



# **Updates to: The Beryllium-Associated Worker Registry Technical Standard and The Beryllium Lymphocyte Proliferation Test Specification**

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# Objectives

- To review the requirements related to monitoring and testing of beryllium exposure and sensitization among Department of Energy workers
- To review the Beryllium Registry Standard and its updates
- To review the Beryllium Lymphocyte Proliferation Test Specification and its updates



# Background: Beryllium (Be)

- Beryllium is a strong, low-density metal used in alloys for a number of industrial applications.
  - Great strength-to-weight ratio, high melting point, thermal stability and conductivity, reflectivity
- Health effects of beryllium exposure include:
  - Sensitization and hypersensitivity
  - Pulmonary dysfunction, berylliosis or chronic beryllium disease (CBD)
  - Lung cancer
- **Be sensitization** occurs after Be exposure and activation of immune cells.
- **CBD** is a granulomatous lung disease that manifests as a result of Be sensitization.



<https://enacademic.com/>



# Chronic Beryllium Disease Prevention Program (CBDPP)

- 10 CFR 850 establishes a CBDPP to:
  - Reduce the number of workers currently exposed to beryllium in the course of their work at DOE facilities managed by DOE or its contractors,
  - Minimize the levels of, and potential for, exposure to beryllium, and
  - Establish medical surveillance requirements to ensure early detection of the disease.



# Definitions from 10 CFR 850

- Beryllium (Be)
  - Be, insoluble Be compound, or alloy containing  $\geq 0.1\%$  Be that may be released as an airborne particulate
- Beryllium-associated worker
  - Current worker who is or was exposed or potentially exposed to airborne concentrations of beryllium at a DOE facility. Includes:
    - Beryllium worker;
    - Current worker whose work history shows that the worker may have been exposed to airborne concentrations of Be at a DOE facility;
    - Current worker who exhibits signs or symptoms of beryllium exposure;
    - Current worker who is receiving medical removal protection benefits



# Definitions from 10 CFR 850

- Beryllium worker
  - Current worker who is regularly employed in a DOE beryllium activity
- Beryllium-induced lymphocyte proliferation test (BeLPT)
  - An *in vitro* measure of the Be antigen-specific, cell-mediated immune response



# Status of 10 CFR 850 Amendment

- **Notice of Proposed Rulemaking**
  - Federal Register - June 7, 2016
- **Develop draft Final Rule** - Completed
  - Based on comments from the public comment period
- **Review and Concurrence Process**
  - **Beryllium-affected Program Offices:** EM, NA, NE, and SC
    - **Completed: August 2019**
- **Office of the General Counsel - September 2019**
  - Comments received – January 15, 2020
  - Adjudication process is ongoing
- **After adjudication, amendment will go to Secretary of Energy to review and concur**



# Status of 10 CFR 850 Amendment Continued

- **Office of Management and Budget Review**
  - Draft final rule and final economic assessment
  - Approves draft final rule and economic assessment
    - Publication in the Federal Register
- **Secretary of Energy** - Approves and signs the final rule
- **Congressional Notification - 5 days**
- **Federal Register** - Published in the Federal Register
- **Final Rule**
  - Effective Date: 30 days after publication date
  - Compliance Date: One year after the effective date
    - Engineering controls – Two years after the effective date



# Status of 10 CFR 850 Amendment Contacts

- **Office of Health and Safety (AU-10)**
  - *Patricia Worthington, PhD., Director*
    - 301-903-5926; [Patricia.worthington@hq.doe.gov](mailto:Patricia.worthington@hq.doe.gov)
- **Office Worker Safety and Health Policy (AU-11)**
  - *James (Jim) Dillard, Director*
    - 301-903-1165; [James.dillard@hq.doe.gov](mailto:James.dillard@hq.doe.gov)
  - *Anthony Pierpoint, PhD., CIH*
    - 301-903-5053; [Anthony.pierpoint@hq.doe.gov](mailto:Anthony.pierpoint@hq.doe.gov)



# Beryllium-Associated Worker Registry (BAWR)

- The DOE Beryllium Registry was established to collect and maintain information on workers who are exposed to beryllium. It is used to:
  - Conduct health studies to better understand the nature of the disease,
  - Measure the burden of health effects related to beryllium exposure, and
  - Evaluate the effectiveness of exposure control programs.
- Data submitted to the registry include:
  - Be-related exposures,
  - Results of Be sensitization testing, and
  - CBD status.
- To maintain confidentiality of worker data, a unique identifier is used to relay employee information to the registry.



Beryllium-Associated Worker Registry (BAWR)

