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TO : T. H. Johnson, Director, Division of Research, Washington

DATE: November 15, 1954

FROM : S. R. Sapirie, Manager, Oak Ridge Operations

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SUBJECT: LICENSING AND INSPECTION FUNCTIONS OF THE ISOTOPES DIVISION UNDER THE ATOMIC ENERGY ACT OF 1954.

SYMBOL: OI:GLH

The following information is submitted in accordance with your recent telephone conversation with Dr. P. C. Aebersold, Isotopes Division, regarding the status of the licensing and inspection functions of the Isotopes Division under the Atomic Energy Act of 1954.

As you are aware, Section 81 of the 1954 Act expressly provides for licensing of applicants seeking to use byproduct material (radioisotopes). The Commission may distribute byproduct material and also may license others to distribute byproduct material. Further, the Commission may exempt classes of uses, users, or kinds or quantities of byproduct material. Section 82 provides that the Commission may export byproduct material or license others to export such material. Section 31 of the 1954 Act directs the Commission to exercise its powers in such a manner as to insure continuation of research and development activities relating to nuclear processes, atomic energy, etc.

Although the 1946 Act did not expressly provide for licensing of byproduct material users, the Isotopes Division developed a procedure whereby a person desiring to procure such materials filed an application and received an Authorization For Radioisotope Procurement prior to obtaining and using byproduct materials. The authorization was in the nature of a license. Suppliers were also authorized to distribute materials and export them. Authorization exempt quantities were established for which applications and authorizations were not required. Thus, a licensing procedure in many ways similar to that provided for in the 1954 Act, has been in operation in the radioisotope program for several years.

The authorization procedure in conjunction with educational, regulatory, and inspection functions of the Isotopes Division has

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proved very effective in assuring radiological health safety in the use of radioisotopes. Several congressional witnesses have testified to this effect:

> "There is already precedent for the sale by the Government to private concerns of materials that are potentially hazardous. I refer to radioactive materials sold by AEC to industry. Although there is no comparison between the relationship of such materials and fissionable fuels to the national security, there is a certain similarity from the point of view of health and safety. Thus far the Government has maintained full and adequate control of the safety aspects of the use of radioisotopes. In some applications of such material extremely hazardous conditions could develop." Jerome D. Luntz, Nucleonics, Hearings before Joint Committee on Atomic Energy, 83rd Congress, 2nd Session, HR 8862, Part I, page 38. (Underscoring Supplied)

> "Under the present law the AEC distributes fissionable and radioactive materials to applicants who can demonstrate their ability to handle them safely and who have a reasonable requirement for them. The AEC has accomplished this result very satisfactorily and effectively, and has thus encouraged much important research with these materials, and as far as I know, with excellent safety and health experience." C. G. Suits, Committee on Research, National Assn. of Mfg., Hearings before Joint Committee on Atomic Energy, 83rd Congress, 2nd Session, HR 8862, Part I, page 458. (Underscoring Supplied)

Members of the Advisory Committee on Isotope Distribution who are appointed on the basis of their eminence in academic, industrial and medical fields, almost without exception, have heartily endorsed the policies and administrative procedures of the Isotopes Division which have kept pace with the increasing growth of the isotopes program. These committee members, in most instances, are regular radioisotope users and their activities are thus governed by these procedures and regulations.

Although the statutory requirements for licensing are very similar to the authorization procedure developed by the Isotopes Division, several changes in procedure will be necessary to bring isotope procedures into strict compliance with the new Act. Other changes, although not required by the Act, are considered desirable. These changes may be summarized as follows:

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LICENSING

1. The application and authorization forms (Form AEC-313, AEC-374) will include the term "license" rather than "authorization." "Byproduct material or irradiation services" will be referred to rather than "Radioisotopes". Since a license involves possible criminal penalties, it is felt necessary to avoid "licensing" any item that does not fall within the strict definition of "byproduct material". (Cyclotron isotopes, for example, do not fall within the definition and will not be subject to issuance of a license, limitations, and possible penalties under the Atomic Energy Act. However, the distribution of AEC-owned cyclotron produced radioactive material will be subject to radiological health-safety requirements as a matter of contract agreement, and issuance of some approval or authorization by the Isotopes Division will continue to be required.)

2. At this time it is proposed that sealed sources and devices containing byproduct materials would not be licensed as utilization facilities, but control would be exercised by licensing the radioactivity, as in the past. This of course, involves a consideration and approval of design features of such sources and devices, but strictly speaking the source would be licensed and not the device. (It is to be noted, however, that radiation from byproducts appears to be within the definition of "Atomic Energy" in Sec. 11c of the Atomic Energy Act of 1954, and devices using byproduct material could be considered within the definition of "utilization facility", as stated in Sec. 11v of the Act. It is our understanding that the "definitions task force" of the Washington Headquarters has recommended the exclusion of equipment and devices utilizing byproduct material from the definition of "utilization facility" on the assumption that license controls exercised over the byproduct material would provide such control as is needed to protect the "health and safety of the public".)

