



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

October 25, 2022

Paula Swain, Executive Vice President,
Human Resources
Incyte Corporation
1801 Augustine Cut-off
Wilmington, DE 19803

SUBJECT: INCYTE CORPORATION, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631703

Dear Ms. Swain:

This is in reference to your application dated June 23, 2022, requesting to renew NRC License No. 07-30728-01. In order to continue our review, we need the following additional information:

1. The NRC Form 313 submitting the renewal application was signed by Patrick Jordan, the Associate Director, EHS and Radiation Safety Officer. Renewal and amendment requests are usually signed by a management representative rather than the Radiation Safety Officer (RSO). The NRC views a letter signed by a management representative other than the RSO as indication that management has reviewed the application and concurs in the statements and representations contained therein. In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge.

Please have a management representative sign the response letter to this request for additional information. If you wish to continue to have the RSO also be the management contact, you may provide that information in the response letter. Please note that this letter is addressed to the management contact currently listed in our database.

2. In accordance with NUREG 1556, Volume 7 "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Revision 1" (NUREG 1556, Vol. 7, Rev. 1) Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," state that "Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office."

3. Your current license lists the following authorized users, who may use, or supervise the use of, licensed materials: Mary Covington, Mark Czerwinski, Patrick Jordan, Ronald Klabe, and Yanlong Li. Item 8 of your application states that all users must be approved by the RSO. Confirm if the list of authorized users on the current license is still correct; and confirm that any users approved by the RSO will be working under the supervision of one of the authorized users listed on the license.
4. Item 9 of the renewal application stated that there were no changes to facilities and equipment. Please submit the following information in accordance with NUREG 1556, Vol. 11, Rev. 1, Section 8.9, "Facilities and Equipment" so that the application contains complete and current information.
 - a. A description of areas for receipt, storage and disposal of radioactive materials.
 - b. A diagram showing the proximity of radiation sources to areas containing flammable or other hazardous materials; and specialized facilities and/or equipment such as waste storage rooms, waste compactors, "hot" labs, etc.
5. Section 10.6 of your application describes emergency procedures for minor and major spills. Confirm that you will develop, implement and maintain procedures for other incidents such as contamination of personnel, loss or theft of licensed material, fires, etc.
6. Section 10.7 of your application contains survey frequency criteria which is different from the guidance in NUREG 1556, Vol. 7, Rev. 1. Current guidance for survey frequency is found in Appendix M, "Radiation Safety Survey Topics." Survey frequency is based on handling, **at any one time**, multiples of the Annual Limit of Intake (ALI), which varies for the radionuclides listed on your license. The following radionuclides have more conservative survey requirements than described in your application:

Microcuries	ALI	Survey frequency		
		monthly < 0.1 ALI	weekly 0.1 ≥ ALI < 1	daily ≥ 1 ALI
H3	80000	< 8000	8000 - <80,000	≥ 80,000
C14	2000	< 200	200 - <2000	≥ 2000
P32	600	< 60	60 - <600	≥ 600
P33	6000	< 600	600 - <6000	≥ 6000
S35	10000	< 1000	1000 - <10,000	≥ 10,000
I125	40	< 4	4 - < 40	≥ 40

Confirm you will use the Appendix M survey frequencies when these quantities of materials handled at any one time, or after each use, if use is less frequent than shown above.

We will continue our review upon receipt of this information. Please reply to my attention either by providing a pdf of a signed response attached to an email to Elizabeth.Ullrich@nrc.gov ; or by regular mail to:

Mail Control No.
 USNRC, Region I
 Division of Radiological Safety and Security
 475 Allendale Road – Suite 102
 King of Prussia, PA 19406

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 240-704-4575 or by electronic mail to Eizabeth.Ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 07-30728-01
Docket No. 030-35986
Mail Control No. 631703

cc: Patrick Jordan, Radiation Safety Officer

INCYTE CORPORATION, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631703 DATED OCTOBER 25, 2022

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SUNSI Review Complete: Betsy Ullrich

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DATE	10/25/22 exu for LF		10/25/22		10/25/22 exu			

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