

Instructions for Completing the North Carolina Biological Agents Registry Reporting Form

Mail completed report and direct all correspondence to:

Office of the BT Coordinator
Epidemiology Section
NC Division of Public Health
1902 Mail Service Center
Raleigh, NC 27699-1902
(919) 733-3421

General Guidelines

Thank you for taking the time to complete this form. All information is required. Please print or type all information. An electronic version of the blank form is available on the State Epidemiology website at: <http://www.schs.state.nc.us/epi/index.html>. Also, please remember to sign and date the Compliance Certification Statement.

Required Information

1. Name of your organization and mailing address
For example: NC Division of Public Health, 1902 Mail Service Center, Raleigh, NC 27699-1902
2. Federal Employer Identification Number (EIN)
3. Name and phone number of the individual responsible for completing the reporting form.
4. Scientific name and strain of each biological agent. The list for these agents is at the end of this instruction list and is excerpted from the CDC select agents list, Appendix A, 42 C.F.R. Part 72.
5. Form of the agent : What best describes the physical form of the agent: purified genomic material, recombinant DNA, or toxin?
6. Usage code: indicate the agent use category: 1=vaccine production; 2=research purposes; 3=stock cultures for quality control; 4=other (specify).
7. Storage form code: indicate in what form the agent is stored: 1=frozen; 2=tissue culture; 3=lyophilized; 4=other (specify)
8. Specify the physical location of each agent by city and county. For example if there are 10 different agents within your organization being used at one site, then simply indicate the city and county. If the agents are located in buildings in different cities, then indicate those locations as well. You may use more than one form if needed.
9. Indicate the name and/or address of the building where the samples are maintained and the room number.

10. Specify the safety level code for each agent using the following codes:

SAFETY LEVEL CODES	
Animal Biosafety Level 2 = ABSL2	Biosafety Level 2 =BSL2
Animal Biosafety Level 3 = ABSL3	Biosafety Level 3 =BSL3
Animal Biosafety Level 4 = ABSL4	Biosafety Level 4 =BSL4
rDNA Large Animal BSL2 = NIH BL2N	rDNA BSL2 = NIH BL2
rDNA Large Animal BSL3 = NIH BL3N	rDNA BSL3 = NIH BL3
rDNA Large Animal BSL4 = NIH BL4N	rDNA BSL4 = NIH BL4
rDNA Large Scale BSL2 = NIH BL2-LS	Handled as a chemical
rDNA Large Scale BSL3 = NIH BL3-LS	Hazard = CHEM HAZ
rDNA Large Scale BSL4 = NIH BL4-LS	

11. Indicate the individual responsible for each biological agent, his/her phone number, and mailing address (if different from the organization address).
12. Compliance Certification: A representative of your organization must demonstrate by signature that the organization complies with all applicable laws, rules, and regulations regarding the safe and appropriate possession, maintenance, security, and transport of biological agents covered by the biological agent registry law of North Carolina.

Reportable Agents List

The biological agents that are reportable under North Carolina law are the select agents listed in Federal Register, 42 C.F.R. Part 72, Appendix A. The DHHS (CDC) maintains this list of select agents and it can be found at their website at:

<http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm>.

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola viruses
4. Equine morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (smallpox virus)
11. Venezuelan equine encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan equine encephalitis virus strain TC-83, yellow fever virus strain 17-D) are exempt.

Bacteria

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Coccidioides immitis

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. Clostridium perfringens epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant organisms/molecules

- Genetically modified microorganisms or genetic elements from organisms on this Appendix, shown to produce or encode for a factor associated with a disease.
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

Other restrictions

- The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Additional Exemptions

- Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.) are exempt.
- Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.