<https://oriseapps.orau.gov/BAWR/>

Office of Environment, Health, Safety and Security

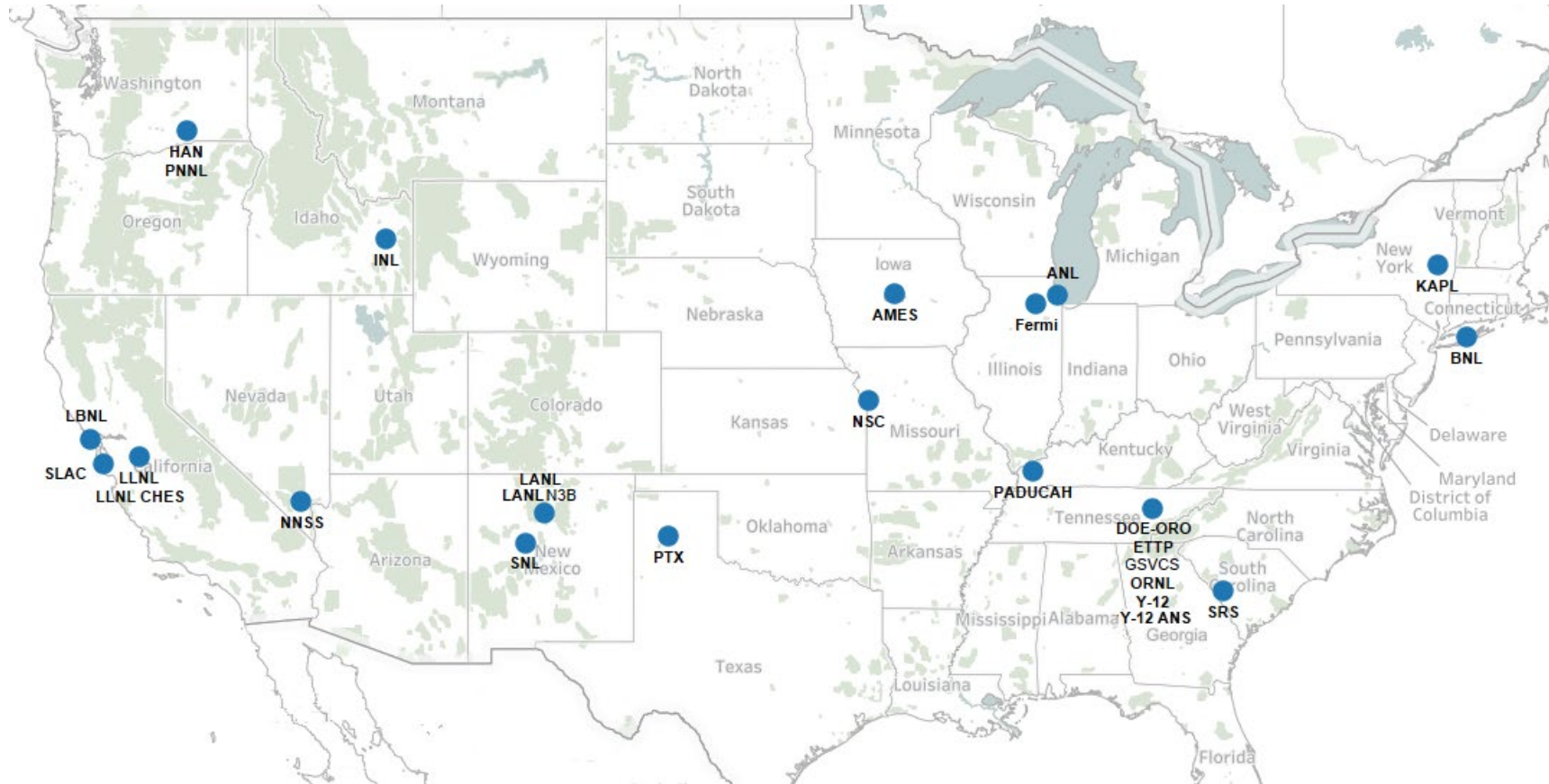


# Sites and Organizations Currently Submitting to the BAWR

Ames Laboratory (AMES)	LLNL Clean Harbors Environmental Services (LLNL CHES)
Argonne National Laboratory (ANL)	Los Alamos National Laboratory (LANL)
Brookhaven National Laboratory (BNL)	National Security Campus (NSC)
DOE Oak Ridge Office (DOE-ORO)	Nevada National Security Site (NNSS)
East Tennessee Technology Park (ETTP)	Oak Ridge National Laboratory (ORNL)
Fermi National Accelerator Laboratory (Fermi)	Pacific Northwest National Laboratory (PNNL)
Golden SVCS, LLC (GSVCS)	Paducah Site (PADUCAH)
Hanford Site (HAN)	Pantex Plant (PTX)
Idaho National Laboratory (INL)	Sandia National Laboratories (SNL)
Knolls Atomic Power Laboratory (KAPL)	Savannah River Site (SRS)
LANL N3B Project (LANL N3B)	SLAC National Accelerator Laboratory (SLAC)
Lawrence Berkeley National Laboratory (LBNL)	Y-12 Atkins Nuclear Secured (Y-12 ANS)
Lawrence Livermore National Laboratory (LLNL)	Y-12 National Security Complex (Y-12)



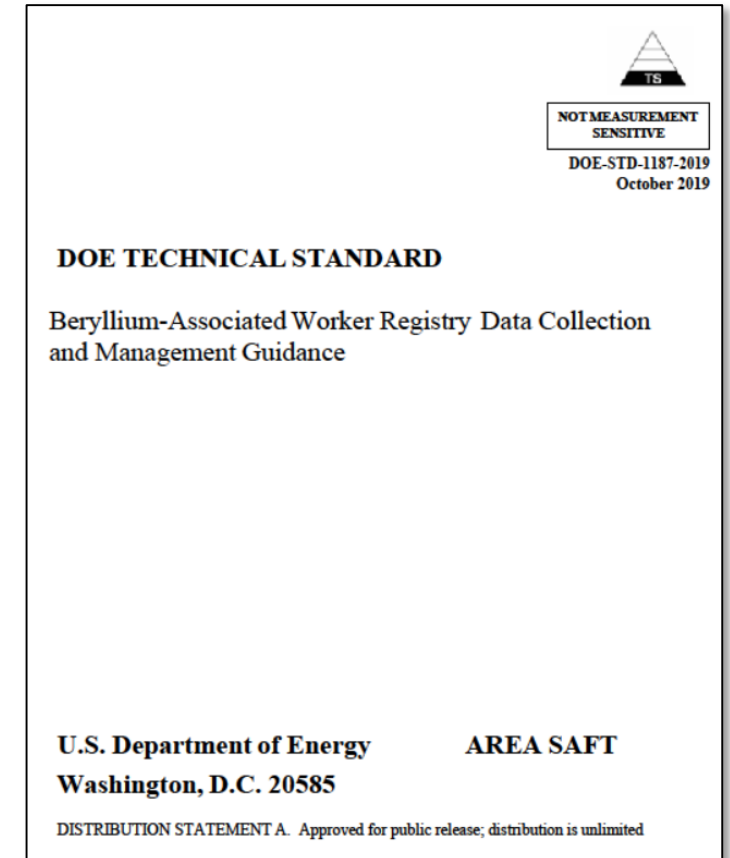
# Sites and Organizations Currently Submitting to the BAWR





# DOE-STD-1187: Beryllium-Associated Worker Registry Data Collection and Management Guidance

- Provides acceptable methods for compliance with the requirements of 10 CFR 850.39
  - Recordkeeping and Use of Information
- Developed for employers subject to 10 CFR 850
  - To guide their submissions to the BAWR
  - To promote consistent reporting and efficient analysis and dissemination of information





# DOE-STD-1187: Data Coordination and Roster

- Site Occupational Medical Directors should identify a Data Coordinator.
- The roster should include:
  - Current workers exposed or **potentially exposed** to Be at a DOE facility,
  - Workers who self-identify and indicate a past history of possible exposure, and
  - Workers who exhibit signs or symptoms of Be exposure or are receiving medical removal protection benefits.
- Roster should include:

*Site Code	*First Hire on Site Date
*Unique ID	Year Employment Ended
*Status Code	Death Date
*Year Born	Immediate Cause
*Gender	Previous Employer Unique ID
*Employer Type	Previous Site

\*Asterisks denote required data fields.



