

Office Memorandum • UNITED STATES GOVERNMENT

TO : N. H. Woodruff, Assistant Manager for Operations
 FROM : S. Allan Lough, Assistant Director, Isotopes Division
 SUBJECT: NOTES ON R. LOWENSTEIN'S REVISED DRAFT OF PROPOSED REGULATIONS ESTABLISHING CRITERIA FOR EVALUATION OF APPLICATIONS FOR RADIOISOTOPES
 SYMBOL: OI:GLH

DATE: January 20, 1953
709241

1. Lowenstein's draft merely changes wording and format of draft forwarded by ORO, October 27, 1952 and attempts a reorganization of regulations already published. Language in parts is not suitable for publication.
2. His draft provides that "The Commission will not approve a domestic application unless it appears on the basis of facts set forth in the application that....". This restricts the Commission to consider only those facts appearing in the application and would prevent consideration of facts obtained from field visits.
3. The last sentence on page one would permit denial of an application if it "would not be in the public interest." We don't have such discretionary authority to withhold isotopes from a properly qualified and equipped individual.
4. 30.30(b) -- "General Authorizations are issued only to institutions or commercial firms." This provision is too limiting. As an example, government agencies holding general authorizations are not institutions or commercial firms.
5. Lowenstein questioned our reason for amending 30.2(a) of the present regulations. This change was made to spell out more definitely the persons who may act for the Commission. Present language in defining Commission closes with "or its duly authorized representative." Our amendment requires that such person be an official to whom the Commission has delegated authority referred to in this regulations, including any official to whom all or part of such authority is delegated by a proper order.
6. Our statement on page 10 that "renewal of a general authorization is subject to review of the applicant's records and facilities" is merely a statement of policy and does not prevent the Commission from considering other factors before renewing a general authorization.

REPOSITORY Oak Ridge Operations
 RECORDS Records Holding Area
 COLLECTION Documents 1944-1994
 BOX No. H-190-4 Bldg. 2714-H
 FOLDER Isotopes Program
2 - Accountability + Control

1063244

7. He questioned the advisability of permitting a person to continue using radioisotopes after his authorization had expired. Half-life of a radioisotope is taken into consideration when application is evaluated. Materials remain subject to health-safety standards, inspections, etc., even though authorization has expired -- thus Lowenstein's fears that we are giving up control of long-lived radioisotopes is groundless.
8. Other minor changes have been made in our revised draft. 30.23(b) was changed in accordance with recommendation of the Sub-Committee on Human Applications to make clear to physicians that our use of the term "medical therapy" included external irradiation of humans from radioisotopes as well as the internal administration of same.

S. Allan Lough

Hutton/jct

COPY

LOWENSTEIN'S
DRAFT

SUGGESTIONS FOR THE REVISION OF PROPOSED AMENDMENTS TO RADIOISOTOPES
REGULATION

I. Amend section 30.21 to read as follows:

30.21 REQUIREMENTS FOR THE GRANTING OF APPLICATIONS

A. Requirements of General Applicability

The Commission will not approve a domestic application unless it appears on the basis of facts set forth in the application that:

1. the radioisotope is requested for one or more of the following purposes: research or development, medical therapy, industrial uses, processing or making of compounds, or such other useful applications as may be developed; and
2. the applicant has suitable equipment and facilities for the protection of health and safety (such as, for example, handling devices, work areas, shields, measuring and monitoring instruments, etc.); and
3. the applicant has suitably trained and experienced personnel and is otherwise qualified to use radioisotopes for the requested purpose.

The Commission may deny any application for authorization to procure radioisotopes upon a finding that the application does not satisfy any requirement specified in this regulation or that for some other reason granting of the application would not be in the public interest.

