

**From:** Klink, David J:(GenCo-Nuc) <david.klink@exeloncorp.com>  
**Sent:** Wednesday, July 30, 2014 4:22 PM  
**To:** Harris, Paul  
**Cc:** Smith, Will; Parker, Meagan; Byre, Everett; Funk, Don  
**Subject:** RE: Incoming and Answer for: EXELON Auditor question on 10 CFR 26.125

Mr. Harris,

Thank you very much for the clarification. I will make sure it is communicated through our department.

David J. Klink

Nuclear Oversight Auditor – Byron Station

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**From:** Harris, Paul [<mailto:Paul.Harris@nrc.gov>]  
**Sent:** Wednesday, July 30, 2014 3:05 PM  
**To:** Funk, Don; Klink, David J:(GenCo-Nuc)  
**Cc:** Smith, Will; Parker, Meagan; Byre, Everett  
**Subject:** Incoming and Answer for: EXELON Auditor question on 10 CFR 26.125

David,

In summary:

1. The “**, or equivalent**” phrase used in Section 26.125(a) is referencing the technical requirement that those subject individuals shall have at least a bachelor’s degree or equivalent.
2. Since the rule is not explicit and regulatory guidance is not provided on how equivalency is determined, as such equivalency is a licensee determination. Therefore “or equivalent” could be an Associate’s degree plus training and qualification; no degree plus skills, training, academia, and experience; or some other combination established by the licensee.

The editorial position is that the “or equivalent” is segregated by the comma, therefore the “or equivalent” refers the need for a bachelor’s degree; not the need to have an equivalent Bachelor’s degree in a technical discipline (e.g., “in the chemical or biological sciences, medical technology...”) which is required at the HHS-Lab, see lab discussion below.

Note that an LTF is not a laboratory; it is a testing facility; the LTF performs immunoassay testing, not confirmatory testing; and, reasonable assurance is provided by: training and qualification requirements; program, processes, and procedures; performance testing and quality control requirements for validity screening and initial validity testing; investigation of errors; accuracy requirements; and, calibrators and controls. Further, the 26.31(i) provision establishes a *de facto* performance metric of 85% that helps provide assurance that authorization or removal of authorization is based on acceptable LTF performance. In these respects, Part 26 is a performance-based rule. The Rule continues to indicate that: “He or she shall have training and experience in the theory and practice of the procedures used in the

licensee testing facility, resulting his or her thorough-understanding of quality-control practices and procedures; the review, interpretation, and reporting-of test results; and proper remedial actions to be taken **in** response to detecting aberrant test or quality control results.” LTF requirements for qualification are rightfully less rigorous than that required for the same person at an HHS-certified laboratory.

Another rulemaking consideration was that the 2008 Rule did not implement additional burden or costs upon licensee. This was spoken in the NRC’s Regulatory Analysis: “This section of the final rule [including paragraphs (a)–(c)] imposes no incremental cost and affords no saving because it restates and clarifies former requirements in Section 2.6(a)–(c) in Appendix A to Part 26, which pertained to the requirements for licensee testing facility personnel responsible for the day-to-day management of operations and supervision of testing technicians, other technicians, non-technical staff, and licensee testing facility personnel files.” This lends to a position that the NRC “grandfathered” persons already doing LTF duties and responsibilities (prior to 2008 Rule issuance) do not need to go back to school to get a “Bachelor’s degree,” which would be a burden and a cost. We differentiated this by inserting the word “field” into the HHS-Lab qualification requirement (see below). This word established a nexus that equivalency for a HHS-Lab is the technical discipline of the Bachelor’s degree; whereas, equivalency for the LTF is based on a person who possess the skills, training, academia, and experience that is “equivalent” to a person having a Bachelor’s degree.

#### **2008 – Current Rule**

As you note, for the current rule we state: 26.125(a) Each licensee testing facility shall have one or more individuals who are responsible for day-to-day operations and supervision of the testing technicians. The designated individual(s) shall have at least a bachelor’s degree in the chemical or biological sciences, medical technology, **or equivalent.**

For the equivalent provision at the HHS Lab we state: 26.155(c) *Day-to-day operations and supervision of analysts.* HHS-certified laboratories shall assign one or more individuals who are responsible for day to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor’s degree in the chemical or biological sciences, medical technology, **or an equivalent field.**

#### **1989 – The Original Rule**

When we look at the original rule, we see that the LTF and HHS qualifications were equivalent in words and structure:

LTF, 10 CFR Part 26, App A, 2.6(a) This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology **or equivalent.**

HHS-Lab, 10 CFR Part 26, App A, 2.5(c) This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology **or equivalent.**


If you have any questions, give me a call.

Thank you,

Paul

*Paul Harris*

**U.S. Nuclear Regulatory Commission / Office of Nuclear Security and Incident Response  
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Senior Program Manager, Fitness for Duty Programs**

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**From:** Funk, Don  
**Sent:** Wednesday, July 30, 2014 12:43 PM  
**To:** Harris, Paul  
**Cc:** Smith, Will; Parker, Meagan  
**Subject:** FW: Question for the Exelon FFD Audit  
**Importance:** High

Paul,

I thought I would forward this to the experts. Could you or someone in the branch please reply to the first e-mail below **and** cc me.

Thanks don

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**From:** Sellers, Loretta  
**Sent:** Wednesday, July 30, 2014 11:19 AM  
**To:** Funk, Don; Skokowski, Richard  
**Cc:** Shuaibi, Mohammed  
**Subject:** FW: Question for the Exelon FFD Audit

Don this call came in about 11AM this morning, the caller is auditing and/or trying to get a clearer explanation of some verbiage in NRC 10 CFR 26. He emailed this information to expedite the process of getting what he needs. Would you please handle this or forward to the appropriate person. Thank you.

*Loretta Sellers  
Administrative Assistant  
RIII Division of Reactor Safety  
US Nuclear Regulatory Commission*  
 [loretta.sellers@nrc.gov](mailto:loretta.sellers@nrc.gov) | 630-829-9704



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**From:** Klink, David J:(GenCo-Nuc) [<mailto:david.klink@exeloncorp.com>]  
**Sent:** Wednesday, July 30, 2014 11:07 AM  
**To:** Sellers, Loretta  
**Subject:** Question for the Exelon FFD Audit

I am asking for clarification on the meaning of the following section;

§ 26.125 Licensee testing facility personnel.

(a) Each licensee testing facility shall have one or more individuals who are responsible for day-to-day operations and supervision of the testing technicians. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall also have training and experience in the theory and practice of the procedures used in the licensee testing facility, and a thorough understanding of quality control practices and procedures, the review, interpretation, and reporting of test results, and proper remedial actions to be taken in response to detection of abnormal test or quality control results.

Specifically, when the regulation says "equivalent" does that mean equivalent bachelor's degree, or experience or something else? Thank you in advance for your assistance.

[David J. Klink](#)

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