# DOE-STD-1187: Be-Related Medical Surveillance

- Data will contain the Be-related medical information obtained by SOMD.
- Medical information includes:
  - BeLPT, Bronchoalveolar lavage, Chest x-rays, Biopsies,
  - Medical referral/follow-up,
  - CT, Cardiopulmonary exercise testing, CBD evaluation, and
  - Be-induced dermatitis.
- Example data tables:

*Site Code	*Site Code	*Site Code	*Site Code	*Site Code
*Unique ID	*Unique ID	*Unique ID	*Unique ID	*Unique ID
*Status Code	*Status Code	*Status Code	*Status Code	*Status Code
*LPT date	*Date CXR	*Referral Offered Date	*Date Lavage	*Date BX
*LPT result	*CXR Result	*Follow-Up Referral	*Lavage Result	*BX Result

- Note: All BeLPT results should be included, even if results are normal.



# DOE-STD-1187: Work History and Exposure Data

- Data will contain information on all Be activities and exposures.
- Note: All employees who have been monitored for Be exposure should be included, even if results are non-detectable.

Work History	Activity and Exposure
*Site Code	*Site Code
*Unique ID	*Unique ID
*Status Code	*Status Code
*Organization Code	*Location Identification
*1 <sup>st</sup> Be Job Start Date	*Room/Area
*Activity	*Process
*Job Title	Operation
*Job Start Date	Task
Job Stop Date	*Actual Exposure
	*Actual Exposure < Reporting Limit
	*Exposure Sample Volume
	*8-hour TWA
	*Exposure Method
	*Sampling Method
	*Analytic Method
	*Exposure Sampling Time
	Sample Number
	*Monitoring Date
	Chemical
	Engineering Controls
	PPC&E
	*Respirator Protection
	*Respirator APF



# Changes to DOE-STD-1187

- Data fields removed:
  - Roster (table 3)
    - Race
    - Death date (not removed but not mandatory)
    - Immediate cause (not removed but not mandatory)
    - First cause
    - Second cause
    - Other cause
  - Smoking (table 4) – entire table removed
- More data fields are required (not retroactive).
  - Work History (table 5)
    - Organization code
    - Beryllium job start date
- Background appendix added
- Status:
  - RevCom review was completed, responses submitted, and sign-off obtained.
  - Finalized version should be posted on DOE Technical Standards website October 2019.

<https://www.standards.doe.gov/news/new-doe-std-1187-2019-beryllium-associated-worker-registry-data-collection-and-management-guidance>

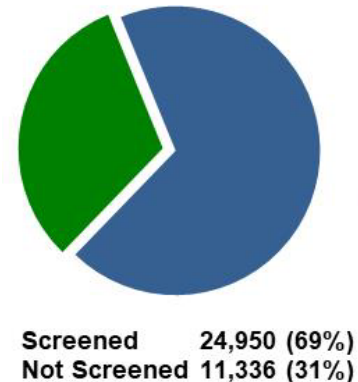


# BAWR Annual Reports

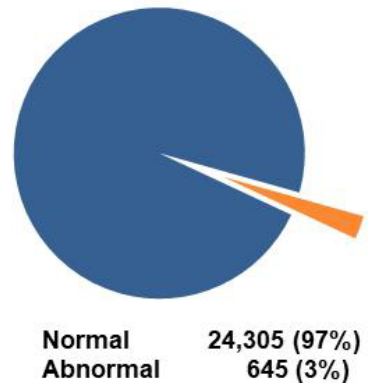
- Annual Summary reports are based on the yearly submissions.
- Yearly and cumulative data analyses are performed.
- The report includes the evaluation of the number of workers, exposure and screening metrics, and disease incidence.

From 2016 to 2017, 34 additional Be-sensitized employees and no additional CBD cases were reported.

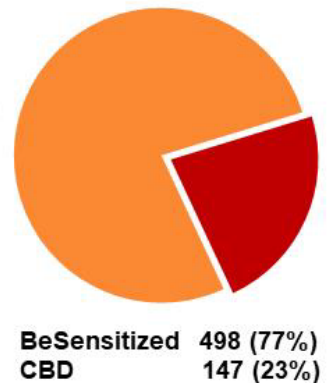
36,286 Employees Reported to the Registry



24,950 Employees Screened



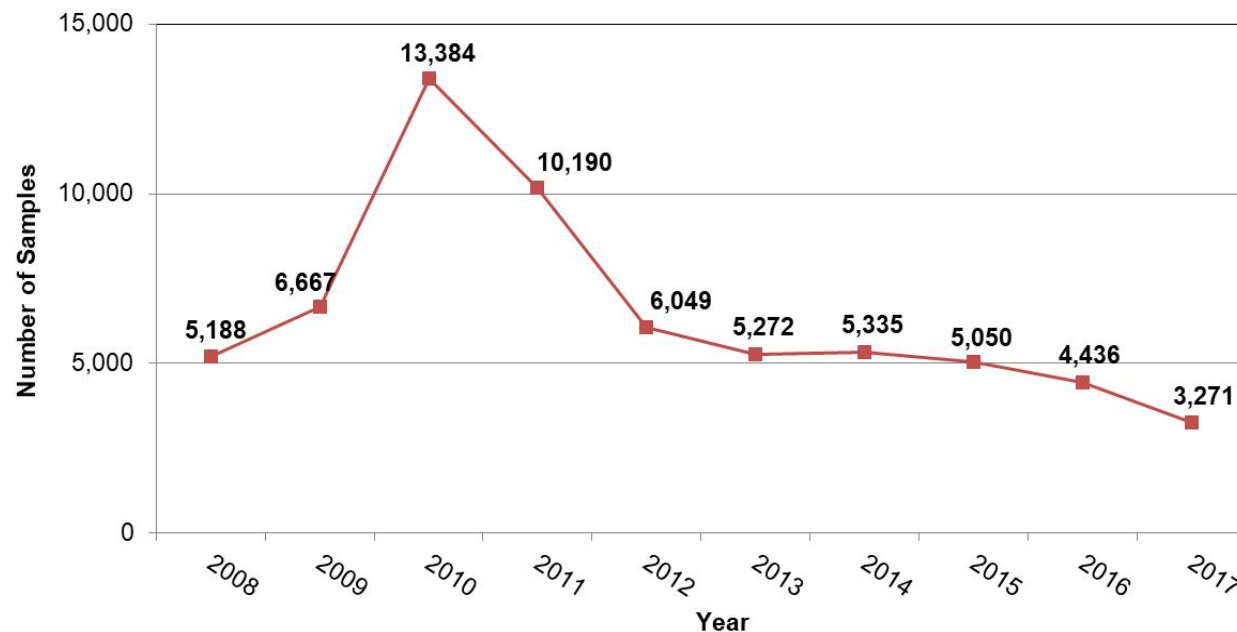
645 Employees with Abnormal Results





# Challenges Encountered with the BAWR

- Frequent turnover of Data Coordinators
- Errors encountered with data submissions
- Limitations in data constrain the interpretability of results in the registry