3. Congressional witnesses, particularly those from industrial groups, in discussing proposed licensing features of the Act, emphasized their desire to know the ground rules applicable to possession and use of materials thus licensed. It is proposed, therefore, to define with more particularity the criteria for issuing byproduct material licenses. The Subcommittee on Human Applications, in its December meeting

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will be requested to recommend definitive medical criteria which may be published in the Federal Register as guidelines to medical applicants. Standards governing manufacture, testing, and labeling of sealed sources, and health-safety regulations of general application have been drafted for early publication in the Federal Register.

4. With the changes in the new Act to permit construction and private ownership of power and dual purpose reactors, and the developing picture with respect to private research reactors, recognition should be given to the fact that the Commission is licensing and regulating possession and use of byproduct material which has originated in privately operated reactors. Such materials are subject to the licensing requirements and limitations in Section 81 and 82 of the Atomic Energy Act of 1954. As such private reactors are placed in operation, and are used to produce byproduct material, the rules and procedures of the Commission with respect to possession and use of such material will be of utmost importance to the persons owning and operating reactors. Another area in which the licensing activity of the Commission directly affects privately owned byproduct material is that pertaining to imports of such material by persons in the United States. The licensing requirements and limitations of the Act also apply to the import of byproduct material.

5. We have recently forwarded a paper recommending procedures for the distribution and licensing of the export of byproduct material to persons in foreign countries. In addition to direct AEC distribution, licenses would be issued to suppliers, export firms, and other persons in the United States authorizing export of byproduct material. If the country involved has executed an "Agreement for Cooperation" with the United States, an order could be placed direct with a U. S. supplier; specific approval by the Commission would not be necessary. The exporter in such case would have a "general license" issued by publication in the Federal Register.

6. The Commission is directed, in other sections of the Act not related to byproduct material, to impose the minimum amount of regulation consistent with obligations to promote the common defense and security and protect the public health and safety. The Isotopes Division will follow this policy in its licensing procedures. Certain items and quantities of byproduct material now are exempted from the application and authorization procedures under the 1946 Act. Under the new Act it is proposed that a general license will be issued by

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publication in the Federal Register permitting possession and use of such items and quantities of material. A general license applicable to everyone is granted by the regulation, thus avoiding individual license applications and specific licenses. A staff paper is pending in Washington, for example, recommending a marked liberalization of the quantities of byproduct material heretofore designated as "authorization-exempt quantities," for which a general license could be granted. (It may, however, be determined to be desirable to exempt such quantities of byproduct material from all licensing provisions in lieu of the above procedure.)

7. Section 183 requires that certain terms and conditions be included in all Commission licenses. The application therefor must be signed under oath or affirmation (Section 182).

8. The Commission is authorized to consider in a single application one or more of the activities for which a license is required. The decision as to whether certain licenses should be combined, however, rests solely in the discretion of the Commission. It may be burdensome on AEC procedures to generally combine byproduct licensing with other licensing activities at this time, and such consolidation would not appear to serve any useful purpose.

Gamma irradiation services, activation analyses or the services which do not produce byproduct material, and stable isotopes will not be subject to issuance of a license under the Atomic Energy Act of 1954. However, it is proposed that such services and materials will be subject to some approval or authorization by the Isotopes Division, when being obtained from AEC facilities.

Evaluation of applications for licenses is essentially a technical problem inasmuch as the basic criteria for issuance of licenses is the protection of public health and safety and the common defense and security.* This involves an extensive knowledge of biological hazards of various radiomaterials, adequacy and suitability of

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* Of course, applications for license must also be evaluated from the standpoint of the proposed use to ascertain whether such use comes within the uses permitted by the Act.

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protective devices, shielding, survey instrumentation, personnel monitoring devices and procedures. With the rapid growth of industrial uses of radioisotopes, the number of uses are increasing in which radioisotopes will ultimately appear in products sold to the public. Thus, technical evaluation of health-safety problems associated with use of radiomaterials becomes even more important. Conversely, as more data is acquired regarding the biological characteristics of radioisotopes, it is often possible to relax licensing requirements for certain byproduct material or certain uses.

Many applications which are disapproved propose uses or procedures which could be highly injurious from a radiological safety viewpoint. In one instance an applicant proposed to receive a weekly radiation dose which, over a period of several weeks, would doubtless have resulted in extremely serious radiation injury and possibly death. Frequently applicants propose to use personnel monitoring instruments which will not respond to the radiation involved; e.g. dosimeters for beta radiation.

