DLR:DAN
Docket No. 27-7

SEP 16 1958

Mr. Seth Gordon, Director
Department of Fish and Game
State of California
722 Capitol Avenue
Sacramento, California

Dear Mr. Gordon:

We wish to acknowledge and thank you for your letter of August 25, which refers to our letter of May 9, 1958.

We are reviewing the information contained in your letter and will write to you concerning the questions raised therein in the very near future.

Very truly yours,

Eber R. Price, Acting Director
Division of Licensing and Regulation

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FORM AEC-318 (Rev. 9-53) U. S. GOVERNMENT PRINTING OFFICE 16—62761-3

D R A F T REC:hgs 9-2[illegible] 58

Isotopes Specialties Company
170 West Providencia
Burbank, California

Attention: Dr. A. M. Goldstein

Gentlemen:

This refers to the inspection conducted on August 12 and 13, 1958, of your activities licensed under AEC Byproduct Material License Nos. 4-580-3 and -7.

It appears that certain of your activities were not conducted in full compliance with conditions of your licenses and the requirements of the AEC's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations, in that:

1. Adequate surveys to determine that concentrations of byproduct material in the air did not exceed the limits specified in Section 20.101(b), Exposure of individuals in restricted areas, and Section 20.103, Concentrations in effluents to unrestricted areas, were not made as required by Section 20.201(b), Surveys.
2. Film badge reports indicated that an employee exceeded the maximum permissible exposure limits specified in Section 20.101(a)(1), Exposure of individuals in restricted areas, during the weeks of September 13, 1957, September 27, 1957, and October 11, 1957, when he received doses of 325 mrem, 930 mrem and 400 mrem, respectively. The 13-week period cumulative dose in each instance exceeded 3 rem.
3. Film badge reports indicated that the subsequent exposures of the individual referred to in paragraph 2 were not limited as required by Section 20.105, Measures to be taken after excessive exposures, after he received a radiation dose of 930 mrem.

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4. The 930 mrem exposure was not reported as required by Section 20.403(c), Notifications and reports of incidents.
5. The effluent from glove boxes was not monitored as required by Condition No. 25 of License No. 4-580-7, which incorporates procedures referred to in a letter dated December 21, 1956, from A. M. Goldstein to the Atomic Energy Commission.
6. Records of surveys as required by Section 20.401(c), Records of surveys, radiation monitoring and disposal, were not complete.
7. The waste storage yard was not posted as required by Section 20.203(e)(1) and (e)(2), Caution signs, labels and signals.

Pursuant to the provisions of Section 2.201(a), Notice of violation, of the AEC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, you are requested to notify this office, within fifteen days of your receipt of this notice, of the corrective steps taken or to be instituted to achieve correction of the above-described violations and the date when such correction has been or will be achieved.

Signed: Mason

Enclosures:
Part 20
Part 2

Isotopes Specialties Company
170 West Providencia
Burbank, California

In the Matter of AEC Byproduct Material Lic — No's ____ and ____.

Attention: Dr. A. M. Goldstein

Gentlemen:

This refers to the inspection conducted on August 12 and 13, 1958, of your activities licensed under AEC Byproduct Material License Nos. 4-580-3 and -7.

It appears that certain of your activities were not conducted in full compliance with conditions of your licenses and the requirements of the AEC's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations, in that:

1. ~~Adequate~~ Surveys to determine that concentrations of byproduct material in the air did not exceed the limits specified in Section 20.101(b)~~, Exposure of individuals in restricted areas,~~ and Section 20.103~~. Concentrations in effluents to unrestricted areas,~~ were not made as required by Section 20.201(b), Surveys. ~~Surveys~~ Weekly routine surveys were not performed. Such surveys are required by Condition No. 15 of License No. 4-580-7 ~~as outlined in Isotopes Specialties Company administrative procedures dated December 2, 1957, and referenced in License No. ______, as Condition No. ______. Specifically the following sections of the administrative procedures were not followed: Section 6A(6), 6C(10), and 8C.~~

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the outline of administrative procedures which was submitted as an attachment to your application dated 12/2/57.

2. Film badge reports indicated that an employee exceeded the maximum permissible exposure limits specified in Section 20.101(a)(1)~~, Exposure of individuals in restricted areas,~~ during the weeks of September 13, 1957, September 27, 1957, and October 11, 1957, when he received

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doses of 325 mrem, 930 mrem and 400 mrem, respectively. The 13-week period cumulative dose in each instance exceeded 3 rem.

3. Film badge reports indicated that the subsequent exposures of the individual referred to in paragraph 2 were not limited as required by Section 20.105, ~~Measures to be taken after excessive exposures,~~ after he received a radiation dose of 930 mrem.