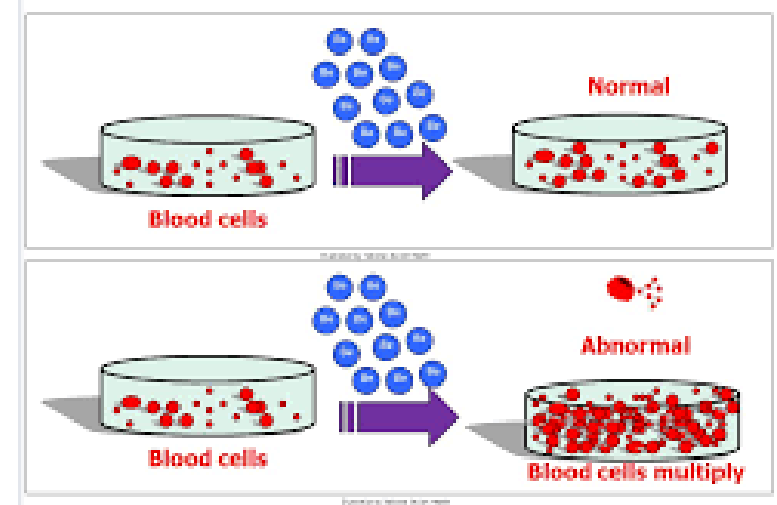


**A decline in exposure sampling has been observed in recent years.**



# Beryllium Lymphocyte Proliferation Test (BeLPT)

- The BeLPT is an assay used to screen for Be sensitization.
  - It examines the body's immune response to beryllium.
  - Sensitization is characterized by abnormal proliferation of lymphocytes exposed to Be as compared to control.
- The BeLPT is used as a surveillance tool for working conditions and as part of the diagnostic criteria for CBD.





# DOE-SPEC-1142: Specification for Beryllium Lymphocyte Proliferation Testing (BeLPT)

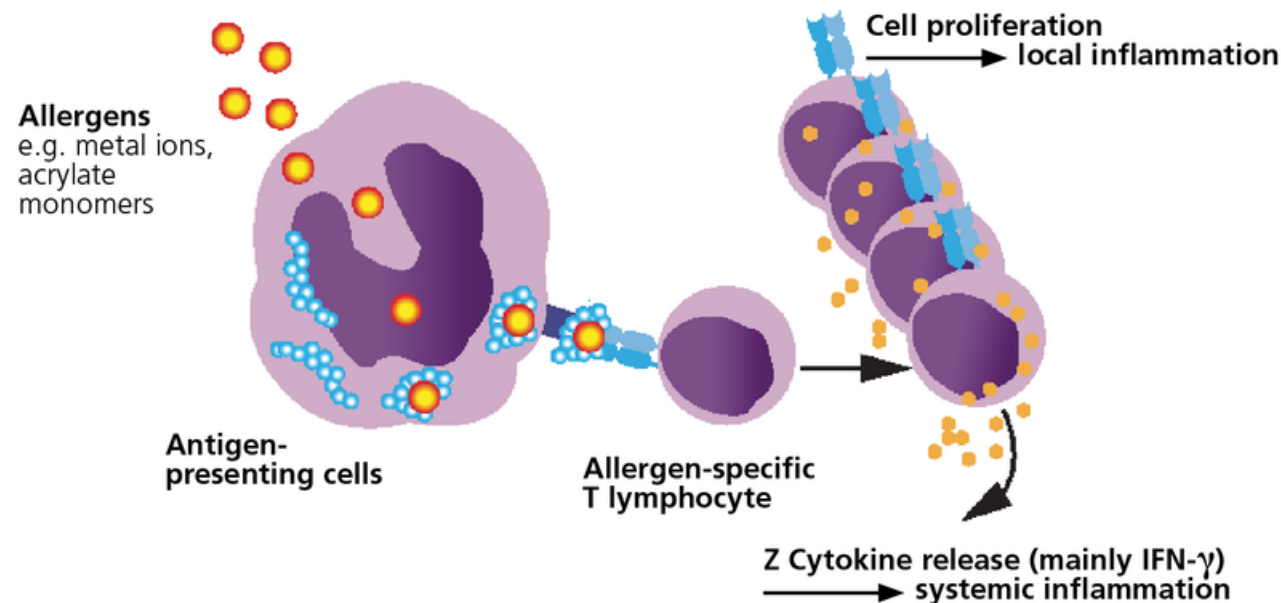
- Informal voluntary consensus standard which details criteria for:
  - BeLPT assay
    - Includes details for sample collection through processing
  - Analysis and reporting of assay results
- The specification is needed to establish acceptable criteria in the performance of the BeLPT.
  - It should be used in all contracts with DOE labs for BeLPT services.
  - Performing labs include:
    - Oak Ridge Associated Universities,
    - National Jewish Health, and
    - Cleveland Clinic.





# Outline of BeLPT Specification

- Principle and Application
  - *In vitro* measurement of T cell response to a specific antigen, Be
  - A measurable response of T cell proliferation indicates sensitivity

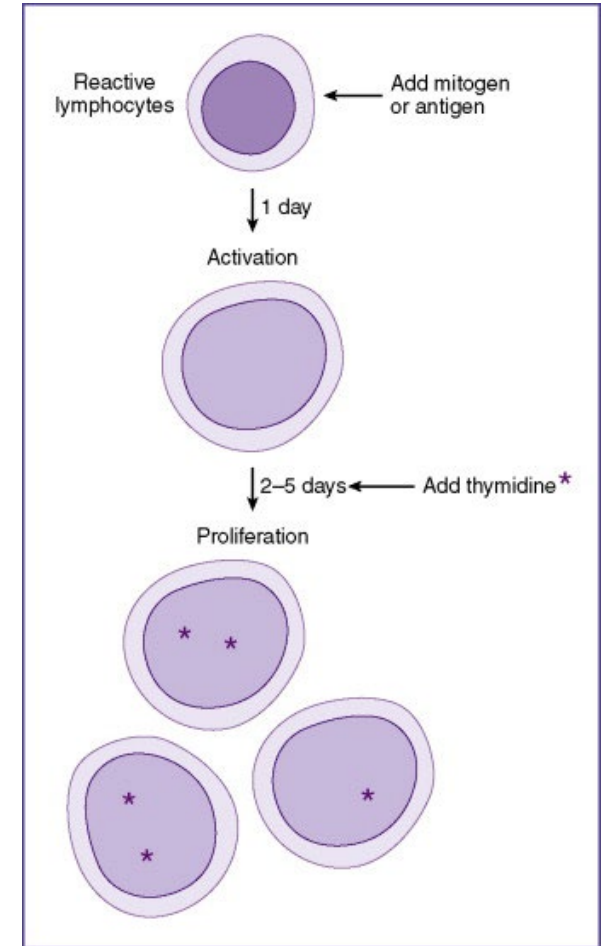


Institut für Medizinische  
Diagnostik Berlin



# Outline of BeLPT Specification

- Tritiated Thymidine Uptake Procedure
- Blood Specimens
- Bronchoalveolar Lavage Specimens
- Calculations
- Results
  