The Allocations Branch, in addition to its purely licensing function, frequently is able to assist byproduct material users by suggesting modifications of the applicants proposed program which would render the proposal safe from a radiological health-safety viewpoint. Often a less dangerous isotopic material can be substituted for the one proposed and prove both safer and more effective for the purpose. This not only contributes to health-safety, but in some instances permits approval of an application which otherwise would be disapproved on grounds of radiological health-safety.

A realistic licensing system for byproduct material necessarily entails a thorough knowledge of biological hazards associated with specific materials and means of protecting against such deleterious effects. In absence of such specialized knowledge, the dual objectives of (1) promoting the use of such materials for research, medical, industrial and other useful purposes and (2) protecting the public health-safety cannot be achieved with any degree of success.

The licensing program of the Isotopes Division appears to have attained these goals with remarkable effectiveness, a minimum of "red tape" and excellent public relations. It is extremely doubtful that any advantage would accrue from changing this procedure or organization except for such changes in procedures, forms, terminology, and terms and conditions expressly required by the new Act. This is particularly true inasmuch as the new Act,

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in so far as domestic use of byproduct materials is concerned, essentially follows the same framework under which byproduct material regulations and procedures already have been established. It would appear that no substantive or insurmountable legal or administrative problems are presented which cannot be worked out within the framework of the present organization of the Isotopes Division.

INSPECTION

Section 25(c) of the Atomic Energy Act of 1954 establishes an Inspection Division which...

> "shall be responsible for gathering information to show whether or not the contractors, licensees, and officers and employees of the Commission are complying with the provisions of this Act (except those provisions for which the Federal Bureau of Investigation is responsible) and the appropriate rules and regulations of the Commission".

Section 161(p) authorizes the Commission to

> "Require by rule, regulation, or order, such reports, and the keeping of such records with respect to, and to provide for such inspections of, activities and studies of types specified in Section 31 and of activities under licenses issued pursuant to Sections 53, 63, 81, 103, and 104, as may be necessary to effectuate the purposes of this Act, including Section 105;".

Inasmuch as the Radiological Safety Branch of the Isotopes Division performs an inspection function with regard to conformance of licensees with radioisotope distribution regulations, it would appear that there may be some overlapping of functions between the two Divisions. It is to be emphasized, however, that the Radiological Safety Branch performs many other services than inspection, functions which are indispensable to licensing and other activities of the Division. The functions of the Radiological Safety Branch may be stated as follows:

1. Inspection for compliance with regulations and instructions.

2. Evaluation of adequacy of facilities for radiological health-safety.

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3. Issuance of recommendations or instructions to correct unsatisfactory radiological health-safety conditions.

4. Cooperation with State and local health groups through joint visits to users of byproduct material and through forwarding of information and regulations pertinent to radiological health safety.

5. Coordination with Allocations Branch, Isotopes Division through use of inspection reports as a guide to future licensing.

6. Assistance to general public, including industry, in matters of radiological health-safety and in answering field inquiries regarding byproduct material licensing procedures and regulations.

7. Collaboration in preparation of radiological health-safety standards.

8. Preparation of educational information in form of technical reports and special studies dealing with radiological health-safety, for which there are inadequate data in the open literature.

The eight staff members (one vacancy at present) comprising the Radiological Safety Branch annually visit from 400 to 500 institutions using byproduct material. Institutions selected for visitation usually are those using long-lived or substantial quantities of the more hazardous material. Facilities, handling equipment, shielding, ventilation, storage facilities, handling procedures, personnel monitoring instruments, records, waste disposal and monitoring procedures and other items of interest are observed and evaluated from the viewpoint of radiological health-safety. Recommendations for correction of marginal or unsatisfactory conditions are issued at the time of visitation. If serious deficiencies exist a formalized radiological safety instruction (administrative order) is issued having the force of law and requiring correction of the unsatisfactory condition by a stipulated time.

In accordance with well established procedures, members of state health departments are invited to make joint visits to byproduct material users with members of the Radiological Safety Branch. This cooperative program has been particularly helpful to state groups which do not possess personnel thoroughly trained in radiological health-safety. The Radiological Safety Branch also keeps state health groups currently informed of AEC inspection standards, and analyzes results of joint visits to determine where concentration of effort would be most helpful.

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In addition to formal inspection activities resulting in recommendations and orders, and follow up visits to assure compliance therewith, the Radiological Safety Branch coordinates its activities closely with the Allocations Branch. In some instances it is desirable to inspect facilities prior to issuing a license. In such cases the Radiological Safety Branch visits the applicant and evaluates his facilities and procedures from a radiological safety viewpoint and then confers with the Allocations Branch with regard to the pending application.

Information appearing in field visit reports of the Radiological Safety Branch is also utilized extensively in evaluating future applications which a byproduct material user might file with the Commission. Radiological Safety Branch representatives also answer many questions as to licensing procedures, pending applications, availability of materials, etc., on the spot, frequently eliminating need for extensive correspondence.