4. The 930 mrem exposure was not reported as required by Section 20.403(c), ~~Notifications and reports of incidents.~~

5. The effluent from glove boxes was not monitored as required by Condition No. 25, of License No. 4-580-7 which incorporates procedures referred to in a letter dated December 16, 1957, from A. M. Goldstein to the Atomic Energy Commission.

6. Records of surveys ~~as~~ were not maintained as required by Section ~~XXXX~~ 20.401(c), ~~Records of surveys, radiation monitoring and disposal, were not complete.~~ were not complete.

7. The waste storage yard was not posted as required by Section 20.203(e)(1) and (e)(2), ~~caution signs, labels and signals~~.

Pursuant to the provisions of Section 2.201(a) ~~Notice of violation,~~ of the AEC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, you are requested to notify this office within 15 days of your receipt of this notice, of the corrective steps taken or to be instituted to achieve correction of the above-described violations and the date when

such correction has been or will be achieved. F, NO

The information gathered during the inspection clearly indicates that adequate surveys have not been made to demonstrate that your activities meet the Commission's Part 20, "Standards for Protection Against Radiation." It is therefore requested that, in answering the above items of non-compliance, you provide the following specific information to supplement your general administrative procedures:

1. Action which will be taken to re-organize your survey program to provide, as a minimum, routine surveys and laboratory areas for surface contamination, routine air surveys in laboratories, surveys to determine radiation dose rates during all phases of gamma source encapsulation, routine surveys of the concentrations of radioactive material in water and air effluents and both air and w surface contamination survey of the unrestricted area surrounding your facility. The frequency of all of these surveys should be such as to reflect, on a daily and weekly basis, the status of compliance with 10 CFR 20. The information should include types of surveys, equipment to be used, method for interpreting data in relating Part 20, ~~frequency and location of surveys~~ and the detailed records of surveys which will be maintained.

π 2. Action which will be initiated to provide a more thorough bio-assay program for those persons potentially ~~exposed~~ exposed to material through ingestion, inhalation or absorption. It is noted that one urine sample of Mr. R. Haslett, taken on March 25, 1958, indicated

internal polonium in sufficient quantities that thorough follow-up was indicated to determine body burden. Also, there was no evidence that a determination was made of radioactivity in the urine prior to starting work with polonium or tritium. No attempt was made to identify the predominant radioisotope in the urine. There appeared to be no systematic routine bio-assay program. You should indicate (1) the program which you will initiate to obtain bio-assay data which reflects the approximate body burden of each radioisotope of all present employees who have worked with radioisotopes. These data should reflect the approximate body burden of each radioisotope with which each employee has worked; (2) provisions to conduct followup urinalysis of individuals whose urine contains radioactivity at levels approaching permissible body burden. Your answer should reflect provisions to conduct bio-assays on individuals who ingest all radioisotopes, including polonium and tritium.

3. The items of non-compliance and radiation safety conditions noted during the recent inspection indicates that your Isotopes Committee is not functioning in a manner which would assure that radiation safety standards within Isotopes Specialties Company meet the requirements of the AEC's Part 20, "Standards for Protection Against Radiation." It is requested that in your answer to the above items of non-compliance that you specify in detail how the Isotopes Committee's functions will be re-constituted to correct existing deficiencies and assure that adequate standards for protection against radiation will be maintained.

In providing the specific details requested above, you may desire to consider re-writing your general administrative radiation safety procedures to include the specific details outlined above and submit the revised procedures as a partial answer to the above items of non-compliance.

Mason

In the Matter of AEC
Byproduct Material License
Nos. 4-580-3 and 4-580-7

Isotopes Specialties Company
170 West Providencia
Burbank, California

Attention: Dr. A. M. Goldstein

Gentlemen:

~~This refers to the inspection~~ conducted on August 12 and 13, 1958, ~~of your activities licensed under~~ AEC Byproduct Material License Nos 4-580-3 and -7.

It appears that certain of your activities were not conducted in full compliance with conditions of your licenses and the requirements of the AEC's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations, in that:

1. Surveys were not made as required by Section 20.201(b) to determine that concentrations of byproduct material in the air did not exceed the limits specified in Section 20.101(b) and Section 20.103.

2. Film badge reports indicated that an employee exceeded the maximum permissible exposure limits specified in Section 20 101(a)(1) during the weeks of September 13, 1957, September 27, 1957, and October 11, 1957, when he received doses of 325 mrem, 930 mrem and 400 mrem, respectively. The 13-week period cumulative dose in each instance exceeded 3 rem.