- Outlines acceptable reagents, procedures, equipment





# Updates to DOE-SPEC-1142

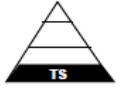
- Statistical analysis methods
  - Least squares method vs. least absolute values methods
  - Recognizes other outlier resistant methods
- Results: characterization of sensitization
  - If at least two of the three BeLPT tests are abnormal, the patient is deemed beryllium sensitized.
- References American Thoracic Society recommendations which may be adopted in 10 CFR 850 in the future:
  - Two abnormal blood BeLPT results; or
  - One abnormal and one borderline blood BeLPT; or
  - One abnormal BeLPT test of alveolar lung lavage cells; or
  - Three borderline abnormal blood BeLPTs.



# Status of DOE-SPEC-1142 Updates

- 8/13/19 Draft submitted to RevCom
- 10/16/19 Comments Due
- 11/16/19 Response to Review Due
- 11/20/19 Submit to AU-1 for final review
- 11/30/19 Additional comments
- 12/10/19 Comments addressed
- 12/16/19 Finalized document approved and posted:

<https://www.standards.doe.gov/news/new-doe-spec-1142-2019-beryllium-lymphocyte-proliferation-testing-belpt>



METRIC

DOE-SPEC-1142-2019  
December 2019

## DOE SPECIFICATION

BERYLLIUM LYMPHOCYTE  
PROLIFERATION TESTING (BeLPT)



U.S. Department of Energy  
Washington, D.C. 20585

AREA SDMP

DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited.



# Summary

- Beryllium is a carcinogen that may also cause sensitization leading to pulmonary dysfunction in some portion of the population.
- The Chronic Beryllium Disease Prevention Program (CBDPP) was established in 10 CFR 850 to minimize the risks to workers exposed to beryllium.
- The Beryllium Registry collects data from DOE sites to monitor worker exposures and the effectiveness of the CBDPP.
- The BeLPT is an important screening tool for protecting workers from chronic beryllium disease.



# Discussion?

- Questions or Comments
- My contact information:  
Daniela Stricklin  
[daniela.stricklin@hq.doe.gov](mailto:daniela.stricklin@hq.doe.gov)  
301-903-0947



# Question 1

- What workers should be monitored for beryllium exposure?



# Answer

- Beryllium and beryllium-associated workers as defined in 10 CFR 850:
  - Current worker who is or was exposed or *potentially exposed* to airborne concentrations of beryllium at a DOE facility. Includes:
    - Beryllium worker;
    - Current worker whose work history shows that the worker may have been exposed to airborne concentrations of Be at a DOE facility;
    - Current worker who exhibits signs or symptoms of beryllium exposure;
    - Current worker who is receiving medical removal protection benefits.



## Question 2

- What information should be submitted to the Beryllium-Associated Worker Registry for DOE workers?



# Answer

- Roster of beryllium-associated workers
- Beryllium task, exposure, and health data on employees on the roster
  - Health data includes BeLPT results, referrals, chest x-rays, etc.
  - Work history
  - Exposure monitoring results



## Question 3

- What results from the BeLPT constitute a sensitized worker?



# Answer

- Today:
  - If at least two of three BeLPT results are abnormal, a worker is deemed sensitized.
- ATS recommends:
  - Two abnormal blood BeLPT, or
  - One abnormal and one borderline blood BeLPT, or
  - One abnormal lavage BeLPT, or
  - Three borderline abnormal blood BeLPT.



# Thank you!

Office of Environment, Health, Safety and Security

**March 2020**



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# **Beryllium-Associated Worker Registry**

*State of Exposure  
Monitoring Data*

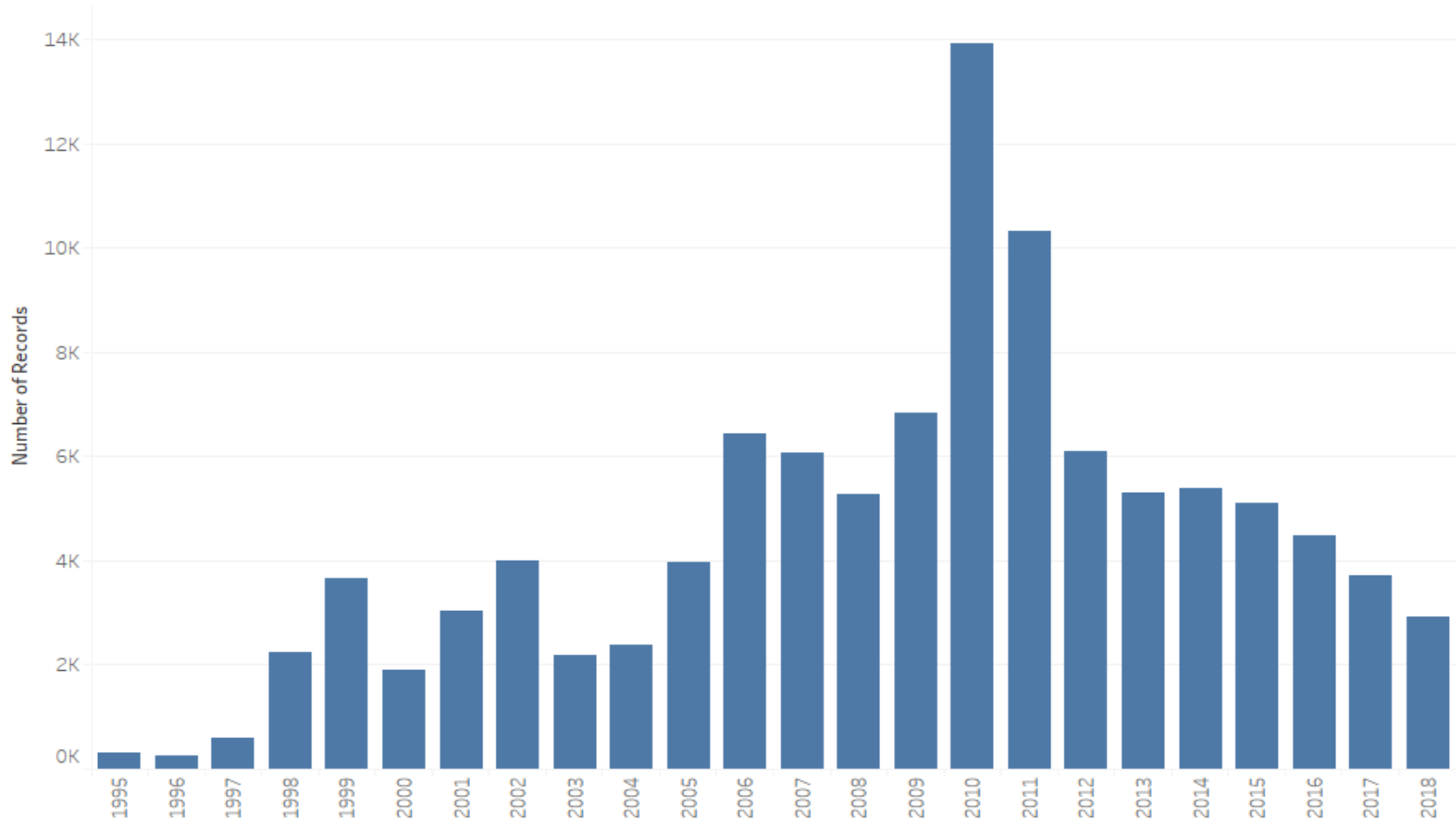
**Eric Adams**  
**Eric.Adams@ornl.gov**

