UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket Nos. 030-04530 and 030-06923
U.S. DEPARTMENT OF AGRICULTURE Washington, D.C. 20250	)	License Nos. 19-00915-03 and 19-00915-06
	)	EAs 92-232 and 93-028

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The U.S. Department of Agriculture (Licensee), Washington, D.C. is the holder of Byproduct/Source Material Licenses Nos. 19-00915-03 and 19-00915-06 (Licenses), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 33. License No. 19-00915-03 authorizes the Licensee to use byproduct material for research and development; in gauging and measuring devices; in field applications as approved by the Radiation Safety Committee (RSC); and for research studies in humans as approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration, and by the Licensee's Radiation Safety Committee (RSC). This is a large, multi-site, broad scope license with no stated possession limit. License No. 19-00915-06 authorizes the Licensee to use cobalt-60 and cesium-137 sealed sources in irradiators at sites and by users approved by the Licensee's RSC.

Licensed activities are conducted by a number of organizations within the Licensee's organization, including (1) the Agriculture Marketing Service (AMS); (2) the Animal, Plant, and Health

Inspection Service (APHIS); (3) the Agricultural Research Service (ARS); (4) the Federal Grain Inspection Service (FGIS); (5) the Food Safety and Inspection Service (FSIS); (6) the National Forest Service (NFS); and (7) the Soil Conservation Service (SCS). Over 3500 permits currently have been issued to individuals in these services to use licensed material at numerous locations around the country.

The Licenses most recently were renewed on February 10, 1990 and May 22, 1986, respectively, and would have expired on February 28, 1991 and May 31, 1991, respectively. Both Licenses continue in force, pursuant to 10 CFR 30.37(b), because of the timely filing of applications by the Licensee to renew the Licenses.

II

Ten inspections of the Licensee's activities were conducted by the NRC between March and October 1992 at several Licensee facilities throughout the country. During the inspections, twelve violations of NRC requirements were identified, five of which were repetitive violations identified during previous NRC inspections. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated March 26, 1993. The Notice states the nature of the violations, the

provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice by letters dated April 22, 1993. In its response, the Licensee admits all of the violations, but requests mitigation of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $10,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer

of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be whether, on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 25th day of June 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On March 26, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for twelve violations identified during ten NRC inspections conducted between March and October 1992. The licensee responded to the Notice in letters dated April 22, 1993, and admits all of the violations, but requests mitigation of the civil penalty. The NRC's evaluations and conclusions regarding the licensee's requests are as follows:

1. **Restatement of Violations**

   A. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

   Item 3 of the application dated July 11, 1989, requires, in part, that Category I locations (major isotope users; facilities that use millicurie quantities of radioiodine and/or perform iodinations; and facilities that perform studies involving human subjects) be inspected at intervals not to exceed three years, and Category II locations (all non-Category I facilities that use licensed material in an unsealed form) be inspected by the Radiation Safety Staff at intervals not to exceed five years.

   Condition 17 of License No. 19-00915-06 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained, in part, in an application dated August 27, 1985, and letters dated April 7, 1986, June 27, 1986, and April 14, 1987. Item K.11. of the application dated August 27, 1985, requires that irradiator facilities be inspected by the Radiation Safety Staff at least every three years.

   Contrary to the above, as of September 9, 1992, certain USDA facilities were not inspected at the required intervals as specified above. Specifically, two Category I facilities, (namely, Miles City, Montana, and Greenport, New York) had not been inspected in the previous three years; and 12 Category II facilities (Hamden, Connecticut; West Lafayette, Indiana; Morris, Montana; Raleigh, North Carolina; University Park, Pennsylvania; Brooking, South Dakota; Lubbock, Texas; Kearneysville, West Virginia; Columbia, Missouri; Wooster, Ohio; Fresno, California; and Salinas, California) had not been inspected in the previous five years; and one irradiator facility (namely, Otis Air

Force Base, Massachusetts) had not been inspected in the previous three years.

This is a repetitive violation.

B. Condition 12 of License No. 19-00915-03 and Condition 13 of License No. 19-00915-06 require, in part, that sealed sources be tested for leakage and/or contamination at intervals not to exceed 6 months or at other intervals as specified by the certificate of registration, not to exceed 3 years; and that records of leak test results be maintained for inspection by the Commission.

Contrary to the above, as of September 9, 1992, 65 sealed sources had not been tested for leakage at six-month intervals, as required, and no other interval was specified by the certificates of registration. In addition, leak test results were not maintained for inspection by the Commission in that leak test records for sealed sources possessed by 13 different users were missing from 29 user files which were reviewed.

This is a repetitive violation.

C. Condition 19 of License No. 19-00915-03 requires, in part, that ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 of 10 CFR Part 20 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in 10 CFR Part 20, Appendix B, Table II.

Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989 and a letter dated March 9, 1990.

Item 11.2 of the application dated July 11, 1989 requires that quarterly summaries of the records of incinerations be furnished to the radiation safety staff.

Contrary to the above, as of September 9, 1992, quarterly summaries were not furnished to the radiation safety staff during the period of July 1991 through June 1992 for seven incinerators at four sites (namely, Athens, Georgia; Clay Center, Nebraska; Fargo, North Dakota; and Ames, Iowa), and surveys of ash residues were not performed for three incinerators at three sites (namely, Clay Center, Nebraska; Grand Forks, North Dakota; and

Plum Island, New York) during the period of July 1991 through June 1992 to assure that ash residue disposed of as ordinary waste did not exceed the concentrations specified for water in 10 CFR Part 20, Appendix B, Table II.

This is a repetitive violation.

D. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on September 22, 1992, licensed material consisting of a nickel-63 electron capture device in a gas chromatograph located in an unlocked storage building, an unrestricted area, at the Boll Weevil Research Laboratory in Mississippi State, Mississippi, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

This is a repetitive violation.

E. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. 10 CFR 20.301(a) requires that no licensee dispose of licensed material except by transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 61, 70, or 72, whichever may be applicable.

Contrary to the above, on October 31, 1991, a USDA facility in Albany, California sent a drum containing 0.51 millicuries of sulfur-35, 0.003 millicuries of carbon-14, and 0.002 millicuries of cadmium-109 to a normal landfill for disposal in the normal trash, a method not authorized by 10 CFR 20.301. In addition, as of September 2, 1992, byproduct material was routinely disposed of by transfer to other licensees (namely, Pennsylvania State University and Cornell University) who were not authorized to receive radioactive waste for disposal in University Park, Pennsylvania and Ithaca, New York.

F. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

1. Item 9.18 of the application dated July 11, 1989, requires, in part, that a contamination level survey be performed by permit holders at least every three months and the results be reported to the Radiation Safety Officer.

Contrary to the above, as of September 9, 1992, results of contamination level surveys performed by various permit holders every three months were not reported to the Radiation Safety Officer. Specifically, 14 permit holders failed to report the results of one or more quarterly contamination level surveys during the period of January 1991 through June 1992.

2. Item 10.4.2 of the application dated July 11, 1989, requires that licensed material be used by Radiation Safety Committee-approved users in accordance with generally accepted safe practices, the rules and procedures specified in the USDA Radiological Safety Handbook, and as specifically prescribed by the Committee and/or the Radiation Safety Officer.

Contrary to the above, as of September 9, 1992, licensed material was used in a manner different than prescribed by the Radiation Safety Committee (RSC) and/or the Radiation Safety Officer (RSO). Specifically, (1) a permit holder in Pullman, Washington authorized to possess one 50-millicurie americium-241 sealed source possessed five 50-millicurie and one 1000-millicurie americium-241 sealed sources, quantities in excess of those prescribed by the RSC or RSO; (2) a permit holder in Fargo, North Dakota authorized to use one millicurie of nickel-63, possessed an 8-millicurie sealed source of nickel-63, a quantity in excess of that prescribed by the RSC or RSO; (3) in Ithaca, New York, a permit holder possessed a source of cobalt-60 which no person performing activities under this license is authorized by the RSC or RSO to possess; and (4) in Mississippi State, Mississippi the permit holder used its irradiator for purposes other than the boll weevil studies

authorized by the RSO, such as irradiation of blood, spiders, and grasshoppers.

3. Item 11.1.7 of the application dated July 11, 1989, requires that users maintain accurate inventories of radioactive materials under their control so that reports can be prepared and submitted when requested by the Radiation Safety Officer.

Contrary to the above, as of September 9, 1992, users' reports of inventories were not submitted when requested. Specifically, 7 of 18 users reviewed did not submit results of inventories requested by the Radiation Safety Officer in 1991.

G. Condition 15 of License No. 19-00915-03 requires that a physical inventory be performed every six months to account for all sources and/or devices received and possessed by the licensee, and that records of inventories be maintained for two years from the date of each inventory.

Contrary to the above, between June 15, 1990, and September 9, 1992, a period in excess of six months, physical inventories of at least 65 sealed sources were not performed and inventory records were not maintained as required.

H. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their facilities or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

49 CFR 177.817(e)(2)(i) requires, in part, that when a driver of a motor vehicle transporting licensed material is at the vehicle's controls, the shipping paper shall be within his reach and either readily visible to a person entering the driver's compartment or in a holder which is mounted on the inside of the door on the driver's side of the vehicle.

Contrary to the above, as of September 1, 1992, a USDA employee at the University Park, Pennsylvania, facility routinely stored shipping papers in the portable gauge case during transportation to and from temporary job sites, and therefore, the shipping papers were not within the driver's reach, readily visible to a person entering the driver's compartment, or in a holder mounted on the

inside of the door on the driver's side of the vehicle during transportation of a portable gauge.

I. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area are instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of March 5, 1992, an ancillary staff member working in a restricted area at the Pacific Southwest Research Station in Berkeley, California had not been instructed in the precautions and procedures to be followed when he performed duties in the laboratory where licensed material was used and had not been instructed in the applicable provisions of the regulations and the conditions of the license.

J. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of 10 CFR Part 19, 10 CFR Part 20, the license, the license conditions, documents incorporated into the license, license amendments, and operating procedures; or, if posting of a document is not practicable, that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees". 10 CFR 21.6 requires, in part, that the licensee post current copies of 10 CFR Part 21.

Contrary to the above, on March 6, 1992, at the licensee's facility in Placerville, California, current copies of 10 CFR Parts 19 and 20 were not posted; on September 1, 1992, at the licensee's facility in University Park, Pennsylvania, a current copy of Form NRC-3 was not posted; and as of September 23, 1992, at the licensee's facilities in Mississippi State, Mississippi and Tuscaloosa, Alabama, copies of 10 CFR Part 21 were not posted.

This is a repetitive violation.

These violations are categorized in the aggregate as a Severity Level III problem. (Supplements IV and VI)

Civil Penalty - $10,000

2. **Summary of Licensee Response**

In its written responses, the licensee admits all of the violations. However, the licensee requests that the penalty

be mitigated in its entirety. In support of its request for full mitigation, the licensee notes its commitment to an independent assessment of the Radiation Safety Program to achieve and maintain compliance with NRC requirements, as well as recent improvements in its program operations. The licensee also states that the violations do not represent a significant health and safety risk to the public, and it has taken or planned effective corrective actions.

The licensee further notes that the Enforcement Conference in January 1993 resulted in a significant elevation of the importance of the program within the licensee's organization, and its management has become involved in the program improvement plan and has committed its support to it. The licensee also indicates that it has been granted exemptions to the USDA hiring freeze for two additional health physicist positions on the radiation safety staff. In view of the above, the licensee contends that payment of the civil penalty is not necessary to assure management attention to this program or to the licensee's commitment to the improvement process.

3. **NRC Evaluation of Licensee Response**

The NRC has evaluated the licensee response and has determined that the licensee has not provided an adequate basis for mitigation of the civil penalty. The severity level of the violations and the civil penalty amount were determined in accordance with the NRC's Enforcement Policy and the enforcement action was consistent with action taken for similar violations by other licensees. Supplement VI.C.7 of the NRC Enforcement Policy gives as an example of a Severity Level III violation, a breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities. The NRC places great importance on management control of activities involving licensed materials to ensure that all NRC requirements are met and that any potential violation of an NRC requirement is identified and corrected expeditiously. Thus, the violations are of significant regulatory concern and were properly categorized in the aggregate as a Severity Level III problem.

Further, in determining the amount of the civil penalty for the Severity Level III problem, the NRC considered the escalation and mitigation factors set forth in the NRC Enforcement Policy. As part of that evaluation, the NRC concluded that the base civil penalty amount for this Severity Level III problem should be increased by 300% because the

violations were identified by the NRC, the corrective actions were neither prompt nor comprehensive, the licensee's prior enforcement history included violations that resulted in the issuance of a $5,000 civil penalty in August 1990, and some of the violations existed for an extended duration.

With respect to the issues provided in the licensee's response as a basis for mitigation of the penalty, the NRC acknowledges that the licensee did commit to an independent assessment to improve implementation of the radiation safety program. However, this commitment was made only after these violations were identified by the NRC in 1992 and an Enforcement Conference was scheduled, notwithstanding the fact that many of these violations were repetitive, existed for an extended duration, and should reasonably have been prevented if appropriate management attention had been provided to the program after the NRC had previously conducted an enforcement conference with the licensee on July 11, 1990, and issued the $5,000 proposed civil penalty to the licensee on August 16, 1990.

The NRC acknowledges that there was a significant elevation of the importance of the program within the licensee's organization, subsequent to the more recent enforcement conference with the licensee on January 19, 1993. Further, management has apparently become involved in the program improvement plan and has committed its support to it. Nonetheless, these actions were not timely, given the licensee's existing enforcement history. If these plans for improvement had not been taken by the licensee, the NRC would have considered more significant enforcement action. The Licensee's answer and reply to a Notice of Violation provide no new information which changes the conclusion reached in the Notice.

4. NRC Conclusion

The NRC concludes that the licensee has not provided an adequate basis for mitigating any portion of the civil penalty. Accordingly, the NRC has determined that the proposed civil penalty in the amount of $10,000 should be imposed.

JUN 23 1993

U.S. Department of
Agriculture (USDA)

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