3. Film badge reports indicated that the subsequent exposures of the individual referred to in paragraph 2 were not limited as required by Section 20.105 after he received a radiation dose of 930 mrem.

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4 The 930 mrem exposure was not reported as required by Section 20 403(c).

5 The effluent from glove boxes was not monitored as required by Condition No 25 of License No. 4-580-7 which incorporates procedures referred to in a letter dated December 16, 1957, from A M Goldstein to the Atomic Energy Commission

6 Records of air surveys were not maintained as required by Section 20 401(c)

7 The waste storage yard was not posted as required by Section 20.203(e)(1) and (e)(2).

Pursuant to the provisions of Section 2.201(a) of the AEC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, you are requested ~~to notify this office within 15 days of your receipt of this notice,~~ of the corrective steps taken or to be instituted ~~to~~ achieve correction ~~of the above described~~ violations and the date when such correction ~~has been or~~ will be achieved.

Based upon preliminary information, it appears that the administrative control and radiation safety procedures incorporated in the referenced licenses are not sufficiently detailed to demonstrate that your activities are ~~in compliance with the provisions of~~ the Commission's ~~"Standards for Protection Against Radiation, Title 10, Part 20, Code of Federal Regulations,~~ and that your quality control procedures are ~~inadequate~~ to assure that certain manufactured products ~~have not been~~ fabricated in accordance with the specifications contained in your licenses.

Pursuant to the provisions of Section 30 32(a), 10 CFR 30, "Licensing of Byproduct Material," and Section 2.202(b), 10 CFR 2, "Rules of Practice," it is hereby ordered that within 30 days from your receipt of this order, the Isotopes Specialties Company shall furnish the Director, Division of Licensing and Regulation, with a revised and detailed complete description of the administrative control and radiation safety procedures which the company proposes to employ to assure that the licensed operations are conducted in a safe manner. The description should include, among other things, the following specific information:

1 A detailed description of a survey program specifying the frequency of surveys which will be conducted to determine surface contamination and levels of air concentrations in restricted and unrestricted areas, dose rates ~~to employees~~ during gamma source encapsulation and other activities, and concentrations of radioactive material in water and air effluents to unrestricted areas. The description should also include a discussion of the equipment to be used, (a) proposed method for interpreting the results of surveys, and the method of maintaining records of the results of the surveys.

2 A detailed description of the bio-assay program for ~~those persons~~ "of your employees who are potentially exposed to radioactive material through ingestion, inhalation or absorption. You should ~~indicate~~ discuss ~~(a)~~ the program which you will initiate to (a) obtain bio-assay data which reflects the approximate body burden of each radioisotope of all present employees who have worked with radioisotopes; and ~~These data should reflect the~~

approximate body burden of each radioisotope with which each employee has worked; (2) provisions to conduct followup urinalyses of individuals whose urine contains radioactivity at levels approaching permissible body burdens.

3. A detailed description of the training and experience of the members of the Isotopes Committee and a description of the operating functions of the Committee which assure the maintenance of health and safety of your employees & the public.

4. A detailed description of the quality control procedures which will be followed to assure that manufactured products containing licensed materials are fabricated in accordance with the specifications contained in your licenses.

The Isotopes Specialties Company may request a formal hearing with respect to this order, or any part thereof, by filing a written request for hearing with the Office of the Secretary, United States Atomic Energy Commission, Washington 25, D. C., within 15 days after the date of this order Filing of a written request for hearing may also be accomplished in person either in the Commission's Public Document Room, 1717 H Street, N. W , Washington, D C , or the Office of the Secretary in Germantown, Maryland.

Pursuant to Section 2 202(b) of the Commission's "Rules of Practice," 10 CFR Part 2, a timely filing of a request for formal hearing with respect to this order or any part thereof, shall stay the order, or such part of the order, pending determination of the issues by the Commission.

Very truly yours,

H L. Price

D R A F T REC:hgs 9-29-58

Isotopes Specialties Company
170 West Providencia
Burbank, California

Attention: Dr. A. M. Goldstein

Gentlemen:

This is in further reference to the inspection of your facilities conducted on August 12 and 13, 1958, and to our letter dated _____, listing items of noncompliance.

The information gathered during the inspection clearly indicates that surveys were insufficient to meet our "Standards for Protection Against Radiation," Air sampling equipment was inoperable for a two month period, there was a high degree of cesium and polonium contamination in laboratories, no routine survey program was in effect and no surveys were conducted in unrestricted areas.

