

VIRGINIA

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Tuberculosis Control Laws in Virginia

Introduction

The *Code of Virginia* was amended in 2001 to better control the spread of tuberculosis (TB) and to help reduce the occurrence of drug-resistant TB in the Commonwealth. These laws address the treatment and containment of active TB disease. This report summarizes the Virginia laws and outlines the legal responsibilities of physicians, laboratories, and directors of medical care facilities.



Role of the Division of TB Control

The Virginia Department of Health Division of TB Control acts as a liaison between the different entities involved in the implementation of the Virginia TB control laws and coordinates all actions taken under the enforcement of these laws. The Division of TB Control provides necessary guidance through these processes and should be contacted with all questions regarding the definition and implementation of the Virginia TB control laws. (Division of TB Control, 1500 East Main Street, Room 119, Richmond, VA 23219, telephone: 804-786-6251, fax: 804-371-0248, <www.vdh.state.va.us/epi/tb/>.)

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Purpose of the TB Control Laws

Virginia's TB control laws have been amended to address the need for specific and detailed TB control measures. The likely consequences of failure to deliver successful treatment are drug resistance, continued transmission of *Mycobacterium tuberculosis*, and increased morbidity and death. TB control measures are intended to:

- Identify cases of active TB disease as quickly as possible;
- Implement appropriate and immediate treatment for cases of active TB disease;
- Establish legal guidelines for TB treatment;
- Prevent the development and spread of drug-resistant TB.

To meet these goals, the Virginia TB control laws empower public health authorities to:

- Activate protocols to address the possible threat of TB to the public health;
- Provide appropriate resources to help people with active TB disease follow and complete the prescribed treatment regimen;
- Restrict the movements of individuals with active TB disease who are unable or unwilling to follow instructions and orders issued by the Virginia Department of Health and/or a private physician, in the event that prior legal measures to protect the public health have failed.

Legal and Clinical Definitions of Active TB Disease

For the purpose of effectively addressing and controlling active TB disease and protecting the public health, the legal definitions are necessarily more broad than those employed clinically.

Legal Definitions of TB (§32.1-49.1)

Active TB disease means a communicable disease caused by an airborne microorganism and characterized by either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or other definitive diagnostic test as established by the Commissioner of Health, (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear and sufficient clinical and radiographic evidence of active TB disease is present as determined by a physician licensed to practice medicine in the Commonwealth, or (iii) sufficient clinical and radiographic evidence of active TB disease as determined by the Commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing or suspected to contain tubercle bacilli is unobtainable.

Tubercle bacilli means disease-causing organisms belonging to the *M. tuberculosis* complex and includes *M. tuberculosis*, *M. bovis*, *M. africanum*, or other members as established by the Commissioner.

TB means a disease caused by tubercle bacilli.

Clinical Definition of TB

Diagnosis of active TB disease is based on history, symptoms, bacteriologic studies, radiography, physical findings, and tubercu-

lin skin test results. A diagnosis of active TB disease may be considered for any patient who has:

- A persistent cough (*i.e.*, a cough lasting for ≥ 3 weeks), or
- Other signs or symptoms compatible with active TB disease (*e.g.*, bloody sputum, night sweats, weight loss, anorexia, or fever).

Active TB disease is strongly suggested by:

- Diagnostic evaluation revealing acid-fast bacilli in sputum,
- Chest radiograph suggestive of TB, or
- Symptoms highly suggestive of TB.

Culture identification of *M. tuberculosis* in body secretions or tissues renders a definitive diagnosis of active TB disease.

Legal Definition of TB Infectiousness (§32.1-50.1.E)

Once established in a person, active TB disease shall be considered present and the patient shall be considered infectious until **both** of the following occur:

- The person has received a complete and adequate course of antituberculosis drug therapy as established by the Commissioner in accordance with guidelines developed by the American Thoracic Society and Centers for Disease Control and Prevention.
- Three successive cultures of specimens of sputum or other bodily fluid or tissue collected at intervals of no less than one week, or other definitive diagnostic test as established by the Commissioner demonstrate no viable tubercle bacilli.

or until:

- The Commissioner or his designee

determines that the clinical, laboratory, or radiographic evidence leads to a diagnosis other than active TB disease.