B. Special Requirements Applicable to Medical Uses by
Institutions

An authorization for radioisotopes procurement (Form AEC-374) will not be issued to an institutional applicant for medical use* (including any administration to human beings) unless it appears from facts set forth in the application that

1. the application satisfies the general requirements set forth in paragraph A of this section; and
2. the medical research institution, hospital, clinic, or other medical organization has appointed** a local isotope committee of at least three members to evaluate all proposals for research, diagnosis, and therapeutic use of radioisotopes within that institution (membership of such committee to include persons expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations); and
3. the institution possesses adequate facilities for the clinical care of patients and for assaying, safe handling, and disposal of radioisotopes; and

* You will note that we have omitted "Staff" in this revision. We have no objection to its inclusion except that it seemed to us to be redundant.

** The draft amendment which we received states that the institution "shall" appoint a committee.

4. the physician designated on the application as the individual user (Item 3, Form AEC-313) is licensed by a State or territory of the United States to dispense drugs in the practice of medicine, and has had experience in the clinical use of radioisotopes for the uses proposed, the handling and administration of radioisotopes, and the management of special clinical cases; and

5. if the application is for a general authorization, the applicant has (i) previously received a substantial number of authorizations for radioisotopes procurement for a variety of radioisotopes for a variety of medical uses; and (ii) appointed a radiological safety officer who will be responsible for the safe handling of radioisotopes.

C. Special Requirements Applicable to Medical Uses by Individuals

An authorization for radioisotope procurement (Form AEC-374) will not be issued to an individual applicant for medical use (including any administration to human beings) unless it appears from facts set forth in the application that

1. the application satisfies the general conditions specified in section 30.21(a); and
2. the applicant is a physician licensed by a State or territory of the United States to dispense drugs in the practice of medicine; and

3. the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor radioactive patients whenever it is advisable; and
4. the applicant has had substantial experience in the clinical use of radioisotopes for the uses proposed, the handling and administration of radioisotopes, and the management of such clinical cases. (The physician must furnish suitable evidence of such experience with his application. A statement from the local isotope committee in the institution where he acquired his experience, indicating its amount and nature, may be submitted as evidence of such experience.)

D. Special Requirements Applicable to General Authorizations for Use in Research and Development

A general authorization for procurement of radioisotopes for use in research and development (not involving their administration to human beings) will not be issued unless it appears from facts set forth in the application that:

1. the application satisfies the requirements specified in section 30.21(a); and
2. the applicant has received a substantial number of authorizations for radioisotopes procurement for a variety of radioisotopes for a variety of research and development uses; and
3. the applicant has established an isotope committee (composed of such persons as a radiological safety officer,

a representative of the business office,* and one or more persons trained or experienced in the safe use of radioactive materials** who must review and approve, in advance of purchase of radioisotopes, proposals for use of radioisotopes; and

4. a radiological safety officer has been appointed who will be responsible for the safe handling of radioisotopes.

E. Special Requirements Applicable to General Authorizations for Use in Processing

A general authorization for procurement of radioisotopes for use in processing will not be issued unless it appears from facts set forth in the application that

1. the application satisfies the general requirements set forth in section 30.21(a); and
2. the applicant has received a reasonable number of authorizations for radioisotope procurement for processing, resale, and distribution of a variety of radioisotopes; and
3. the applicant has appointed a radiological safety officer who will be responsible for the safe handling of radioisotopes.

* That a representative of the business office should be included appears in the draft which we received. It seems somewhat out of place, however, in a regulation concerned primarily with safety and health considerations and the utility of proposed uses.

** Query as to why the suggested membership includes both a radiological safety officer plus persons experienced in "the safe use of radioactive materials."

F. Special Requirements Applicable to Use of Sealed Sources of Radiation Devices

An authorization for medical use (including any administration to human beings) of sealed sources such as, for example, teletherapy units, beta applicators, etc., will not be issued unless it appears from facts set forth in the application that

1. the applicant or, if the application is made by an institution, the physician designated as the individual user has had specialized training in the therapeutic use of such devices or has had experience equivalent to such training; and
2. the application satisfies all other applicable requirements set forth in this regulation.

