

Hi Dinesh:

One topic I would like to see covered in a bit more detail is one that may be covered under the subject of Corrective Action (Section 5.5 of NEI 17-06.)

My understanding is that a Certifying Organization will often provide a Certificate that covers the safety claim, with specified conditions, for a certification period of perhaps 3, 4, or 5 years. My concern is that if a licensee places a new certified device into service (i.e., installs it), and also purchases spares for the device to be stored in the warehouse, and then the installed device fails after the expiration of the Certificate, what review is performed to ensure that the spare items in the warehouse are still acceptable for use? I see two possible scenarios for this:

- a) The original vendor has decided to discontinue the production of the device, because of poor performance history experienced from the oil and gas industry, and has designed a completely new design model to replace the old one. However, the nuclear licensee has not experienced such poor performance with his equipment, other than the sudden failure that occurred after the certificate has expired. How would the licensee know that the Certificate for the version of this model that he has in his warehouse has expired, and what steps need to be taken before considering to use the models in the warehouse to replace the failed installed model? What should be the right process for addressing this?
- b) The original vendor has decided to submit an enhanced model to the certifying organization for certification that entails making only a slight modification to the same model (e.g., software revision, gasket material, terminal box cover, etc.) to address feedback from the field, and the original design model is no longer sold for the same applications. How would the licensee know that the items he has in his warehouse might need to be upgraded before they can be installed?

I'm not sure that this falls under Part 21, because it's not really because of a defect—just product improvements. It's just that the vendor may have unilaterally upgraded his product line to address feedback from the installed customer base. What process should be employed to ensure that licensees are made aware of the expiration of the certificate for items they may have stored in their warehouses, and how would they know there may be a need to upgrade or refurbish such items before they can be used to replace a failed installed item?

Thanks,

Dave

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**Sent:** Thursday, August 22, 2019 4:20 PM

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**Subject:** DI&C IAP - MP#3 - Draft NEI 17-06

Hi Dinesh,

I hope this email finds you well. Per NEI's request during yesterday's public meeting, please see attached comments for your consideration on the draft NEI 17-06. Please note that the comments are shown as embedded balloons highlighted throughout the document.

V/r

Ismael