# Background

- Exposure Monitoring Data
  - IH sampling for exposed/potentially exposed workers
  - TWA normalized
  - Core data for analysis
- STAND Package
  - Built in R
  - Addresses non-detectable, left censored data

# Monitoring Exposure Baseline

Exposure Monitoring Records by Year

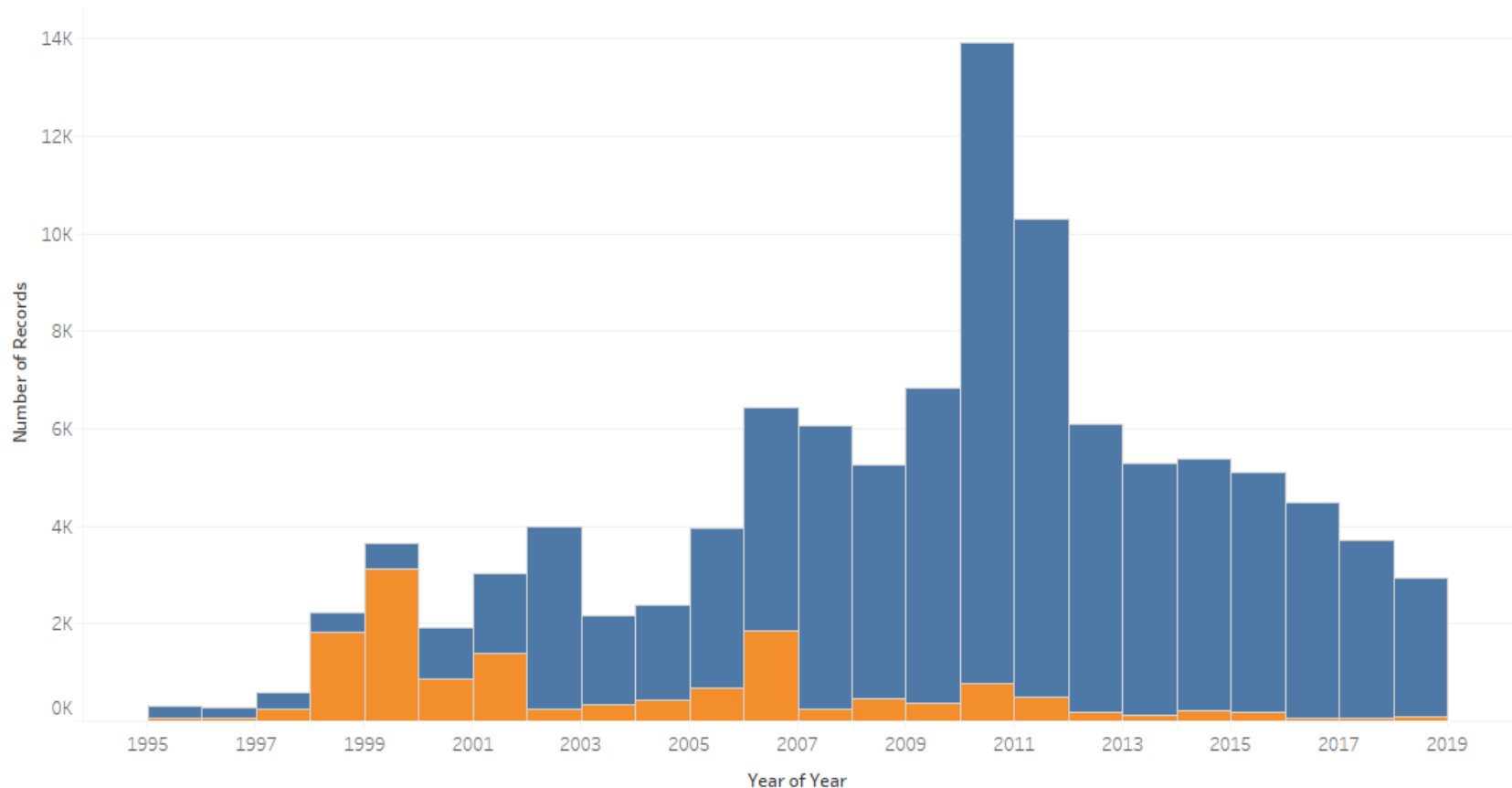


- 107,854 total records

- 106,356 span 1995-2018

# Monitoring Exposure Data Integrity

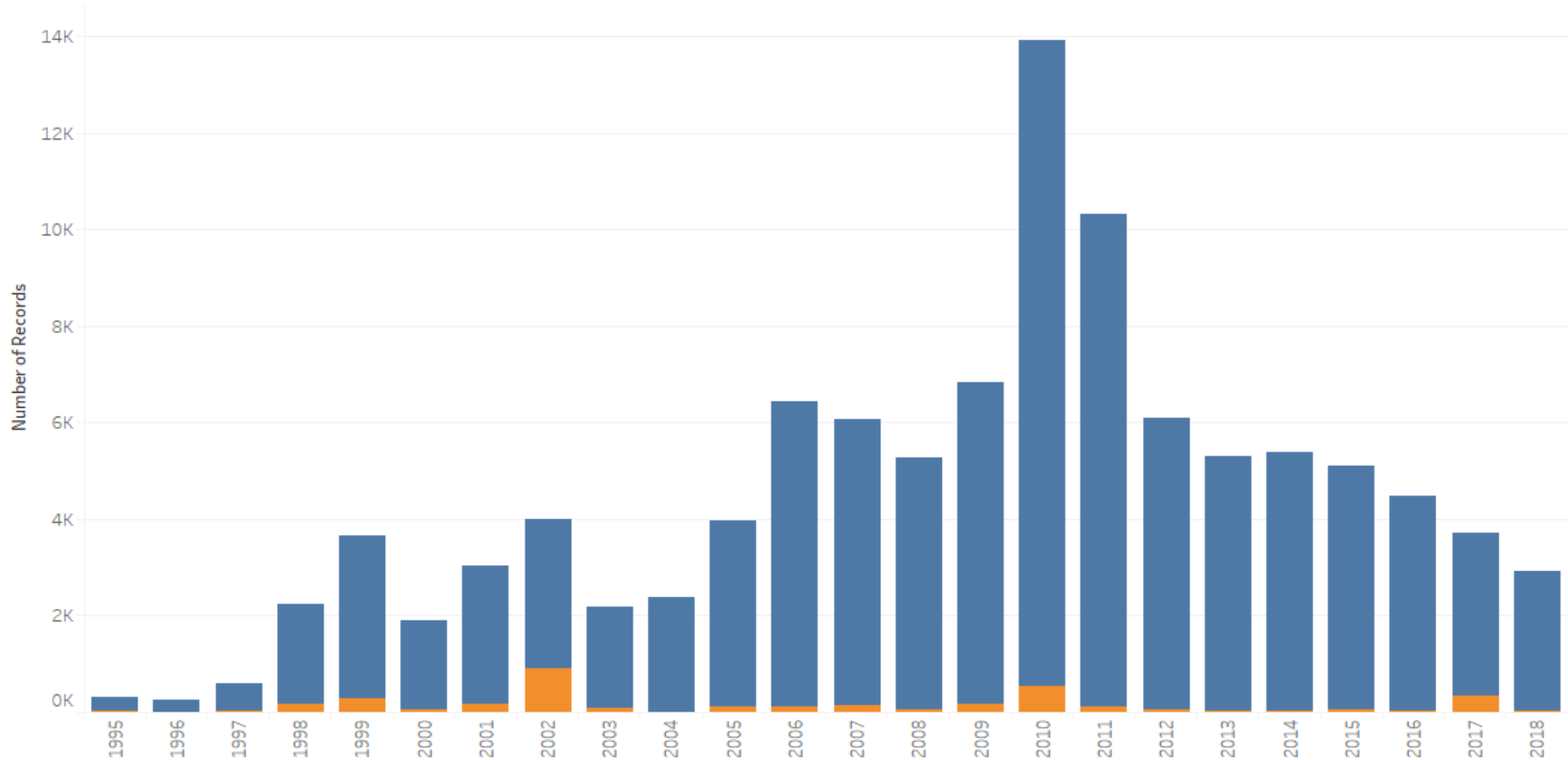
Exposure Monitoring Records by Year With  
TWA Recalculated Variation > 25%



