

Office Memorandum • UNITED STATES GOVERNMENT

TO : T. H. Johnson, Director, Division of Research, DATE: November 2, 1954
Washington

FROM : Paul C. Aebersold, Director, Isotopes Division,
Oak Ridge 716593

SUBJECT: PROVIDING RADIOISOTOPES AT REDUCED PRICES FOR MEDICAL, BIOLOGICAL,
OR OTHER RESEARCH USES

SYMBOL: OI:GLH

Recommendations of the Joint Committee on Atomic Energy

The Subcommittee on Research and Development, Joint Committee on Atomic Energy, has made the following recommendations:

"The Subcommittee offers the suggestion that the Commission review its policy on pricing isotopes for medical research and seriously consider making isotopes available to all responsible medical research workers on the same basis as they are now available for cancer... Lastly, in view of the potentially enormous and manifold benefits that can accrue to mankind as a result of employing radioactive isotopes in research, the Subcommittee believes that furnishing such isotopes as elements and in chemical compounds at less than cost for employment in selected other fields, such as biology, would be very much in the public interest".

Present Program for Subsidizing Cancer Research

BACKGROUND

The Atomic Energy Commission cancer program was begun in 1948 at which time a limited number of radioisotopes were made available at no charge for approved cancer research programs. The program was subsequently broadened in 1949 to make any radioisotope available for such programs. In 1952 the Commission began charging 20% of the catalog price for radioisotopes to be used in cancer research, diagnosis and/or therapy.

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BOX No. 1

FOLDER General Correspondence - 1954

COSTS

Expenditures for this program are as follows:

Fiscal Year	1948	\$ 25,648	
	1949	172,021	
	1950	313,126	
	1951	386,582	
	1952	521,307	
	1953	234,067	
	1954	238,170	
	1955 (Thru 10/15/54)	302,000	(Based on Allocations made by Isotopes Division)

SCOPE OF PROGRAM

The present program permits an 80% discount (based on ORNL Catalog Price) to radioisotope users using such materials for "cancer research, diagnosis, and therapy". Routinely used therapeutic sources such as teletherapy units, Strontium 90 eye applicators and Cobalt 60 needles do not qualify for a discount. Non-cancer research, diagnosis, and therapy is excluded. Phosphorus 32 for treatment of polycythemia vera as well as leukemia, is available under the program. Only the amount of the radioisotope in the final product is subsidized if a user wishes to purchase a commercially available compound. In some cases where the synthesis is to be performed by the user himself and the proposed yield appears reasonable, a user can obtain at a discount the total amount of material used in the synthesis of a compound.

PROCEDURES FOR OBTAINING DISCOUNT

Radioisotope users, prior to receipt of radioisotopes, file an application, Form AEC-313, with the Isotopes Division. The application is evaluated from the viewpoint of health safety and, if approved, an authorization (license) is issued which authorizes the holder to procure, possess, and use the radioisotope.

If the applicant also wishes a discount on a radioisotope to be used for cancer research, he attaches a supplementary sheet to Form AEC-313 describing in some detail his proposed cancer research program and justifying the amount of activity requested, relating it to past experience and future plans. Frequently the applicant fails to give sufficient data to permit a realistic evaluation of the proposed program and this leads to additional correspondence and delay. In many instances the applicant finds that he can execute his program with

less activity than originally requested. This results in a saving insofar as the cancer isotopes fund is involved, but entails considerable expenditure of technical and administrative time within the Isotopes Division.

If the proposed program is approved, a statement is placed on the authorization form indicating that the activity may be purchased at a reduced price. If a purchase order is placed with an AEC National Laboratory or commercial supplier the purchaser pays only 20% of the ORNL catalog price for the activity. If a commercial supplier furnishes a routinely available compound, the discount applies only to the activity appearing in the final product. In some cases this is only a small portion of the total cost of the compound.

Reimbursement Procedure for Commercial Suppliers Having Allowed Approved Discounts

A commercial supplier who allows a discount approved by the Isotopes Division, files Form AEC-353 (Radioisotope Credit Request) with the Isotopes Division requesting a credit as reimbursement for the discount allowed to his customer. Upon approval of this form the supplier forwards it to an AEC National Laboratory which credits his account for the amount approved. The credit can be applied only for the purchase of radioisotopes and becomes invalid if not used within a stipulated time. This permits AEC National Laboratories to close their accounting records within a reasonable time after the close of each fiscal year.

