

## Office Memorandum • UNITED STATES GOVERNMENT

TO : N. H. Woodruff, Assistant Manager for  
Operations

FROM : P. C. Aebersold, Director, Isotopes Division

SUBJECT: FUNCTIONS OF THE RADIOLOGICAL SAFETY BRANCH, ISOTOPES DIVISION

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In consideration of changes in licensing procedures occasioned by the Atomic Energy Act of 1954 and establishment of an Inspection Division it appears appropriate to review functions of the Radiological Safety Branch and outline possible modifications of procedures.

Present Activities of the Radiological Safety Branch

The RSB consists of eight staff members who annually visit approximately 400 to 500 institutions using substantial quantities of byproduct material or especially hazardous radionuclides. Facilities, equipment, procedures, waste disposal, and other items are observed and evaluated to determine adequacy from the viewpoint of radiological health safety. Visitation may be made (a) to evaluate adequacy of facilities and equipment prior to issuing a license; (b) to assist a licensed user with regard to health safety problems; (c) to determine if a user is complying with terms and conditions of his license and AEC regulations and health safety standards.

Recommendations for correction of unsatisfactory conditions are made at the time of visitation. If substantial deficiencies exist the RSB prepares an administrative order for signature of the Director, Isotopes Division requiring correction of the unsatisfactory conditions by a stipulated time. In practice the majority of deficiencies detected are willingly corrected by the users without need for a special administrative instruction.

The RSB performs other duties designed to promote safe use of byproduct material. Letters of inquiry from licensees or other interested persons regarding radiological health physics are answered. Prototype and production models of devices containing byproduct material are appraised from a radiological safety viewpoint and recommendations are made as to desirable changes in design that would result in a higher degree of safety. Technical

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papers on radiological health safety are prepared for distribution by the Division or publication in AEC and other journals. RSB representatives also work closely with various committees such as the National Committee on Radiation Protection, American Standards Association, and other groups which formulate industrial codes for safe handling of radiation emitters. The RSB also collaborates in the preparation of radiological health safety standards for publication as federal regulations. To an ever increasing extent the RSB staff members jointly discuss and agree on policies and procedures with the Allocations Branch staff.

The primary objective of the RSB is to assist users in establishing procedures which will offer maximum safety in use of byproduct materials - to prevent infraction of regulations rather than to inspect with the sole object of determining whether the letter of the law is being met. The RSB also coordinates its activities closely with state health groups, keeping them currently informed of AEC standards and procedures and making joint visits to users where feasible. RSB personnel also answer many questions as to licensing procedures, pending applications, availability of materials and similar items during field visitations frequently eliminating the need for extensive correspondence on the part of the user and the Division.

In the past emphasis has been placed on visiting licensees after issuance of a license. It has been found desirable to visit some applicants prior to acting on an application for their initial license. Many more are visited after issuance of their initial license at such time as new or unusual uses or quantities are proposed or when an expansion of their program is proposed.

#### Proposed Functions and Procedures of the Radiological Safety Branch

##### a. Educational Activities and Safety Consultation

Educational activities and safety consultation with licensees, and applicants for licenses, will continue along present lines. Upon request from such persons the RSB will offer advice and assistance in solving radiological safety problems and meeting AEC standards. Cooperation with the NCRP, ASA, state health groups and similar groups will continue. Personnel will prepare technical papers of particular interest to licensees and collaborate in further development of AEC radiological health safety standards.

b. Visitation Prior to Issuance of Licenses

It is proposed that greater emphasis be placed on evaluation of facilities and equipment prior to, rather than after, issuance of a license. As industrial uses of byproduct materials have increased, the quantities per operation or use have also increased markedly. Whereas many research uses may involve only small amounts of radioactivity, the application of radiomaterials in industry requires large quantities and frequently the more dangerous materials such as Cobalt 60, Strontium 90 and Polonium 210. This is particularly important in view of the increasing number of applicants with marginal training and experience who have proposed to use hazardous materials.

The Isotopes Division, in meeting this trend, has found it increasingly desirable to evaluate some facilities prior to issuing a license. Experience has shown that the persons visited before a license is issued have fewer problems and have given less trouble from a radiological safety viewpoint than licensees inspected several months or a year after the licensed work has been in process.

Early visitation of applicants is of considerable value to those applicants inasmuch as AEC requirements can be explained to them personally. During visitation AEC rules, recommendations of the NCRP, responsibilities of other groups, and sources of information on health safety can be explained to the applicant or licensees. The Advisory Committee on Isotope Distribution has also indicated that visitation permits a fair evaluation and appreciation of a user's experience and competence in matters of health safety. Since the AEC does not give examinations to such users, a discussion with the responsible person is useful in determining such qualifications which may not be evident from the application. Extensive correspondence in this regard also may be avoided.