This indicates that your survey program should be reorganized to include, as a minimum, routine daily surveys in laboratory areas for surface contamination, routine weekly air surveys in laboratories at times when the concentration of radioactive material in the air is at its greatest, surveys to determine radiation dose rates during all phases of gamma source encapsulation, a survey of the concentrations of radioactive material in water and air effluents and a thorough air and surface contamination survey of the unrestricted areas surrounding your facility. The frequency of all of these surveys should be such as to reflect on a daily and weekly basis the status of compliance with 10 CFR PART 20.

In order that we may evaluate the survey program which you will institute, you should submit the following:

1. An outline of the types of surveys that will be conducted in your facilities, specifying the equipment which will be used and the method for interpreting data derived from this equipment. The surveys should include provisions for

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determining concentrations of radioactive material in the air, ~~quantities of surface contamination~~ and levels of radiation.

2. The frequency ~~at which~~ that each type of survey will be made on a routine basis.
3. The location at which routine surveys will be conducted.
4. ~~XX~~ Provisions for conducting additional surveys in the event of unusual circumstances.
5. The method for maintaining records of surveys. Survey records should include results of surveys conducted at 703 South Main Street, Burbank, California, and appropriate unrestricted areas as well as your present laboratory facilities.

The results of the inspection have indicated that your bio-assay procedures, as outlined in your administrative instructions dated December 2, 1957, may be inadequate in that: a) no determination was made of the radioactivity in the urine prior to starting work with polonium or tritium; b) no attempt was made to identify the predominant radioisotope in the urine; and c) after completion of polonium work, no follow-up urinalyses were made on employees whose urine contained radioactivity in ~~excess of the tolerance for the type of analysis in question.~~ quantities which indicated that a thorough follow up to determine the total body burden should be made.

In view of the foregoing, it is requested that the following information be submitted:

1. Bioassay data which reflects approximate Body Burden indicate the gross alpha, beta of each radioisotope and gamma activity in the urine of all present employees who have worked with radioisotopes while in your employ. These data should reflect the approximate body burden Please describe the analysis procedures used.

2. Proposed provisions to conduct follow-up urinalyses on individuals whose urine contains radioactivity in excess of tolerance.

3. Proposed provisions to conduct uninalyses on individuals who may inhale or ingest radioisotopes other than polonium or tritium.

In addition to the above, our re-evaluation of the safety of your facilities, activities and procedures requires further clarification of certain phases of your operations.

The ventilation system does not appear to be satisfactory for the type of work being performed. The combination of filters and blower system in your facility could result in an unexpected loss of air flow or negative pressure. Since the CSW-6 filters have no prefilter, they may become clogged and thereby raise the static pressure through the filter. This would result in a greater volume of air passing through other hoods and boxes and a consequent loss of negative pressure in the box with the clogged filter.

The true effectiveness of your ventilation system is not known since the surveys you conducted were inadequate and your records were incomplete. In order that we may evaluate the ventilation system, you should submit the following:

1. A schematic diagram of your entire ventilation system, including location of filters and blowers;
2. The volume of air flow through hoods and glove boxes;
3. The linear air velocity through each hood with the windows of all hoods in their normal working position;
4. The minimum pressure differential that will be maintained between the glove boxes and the laboratory in which they are located;
5. A description of the equipment used to continually monitor the effluent from glove boxes and the method for interpreting and recording data derived from this equipment; and
6. The method which will be followed to determine that the hoods and glove boxes in which byproduct material is used maintain air flow or negative pressure.

As you know, Advance Industrial X-Ray Engineering Corporation was recently involved in an accident in which a radiography source became separated from a cable coupling on a Model LSS-3A(?) radiography camera manufactured by Isotopes Specialties. The use of byproduct material in this camera was licensed in reliance on drawings and specifications submitted to us by Isotopes Specialties. Specifications indicated that the source capsule would be soldered to the coupling. The fact that this source capsule was not soldered materially contributed to the circumstances leading to the over-exposure of an individual. Therefore, you are requested to specify the quality control procedures which will be followed in all phases of your manufacturing operations to assure that devices manufactured by you meet the specifications which you have furnished to us concerning such devices.

The administrative instructions dated December 2, 1957, lists members of an Isotope Committee and outlines the Committee's functions. The items of noncompliance noted during the inspection indicate that the Committee is not functioning in a manner which would assure that radiation safety standards within Isotopes Specialties meets the requirements of the AEC's "Standards for Protection Against Radiation," Please specify in detail how the Isotope Committee's functions will be reconstituted to correct existing deficiencies and assure that adequate standards for protection against radiation will be maintained.

We look forward to your reply to this letter at your earliest possible convenience.

Signed: Mason