does not authorize the Department or local health departments to institute isolation and quarantine of animals or "close down" veterinary hospitals and clinics or animal facilities. Pursuant to N.J.S.A. 26:13-2, the terms "isolation" and "quarantine" specifically refer to individuals or groups of human individuals and not animals. Therefore, N.J.A.C. 8:57-1.11 only applies to isolation and quarantine of persons and does not apply to animals, veterinary hospitals or clinics or animal facilities. The Department and local health departments, however, have authority to isolate or quarantine animals infected with, or suspected of, zoonotic diseases housed in licensed animal facilities but not veterinary facilities, pursuant to N.J.A.C. 8:23A-1.9(n) and N.J.S.A. 4:19-15.14. When isolation and quarantine of animals at animal facilities is appropriate, the Department's veterinary staff collaborates with local health departments, involved veterinarians and facility management to devise specific protocols for control of the disease. Each disease outbreak is unique and protocols are modified to address each situation depending on the agent suspected or diagnosed, the layout of the facility, staffing, resources and other factors.

Veterinarians currently contact and consult with the Department's veterinary staff regarding isolation, quarantine, biosecurity, and other disease control measures at veterinary hospitals and clinics. The Department's veterinary staff serves as a technical resource and distributes reference materials covering isolation, quarantine and disease control to veterinarians to support disease control efforts in their facilities.

In the event of a large scale disease outbreak, the Department, in collaboration with local health departments, may refer animals to veterinary hospitals and/or animal facilities and work with veterinarians to implement isolation and quarantine procedures appropriate for the situation. Depending on the situation, the Department may assume this role as part of a coordinated emergency response. It is not and would not be the intention of the Department to have any veterinary facility closed.

Therefore, the Department believes that the existing authority, procedures, and process with regard to isolation and quarantine of animals is sufficient for the Department and local health officers to address a zoonotic disease or a communicable disease outbreak in domestic companion animals and declines to amend N.J.A.C. 8:57-1.11 by including specific protocols for isolation and quarantine of animals. At this time, the Department does not believe it is necessary to establish separate protocols for isolation and quarantine in animal facilities beyond

those requirements established at N.J.A.C. 8:23A-1.9(f) through (i) and (l) and (n).

N.J.A.C. 8:57-1 Appendix A

9. COMMENT: The commenter states that within the test plan phase for electronic laboratory reporting (ELR), the laboratory should be sending hard copies of the public health reports rather than copies of reports that are sent to the ordering physician, because the report that is sent to the physician does not have all of the data elements required for public health reporting. (5)

RESPONSE: The Department disagrees with the commenter and makes no change on adoption. An essential component of electronic laboratory reporting is the conversion of text test results, which a human can read and understand, into numerically coded test results, which a computer can read and interpret. During the testing period referenced by the commenter, it is the Department's intention to ensure that the laboratory coded its text test results accurately. The Department will compare the coded information received electronically with the text information contained in a copy of the report the laboratory provides to the ordering physician. Once the test of the coded information is successfully completed, the Department will require the submission of only the electronic report. The commenter references a "public health report," but this is not a term defined in statute or rule, and therefore the content of such a report is not standardized among different laboratories. In the case

of commenter's laboratory, the "public health report" used to perform the required reporting of communicable diseases does not include the detail necessary to ensure that the coding of the laboratory result was performed accurately. The commenter also states that the report sent to the physician does not have all the data elements required for public health reporting. That statement may be true for some laboratories, but in the test phase referenced by the commenter, the focus of the testing is the accuracy of coding of text test results, not the completion of all data fields required for reporting.

N.J.A.C. 8:57 General

10. COMMENT: The commenter suggests that the Department "include its website url address" throughout the rules for easy reference of local health departments. (5)

RESPONSE: The Department has considered the commenter's suggestion but disagrees. The Department has already included Department web page addresses throughout N.J.A.C. 8:57, as appropriate, for the regulated community and the public to access forms, guidance documents, and other information that has been referenced in the rules. The Department does not believe it is necessary to add the Department's web page address anywhere else in N.J.A.C. 8:57 and makes no change on adoption.

