Yoon I. Chang, PhD [] Argonne National Laboratory-East 9700 South Cass Avenue Argonne, IL 60439-4832

Subject: Enforcement Letter (NTS-CH-AA-ANLE-ANLE-1999-0009)

Dear Dr. Chang:

This letter refers to the Department of Energy's (DOE) evaluation of the facts and circumstances concerning the above referenced Noncompliance Tracking System (NTS) report describing bioassay program deficiencies at Argonne National Laboratory-East (ANL-E). This report was submitted to DOE on December 23, 1999.

Approximately thirteen months previous to this NTS report's submittal, DOE's Office of Enforcement and Investigation (EH-Enforcement) issued to all DOE and contractor Price-Anderson Amendments Act coordinators a memorandum explaining EH-Enforcement's experience with and concern regarding contractor bioassay program deficiencies and noncompliances. The memorandum instituted a 120-day moratorium (the "Bioassay Moratorium") in which EH-Enforcement would exercise enforcement discretion for any contractor internal dose evaluation program that complied with three conditions:

- Any internal dosimetry evaluation program deficiency that was identified by a program review and that met previously identified NTS reporting thresholds, was reported into the NTS.
- For each reported deficiency, planned or proposed corrective actions were also entered into the NTS.
- Corrective actions entered into the NTS were implemented by the contractor within a reasonable period of time.

Following the conclusion (on April 1, 1999) of the Bioassay Moratorium, EH-Enforcement issued a supplemental memorandum summarizing the results of the moratorium by listing reported deficiencies in the following internal dose evaluation program areas: program documentation, field implementation, and quality assurance. Copies of these memoranda are enclosed for your reference. DOE's review of NTS report NTS-CH-AA-ANLE-ANLE-1999-0009, "Bioassay Program," determined that significant deficiencies existed in ANL-E's internal dose evaluation program preceding the Bioassay Moratorium, and these deficiencies were consistent with a number of those described in EH-Enforcement's memorandum initiating the moratorium. Furthermore, the University of Chicago (University) did not avail itself of the opportunity for enforcement discretion by submitting its "Bioassay Program" NTS report during the moratorium. In typical circumstances, DOE would use the basis of this investigation would likely be the issuance of a Preliminary Notice of Violation since the reported deficiencies were similar in nature to those that resulted in DOE taking various enforcement actions prior to the moratorium.

However, DOE is aware the University implemented fundamental changes in its approach to fulfilling its regulatory responsibilities at ANL-E subsequent to the November 19, 1999, enforcement conference concerning other nuclear safety issues. As a result, you reassessed this internal dosimetry issue and reported it to DOE along with corrective actions. Because of these fundamental changes, DOE has decided to issue this Enforcement Letter in lieu of initiating additional enforcement measures. Nonetheless, DOE, as indicated in its December 14, 1999, letter to you, remains concerned regarding the effectiveness of the radiation safety program in place at ANL-E and will closely monitor the University's corrective actions with respect to NTS report NTS-CH-AA-ANLE-ANLE-1999-0009.

Please contact Mr. Steven Zobel of my staff at (301) 903-2615 should you wish to discuss this issue further.

Sincerely,

R. Keith Christopher Director Office of Enforcement and Investigation

Enclosures: Bioassay Moratorium Memorandum Bioassay Moratorium Supplemental Memorandum cc: D. Michaels, EH-1
M. Zacchero, EH-1
H. Wilchins, EH-10
S. Zobel, EH-10
D. Stadler, EH-2
O. Pearson, EH-3
J. Fitzgerald, EH-5
J. Decker, SC-1
M. Johnson, SC-80
R. Schwartz, SC-83
R. San Martin, DOE-CH
C. Zook, DOE-CH-ARG PAAA Coordinator
R. Purucker, DOE-CH-ARG PAAA Coordinator
A. Cohen, ANL-E PAAA Coordinator
Docket Clerk, EH-10