Clinical Definitions of TB Infectiousness

Patients who have suspected or confirmed active TB disease should be considered infectious if they a) are coughing or are undergoing cough-inducing procedures, b) have positive acid-fast bacilli sputum smears, or c) show cavitation on chest radiograph; *and* if they a) are not on chemotherapy, b) have just started chemotherapy, or c) have a poor clinical or bacteriologic response to chemotherapy.

Infectiousness appears to decline very rapidly after adequate treatment is started, but how quickly infectiousness declines varies from patient to patient. Decisions about infectiousness should be made on an individual basis.

A patient who has drug-susceptible TB can be considered non-infectious and isolation may be discontinued when all of the following conditions are met:

- The patient has received adequate treatment for 2-3 weeks.
- Symptoms have improved (*e.g.*, reduction of cough, resolution of fever).
- Three consecutive sputum specimens obtained on different days are negative by smear.

Enforcing the Virginia TB Control Laws

Virginia's TB Control Laws enable health officials to activate a series of measures of escalating authority. These measures

address individuals with active TB disease whose failure to follow treatment puts them at high risk of developing drug-resistance and of transmission to others.

- An **examination request** may be issued by the local health director.
- A **counseling order** may be issued by the local health director.
- An **outpatient treatment order** may be issued by the local health director. Any disagreement regarding the treatment plan will be resolved by the Commissioner.
- An **emergency detention order** may be issued by the Commissioner.
- While the emergency order is in effect, the Commissioner will prepare for the isolation hearing which may result in **court-ordered isolation**.

Determining which of the above measures to use must be based on a process that ensures that the needs and the rights of the patient as well as those of the public are met.

For patients undergoing inpatient treatment, the hospital or other health care facility is required to submit a treatment and discharge plan to the local health director for approval. In the case of outpatient treatment, the local health director may request to have the treatment plan submitted. (See TB Reporting and Planning)

Rights of People with Active TB Disease

- A person will not be physically forced to swallow medication.
- All warnings and orders will be in a language the person can understand.
- A person subject to a court order has the right to appeal.
- Any action (*e.g.*, a counseling order or order for treatment) will be supported by proper documentation.
- A person who cannot afford legal counsel will have it provided for him.
- Neither the Commissioner nor any health department employee shall disclose to the public the name of any person reported with active disease.

Immunity from Liability (§32.1-38)

Anyone making a report under the guidelines of Virginia's TB control laws is immune from civil liability or criminal penalty unless he or she has acted with gross negligence or malicious intent. Neither the Commis-

| Legal and Clinical Infectiousness | | |
|--|--|--|
| Evidence/Determination | Legally Infectious | Clinically Infectious |
| Clinical Suspicion Smear negative Culture negative | Yes The Commissioner may determine that this patient is considered infectious. | No |
| Clinical Suspicion Smear positive Culture pending | Yes A medical evaluation may determine that this patient is considered infectious. | Yes A medical evaluation may determine that this patient is considered infectious. |
| Smear positive Culture positive | Yes | Yes |
| Smear negative Culture positive | Yes | No |

sioner nor any health department employee will disclose the name of anyone making such a report or the name of anyone reported.

TB Reporting and Planning

Reporting Requirements for Physicians and Medical Facilities (§32.1-50)

The physician who diagnoses or treats a patient for active TB disease is required to report to the local health director or to another professional employee of the health department within 24 hours by the most rapid means available, preferably telephone or telephone transmitted facsimile. The head of a medical care facility providing inpatient or outpatient diagnosis or treatment for active TB disease also is required to make this same report.

There are three elements to this reporting process:

Initial report – to be completed when there are reasonable grounds to suspect that a person has active TB disease. This report must include the following:

- The patient's name;
- The patient's date of birth;
- The patient's gender;
- The patient's address;
- Pertinent clinical, radiographic, microbiologic, and pathologic reports, whether final or pending;
- Any information necessary to locate the patient for follow-up.

Secondary Report – to be completed simultaneously with or immediately following the initial report. It provides more detailed clinical and management information:

- Date and results of PPD test;
- Date and results of initial and follow-up chest x-rays;
- Dates and results of bacteriologic testing;
- Start date and doses of TB medications regimen;
- Date and results of drug-susceptibility testing;
- Patient's HIV status;
- Contact screening information.

Following the submission of the initial report, the local health director will request this secondary report if it was not submitted at the same time as the initial report.

