

CONVERSATION RECORD
(time) (date)

TIME | DATE

10/15/09

VISIT CONFERENCE TELEPHONE X

INCOMING
 OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Kirk Rozycki, RSO

Spectron

574-271-2800

SUBJECT

C/N's 318192 (pharmacy appl.) & 318193 (cyclotron appl.)

SUMMARY

Subsequent to my review of the licensee's letters dated 9/30/09 in response to my deficiency letters dated July 30, 2009, I contacted Mr. Rozycki to discuss the following items that will require clarification or additional information:

C/N 318193 (cyclotron):

1. Describe in greater detail how each proposed authorized user has obtained 40 hours of radiation training (ref. item 3 of 7/30/09 NRC letter). For D. Trump and Z. Reichert, provide greater detail that demonstrates that each has a minimum of 6 months experience in similar types of activities that they will be performing (ref. item 3 of 7/30/09 NRC letter).
2. Please respond to item 3 of the 7/3/09 NRC letter for the additional proposed authorized users, i.e., Minor, Miller, Hickman, Holiday and Peters, that were included in your 9/30/09 response.
3. In item 5.c. of your letter, please more clearly define what you mean by "greater than normal levels" as an indicator of filter saturation. Also, be more definitive with regard to your statement that effluent release that routinely rises above background to near the Part 20 release rate is indicative that a filter needs to be replaced. (ref. item 5.c. of 7/30/09 NRC letter).
4. Submit your calibration procedure for the effluent monitoring system. We also noted that your Alarm set points for effluent release are well above the Part 20 limit for F-18 (i.e., 1E-7 uci/ml). Based on the level that you established for an Alert, i.e., 0.1 uci/cc, if you had an average release in one day of 1E-2 uci/ml which is a concentration that would not activate the alarm, the annual average concentration would be 2.7E-5 uci/ml, which would exceed the Part 20 limit for F-18. Please revise your alarm set points so that you become aware of a release before it reaches Part 20 limits. (ref. item 5.d of 7/30/09 NRC letter)
5. With regard to safety procedures when handling targets and conducting routine and periodic maintenance of delivery lines, please define what you mean by the maximum amount of time that you will allow to pass before working on targets or performing maintenance on delivery lines. You should incorporate a requirement to conduct a radiation survey to verify radiation levels are at background before conducting these activities. Also, clearly define what you consider to be "reasonable levels" of radiation in determining if work in and around the cyclotron can or should be suspended. (ref. items 5.g. and 5.h. of 7/30/09 NRC letter).
6. Describe the training that R. Galloway and G. Hiatt have received in performing routine and periodic maintenance on delivery lines that lead from the cyclotron to hot and mini-cells, and the chemical synthesis units. (ref. item 5.h of 7/30/09 NRC letter).
7. Please confirm that all workers who handle targets, filters, as well as maintain and work on the cyclotron and its delivery lines will wear self-reading pocket dosimeters and/or alarming rate dosimeters. (ref. item 6.a. of 7/30/09 NRC letter).
8. Regarding a bioassay program, please confirm that your air handling systems will maintain all areas where radioactive materials are used and stored at negative pressure such that in the event of a release in worker breathing zones, the effluent will be carried out of the building, thereby minimizing potential for internal exposure. Nevertheless, you must submit a program for evaluating for uptake of F-18 in the event you have a release and

the HVAC system fails to carry effluent out of the building. Given the short half-life of F-18, this evaluation must be conducted within a few hours of a possible intake.

9. Given the potential for a significant exposure to the skin from F-18 resulting from, e.g., a contamination event, please describe procedures for: 1) minimizing the possibility of skin exposure; and 2) a procedure for conducting and evaluating skin dose.

C/N 318192 (pharmacy):

1. You indicated that you wish to name R. Galloway and M. Hiatt as authorized users. Since this license will be a nuclear pharmacy license and these two individuals are not pharmacists, please describe what material you wish them to be authorized to use.
2. Same as items 3 and 4 above for the cyclotron application (ref. items 4.c and 4.d of 7/30/09 NRC letter).
3. Same as item 8 above (ref. item 5 c. of 7/30/09 NRC letter).
4. Delete reference to Molybdenum-99/Techetium-99m generators since your license will not include authorization of this material.

QJF

ACTION REQUIRED

Respond to the above by 10/30/09,

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null		10/15/09

ACTION TAKEN

SIGNATURE	TITLE	DATE
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