II. Amend section 30.30 to read as follows:

30.30 ISSUANCE OF AUTHORIZATIONS

A. Upon approval of an application, the Commission will issue an Authorization for Radioisotope Procurement, Form AEC-374. The Authorization shall be the only valid approval for procurement, and its issuance shall be based upon the representations made in the application and shall be subject to and in accordance with the regulations in this part and the terms and conditions stated in the application.

B. An Authorization for Radioisotope Procurement issued by the Commission is a "specific" authorization unless the authorization expressly states that it is a "general" authorization. A specific authorization authorizes procurement only of the radioisotopes specified in the authorization, in the quantity or quantities and for the specific

use or uses designated therein. General authorizations are issued only to institutions or commercial firms. A general authorization authorizes the procurement of any quantity of any radioisotope of atomic No. 3 to 83.*

III. We do not understand why the Isotopes Division proposes to amend section 30.2(a) in the manner specified at the bottom of page 10 of the proposed amendments.

IV. Re proposed amendment to section 30.13:

We are somewhat troubled by the first proviso in this proposed amendment. The first proviso contains an exception — "except as otherwise permitted by the regulations contained in this part." Although this merely continues the present language of existing 30.13(a), there is no other provision of the regulation which seems to pertain to increases in the radioactivity of scheduled items or quantities.

V. We would suggest revision of the proposed new section 30.32 to read as follows:

30.32 EXPIRATION

An authorization for procurement of radioisotopes shall expire at the end of the period stated therein without the necessity of notice or warning from the Commission. The holder thereof shall neither order nor

*We have omitted from this suggested revision of proposed section 30.35(b) the express statement as to renewal of general authorizations. It seems unnecessary since, as we understand it, there is an expiration date specified in AEC-374 (authorization form). Moreover, annual renewal is subject to other conditions than merely review of the applicant's records and facilities (e.g., the applicant's continuance of its isotopes committee, if it is an institutional user for medical purposes).

receive radioisotopes after the expiration of such authorization and no person shall transfer radioisotopes to another person after the expiration date of the other's authorization. Expiration of a holder's authorization does not affect his authority to retain possession of previously acquired radioisotopes for the use or uses specified in the authorization and subject to all the conditions incorporated therein.

(Note: The proposed amendment clarifying section 30.32 along the foregoing lines permits a person who acquired radioisotopes under a valid authorization to continue to hold and use those isotopes for an indefinite period even though he is no longer authorized to procure additional isotopes. From a policy standpoint, we would be inclined to question the advisability of this. Although we recognize that in many cases there may be ample justification for permitting holders to use an existing inventory of radioisotopes during a longer period than that permitted for procurement, it would seem that some safeguards should be provided to insure that such holder continues to adhere to all health and safety requirements.)

VI. We would suggest modification of the proposed new section 30.54 by inserting the words "or appropriate" after "necessary."

VII. The broad definition of "research and development" contained in the proposed amendments includes some medical uses. This may give rise to difficulty. For example, the draft of amended section 30.35(a) which we received from you would permit an applicant to use radioisotopes for "any research and development activity." The broad definition of "research and

development" would permit some medical uses under this provision although that is certainly not the intent of the Isotopes Division. Accordingly, we suggest that the proposed definition of "research and development" should not be added to the regulation or, if it is added, that the following be added thereto:

"provided that 'research and development' as used herein shall not be deemed to include the administration of radioisotopes to human beings."

C O P Y*Office Memorandum* • UNITED STATES GOVERNMENT

TO : J. Wallace Ould, Assistant General
Counsel, Oak Ridge Operations Office
ATTENTION: H. S. Hiestand

FROM : Robert Lowenstein, Attorney,
Office of the General Counsel, Washington

SUBJECT: PROPOSED AMENDMENTS TO RADIOISOTOPES REGULATIONS
PROPOSED STABLE ISOTOPES REGULATIONS

DATE: December 10, 1952

After discussing the proposed amendments with Sparky Hiestand, and with Steve Cobb during his recent visit to Washington, I prepared the attached suggested revision. As you will note, it is not presently in a form appropriate for publication in the Federal Register.