Subsequent reports – to be completed

when updated information is available. These reports will provide:

- The patient's updated clinical status;
- Updated bacteriologic and radiographic results;
- An assessment of the patient's adherence to treatment;
- The name of the patient's current provider;
- The patient's current or revised regimen;
- Updated contact information for locating the patient;
- Any information required by the initial or secondary reports that was not available at the time of reporting.

Subsequent reports are required when the patient's regimen changes; the patient's clinical status changes (*e.g.*, suspected treatment failure); or the patient's treatment ceases.

For the purpose of these reports, cessation of treatment will be inferred from the following events: (§32.1-50.B)

- The patient fails to keep a scheduled appointment for treatment.
- The patient relocates without taking steps to transfer care.
- The patient discontinues care either upon or against the advice of the treating physician.

Reporting Requirements for Laboratories (§32.1-50.E)

Reporting requirements for laboratories doing business in the Commonwealth ensure that testing for antimicrobial susceptibility is completed on each initial isolate from a patient with active TB disease.

Laboratories are responsible for reporting results that are diagnostic of or are highly correlated with active TB disease, whether this testing is done in-house or is referred to an out-of-state laboratory.

Elements of Reporting for Laboratories

The reporting requirements for laboratories include the following:

- Results of cultures positive for tubercle bacilli;
- Results of smears suggestive of tubercle bacilli;
- Results of tests for antimicrobial susceptibility performed on cultures that are positive for tubercle bacilli.

To fulfill this reporting requirement, the director of the laboratory **must**:

- Report a positive smear and/or positive

culture **and do one of the following**:

- Submit a representative and viable sample of the initial culture to the Virginia Division of Consolidated Laboratory Services; or
- Submit to the local health director a report of antimicrobial drug susceptibilities performed by a laboratory certified by existing state or national agencies to perform such testing.

Note

When initially reporting a culture that is positive for tubercle bacilli, the director of the laboratory must communicate to the local health director his or her intention to file a written report in lieu of submitting a culture sample.

TB Treatment Plans: Development and Reporting (§32.1-50.1)

The physician who is treating a patient with active TB disease and the head of a medical care facility providing inpatient or outpatient treatment for active TB disease must work with the patient to develop an individualized, written plan of treatment. The treating physician or the head of the medical care facility is required to maintain written documentation of the patient's adherence to the treatment plan.

Elements of a Treatment Plan (§32.1-50.1.A)

As it is important that patient-centered programs be developed to assess each patient's needs so that therapy can be completed, this treatment plan must:

- Be tailored to the patient's medical and personal needs;
- Be maintained and updated as needed;
- Identify the method for effective treatment;
- Identify the method for prevention of transmission.

This treatment plan must specifically include:

- The patient's verified address;
- The name of the medical provider who is responsible for treatment;
- The planned course of antituberculosis drug therapy;
- The estimated date of completion of treatment;
- The means of ensuring successful

completion of treatment.

The treatment plan should be updated monthly in conjunction with consultation with the patient. This monthly review of clinical progress will evaluate the response to therapy and identify adherence problems.

Reporting Process (§32.1-50.1.B & C)

While a treatment plan should be developed for all patients with active TB disease, reporting requirements differ between outpatient and inpatient treatment programs.

For outpatient TB cases, the medical provider **may be requested** to submit the patient's written treatment plan to the local health director.

Submission of the treatment plan is **required** for all individuals receiving outpatient treatment who:

- Are HIV positive,
- Have confirmed or suspected resis-

tance to rifampin with or without resistance to any other drug,

- Have a history of relapsed TB or prior treated or untreated TB,
- Have a demonstrated history of non-adherence to a treatment regimen.

For inpatient TB cases, the medical provider **is required** to submit the patient's written treatment plan to the local health director for approval, regardless of what other factors may or may not be present (*e.g.*, HIV-positive status, drug-resistant TB, etc.). When there are changes to an inpatient's treatment plan, the revised treatment plan must be submitted to the health director.

For inpatients or inmates with newly diagnosed or not previously reported TB, the treatment plan must be submitted and approved by the health director or designee prior to discharge. For previously diagnosed inpa-

tients or inmates who are known to the health department and whose treatment plans have not changed, the health department must be notified only of the impending discharge.