N.J.A.C. 8:57-2.2(b)(2)

11. COMMENT: The commenter states that the Department should provide explicit language to ensure that laboratories that report electronically will be permitted to continue reporting in that format. The commenter requests the Department to add specific language to the description of the DHAS-43 form at Appendix B set forth at N.J.A.C. 8:57-2.2(b) stating that laboratories currently reporting electronically are not required to submit written reports. (5)

RESPONSE: The Department disagrees with the commenter's remarks. The purpose of N.J.A.C. 8:57-2.2 is to set forth in one location at the beginning of the subchapter all the documents and forms incorporated by reference within the subchapter. N.J.A.C. 8:57-2.5(a) and 2.8(a), applicable to clinical laboratories, both state that the laboratories can report the specified information to the Department using either an electronic file or the DHAS-43 form. Therefore, electronic reporting is still an option for laboratories in accordance with the Instructions for Electronic Submissions of Laboratory Results Indicative of HIV Infection at Appendix G. The Department makes no change on adoption in response to this comment.

N.J.A.C. 8:57-2.8(b)

12. COMMENT: The commenter states "most automated laboratory reporting systems must prioritize their definition for selecting which state to send a reportable result." The commenter notes that its laboratory reporting system first checks for a patient's address and only

checks for provider's address if the patient's address is unknown. The commenter states that its system would not permit reporting based on the provider's address alone. The commenter requests the Department to revise the wording at N.J.A.C. 8:57-2.8(b) to state that the laboratory shall report specimens sent to the laboratory by and "obtained from residents of New Jersey, or if unknown, from a healthcare provider or institution located in New Jersey." (5)

RESPONSE: The Department disagrees with the commenter and declines to make any change on adoption. N.J.A.C. 8:57-2.8(b) requires reporting of specimens sent from either healthcare providers or institutions located in New Jersey, or obtained from residents of New Jersey. The commenter would still meet the reporting requirement by searching for and reporting based on the address of a New Jersey resident, if that is the only option available based on the commenter's automated reporting system. The Department declines to make the commenter's suggested change because such a change would limit the option for reporting by making the use of a resident's address the primary requirement.

N.J.A.C.8:57-2.9(a)

13. COMMENT: The commenter recommends the inclusion of "provided to the testing laboratory" at N.J.A.C. 8:57-2.9(a) to ensure that laboratories receive the name and address of the person being tested so they can meet their reporting requirement. (5)

RESPONSE: The Department agrees with the language suggested by the commenter because most providers and responsible parties already send identifying information to laboratories along with the specimens to be tested in order to obtain results for patients. Accordingly, on adoption, the Department will add the commenter's suggested language at N.J.A.C. 8:57-2.9(a) to better ensure that laboratories receive the necessary information from providers and responsible parties to accurately complete their reporting requirements.

N.J.A.C.8:57-2.10(a)

14. COMMENT: The commenter states that the time requirement at N.J.A.C. 8:57-2.10(a) is in conflict with the Instructions for Submission of Positive HIV Diagnostic Specimens at Appendix F, which allows a longer submission timeframe. The commenter requests the Department to add the longer timeframe at N.J.A.C. 8:57-2.10(a). (5)

RESPONSE: The Department agrees with the commenter's request because the correct timeframe for submission and the existing practice is within one week as stated in Appendix F, which also allows laboratories to submit in less than a week if possible. Accordingly, the Department will revise N.J.A.C.8:57-2.10(a) to change "24 hours" to "within one week" for consistency of the required timeframe.

N.J.A.C. 8:57-2 Appendix F

15. COMMENT: The commenter recommends that the Division of HIV/AIDS Services accept the aliquot tubes currently being used by the

laboratory for submission of residual specimens for STARHS as referenced in Appendix F. The commenter states “the introduction of the cryogenic vial for specimen submission requires an additional pour-off, potential pour-off error and adds a safety issue concern. Allowing the laboratories the option to use their own tubes means minimum specimen handling and will not require extra labor in the laboratory.” (5)

RESPONSE: The Department agrees with the commenter’s suggestion. Cryogenic vials and vials currently being used by laboratories for specimen submission are comparable and achieve the same outcome. The Department believes it is appropriate on adoption to provide an option for specimen submission that would allow for safer handling and minimize errors and will revise Appendix F to add submission vials currently used by laboratories. Accordingly, the Department will also revise Appendix F to state the appropriate materials and procedure for specimen collection, storage and processing using cryogenic vials and vials currently used by laboratories.

