

INFORMATION ON THE DOE FORMER BERYLLIUM VENDOR MEDICAL SURVEILLANCE PROGRAM

What is the purpose of the DOE Former Beryllium Vendor Medical Surveillance Program?

The main purpose of this surveillance program is to determine for former workers whether or not they may have become sensitized to beryllium and are at an elevated risk for chronic beryllium disease. If the former worker is found to be sensitized to beryllium, they will be referred to the Department of Labor to determine their benefit status for further medical evaluation.

What is the Beryllium Lymphocyte Proliferation Test (Be-LPT)?

In the Be-LPT, disease-fighting blood cells that are normally found in the body, called lymphocytes, are examined in the laboratory and separated from your other blood cells. Beryllium and other test agents are then added to small groups of these lymphocytes. If these lymphocytes react to the beryllium in a specific way, the test results are "abnormal." If they do not react to beryllium, the test is "normal."

Experts believe that the Be-LPT shows abnormal results in individuals who have become "sensitized" or "allergic" to beryllium. It is unclear what this sensitization means. Studies have shown it to be an early sign of CBD in many individuals. In others, sensitization might simply mean that the person was exposed to beryllium and that his or her body has reacted. It might mean that an individual is more likely than others to get CBD. You are being offered the Be-LPT because doctors believe it is useful in detecting cases of CBD early or cases that might otherwise be missed or diagnosed as another type of lung problem. Once CBD is identified, doctors can determine the treatment that is needed to minimize the lung damage that CBD causes.

As in any other medical test, the Be-LPT sometimes fails or provides unclear results. The laboratory calls these results "uninterpretable." Even when the test appears successful, it may appear abnormal when a person is not sensitized or allergic to beryllium. This is called a "false abnormal" result. It is also possible that the test will show "normal" results when a person is actually "sensitized" to beryllium. This is a "false normal" result. If you have an "uninterpretable" or borderline abnormal blood Be-LPT result, you may be asked to provide another blood sample so the test can be repeated. A repeat test may be offered to confirm an abnormal test result. If you have two "abnormal" tests in a row, you may want to consider further medical tests to confirm or rule out CBD. **Remember that you may refuse further tests at this point or at any point during your medical evaluations.**

If your Be-LPT is "abnormal," future testing may be covered by the Department of Labor Energy Employees Occupational Illness Compensation Program Act of 2000 (DOL EEOICPA), and ORISE staff will make sure you have the information you need to apply for these benefits.

Do I have to have the Be-LPT done?

No. Your participation in the medical surveillance program is strictly voluntary. You may refuse any of the tests offered to you, including the Be-LPT. If you change your mind, you are

free to participate further in the program at any time. Talking with your family, your doctor, or other people you trust may help you decide. Health professionals in the clinic that provide the tests can also help answer any questions that you might have.

What will happen if I decide to have the Be-LPT blood test?

A small amount of your blood (about 2-4 Tablespoons) will be drawn from a vein in your arm and sent to one or two laboratories. There is little physical risk in drawing blood. Slight pain and bruising may occur in a few individuals. Rarely, a needle puncture may become infected. A chest x-ray may also be offered when you have the Be-LPT, if you are experiencing any symptoms that may be related to CBD.

When will I receive the results of my Be-LPT blood test?

It could take 6 to 8 weeks for you to receive a letter informing you of your test results. The test itself usually takes 8 days to perform. The testing laboratory reports results to the ORISE physician who will notify you.

If my Be-LPT results show that I am not sensitized to beryllium, is my testing finished?

This is a good question. A small percentage of workers who have normal test results will be found to have abnormal results on their second or third test. In some cases a worker who is no longer working with beryllium and no longer actively exposed to beryllium may develop the sensitization many years later. If you have had a normal test and develop concerns about having chronic beryllium disease symptoms or a respiratory condition that your physician cannot diagnose, we will offer you retesting if funding is still available.

Could an abnormal Be-LPT affect my work with beryllium in the future?

If you are found to have a consistently abnormal Be-LPT or if you have CBD, it is advisable to stay away from environments where beryllium may be present. If you return to work at a DOE site, a federal regulation requires that the results of beryllium sensitization and disease testing be transferred to your regular site medical file. This may directly affect your right to work with beryllium at a DOE site. Also, the chance of loss of confidentiality of this information may be higher once the test results are transferred to your medical file.

What will happen to the records of the medical examination results?