Any patient (outpatient or inpatient) being started on anti-tuberculosis medications must have a treatment plan on file. The treatment plan is subject to approval by the local health director. Any disagreements between the written treatment plan and established standards of care will be addressed by the Commissioner of Health. Documentation of adherence to the treatment plan will be submitted to the local health director upon request. Any questions regarding this process should be directed to the Division of TB Control.

We thank all health professionals for your efforts to control TB and appreciate your continuing cooperation and support.

*Submitted by Venkatarama R. Koppaka, M.D., Ph.D.,
Director, Division of TB Control.*

Comparative Epidemiology of Tuberculosis Among U.S. Born TB Cases and Non-U.S. Born Cases in Virginia

Background: Tuberculosis (TB) among the foreign born has increased steadily in Virginia, now accounting for over 60% of statewide morbidity (Figure 1). From 1999 to 2000, the number of reported TB cases in the foreign born increased 17% from 158 to 185. At the same time, a decrease of 41% occurred in the US born population. In the year 2000, foreign born persons with TB came from >40 different countries and spoke at least as many languages. Their mean age was 38 years compared to 61 years for US born. This population group presents unique challenges that must be addressed to insure the eventual elimination of TB in the state.

Objectives: The purpose of this study was to develop a comprehensive epidemiologic profile of TB among non-US born persons and to identify characteristics of their diagnosis and management that distinguish them from US born persons with TB.

Methods: The Virginia Division of TB Control uses an Epi-Info database for primary collection of TB surveillance data. In this

study, case data from 621 patients from 1999 and 2000 were reviewed.

Results: Of the 621 patients, 343 were foreign born and 278 were US born. The

foreign born group was comprised of 47% Asians, 34% whites, and 19% blacks compared to 58% blacks and 42% whites in the US born group. The foreign born cases had a lower mean age (40 years vs. 58 years). Fifty-seven percent of the foreign born were male compared to 62% of the US born.

Foreign born cases were statistically significantly more likely to have extra-pulmonary disease, have a history of prior TB, have been treated using directly observed therapy (DOT), and have drug-resistant disease (Table 1). Resistance to isoniazid was significantly higher in the foreign born. Multi-drug resistant disease, however, was not significantly different among the two groups. Table 2 shows the percentage of drug-resistant cases by country of origin for the past two years.

Over time, drug resistance has increasingly been concentrated in the non-US born population. In 2000, 90% of TB drug resistance in Virginia was in the foreign born (Figure 2).

US born cases were significantly more likely to have a history of substance abuse and to be residents of long-term care

Figure 1. Tuberculosis Cases, Virginia, 1991-2000

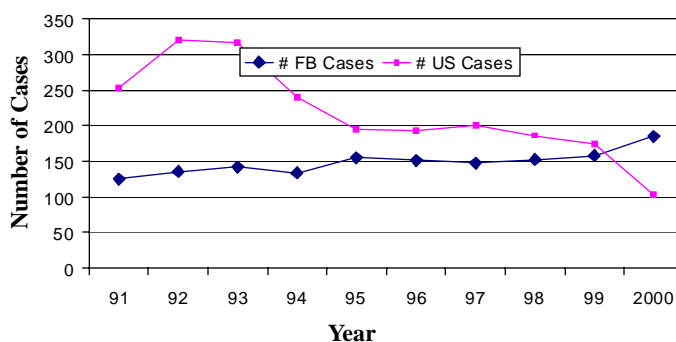
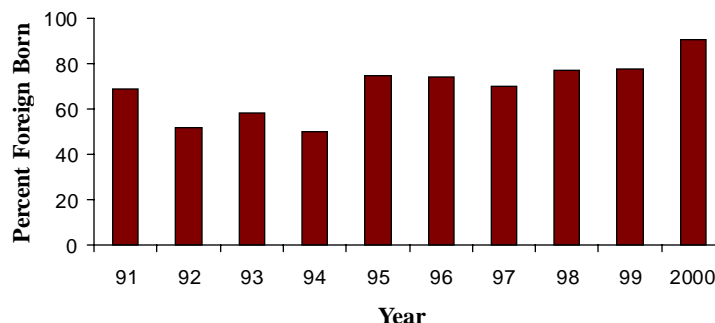


Figure 2. Percentage of Foreign Born Among Drug-Resistant TB Cases, Virginia, 1991-2000



facilities such as nursing homes, adult homes, and mental health facilities. No significant differences were found between the groups in prevalence of HIV co-infection, unemployment status, homelessness, or smear-positivity at diagnosis. (Persons with a positive smear are more likely to be infectious.) Both groups utilized the state's housing assistance program with equivalent frequency.