N.J.A.C. 8:57-2 General

16. COMMENT: The commenter suggests that the Department should “provide a list, in addition to the organisms to report, the accompanying assays that are reportable by differentiating reportables by methods, culture sites, or serology assays—similar to the documents provided by the New York State Department of Health and the Florida Department of Health.” The commenter believes that her suggestion

would lead to more effective reporting and efficient follow-up, thereby eliminating unnecessary reports. (5)

RESPONSE: The Department appreciates the commenter's suggestion and has reviewed the information provided by the New York State Department of Health and the Florida Department of Health on HIV/AIDS reporting. The Department already provides similar information, to the information that the commenter is requesting, at the following web page http://www.state.nj.us/health/aids/laws_regs_rules.shtml. The Department believes that the information provided in the rules at N.J.A.C. 8:57-2 and on the web page already lead to "effective reporting and efficient follow-up." The Department makes no change on adoption but will continue to monitor the web page and will make changes in the future, if necessary.

N.J.A.C. 8:58

17. COMMENT: The commenter states that his comments represent his own "personal" opinion. The commenter states that he was pleased about the Department's decision to recodify N.J.A.C. 8:57-3 into its own chapter at N.J.A.C. 8:58 because the move of occupational illnesses, including occupational-related poisonings, into its own chapter provides recognition by the Department of the importance of the issue of poisonings in the workplace. However, the commenter expresses concern that by separating out occupational poisonings from non-occupational poisonings, the Department is diminishing the importance of non-

occupational forms of poisonings as they relate to public health. The commenter believes that it is odd for the Department to include "non-communicable food-related illnesses such as paralytic shellfish poisoning, ciguatera poisoning, scombroid or mushroom" under N.J.A.C. 8:57-1.6. The commenter states, "since it is desirous to uncover early evidence of terrorist activity with the use of a chemical or radiological weapon of abuse separating out and not including poisonings as reportable will now be unaddressed." The commenter describes a situation the "summer of 2002" involving "4 unusual toxicological events in one hospital intensive care unit in a short period of time." The commenter states that the "poisoning center" reported the events to the Department under N.J.A.C. 8:57-1.6 but the Department referred the issue to its "licensing side." The commenter believes that "a staff nurse" was allowed to work for "4 additional months and continued to cause the death of several more patients before the hospital reported the occurrence and there was any law enforcement activity." The commenter believes that the deaths of the patients was not reported because they were already very sick and were expected to have poor outcomes. The commenter believes that non-occupational poisonings have to be addressed especially as related to "potential terrorist acts and nosocomial events," which will potentially strengthen efforts to address medication safety. (2)

RESPONSE: In the Summary of the Department's Notice of Proposal for N.J.A.C. 8:57 and 8:58 published on April 21, 2008 at 40

N.J.R. 1962(a), the Department explained that it is appropriate to recodify N.J.A.C. 8:57-3 into its own chapter at N.J.A.C. 8:58 because "occupational and environmental diseases, injuries, and poisonings are markedly different in scope, source, and preventability than communicable diseases and therefore warrant their own chapter." The Department also recodified illnesses related to occupation and environment into its own chapter for organizational efficiency, as the Department has an entire service dedicated to occupational epidemiology and disease control. Other types of illnesses due to poisoning, including foodborne, nosocomial, and those which might represent early evidence of terrorist activity remain at N.J.A.C. 8:57 because the part of the Department that is charged with responding to those types of incidence is the Communicable Disease Service (CDS), which is also responsible for reports of communicable diseases. The Department does not believe that the recodification diminishes the importance of the reporting of these non-occupational "sentinel" events. The Department has included a new subsection at N.J.A.C. 8:57-1.6(e) which states that "health care providers and administrators shall immediately report to the Department all cases of persons who harbor or are suspected of harboring any illness or health condition that may be reasonably believed to be a potential cause of a public health emergency as set forth in the Emergency Health Powers Act, N.J.S.A. 26:13.4" to emphasize the importance of such reporting. The new subsection includes the type of chemical or radiological event with

which the commenter seems to be concerned as it relates to poisonings. The 2002 incident referenced by the commenter involved hospitalized patients who died due to medication overdoses. At the time the poison center made the report to the Department, the poison, an injectable prescription medication, was already known. An investigation into whether the patients' death could be the result of unintentional medication errors by hospital staff or the result of intentional criminal activity was already being conducted by the hospital. The report was referred to the hospital licensing part of the Department because that service evaluates hospital practices and procedures, including how medications are distributed and administered within the hospital, and that service would be best able to assist the hospital in their investigation. The police department was brought into the investigation once it became clear that the cause of death was likely to be a result of criminal activity.

