

News Items of Technical or Regulatory Importance Vol. 6-16 June 30, 2016

Plexus-IEM Merger News

We're pleased to announce that the old Integrated Environmental Management, Inc. (IEM) is no more. We are now fully merged with our new company, Plexus Scientific Corporation (Plexus), and officially called the Nuclear Solutions Division (NSD). If you visit the web site at http://www/plexsci.com, then click on the little radiation symbol at the bottom of the page, you'll see us in our completely morphed state. Plexus-NSD is up and running! While you're there, check out the capabilities of the rest of the company as we think you'll be pleased with everything we can now offer our valued clients.

Revised Distribution License Guidance

In the June 23, 2016 edition of the Federal Register (81 FR 40928-40929), the U. S. Nuclear Regulatory Commission (USNRC) announced the release of a new draft of NUREG-1556, Volume 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees". Once finalized, the draft will become Revision I of Volume 16, which hit the streets back in December of 2000. Most of the information from Rev. 0 has been preserved in Rev I, but you will now see updated information on safety culture, security of radioactive materials and protection of sensitive information as well as other changes to reflect current regulatory policies and practices.

The requirements for distributing generally-licensed materials, products or devices are found in Title 10, Code of Federal Regulations, Parts 30, 31 and 32. However, Volume 16 of NUREG-1556 was designed to assist applicants in how to prepare applications to distribute, inform them of what the USNRC's expectations are, what the agency believes are "acceptable methods" for implementing their regulations, and how they will go about the application review process. In fact, if you read the Federal Register notice, it clearly states that Volume 16 "is intended for use by applicants, licensees, and the NRC staff". While you're certainly free to generate any sort of distribution license application that would make you happy, we can assure you that you will enjoy life better, and save yourself some time and hard-earned money, if you follow the agency's guidance.

The USNRC wants to hear from you on what you think of the contents of Rev. I of Volume 16. You can download your very own copy of the proposed draft at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v16/r1/. Comments are due by July 25, 2016, so don't delay.

Initial vs. Subsequent Distributions

While we're on the subject of distributing things, we've seen a few too many cases lately where companies with exempt distribution licenses are confused about what constitutes an "initial distribution" and how that differs from when their gadgets are later redistributed to someone else. This is an important distinction because initial distributions of items that don't require a license to possess can only be made by companies licensed to do so. However, subsequent distributions of those same items are exempt from regulation.

While the rules of the game are pretty straight forward for domestic manufacturers and distributors, the picture can get a little complicated when non-domestic suppliers enter the picture and when Agreement States are involved. Let's go through a couple of scenarios to see where the problems might lie and why there have been so many license-related enforcement actions lately.

For our first scenario, Company A makes a gadget that contains some radioactivity. They want to sell mass quantities of their gadget to Company B, who will then distribute them throughout the land. In order to do that, Company A first needs a license to possess the radioactivity for the purposes of manufacturing the gadgets. If they are in an Agreement State, they will end up with an Agreement State possession license. Company A also needs to obtain an exempt distribution license from USNRC (i.e., two licenses are required for Company A). However, once the gadgets are made and the sale/transfer to Company B takes place, Company B and its customers don't need to do anything other than exchange money for goods. No tracking, no trending, no QC, no reporting, no nothing.

Our second scenario has Company A now buying its gadgets from a foreign manufacturer instead of making them in-house. They then want to sell mass quantities to Company B, who will distribute them throughout the land. That sounds like a good deal because Company A won't need a license to manufacture the gadgets. And because it is not doing the initial distribution, they can ignore the distribution license requirements . . . right? WRONG! Under this scenario, the foreign manufacturer would be the initial distributor of the gadgets (to Company A) and thus needs a USNRC license to do so. However, once the gadgets are sent to Company A, who then sends them to Company B, no more regulating required for either A or B. What's key in this scenario is that someone in the food chain needs to have a distribution license before even one of those gadgets is transferred for the first time to someone in the US. It flat-out doesn't matter if the gadgets were born outside of our borders.

Our third scenario has Company A manufacturing the gadgets like they did in the first scenario, but they are then exporting them to a foreign customer, who incorporates them into a widget, defined as "not a gadget". The foreign customer then exports widgets to Company B in the US to distribute them throughout the land. Company A still needs its Agreement State manufacturing license, but its sale of gadgets only needs to take into account the 10 CFR 110 requirements for export of radioactive materials, meaning they don't need a USNRC distribution license. However, the tracking/trending/QC/reporting features of a distribution license need to come into play somewhere, thus the foreign customer would be considered the initial distributor of gadget-bearing widgets to Company B, who is then exempt from regulation.

Problems arise when exempt items are distributed anywhere in the US by companies that do not have a USNRC license to do so, and non-domestic companies aren't exactly lining up for the opportunity to apply for a USNRC distribution license. That means Company A loses a customer or manufacturer, and Company B loses its source of gadgets or widgets to distribute.