Examination of the proposed amendments and comparison with the Draft Information Manual on Isotopes Distribution which we had previously received from you disclosed a number of seeming discrepancies:

1. Section 30.23(a)(2) of the proposed amendments does not restrict the kinds of uses which private practitioners may make of radioisotopes in their medical practices. On the other hand, the proposed manual limits such use to routine diagnosis and therapy (see page 8 of the Manual). I discussed this matter with Steve Cobb who advises that the Manual should be changed. Bev Thompson raised the question with Chuck Dunham, Biology and Medicine, who has also suggested that the Manual be changed.

2. Section 30.23(b)(2) of the proposed amendments provides that a physician who wants to use radioisotopes in his private practice "may" submit a statement from the local isotopes committee in the institution where he acquired his experience as evidence of such experience. The proposed Manual states that such a certificate "must" be submitted (see page 9).

I discussed this, too, with Steve Cobb who suggests changing the Manual to conform to the proposed draft of regulation.

3. The proposed amendments provide in section 30.35(a)(1) that an applicant for general authorization for research and development must have received a "substantial" number of previous authorizations. On the other hand, the Manual (page 12) requires that the applicant need have received previously only a "reasonable" number of authorizations.

1063255

C O P Y

J. Wallace Ould

- 2 -

December 10, 1952

Steve Cobb suggests again that the Manual be changed to conform to the proposed amendment.

4. The proposed new regulation covering stable isotope distribution includes a definition of "distributor" although the word does not seem to be used anywhere else in the proposed regulation. It should be deleted.

5. The Manual provides that electro-magnetically concentrated stable isotopes are available on loan only. No such provision is contained in the draft of the new regulation. I understand that this restriction was not included in the proposed regulation because it is expected that the electro-magnetically concentrated stable isotopes will shortly be available in sufficient supply to permit their sale. I call it to your attention only because you may wish to amend the proposed regulation so as to expressly set forth the fact that some isotopes will be available on loan only.

6. I notice that there is a very broad definition of stable isotopes in section 31.2 of the proposed regulation, whereas section 31.20 lists only six specific isotopes plus "electro-magnetically concentrated stable isotopes." If the Isotopes Division does not contemplate making substantial additions to the list of stable isotopes, I wonder if it would not be more appropriate to define stable isotopes by reference to the isotopes presently listed in 31.20.

7. In connection with electro-magnetically concentrated stable isotopes, the last two sentences on page 17 of the Manual set forth certain restrictions in addition to those mentioned above which you may want to consider setting out in the regulation.

Enclosure:

Suggested Rev. of Proposed Amendments

CC: Dr. Chas. Dunham, B&M, Washington
S. G. English, Div. of Res., Washington

1063256

C O P Y*Office Memorandum* • UNITED STATES GOVERNMENT

TO : J. Wallace Ould, Jr., Assistant General Counsel DATE: January 9, 1953

FROM : T. R. Jones, Administrative Officer, Isotopes Division

SUBJECT: PROPOSED AMENDMENTS TO RADIOISOTOPES REGULATIONS AND
PROPOSED STABLE ISOTOPE REGULATIONS

SYMBOL: OI:GLH

Reference is made to memorandum of December 10, 1952, from Robert Lowenstein and the attachment thereto suggesting certain revisions of the proposed amendments to radioisotopes regulations and stable isotopes regulations. In accordance with this memorandum and suggestions of the Sub-Committee on Human Applications of the Advisory Committee on Isotopes Distribution, we have made a number of minor changes in our original draft and are enclosing two copies for your consideration.

With respect to items 1 and 2 of the aforementioned memorandum we are modifying the manual to conform with the proposed amendments. As regards items 3 and 4 we have substituted "reasonable" for "substantial" on pages 8, 9, and 10 of the regulations and have deleted the definition of "distributor" under the stable isotopes regulations. As to items 5 and 7 of the memorandum we consider that the basic purpose of the regulations is to cover the licensing function of the Commission and the transfer of AEC property, whether by sale or bailment, is controlled by contract.