Summary of Agency Initiated Changes:

1. At N.J.A.C. 8:57-1.2(b)1, the Department on adoption will correct the spelling of antimicrobial.

2. At N.J.A.C. 8:57-1.5(b), the Department on adoption will correct the spelling of Creutzfeldt-Jakob disease. This disease appears in the existing rule and the Department did not notice the spelling error until after the publication of the Notice of Proposal on April 21, 2008. (40 N.J.R. 1962(a))

3. At N.J.A.C. 8:57-1.5(b), the Department on adoption will add the word “syndrome” after Rubella, congenital to more clearly specify the infectious disease condition to be reported by using the medically correct name of the disease. This disease appears in the existing rule and the Department did not notice the error until after the publication of the Notice of Proposal on April 21, 2008. (40 N.J.R. 1962(a))

4. At N.J.A.C. 8:57-2.2, the Department on adoption will revise N.J.A.C. 8:57-2.2(d)1 to correct a typographical error in the phone number that health care providers, responsible parties or clinical laboratory directors are to use when requesting pre-addressed envelopes.

5. At N.J.A.C. 8:57-2.3, the Department on adoption will revise the definition of “Laboratory HIV results” to remove the examples including the term “polymerase chain reaction (PCR)” for the reasons set forth in 6 below and to maintain consistency with the viral load test results that are required for reporting.

6. At N.J.A.C. 8:57-2.5(a), the Department on adoption will remove the term “Polymerase Chain Reaction (PCR)” and replace that term with “HIV” to specify the viral load tests for which results must be reported to the Department. The Department makes this change on adoption because this change will more precisely reflect what laboratories and the regulated communities are already doing when they submit HIV viral load tests to the Department and will not, in practice, increase their reporting requirements. Removal of the term Polymerase Chain Reaction (PCR)

will avoid confusion to the laboratories and regulated communities since there are various types of PCR tests. By using the term “HIV viral load test,” the Department provides better clarity to the regulated community about the required reporting. By using this term the Department will be able to capture more HIV cases when investigations for follow-up are conducted, thereby impacting on the epidemic and reporting of data to the CDC. This change will further the protection of consumers by enhancing surveillance activities as well as HIV case finding. An increase in case finding along with surveillance will result in greater federal funding to the Department.

7. At N.J.A.C. 8:57-2.9(a), the Department on adoption will make a technical revision to change the word “administrator” to “responsible party,” in order to use the appropriate defined term and maintain consistency with the rest of the rule.

8. At N.J.A.C. 8:57-6.2(a)1, the Department on adoption will include the web page address for electronic retrieval of the IMM-3 form.

9. Within the Appendix to N.J.A.C. 8:58, Occupational and Environmental Disease, Injury, or Poisoning Report by Health Care Provider form, the Department on adoption will correct a typographical error within the Diagnostic Information box. Under the heading of Diagnosis, the Department will change “Pneumoconiosis, Other and Unspecific” to “Pneumoconiosis, Other and Unspecified.”

Federal Standards Statement

N.J.A.C. 8:57-1

The readoption of N.J.A.C. 8:57-1 with amendments, repeals and new rules is not adopted under the authority of, or in order to implement, comply with, or participate in, any program established under Federal law or under a State statute that incorporates or refers to Federal law, Federal standards, or Federal requirements. Therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-2

The readoption of N.J.A.C. 8:57-2 with amendments, repeals and new rules is not adopted under the authority of, or in order to implement, comply with, or participate in any program established under Federal law. N.J.S.A. 26:5C-8 is a State statute that covers disclosure requirements for the contents of a record, which contains information about a person who has, or is suspected of having, HIV or AIDS and, as applicable, allows disclosure for research purposes upon review by an Institutional Review Board constituted pursuant to 45 CFR 46.101 et seq. To the extent that N.J.A.C. 8:57-2 involves health related statistical and epidemiological monitoring of HIV and AIDS trends in New Jersey, the Department complies with Sections 304 and 306 of the Public Health Services Act, 42 U.S.C. §§242b and 242k, which establish general requirements, as applicable, for the coordination of health statistical and epidemiological activities, research, evaluations, and reporting fields, although these Federal laws do not specifically apply to HIV and AIDS. The Department

also elects to incorporate by reference in this subchapter the Centers for Disease Control and Prevention of the United States Public Health Services case definitions of HIV and AIDS available in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Report (MMWR) published on December 18, 1992 and in Volume 43 No RR-17 of the MMWR published on September 30, 1994 and updates found at www.cdc.gov/mmwr. The Department meets but does not exceed the Federal laws and standards discussed above and therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-3

N.J.A.C. 8:57-3 would be reserved for future use. The Department will discuss adopted N.J.A.C. 8:58 below.

