Lawrence Livermore National Laboratory

LLNL Select Agent Human Reliability Program

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Origins of the Select Agent Human Reliability Programs at LLNL and LANL

- The Department of Energy has a long history of working with nuclear materials.
  - The risks associated with these materials lead to a requirement for a human reliability program for those who work with high risk nuclear materials – Special Nuclear Materials (SNM)
  - As a result DOE has a well established Human Reliability Program (HRP) for nuclear materials.
- The Centers for Disease Control and Prevention (CDC) <u>does not require</u> a human reliability program for work with high risk biological materials – Select Agents (SA).
- However, based upon the similarities of high risk nuclear materials and high risk biological materials, LLNL and LANL have implemented a Select Agent Human Reliability Program (SAHRP).
- In 2003 a working group was convened to define a biosecurity program, which decided a SAHRP was necessary and what its requirements should be.
- In 2004 LLNL and LANL were instructed by the University of California, which managed both laboratories at the time, to implement a Select Agent Human Reliability Program.
- Since that time, both LLNL and LANL have had a SAHRP in place.

DOE's Human Reliability Program (10 CFR 712)

- DOE's Human Reliability Program is defined in 10 CFR 712.

- HRP certification is required for people in positions that:
  - Afford access to category I special nuclear materials (SNM).
  - Involves nuclear explosive duties or has responsibility for working with, protecting, or transporting nuclear explosives, nuclear devices, or selected components.
  - Affords access to information concerning vulnerabilities in protective systems when transporting nuclear explosives, nuclear devices, selected components, or Category I quantities of SNM.
  - Affords the potential to significantly impact national security or cause unacceptable damage.

Requirements for HRP Certification (10 CFR 712)

- The general requirements for HRP certification are:
    - A "Q" clearance.
    - Annual submission of the "Questionnaire for National Security Positions".
    - Signed releases, acknowledgements, and waivers to participate in the HRP.
    - Completion of initial and annual HRP instruction.
    - Annual completion of a supervisory review, medical assessment, management evaluation, DOE personnel security review.
    - A psychological evaluation consisting of a generally accepted psychological assessment (test) and a semi-structured interview.
    - Initial drug & alcohol test and random drug & alcohol tests for use of illegal drugs and alcohol at least once each 12 months.
    - Successful completion of a counterintelligence evaluation, including a polygraph examination if required by the position.

History of LLNL SAHRP Development

- UC managed laboratories established a Biosecurity Working Group to address the issue of security related to Select Agents in 2003.

- 50 Representatives from science and security from:
  - LLNL
  - LANL
  - BNL
  - UC
  - SNL
  - DOE HQ, Livermore and Albuquerque field offices

- The working group developed a set of recommendations including the requirement for a human reliability program.

- Each laboratory used these recommendation to determine if a SAHRP was necessary and, if so, what the elements of the SAHRP would be.

Requirements for certification in the LLNL SAHRP.

- At LLNL SAHRP certification is required for people in positions that:
  - Afford unescorted access to Select Agents.
- From the working group conclusions LLNL established its' Select Agent Human Reliability Program (SAHRP) with the following elements:
  - DOJ Security Risk Assessment approval required.
  - Annual medical evaluation.
  - Annual psychological evaluation.
  - Periodic credit check.
  - Annual criminal record check.
  - Resume Verification.
  - Initial and Random drug and alcohol testing (at least annually).
  - Signed releases, acknowledgements, and waivers to participate in the SAHRP.
  - Completion of initial and annual SAHRP instruction.

Differences Between the LLNL SAHRP and the DOE HRP

- The LLNL SAHRP is patterned on the standard DOE Human Reliability Program (HRP)

- The LLNL SAHRP has the following distinctions from the HRP program:
  - A "Q" clearance is not required (the DOJ SRA approval is substituted).
  - No polygraph testing is required.
  - No written psychological evaluation (this is done annually in a semi-structured interview format).
  - DOE does not perform the annual personnel security review this is done by LLNL.
  - The SAHRP is not administered by DOE but is administered by the individual laboratories.
  - The SAHRP Certifying Official is the LLNL Laboratory Assurance Manager not a DOE employee.

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Lessons Learned & Concerns

- The SAHRP is a culture shock for biologists when coming to LLNL.

- The more restrictive the guidelines the harder it is to recruit.

- Instituting new "two person" requirements has a powerful economic impact on Select Agent operations.

- At smaller scale facilities like LLNL a "two person" requirement is also harder to implement due to smaller numbers of authorized people.

- The SAHRP is required for those with <u>unescorted</u> access to select agents; this is one mechanism to help mitigate the security risk of allowing researchers to work alone.