SUGGESTED EXPANSION AND MODIFICATIONS OF THE PRESENT PROGRAM

Administration of a program whereby radioisotopes would be made available at reduced prices for medical, biological, or other research purposes could be accomplished in several ways:

- (1) Supplier Allows Discount on Basis of User's Certificate as to Proposed Use. AEC Approval Not Required

AEC National Laboratories and commercial suppliers could sell radioisotopes at a reduced price to any radioisotope user certifying to the Laboratory or supplier that the radioisotope was for medical, biological, or other research. Such certification would be made by the radioisotope user after he had obtained his license. Single licenses often authorize use of an unlimited quantity of radioisotopes for a number of specific uses. Thus, the Isotopes Division, under

this procedure, would have no opportunity to approve the use or quantity of radioisotope obtained under the subsidy. The AEC National Laboratories would charge the difference between catalog price and the reduced price to a fund set up for this purpose. Commercial suppliers would file an application (Form AEC-353) with the Isotopes Division requesting a credit for the reduced price passed on to their customers. Credits thus issued would also be charged to the special fund.

This procedure is similar in some respects to the present method of handling cancer discounts. Under this procedure, however, the isotope user would not obtain an approval for discount from the Atomic Energy Commission. Although this would eliminate paper work from the viewpoint of both the user and the Isotopes Division, it appears impracticable from the Commission's standpoint. The primary objection would be the lack of budgetary control. The obligations under the program at any particular time could not be determined with any degree of certainty. Since anyone certifying that the material ordered was for medical, biological, or research purposes, could obtain large quantities of material from a number of different suppliers, the amount of discount extended by suppliers might greatly exceed funds appropriated for this purpose. Discount reports could be submitted on a quarterly basis by all suppliers; however, unless funds always exceeded demand, last quarter adjustments would be complicated.

(2) Supplier Allows Discount on Basis of User's Certificate as to Proposed Use. AEC Approves Purchase Order and Forwards to Supplier

Budgetary control could be achieved under (1) above if all purchase orders for medical, biological or research purposes were routed through the Isotopes Division prior to acceptance by the distributor or supplier. In all probability, commercial concerns would find this procedure undesirable inasmuch as delays would be encountered in their accepting and filling the order. Because of delay, possible loss of a sale, possible loss of purchase orders forwarded to the Commission, and other factors, this procedure would no doubt be objectionable to suppliers. The Isotopes Division also would prefer not reviewing and handling purchase orders and related documents of private concerns. It is to be particularly noted that this would result in a tremendous volume of paper work inasmuch as purchase orders would approximate 30,000 items annually.

(3) Reduction in Price of Radioisotopes Used Primarily for Medical, Biological or Research Purposes

A third possibility would be a flat reduction in price of those processed radioisotopes which are used primarily for medical, biological or research purposes. Such isotopes would be sold at the reduced price with no inquiry as to whether the isotope was to be used for medical, biological or research purposes. The difference between cost and the reduced price would be charged to the special fund. Secondary suppliers would not be reimbursed for reductions of prices since they, in turn, would purchase the isotope at reduced prices from AEC National Laboratories.

There is no single isotope used exclusively for medical, biological or research purposes. This procedure, therefore, would result in subsidizing activities for other purposes. Iodine 131, for example, is a highly useful research tool and should be made available at reduced prices. Relatively large quantities, however, are also used for industrial and commercial purposes. Selections of isotopes to be reduced in price would be arbitrary and, in effect, deny some research workers the benefits of the reduction and afford a subsidy to some commercial operations. The subsidy to provide medical and research assistance also would be hidden.

Suppliers with inventories of long-lived isotopes would lose money on such stocks if the isotopes were made available from AEC National Laboratories at a substantially reduced price. Further, if the appropriation was inadequate to meet demand, or the subsidy was eliminated at a future date, it would be necessary to raise prices drastically which would have a marked adverse effect on research programs. Also, a gross reduction in prices would have a depressing effect on imports and the economics of foreign suppliers, such as AECL and Harwell.

(4) Suggested Procedures Recommended for Consideration by the Isotopes Division. Extension and Simplification of Present Procedures

The following program and procedures are recommended by the Isotopes Division:

- (a) Radioisotopes would be made available at a 50% reduction in price if used for medical or biological research, medical diagnosis or therapy,

and physical research by institutions and other groups willing to publish the results of their investigations. Equal contribution by the user (rather than the present 20% contribution) would tend to minimize waste on the part of the user. This would justify a relaxation of the present controls on amounts requested under the subsidy. Federal agencies would pay the full catalog price in all instances.

- (b) An applicant would continue to file an application and receive a license authorizing possession and use of the radioisotope. If he wished a discount he would also complete a relatively simple form certifying that the isotope would be used for specified purposes and that the quantity requested represents his actual needs for such use.

Applications involving relatively small sums (possibly less than \$500-1000 in subsidy) could be approved solely on the basis of the certification with no further inquiry as to possible revisions of procedures that might lessen the needs for the isotope, etc. A signed certificate would be in Commission files supporting the discount. The obligation could be posted to accounting records. Since such subsidies would be approved as a matter of form, they could be processed in many instances on the day received. Although some few users might misuse the isotopes or indulge in some waste, these losses may be less than the relatively high costs in time and salary entailed by a detailed review of such programs.