N.J.A.C. 8:57-4

The Department is not readopting these rules or adopting the amendments under the authority of, or in order to implement, comply with, or participate in any program established under Federal law, or under a State statute that incorporates or refers to Federal law, standards, or requirements. However, in order to establish one medical standard, the Department has elected to use the recommendations of the Advisory Committee on Immunization Practices (ACIP) rather than the vaccine recommendations of other medical advisory bodies. The rules do not impose requirements which exceed the recommendations of the ACIP and therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-5

The readoption of this subchapter with amendments and repeals and new rules is not adopted under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-6

The readopted rules with amendments and adopted new rules are adopted pursuant to State statue. The readopted rules with amendments and adopted new rules do not impose standards on institutions of higher education or health care providers in New Jersey that exceed those contained in Federal guidelines as set forth by the Advisory Committee on Immunization Practices (ACIP), U.S. Public Health Service, U.S. Department of Health and Human Services, as published in the December 23, 2005 issue of Morbidity and Mortality Weekly Report, Volume 54, No. RR-16 Recommendations and Reports: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-7

The readoption of these rules is not adopted under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or

refers to Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

N.J.A.C. 8:57-8

These rules readopted with amendments and adopted new rules are not adopted under the authority of, or in order to implement, comply with, or participate in, any program established under Federal law, or under a State statute that incorporates or refers to Federal law, standards, or requirements. However, in order to establish one medical standard, the Department has elected to use the recommendations of the Advisory Committee on Immunization Practices (ACIP) rather than the vaccine recommendations of other medical advisory bodies. The rules do not impose requirements which exceed the recommendations of the ACIP and therefore, a Federal standards analysis is not required.

N.J.A.C. 8:58

The readopted rules and the adopted amendments and new rules are not adopted under the authority of or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, no Federal standards analysis is required.

Adopted Amendments to Other Rules

The Department's adopted amendments to N.J.A.C. 8:36-18.4, 8:39-27.4, 8:43D-15.4, 8:43H-20.2, and 8:52-12.3 are technical to correct citations, and are not made pursuant to the authority of or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, no Federal standards analysis is required.

Full text of the readopted rules may be found in the New Jersey Administrative Code at N.J.A.C. 8:57.

Full text of the adopted amendments, new rules and recodifications follows (additions indicated in boldface with asterisks *thus*; deletions from the proposal indicated in brackets with asterisks *[thus]*):

8:57-1.2 Incorporated documents

(a) (No change from proposal.)

(b) The Department incorporates by reference, as amended and supplemented, in this subchapter the following documents:

1. Performance Standards for *[Antimicorbial]* *Antimicrobial* Susceptibility Testing; Seventeenth Informational Supplement (M100-S17), written and published by the Clinical and Laboratory Standards Institute, which provides annual updates of the latest recommendations for detecting emerging resistance of aerobic bacteria.

i. (No change from proposal.)

2. (No change from proposal.)

8:57-1.5 Reportable communicable diseases

(a) (No change from proposal.)

(b) Health care providers and administrators shall report within 24 hours of diagnosis as set forth at N.J.A.C. 8:57-1.6 confirmed cases of the following reportable diseases:

…

[Creutzfeld-Jakob] *Creutzfeldt-Jakob* disease;

…

Rubella, congenital *syndrome*;

…

(c)-(e) (No change from proposal.)

8:57-1.7 Reporting of positive laboratory results denoting diseases

(a) A clinical laboratory director shall immediately report by telephone the information set forth at (c) below on any positive culture, test, or assay result specific for the following organisms to the local health officer *of the jurisdiction where the person lives, or if unknown, to the local health officer in whose jurisdiction the health care provider or health care facility requesting the laboratory examination is located*:

…

1.-3. (No change from proposal.)

(b)-(f) (No change from proposal.)

(g) A clinical laboratory director for a clinical laboratory *, operated by or located within a hospital licensed under N.J.A.C. 8:43G,* performing

culture and sensitivity testing on isolates from human specimens shall annually report a cumulative summary of the names of the species identified, the number of isolates tested per species, the names of antimicrobial agents tested, and the percentage of microorganisms susceptible to the antimicrobial agents tested in the manner described below:

1. - 4. (No change from proposal.)