Your test results will be treated as DOE-owned, confidential medical records (to be maintained for 75 years after your last examination) and used or disclosed only as provided by the Privacy Act of 1974, the Americans with Disabilities Act (ADA), or as required by a court order or under other law. The results of tests and examinations may be published in reports or presented at meetings, but will not identify any individuals. The results of your Be-LPT and other screening tests will be made available to you and, upon your request, to your personal physician.

The voluntary surveillance program will provide free testing for beryllium sensitization. Identifiable information about you and your test results will be placed in a database that will be used by the surveillance team to notify you of results, keep track of where you are in the surveillance process, and to contact you about future testing. It is possible, that at some time in

the future, other researchers who are studying CBD and beryllium exposure may request this database. The information would not be given to these researchers unless their proposed use of the information has been reviewed and approved by an Institutional Review Board (IRB), which is required by law to review research proposals involving humans as participants to ensure protection of their rights and welfare. This includes reviewing the scientific merit of the research and the methods proposed to ensure that the human participation is justified and ethical.

If you give permission for release of your information for future research, it will only be good for six years, starting with the day you sign page six of this form. The results of your Be-LPT test(s) and any other examinations or testing you have may be available to the people listed below. Some of these people may require access to records that identify you by name:

1. The ORISE clinic staff members who provide your medical testing.
2. Medical Specialists, including DOL EEOICPA claim managers, who provide or arrange for additional medical treatment or tests, if necessary.
3. ORISE staff members and their consultants, who will review beryllium program information including results of medical tests.
4. Researchers who are studying beryllium-related disease may have access to the records after receiving approval from an Institutional Review Board (IRB).
5. Others as required by the Americans with Disabilities Act, the Privacy Act of 1974, or as required by court order or under another law.

What should I do if I want to be tested, but I don't want my identifiable information released to approved research projects in the future?

Please let us know at the time you arrive at the clinic if you do not want your identifiable information made available to future researchers. Your records will be marked for separate handling. Non-identifiable information will be entered in the Beryllium Registry as required by law (see below).

What laws protect my privacy if I consent to participate in the blood Be-LPT testing program?

State medical and nursing licensing boards enforce codes of ethics that require doctors and nurses to keep medical information confidential. The Privacy Act prevents unauthorized access to your DOE records without your permission. The information in records kept by your employer must be handled in accordance with the Americans with Disabilities Act and the Privacy Act of 1974. The consent form you sign also provides additional protection.

Can privacy and confidentiality of my medical records be guaranteed?

No. Access to or release of records could be required under court order, or DOE directive, but it is unlikely. It would also be available as the Freedom of Information Act or Privacy Act provide, such as to Congress, to an individual upon a showing of compelling circumstances affecting the health and safety of an individual, etc. If you apply for another job or for insurance, you may be requested to release the records to a future employer or an insurance company. **Personal identifiers will not be published in any reports.**

What is the Beryllium Registry and how is it used?

Your health issues are major concerns to DOE. The DOE Beryllium Registry was developed to help DOE understand, conduct, and improve its environmental, safety, and health responsibilities regarding past, present and future beryllium exposure effects and more effectively prevent or control future disease. The Beryllium Registry collects and maintains information on all current and former workers who are known or suspected to have been exposed to beryllium. Information to be collected includes basic facts such as year of birth, gender, employment years, years and types of exposures to beryllium, beryllium jobs, dates and results of beryllium sensitization testing and/or CBD status such as the Be-LPT or other studies recommended by physicians, and causes of death. The Registry will not contain any personally identifiable information such as names, addresses, phone numbers, or SSNs. A unique identifier will be assigned to each worker's records by the ORISE staff conducting the former beryllium workers medical surveillance program. This unique identifier, not your name, will be used on all records sent to the Beryllium Registry.

Information in the Registry will assist DOE in understanding the effectiveness of its efforts to reduce exposures and related health problems by providing information on workers who were exposed to beryllium, the work environment, specific job tasks and subsequent medical problems. Information in the Registry will allow an evaluation of the health effects related to beryllium disease. For example, physicians and scientists need to learn more about CBD and the factors in the work environment that may influence the risk of developing the disease. The Registry may also be useful for studies to better understand the nature of beryllium disease. However, use of information in the Registry for studies can only occur after review and approval by the appropriate IRB(s). The risk of being identified from the deidentified data in the registry is slight but it is not zero. Researchers, who are given permission to conduct studies using the information in the Registry, will not have access to personally identified information, because the Registry contains no names or similar identifiers. These researchers must promise not to attempt to link the registry data to individuals. Reports by the Registry will be summary in nature without using names or other personally identified information.