

Mark Czerwinski

From: Lawyer, Dennis <Dennis.Lawyer@nrc.gov>
Sent: Thursday, January 15, 2015 11:29 AM
To: Mark Czerwinski
Subject: Incyte Corporation, Request for Additional Information Concerning Application for a License Amendment, Control 585630

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Mark Czerwinski,

This is in reference to your letter dated December 18, 2014, requesting for amendment to Nuclear Regulatory Commission License No. 07-30728-01, Docket No. 03035986. In order to continue our review, we need the following additional information:

1. Prior to termination of a license, 10 CFR 30.35(g), 30.36(k)(4) and 30.51 require that you submit certain records to the NRC.
 - a. for unsealed materials with half-lives greater than 120 days, records for disposal made pursuant to 10 CFR 20.2002 (alternate disposal procedures, including burial authorized prior to January 28, 1981), 20.2003 (disposals to the sanitary sewerage system), 20.2004 (incineration of wastes), 20.2005 (disposal of specific wastes including liquid scintillation cocktail and animal tissue), and 20.2103(b)(4), evaluations of effluent releases.
 - b. records important for decommissioning as described in 30.35(g), 40.36(f) and 70.25(g). Examples of such records include but are not limited to: records of contamination, identifying the radionuclides, quantities and concentrations; as-built drawings and modifications of structures and equipment in restricted areas and locations of inaccessible contamination such as buried pipes; a single list, updated at least every 2 years, of areas to which access is limited for the purpose of radiation protection (restricted areas); and records related to the provision of financial assurance.

Please state that you are retaining records for all of the above records as required for the Buildings E336 and E400, Route 141 & Henry Clay Road, Wilmington, Delaware facility.

2. The DuPont Experimental Station Building 336 and 400 Radiological Final Survey Report had several items that did not appear to be accurate or was missing information needed to validate and confirm results. Please clarify the following and resubmit the report as needed.
 - a. The report describes P-33 as a potential contaminate in some of the laboratories, specifically Building E336 labs 238, 266, Dock Cabinet, and Building 400 Lab 1440. The report in section 2.3 states that only H-3 and C-14 were considered potential contaminants but then states that P-33 was identified as a potential contaminate. Please explain what the distinction is made in this section and what implications it had on the survey design.
 - b. It is unclear how you determined the DCGLw for P-33. Please provide the specific reference or DandD calculation that supports this value.
 - c. In section 2.10, step 1 discusses P-33 as radioactive material used in the facility but then it infers that it could not exceed the DCGL. No justification is made on this statement. Step 2 did not discuss P-33.
 - d. There is no discussion of how P-33 was surveyed or if the results for the data given support release of the facility for P-33.

- e. Section 2.4 states that laboratory rooms where relatively high activity concentration of radioactivity were used were treated as Class 2 areas. There was no discussion of which labs were class 2 and if any were class 3. If any laboratory was considered Class 2, based on the survey diagrams given, there was no apparent systematic square grid with random start surveys performed as stated in section 2.9.
- f. Section 2.7, Table 4 is titled, "List of radionuclides listed on license (with data) and recent use." Please define what recent use means. In particular, were some laboratories not included that had tritium and carbon 14 use longer than 4 years ago?
- g. Section 2.9 describes detector surveys. For scan surveys, it does not describe the percentage of area that was scanned. Normally this is different for Class 2 and 3 areas, but this did not appear to be described either. Very few static surveys were performed on walls. Were walls scanned?
- h. For the table described as Survey Data, subtitled Survey Meter Information:
 - The serial number of the meter is the same as the serial number of the probe. Calibration data shows that the meter number and probe number is different. This makes it unclear as to how efficiency of the detector was determined if the probe has the same serial number.
 - Meter 3 states that it used Ludlum model 43-37 probes, but the detector size is 126 square centimeters. Model 43-37 should be 584 square centimeters.
 - The page gives formulas in the bottom section. These values are sometimes not given or not clear in the above data chart. For example, the human factor efficiency that is used is not given. Counting interval is not given. Source efficiency in formula is stated as just efficiency, 2pi efficiency is displayed. Background Counts is given as Background (c) in table. T counting time in minutes is different for background and survey counting and thus needs to be factored. Source efficiency is not given. Based on these factors this license reviewer could not duplicate the numbers calculated in the survey data. Also carbon-14 is a low energy beta and a source efficiency of half that for P-33 is normally used. Please provide all data used and make the data in the table consistent with the variables listed on the page. It is suggest to send a detailed example calculation.
- i. Building 336, Lab 228 survey data shows the Gross high (cpm) being lower than the Gross Average (cpm) which seems to be an inaccuracy. Please correct or explain.
- j. Surveys do not appear to include Building E336 Dock cabinet or 282 Freezer Farm which was described in section 2.7. There is a survey for the Deck Area which did not seem to correlate with any description in section 2.7.
- k. The calculations for carbon 14 did not seem to include a factor for the low energy self-absorption of measuring low beta energy on surfaces. Please describe what factors were used and how this was accounted.
- l. Calibration data was supplied for four instruments. Only two were used for these surveys. Why was the additional detector calibration data submitted? Is the survey data inaccurate to the which detectors were used?

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office (Address below) and refer to Mail Control No. 585630. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-2713.

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