- 14,379 > 25% Variance
- 13,335 > 50% Variance

# Monitoring Exposure Data Integrity

Dropped Exposure Monitoring Records by Year

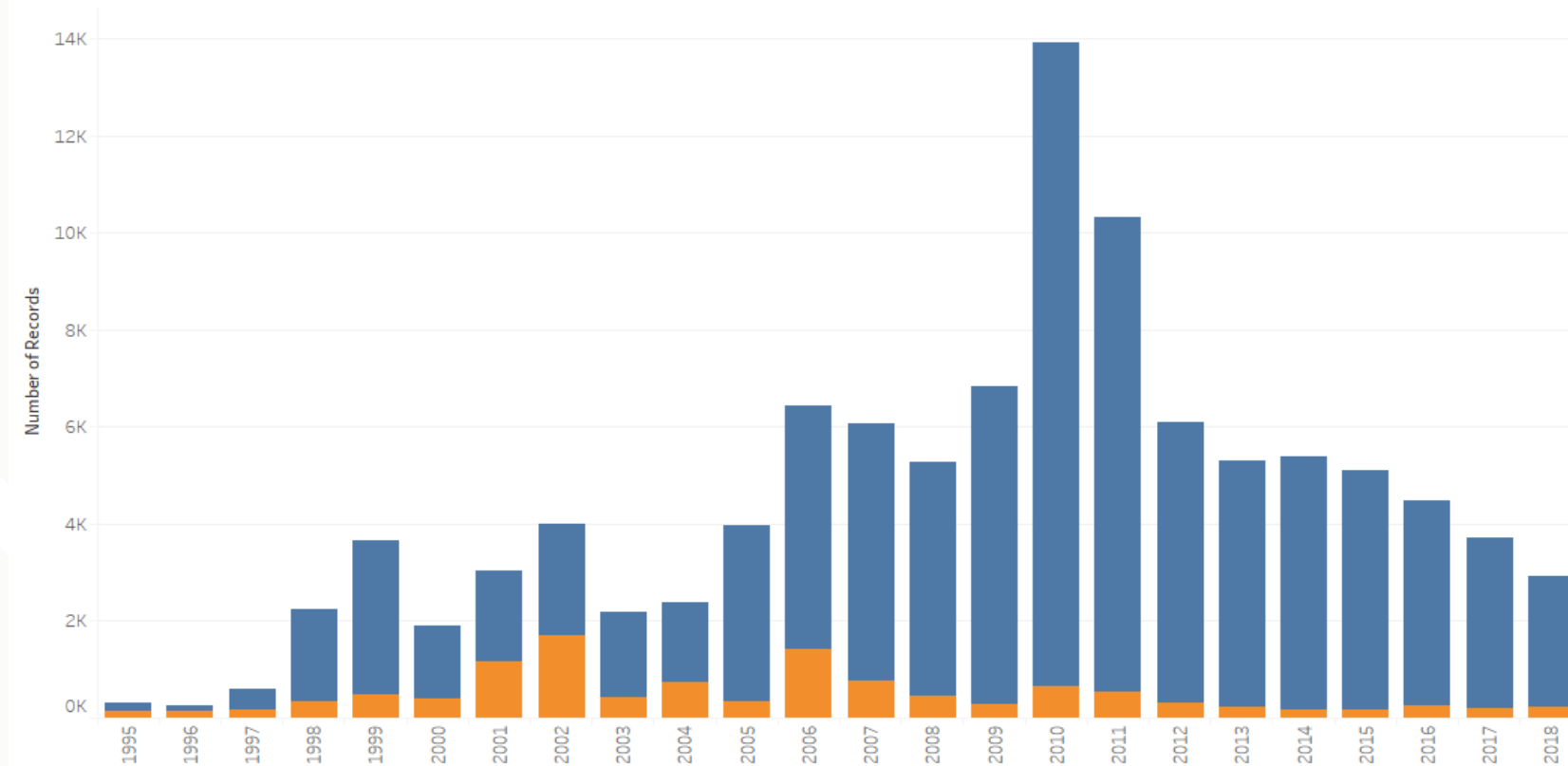


- 318 missing TWA
- 493 “failed” samples

- 3,043 “soft” duplicates
- Total drop rate: 3.91%

# Monitoring Exposure Censoring

Censored Exposure Monitoring Records by Year

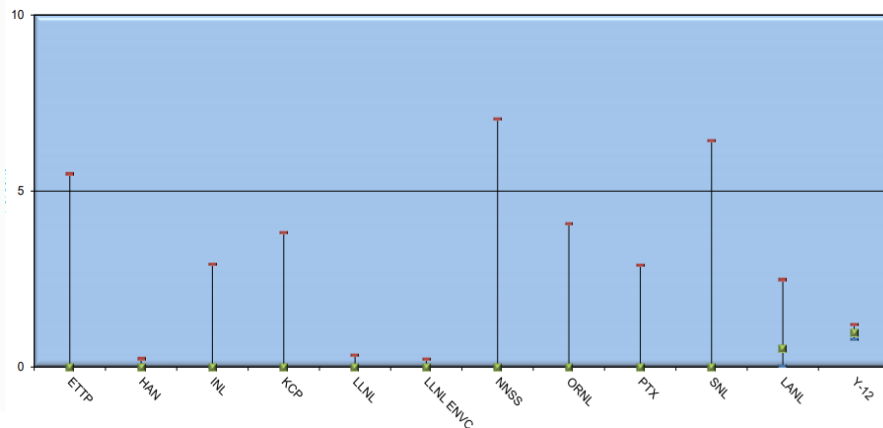


- 11,683 censored records
- Represents 10.98%

# Data Trending to “Small n”

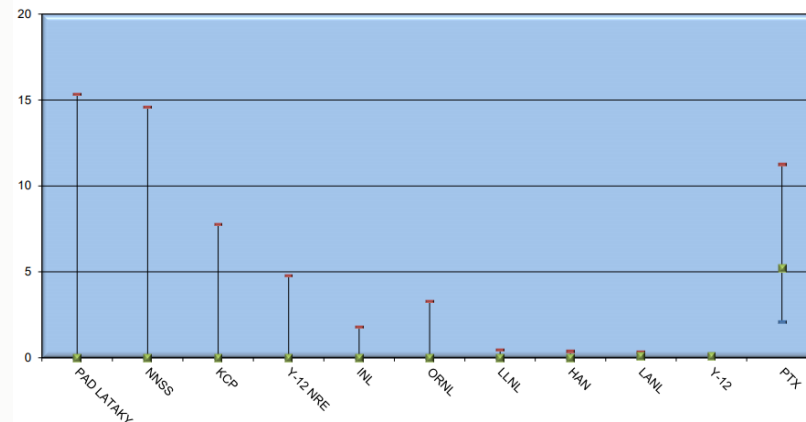
Percent of Exposure Monitoring Results Exceeding the Action Level by Site for Calendar Year 2011  
(Ranked by Percent Exceeding)

Percent Exceeding 0.2  $\mu\text{g}/\text{m}^3$  Based on a 95 Percent Confidence Limit



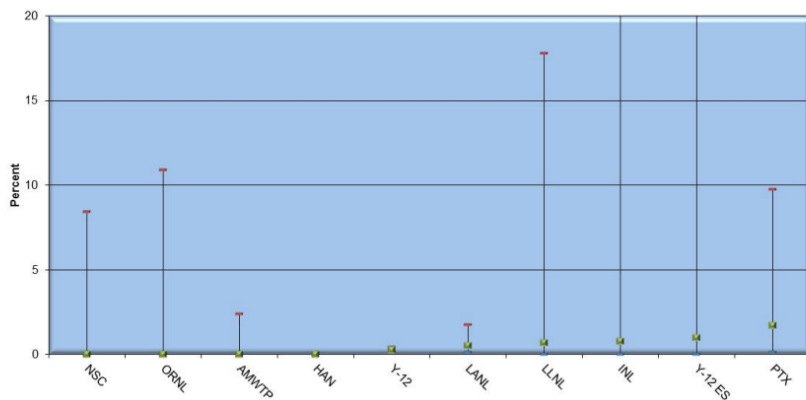
Percent of Exposure Monitoring Results Exceeding the Action Level by Site for Calendar Year 2013  
(Ranked by Percent Exceeding)

Percent Exceeding 0.2  $\mu\text{g}/\text{m}^3$  Based on 95 Percent Confidence Limits