In addition, there were no statistically significant differences between the groups in terms of sputum conversion after 2 months of therapy or in successful completion of therapy within 12 months (Figure 3). These two indices are important measures of treatment and program success.

Conclusions: Recognizing cultural and epidemiologic differences in sub-populations and developing the tools to address these differences is critical to successful control of TB. Despite clear differences between the two population groups, completion of therapy and 2-month sputum conversion (key indicators of program effectiveness) were similar in both groups. The data suggest that our program is responding successfully to the changing epidemiology of TB in Virginia, although continued adjustment will be necessary to maintain this standard. One of these steps has already been taken. We have recently redesigned our surveillance data base to gather more detailed information on persons born outside the US. We hope to use the additional information to better serve this growing population group.

Submitted by Lex Gibson, Deputy Director, Division of TB Control.

For more information about tuberculosis, visit the Division of TB Control website: www.vdh.state.va.us/epi/tb/

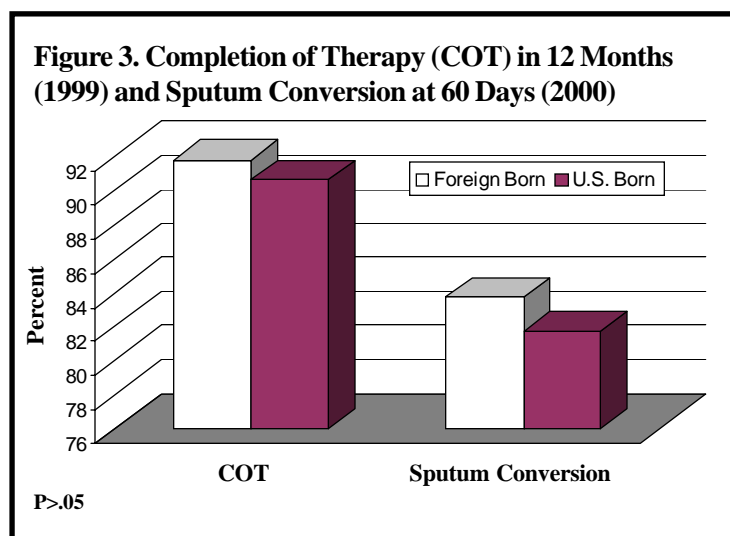


Table 1. Characteristics of TB Cases in Virginia, 1999-2000

| Characteristic | Foreign Born (n=343) Number (%) | US Born (n=278) Number (%) | p Value |
|-------------------------------------|---------------------------------|----------------------------|---------|
| Extrapulmonary disease | 99 (29) | 60 (22) | .0483 |
| Any drug resistant disease | 56 (16) | 8 (3) | <.0001 |
| Isoniazid resistance | 36 (11) | 5 (2) | <.0001 |
| Smear positivity at diagnosis | 141 (41) | 98 (35) | .1590 |
| History of prior TB disease | 33 (10) | 12 (4) | .0173 |
| HIV-coinfection | 17/212* (8) | 14/176* (8) | .8691 |
| Use of directly observed therapy | 252 (74) | 168 (60) | .0008 |
| History of substance abuse | 10 (3) | 39 (14) | <.0001 |
| Unemployment | 41 (12) | 40 (14) | .4376 |
| Homelessness | 8 (2) | 15 (5) | .0724 |
| Resident of long-term care facility | 9 (3) | 28 (10) | .0002 |
| Housing assistance program | 22/184† (12) | 13/104† (13) | .9584 |

*Not all patients were tested for HIV-coinfection.
†Data available for 2000 only.