Frequently facilities can be constructed or altered readily before a program is fully underway. Considerable expense may be incurred in altering facilities at a later date, particularly if an industrial operation is involved. Work stoppages have been necessary in some instances in order to correct unsafe conditions that could have been remedied with little expense and inconvenience at the outset.

It is proposed, therefore, in the interest of health safety and assistance to licensees to place even greater emphasis on visitation of facilities prior to issuing licenses. This

visitation would be undertaken in conjunction with pending applications and for purposes of radiological health safety consultation. This would not be "inspection" in the customary sense. Remedial action or questions of compliance such as the proposed Inspection Division may consider would not be involved.

Perhaps it is appropriate to mention here that the RSB even now resolves better than 95% of its visits and problems through education. Nearly all users are willing and anxious to conform both to safe practices and A.E.C. regulations. The scientific and professional world is not as acutely aware of the whereabouts or existence of Federal Regulations as their counterparts in the business world. Thus a helpful discussion of policies, procedures, recommendations and philosophies has proved to be most effective. It is for such reasons that the field man must be thoroughly conversant with the licensing policies and procedures. Users or prospective users look to this AEC representative for the answers to many questions and problems and are not singularly interested in regulatory matters.

c. Visitation After Issuance of a License

After a license is issued visitation could be categorized as "safety consultation" or "inspection". Frequently the RSB is requested by a licensee to visit his plant or laboratory and advise on radiological safety problems existing at that time or which might develop at a later date. Possible violation of license terms or regulations is not an issue. This radiological safety consultation with licensees is not an "inspection" and would be an independent function of the Isotopes Division. If a violation was evident, of course, this would be called to the attention of the licensee and he would be instructed to correct the situation.

1. Coordination of Inspection with Inspection Division

Visitation prior to licensing will reduce the need for later inspection. It will be necessary, however, to continue an inspection program to detect unsafe conditions that may develop over a period of time and which would not be evident at the beginning of an operation. This activity would be closely coordinated with the Inspection Division.

Inspection criteria are already established by the Isotopes Division. Rules for determination of "essential visits" (INSPECTIONS) are also established. A procedure exists whereby the RSB at any particular

time can determine whether a licensee has acquired a sufficient amount of hazardous material to warrant a visit. Quite often an application for a modified or new license from a previous radioisotope user contains information or raises questions which indicate the necessity for a prompt visit. Thus many inspection visits of old users are, in reality, related to a recent application which is held pending the outcome of the field visit. There appears little justification for disturbing this procedure which functions very smoothly and effectively.

In brief it would be impracticable for the RSB inspection function to be subordinated to authority of the Inspection Division to the extent that the RSB could inspect only at the specific request of the Inspection Division. Lacking contact with the licensing function, the latter would not be in a position to know when an inspection might be necessary. A bureaucratic approach in which the Isotopes Division informed the Inspection Division of this need and then received an official request to inspect could hardly be justified.

We would propose, therefore, that the Isotopes and Inspection Divisions agree on general inspection criteria and policy. Within the framework of these general rules the RSB would inspect licensees who obtained enough materials to become an "essential inspection". It would not be necessary to consult the Inspection Division prior to each inspection. It is proposed further that a report of each inspection be furnished to the Inspection Division including any recommendations or instructions issued for correction of unsatisfactory conditions. The Inspection Division, therefore, would be fully informed of results of inspections and corrective actions taken and could take further action, such as criminal prosecution, which it might feel necessary.

Where an obvious violation of law is apparent and criminal prosecution is contemplated responsibility for investigation would rest solely with the Inspection Division. Regulatory action, other than criminal prosecution, should remain the province of the Isotopes Division. The office issuing a license with conditions attached should be free to impose additional conditions without delay in the interest of health safety. Thus, the Isotopes Division should be

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free to modify, suspend, or revoke licenses which it has issued. Any other procedure would be administratively cumbersome, result in conflicting authority, and prove confusing to the licensee. The public relations value of minimizing confusion for the very large number of isotope users (over 4,000 groups) should not be overlooked.

We believe that it should be borne in mind that the Isotopes Division has been licensing and inspecting users of byproduct material for over eight years and has well developed procedures and regulations. Results of the program attest to the effectiveness and merits of the procedures which have been developed through practical experience. The value of this experience should not be dispensed with lightly.

The modified procedures and coordination outlined above would require a minimum of disruption of Isotopes Division functions. On the other hand the interests and authority of the Inspection Division to gather information to show whether licensees are complying with the Atomic Energy Act and appropriate rules and regulations of the Commission are fully satisfied.

In order that uniformity of inspection and licensing procedures and recommendations can be assured it is recommended that routine inspection of isotope licensees be restricted to staff members of the RSB.

If you concur in the above procedures, we shall appreciate your forwarding these recommendations to Washington.

  
Paul C. Aebersold

cc: O & P, ORO  
Dr. T. H. Johnson, Washington  
Dr. J. C. Bugher, Washington