

CONVERSATION RECORD  
(time) (date)

TIME DATE

10/12/10

VISIT

☐ CONFERENCE

TELEPHONE ☒ X

☐ INCOMING

☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

Marc Weichelt

ORGANIZATION (OFFICE, DEPT. ETC.)

Essential Isotopes

TELEPHONE NO.

573-882-0245

SUBJECT

C/N's 318475 and 318478

SUMMARY

I contacted Marc and informed him that I completed the review of Essential Isotope's (EI) reply to the telephone deficiencies of March 5, 2010. I requested that he provide the following additional information.

Understanding that EI has engineering controls and procedures in place that will minimize the likelihood of an accident that could result in the release and intake of licensed material, and since their license authorizes 20 curies of F-18 and the ALI is 50 millicuries, EI must develop and submit a bioassay program for both production and pharmacy licenses in the event there is, e.g., a break in a delivery line that results in an airborne release or skin contamination that results in inhalation or ingestion of licensed material.

Also, regarding your filter change-out program, you stated that filters are changed "once filter pressure drops become too high." Is there a threshold value or percent value? What is "too high?"

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE

DATE

10/12/10

ACTION TAKEN

SIGNATURE

TITLE

DATE