(h) (No change from proposal.)

8:57-2.2 Incorporated documents

(a)-(c) (No change from proposal.)

(d) Completed forms shall be addressed to “Surveillance” and mailed to the Division of HIV/AIDS Services at PO Box 363, Trenton, New Jersey 08625-0363 in an envelope marked “Confidential.”

1. Health care providers, responsible parties or clinical laboratory directors may contact the Division of HIV and AIDS Services at (609) 984-*[6940]* *5940* to request pre-addressed envelopes.

(e) (No change from proposal.)

8:57-2.3 Definitions

The following words and terms, when used in this subchapter shall have the following meanings unless the context clearly indicates otherwise.

…

"Laboratory HIV results" means clinical laboratory results showing the presence of HIV or components of HIV, or laboratory results showing the presence of antibodies to HIV, or results from *viral load* laboratory tests *[conducted to measure the quantitative presence of HIV ribonucleic acid (RNA) (viral load tests), such as quantitative polymerase chain reaction (PCR) tests, or tests used only for HIV infected individuals]*.

…

8:57-2.5 Reporting HIV Infection for clinical laboratories

(a) A clinical laboratory director shall, within five working days of completion of a quantitative *[Polymerase Chain Reaction (PCR) also known as a]* *HIV* viral load test regardless of test result, or any other laboratory test, which has results indicative of infection with HIV, report in writing such results to the Department using one of the following two methods:

1.-2. (No change from proposal.)

(b) (No change from proposal.)

8:57-2.9 Testing procedures

(a) No health care provider or responsible party may direct a person to be tested for HIV, a component of HIV, or antibodies to HIV, unless the name and address of the person whose specimen is being tested is known and recorded by the health care provider or *[administrator]* *responsible party and provided to the testing laboratory*, except that the Commissioner may designate facilities which are permitted

to test for antibodies to HIV without obtaining the name and address of the person being tested.

1. (No change from proposal.)

8:57-2.10 Specimen submissions

(a) A health care provider, responsible party or clinical laboratory director shall, within *[24 hours]* *one week* of completion of a confirmatory diagnostic test indicative of HIV infection, send the residual specimen of such test to the State's Public Health and Environmental Laboratories (PHEL) except as noted in (b) below.

1.-2. (No change from proposal.)

(b) (No change from proposal.)

8:57-6.2 Incorporated documents

(a) The Department incorporates by reference in this subchapter the Annual College Immunization Status Report form (IMM-3), available in the subchapter Appendix, and through the following methods:

1. *[For electronic submission at (website to be provided upon adoption of this section)]* *Electronically at http://nj.gov/health/forms/imm-3.dot*;

2.-3. (No change from proposal.)

APPENDIX F

New Jersey Department of Health and Senior Services

Division of HIV/AIDS Services, Epidemiologic Services

Instructions for Submission of Positive HIV Diagnostic Specimens

A. Purpose

The purpose of these guidelines is to describe the procedures for the care, handling and submission of serum specimens from positive HIV diagnostic specimens. These serum specimens shall be tested using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). Results from these tests will allow the New Jersey Public Health and Environmental Laboratory (PHEL) to distinguish whether an HIV infection is recent or has been ongoing, thus allowing for the determination of incidence i.e., the number of new or recent infections in a given population.

Surplus serum from the positive HIV diagnostic specimens shall be collected *[and]* *,* frozen *[using vials and mailing labels supplied by the Division of HIV/AIDS Services (DHAS)]* *, and labeled with the laboratory assigned accession number*. Ideally, a minimum of 0.5 mls should be collected for each aliquot. The frozen serum specimen shall be sent to the PHEL for processing and testing with the STARHS.

B. Materials

The materials used for submission of specimens include:
1. Cryogenic vials - supplied by the DHAS *or standard aliquot tubes and labels used by the testing laboratory*.
2. *[Specimen labels – supplied by the DHAS. The label shall be used to identify the sample (barcode, number etc).]* *Storage boxes for vials.*
3. – 7. (No change from proposal.)

C. Specimen Collection, Storage and Processing

1. Aliquot the serum (0.5 mls per cryogenic *or standard aliquot tubes*. Use a label to identify the specimen.
2. (No change from proposal.)

D.-E. (No change from proposal.)