There are some things Company A might consider for scenarios two and three, in order to keep itself and Company B in business. For scenario two, if the foreign manufacturer says "no way" to a USNRC distribution license, they can always export the gadgets to Company A, who could then secure the distribution license and serve as the initial distributor. For scenario three, if the foreign also has no interest in becoming a USNRC licensee, Company A could secure a distribution license and track the sale of gadgets to the foreign customer as the initial distributor. If the gadgets then come back into the US inside of widgets, no more regulating is required. Of course, the USNRC needs to be on board for these and other possible solutions.

The bottom line is that securing a distribution license under any scenario is difficult enough, and the requirements for the privilege of being an initial distributor can be overwhelming. (Contrary to the USNRC's position, securing a distribution does not come with minimal cost or paperwork.) However, the moral of this story is that distributing exempted items by making assumptions about who is or who is not the initial distributor generally leads to trouble. It is a wise use of one's time to ensure whatever scenario seems right to you is covered by the correct compliment of licenses before gadgets and widgets are placed into commerce.

A Sad Day for Clean Energy Proponents

If you're a frequent visitor to the daily news feed posted on the Plexus-NSD web page, you've probably at least heard about the pending closure of California's Diablo Canyon nuclear power plant. On the heels of the San Onofre plant in southern California shutting down a couple of years ago, the announced closure of the Clinton and Quad Cities plants in Illinois, and the soon-to-close Fort Calhoun plant in Nebraska, to name a few, the news is disturbing on so many levels. However, the negative impacts on our

environment from these shut-downs should cause most folks - who are not as enamored with all things nuclear as us health physicists - to sit up and take notice.

The CASEnergy Coalition posted a telling article on its web site (caseenergy.org) just before the Diablo Canyon announcement that is worthy reading for your next coffee break. To quote from the article, "When the San Onofre nuclear plant retired in 2013, California lost 25 percent of the state's emission-free electricity and experienced a significant rise in carbon emissions – as much as 35 percent. As California already gets 60 percent of its electricity from natural gas, they cannot afford to take such a large proportion of their clean power offline." (http://casenergy.org/2016/04/nuclear-energys-impact-on-clean-power-plan-compliance/) Diablo Canyon provides another good percentage of carbon-free electricity in California that, when its lights go out, will be sorely missed by residents concerned with the quality of their air.

One would like to think there is a growing public recognition of the folly of walking away from nuclear power. For example, just yesterday there was a recent article in the Rutland Herald, "An Honest Renewable Energy Standard Includes Nuclear", that referred to the number of nuclear plants worldwide that were either temporarily or permanently removed from service in 2014, resulting in "an additional 100 to 200 tons of carbon emissions in 2015". However, the number of these articles is outweighed by the sheer volume of articles like the one from yesterday's New Times, which bid good riddance to Diablo Canyon because "nuclear power plants should never have been built", they "always leak radiation", and nuclear power "has always been a bad idea; good only on paper". Sigh.

We tip our collective hats to the power plant health physicists that know better than anyone about the benefits of an energy source that contributes almost 60% of the zero-carbon electricity in the US. We're sure some of them are worrying about their professional futures, but we hope the country comes to its senses sooner rather than later before too many jump ship. And with that, we'll take a short walk outside for a breath of fresh air. (Yes, we have nuclear power in Maryland!)

Radiation Safety Training

We're pleased to announce the recent launch of Plexus-NSD's radiation safety training program. The objective of the program is to help our clients ensure their work force is using radiation and radioactivity safely and in compliance with all rules, that their workers are aware of the radiological hazards in the work place and how to protect themselves, to help clients develop a positive health and safety culture, and to more efficiently manage radiation safety. We are true believers in the fact that effective training results in improved health/safety competence, avoids the stress of accidents, and goes a long way to minimizing the unnecessary cost of dealing with accidents and incidents of non-compliance. We thus want to share that knowledge and expertise with other users of radioactivity or radiation-producing machines.

Our courses are designed to help workers understand the hazards posed by radiation, radioactivity and other hazards in the workplace, and our instructors are experienced professionals with many years of real-life experience in handling and working with radiation sources (i.e., we teach a lot of things because we've seen a lot of things). For more information on our program, why it is a bit different from others being offered around the country, and to see a list of just a few of the classes we offer now or are soon to offer, we invite you to stop by http://www.iem-inc.com/company/services/training, which just happens to be a new addition to our web site. You can also give us a call at (443) 319-8055 to learn more, to test us on whether we know as much about radiation safety as we say we do, or to just listen to the soothing-yet-inspiring voice of some of our instructors.

To Learn More . . .

We hope you are able to find one or two useful or thought-provoking items in this and other editions of the Plexus-NSD e-Newsletter. We try to pick topics that are not only of interest to us, but hopefully to our readers. Please give us a call at (443) 319-8055 if you have any questions, don't understanding if something we've written might pertain to you or your program, or if we can be of professional service on any radiation-related topic whatsoever. Finally, don't forget to drop in on the Plexus-NSD web

site from time to time for even more news (scroll to the bottom of the page for the latest radiation-related news feed!), other resources, topical tutorials, and a handy-dandy tool box. Last but not least, when you are celebrating our Nation's independence this weekend, PLEASE leave the fireworks to the professionals! Best wishes, and Happy 4th.

Carol D. Berger, Nuclear Solutions Division