Applications involving more subsidy than stipulated amounts would be scrutinized with care as is now done under the cancer program. The application form would include an instruction to attach a brief justification of the proposed amount (if his total requests involve more than a certain amount of subsidy). If an applicant receives several approvals, individually less

than this amount but collectively in excess of the stipulated figure, his program could also be examined with the view toward effecting economies.

The above procedure would permit rapid handling of 80-90% of subsidy applications (assuming that the program was satisfactory from a health safety viewpoint and a license could be issued). In addition to expeditious handling of applications, considerable savings in technical and administrative time would result.

- (c) Upon approval of the discount form two copies would be returned to the user. The amount of the approved discount would be posted to a journal maintained by the Division. Thus, obligations would be known at any time and budgetary control maintained. The user would send the approved discount form to his supplier and obtain a discount as under the present program. The supplier, in turn, would be reimbursed by the Commission through the issuance of a credit (Form AEC-353 presently in use) which would be applied as a credit in trade for procurement of radioisotopes from AEC National Laboratories. Suppliers would be reimbursed only for radioisotopes sold at a discount which originated in AEC facilities.
- (d) The discount for labeled compounds purchased from commercial suppliers would be based on the cost of the radioactivity used in the synthesis rather than that appearing in the final product. If a user wishes to prepare a commercially available labeled compound in his own laboratory the gross amount of activity would be subsidized provided tracer experiments support reasonable yields in the synthesis.
- (e) Discounts would ordinarily be confined to domestic uses and not allowed on isotopes to be exported. However, if a discount were deemed desirable, an Agreement for Cooperation between the United States and a foreign nation could provide for such dis-

count to the nation involved. A discount for isotopes procured by foreigners for research purposes would stimulate foreign use to some extent. A portion of the foreign market presently served by Harwell would be diverted to the United States, if such subsidy resulted in appreciable savings to foreign users.*

Scope of Proposed Discount or Subsidy Arrangements and Exceptions

- (a) Items involving less than \$10 of subsidy would not be approved since the savings to the user would be offset by the administrative costs of handling such small discounts.
- (b) Under the present cancer research subsidy program non-cancer research, diagnosis, and treatment (including treatment of non-malignant thyroid disease) are not subsidized. Routinely used therapeutic sources such as Strontium 90 eye applicators and Cobalt 60 needles do not qualify for a discount.

It is recommended that, under the proposed program, radioisotopes be made available at reduced prices for the following:

1. All biological or medical research uses;

*Note: In lieu of the above procedures, based on reduction of prices, arrangements could be made under Section 31 of the Act, to provide assistance to public and private institutions or persons in conduct of research and development activities relating to utilization of radioisotopes for medical, biological, agricultural, health or military purposes. A contractual document (standard form) would be completed by the user requesting research assistance through issuance by the AEC of a dollar credit applicable to purchase of radioisotopes. Upon approval of his program the AEC would execute the document and issue the requested credit. This credit would be accepted by AEC National Laboratories toward the purchase of radioisotopes. If commercial suppliers furnish the materials and accept the credit, the supplier could be reimbursed as at present using Form AEC-353.

2. All physical research, including industrial research conducted by institutions and other groups willing to publish the results of their investigations. Support of such research would be beneficial to the AEC, research workers, and ultimately the public. Research in chemistry, physics, metallurgy, and biology results in solution of many problems of particular interest to the AEC. A great deal of basic knowledge also results which can be applied in other fields such as medicine.
3. All medical diagnostic or therapeutic uses except for: teletherapy sources, Sr 90 applicators, Co 60 needles and Au 198 (colloid).

Estimated Annual Cost to the Commission for the Proposed Program

	<u>Cost to AEC</u>
Biological Research	\$ 110,000.00
Physical Research	60,000.00
All medical diagnosis except hyperthyroidism	20,000.00
All medical research and therapy (including present cancer program) except teletherapy, Sr 90, Co 60 Au 198	*545,000.00
	<u>\$ 735,000.00</u>

The above estimates are based on 1953 sales figures for isotopes used primarily for research and medicine. Estimates include a 20% factor for normal growth of the program since 1953 and a 20% factor for probable stimulus to the program if the suggested subsidy is allowed. It is highly probable that research will be stimulated significantly in many fields and the increased demand might greatly exceed the current rate of growth upon which these estimates are based. Costs of the proposed program in subsequent years may reach \$1,000,000.

* If hyperthyroidism is not included, cost for this item could be reduced by \$158,000. Total cost for the entire program would be \$577,000.00.

The proposed program could best be put into effect with the beginning of the new fiscal year. Administration of the present cancer program requires one technical man-year. In view of the wide scope of the proposed program an additional technical man and one secretary would be required. It is to be noted, however, that salaries and the administrative costs of administering the proposed program would be less than 2% of the funds to be allocated under the program.

The question as to whether we allow a reduction of price based on Section 81 of the Act or provide research assistance under Section 31 may involve certain legal considerations which have not been resolved at this time.

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