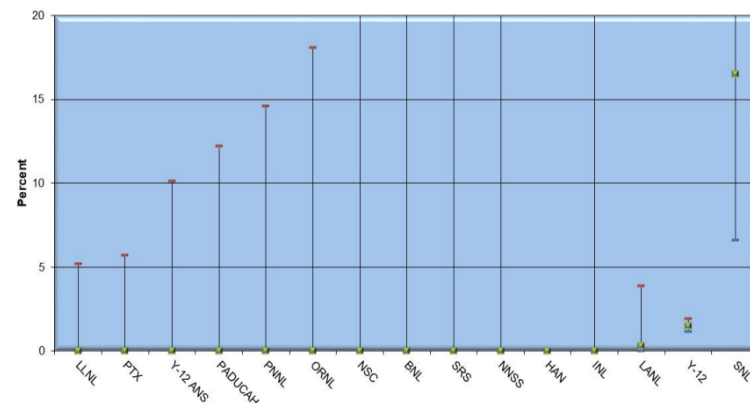
Percent of Exposure Monitoring Results Exceeding the Action Level by Reporting Organization for Calendar Year 2015  
(Ranked by Percent Exceeding)

Percent Exceeding 0.2  $\mu\text{g}/\text{m}^3$  Based on 95 Percent Confidence Limits



Percent of Exposure Monitoring Results Exceeding the Action Level by Reporting Organization for Calendar Year 2017  
(Ranked by Percent Exceeding)

Percent Exceeding 0.2  $\mu\text{g}/\text{m}^3$  Based on 95 Percent Confidence Limits



# Conclusion

- Quality continues to improve
- Monitoring exposure data is in good shape
- Velocity trending downward
  - Analytic impact of small “n”s
  - Reduced statistical confidence

Thank You  
Questions/Open Discussion

**March 2020**



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*State of Exposure  
Monitoring Data*

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