Table 2. Drug-Resistant TB Disease Among Foreign Born in Virginia, 1999-2000

| Country | TB # Cases | Number Resistant (%) |
|-------------|------------|----------------------|
| Philippines | 42 | 8 (19) |
| Vietnam | 38 | 13 (34) |
| Ethiopia | 34 | 3 (9) |
| India | 27 | 1 (4) |
| South Korea | 19 | 3 (16) |
| Peru | 18 | 8 (44) |
| Honduras | 15 | 1 (7) |
| El Salvador | 14 | 1 (7) |
| Bolivia | 13 | 3 (23) |
| Somalia | 8 | 0 (0) |

Cases of Selected Notifiable Diseases Reported in Virginia*

Total Cases Reported, June 2001

Regions

**Total Cases Reported Statewide,
January through June**

| Disease | State | Regions | | | | | Total Cases Reported Statewide, January through June | | |
|-------------------------------------|-------|---------|----|----|-----|-----|---|-----------|----------|
| | | NW | N | SW | C | E | This Year | Last Year | 5 Yr Avg |
| AIDS | 64 | 9 | 23 | 1 | 16 | 15 | 471 | 406 | 473 |
| Campylobacteriosis | 99 | 24 | 19 | 20 | 12 | 24 | 228 | 210 | 248 |
| <i>E. coli</i> O157:H7 | 8 | 5 | 1 | 0 | 1 | 1 | 20 | 16 | 20 |
| Giardiasis | 33 | 6 | 15 | 6 | 2 | 4 | 180 | 180 | 165 |
| Gonorrhea | 884 | 23 | 53 | 78 | 233 | 497 | 4600 | 4946 | 4281 |
| Hepatitis A | 12 | 0 | 7 | 3 | 2 | 0 | 67 | 70 | 90 |
| B, acute | 22 | 1 | 3 | 3 | 8 | 7 | 76 | 74 | 62 |
| C/NANB, acute | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 7 |
| HIV Infection | 109 | 3 | 32 | 4 | 49 | 21 | 476 | 367 | 425 |
| Lead in Children[†] | 57 | 4 | 7 | 10 | 22 | 14 | 275 | 225 | 247 |
| Legionellosis | 1 | 0 | 0 | 0 | 0 | 1 | 7 | 8 | 10 |
| Lyme Disease | 26 | 3 | 14 | 1 | 3 | 5 | 53 | 37 | 17 |
| Measles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Meningococcal Infection | 4 | 0 | 0 | 2 | 1 | 1 | 25 | 29 | 29 |
| Mumps | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 5 | 5 |
| Pertussis | 2 | 2 | 0 | 0 | 0 | 0 | 12 | 21 | 17 |
| Rabies in Animals | 50 | 7 | 8 | 9 | 11 | 15 | 218 | 312 | 294 |
| Rocky Mountain Spotted Fever | 3 | 0 | 0 | 0 | 2 | 1 | 3 | 1 | 3 |
| Rubella | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Salmonellosis | 115 | 12 | 43 | 17 | 23 | 20 | 500 | 347 | 406 |
| Shigellosis | 39 | 1 | 10 | 6 | 5 | 17 | 93 | 157 | 150 |
| Syphilis, Early[§] | 23 | 1 | 1 | 0 | 7 | 14 | 141 | 153 | 278 |
| Tuberculosis | 21 | 3 | 7 | 0 | 11 | 0 | 120 | 130 | 160 |

Localities Reporting Animal Rabies This Month: Accomack 1 fox, 2 raccoons; Albemarle 1 raccoon; Augusta 1 raccoon; Bedford 1 raccoon; Botetourt 1 raccoon; Charlotte 1 fox; Fairfax 2 foxes, 5 raccoons; Fauquier 1 raccoon; Floyd 1 raccoon, 1 skunk; Frederick 1 raccoon; Gloucester 1 cat; Halifax 1 raccoon; Hampton 1 raccoon; Hanover 1 bat, 1 skunk; Hopewell 1 raccoon; James City 1 fox, 1 raccoon; Loudoun 1 raccoon; Lunenburg 1 raccoon; New Kent 1 cat; Northampton 2 raccoons; Pittsylvania 2 raccoons; Powhatan 1 raccoon; Prince George 2 raccoons; Pulaski 1 fox; Richmond City 1 bat; Rockbridge 1 raccoon; Rockingham 1 raccoon; Russell 1 skunk; Southampton 1 raccoon; Stafford 1 cat; Tazewell 1 skunk; Virginia Beach 3 raccoons; York 1 fox, 1 raccoon.

Toxic Substance-related Illnesses: Asbestosis 35; Cadmium Exposure 1; Lead Exposure 11; Pneumoconiosis 3.

*Data for 2001 are provisional. †Elevated blood lead levels $\geq 10\mu\text{g/dL}$.

§Includes primary, secondary, and early latent.

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