The Radiological Safety Branch confers with industrial and other users of byproduct material with regard to radiological health-safety procedures, proposed radiological health-safety standards, and, in some instances, reviews prototype and production models of devices containing byproduct material. This last function, performed only from a radiological safety standpoint, may result in considerable savings to a manufacturer and issuance of a license for the byproduct material after minor changes in design. Standards governing the manufacture, labeling, and testing of sealed radioactive sources, for example, were discussed in some detail with manufacturers of such sources before sending such proposed standards to Washington for publication in the Federal Register.

Through their many contacts both the Allocations Branch and the Radiological Safety Branch are qualified to collaborate with other staff members of the Division in initial drafting of standards and regulations. Members of the Radiological Safety Branch are well acquainted with the purpose and intent of regulations and standards and they are cognizant of the unsatisfactory conditions which such standards are designed to correct or avoid. This permits a highly realistic approach in inspection of facilities to determine if they comply with Commission standards.

Staff members also prepare papers on radiological health-safety, particularly covering those fields where gaps in the literature appear. These papers appear in AEC publications and also in commercial journals and magazines. Radiological Safety Branch representatives also work with various committees concerned with health-safety such as the numerous subcommittees of the NCRP,

the American Standards Association, the Committee on Use of Radioisotopes in Hospitals, etc. Staff members in these cases keep the committees and other groups currently informed of procedures and controls of the Isotopes Division, AEC regulations, etc., and coordinate the activities of all groups so as to avoid conflicting recommendations.

Although a purely inspection activity is essential and it is necessary at times to issue formalized orders and to enforce compliance with regulations, the Radiological Safety Branch emphasizes the value of education in effecting radiological health-safety. An effective radiological health-safety program is possible only if a great amount of preventive activity is undertaken. Although numerous instances of unsatisfactory conditions are found, and corrected in routine visits, the primary objective and philosophy of the Radiological Safety Branch is to prevent infractions of regulations and to maintain sound safety procedures.

Experience of the Radiological Safety Branch in visiting users is invaluable in establishing criteria for evaluation of applications for licenses, safety standards, and licensing and inspection procedures. Field visits often elicit information and data useful in appraising the hazards associated with certain devices or specific radiomaterials while in actual use. Standards may be adjusted accordingly.

In addition to developing radiological standards the Radiological Safety Branch also studies relative biological hazards of byproduct material in various media and recommends quantities of specific byproduct material which may be exempted from the licensing procedure or covered under a general license.

It is to be stressed that the functions of the Radiological Safety Branch are so closely interwoven with the licensing functions of the Allocations Branch that close association and cooperation between the two branches is indispensable if radiological health-safety in the use of byproduct material is to be assured with a minimum of inconvenience and administrative procedures from the viewpoint of the user. Criteria for inspections are well established and have proved most effective in promoting health-safety. Such criteria, however, are revised and adapted to meet changing requirements occasioned by new and broader uses of byproduct material and current concepts of radiological health-safety.

It would be undesirable to separate the purely inspectional functions (fact finding) of the Radiological Safety Branch from the other duties inasmuch as one visit to a user serves many purposes.

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Separation of the functions would result in dual visitation by different groups, unduly burdening byproduct material users with a multiplicity of visits, increased travel expenses, and other objectionable results. Further, the integration of licensing and inspection within one division permits close coordination of the two groups and activities. As a matter of fact, the programs are so closely allied that members of each branch work a stipulated number of weeks each year with the other branch in order to keep currently informed of procedures, work loads, and program objectives.

Although the Inspection Division is responsible for gathering information regarding possible violation of Commission regulations by licensees, such as byproduct material users, we believe that this function can be adequately covered by the activities of the Radiological Safety Branch. There is no doubt that members of the Radiological Safety Branch, in conjunction with their other duties, can investigate possible violation of byproduct material regulations with facility, economy, and effectiveness.

CONCLUSION

The licensing and inspection functions, procedures, criteria, rules and regulations, governing the possession, use, and transfer of byproduct material are well defined and established. The great bulk of Commission licensees, from a numerical viewpoint, will be seeking licenses solely for byproduct materials. Continuation of an AEC wide office, such as the Isotopes Division, solely devoted to licensing byproduct material uses, and inspecting, advising, and educating with regard to health-safety, is in the interest of the many byproduct material users. There would appear to be little advantage in confusing these well defined procedures by combining them with other licensing procedures in which the majority of byproduct material users are not interested. It is not desirable, and probably not economical, to separate the licensing and inspection functions. The Radiological Safety Branch performs more than an inspection service, although this is an important phase of the Division work. Close coordination of the licensing and inspection activities has proved to be very effective in promoting and maintaining radiological health safety in the use of byproduct material.

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