With reference to item 6 of the memorandum 3l.2(c), changed to 3l.2(b), is intended to be a broad definition of "stable isotope" embracing not only the one hundred and seventy stable isotopes presently distributed by the Commission but other isotopes which may become available. 3l.20, on the other hand, is merely a statement of those isotopes generally available from the Commission and is included only for informational purposes.

Generally, we believe that our enclosed draft, as modified, is an accurate and congruent statement of the criteria, policies, and rules in current use by the Isotopes Division. In our opinion the suggested revision attached to Mr. Lowenstein's memo, although possessing merit, is not a material improvement over the original draft submitted by this office and in certain respects fails to present fairly and accurately the purpose and intent of our proposed amendments. Some of the revisions proposed in that memorandum appear only to change words, or to revise the format of the regulations as heretofore approved and published. We do not believe the suggested

1063257

J. Wallace Ould, Jr.

- 2 -

January 9, 1953

changes are necessary, and desire not to revise the present format and organization of the sections of the regulations.

Without attempting a comprehensive analysis of Mr. Lowenstein's suggested revision, and the questions raised therein, the following points are noted:

30.21(a) "The Commission will not approve a domestic application unless it appears on the basis of facts set forth in the application that..." It appears that this limitation unduly restricts the Commission to consider only those facts set forth in the application. As a matter of fact other factors are weighed in the consideration of an application, including information obtained from job-site visits by our Advisory Field Service Branch. It appears undesirable that we should restrict ourselves to consideration of only those facts patent on the face of an application. It also seems unreasonable to require details of facilities, instrumentation, etc. on each application when this information may already be in our files. This restrictive provision appears throughout the draft.

The last sentence on page one would permit denial of an application if it "would not be in the public interest." In view of the studies made by your office regarding statutory grounds for refusing to issue an Authorization for Radioisotope Procurement, we question whether this office has the discretionary authority to deny, ipso facto, an application as not being in the public interest.

With regard to annotations one and two on page five, it is to be noted that the isotope committee required for a general authorization (for research and development) need not include all of the persons we have suggested -- representative of the business office, etc. Membership of the Committee rests with the institution involved. As a matter of fact, however, the larger or more responsible users do include the members we have mentioned. The radiological safety officer may or may not be a member of the Committee. A business office representative can control purchase of radioisotopes by establishing purchase order procedure, etc. The radiological safety officer may or may not be experienced in "the safe use of radioactive materials", but may be responsible for the safety program. Hence, an experienced person should be on the committee.

30.30(b) page 7, states that "General Authorizations are issued only to institutions or commercial firms." Aside from the fact that the word "only" interjects a limitation on issuance of general authorizations not intended originally, "institutions or commercial firms" does not embrace all the types of groups or other entities which may receive general authorizations. The suggested revision is too limited.

Item III, page 7. The purpose in amending 30.2(a) is to define more precisely, in relation to the isotopes program, the persons who may act for the Commission - i.e. (1) an official to whom the Commission has delegated authority, and (2) any official to whom such authority is delegated by a proper order. Among other advantages this eliminates the possibility that state health or public health officials, with whom we work closely in field inspections, will be considered authorized representatives of the Commission.

"IV, Re proposed amendment to section 30.13:" Under the first proviso of this section a person possessing several exempt quantities in separate containers may not combine them except as otherwise permitted by the regulations. If, however, at a later date, he should apply for an authorization to permit him to combine these exempt quantities an authorization could be issued to permit him to do so. This is one illustration of several possibilities where the exception would be applicable.

Note one, page 7. The statement that "renewal of a general authorization is subject to review of the applicant's records and facilities" is an express statement of our policy of reviewing facilities of a general authorization holder before renewing the authorization. Since there are no words of limitation such as "... subject only to review of the applicant's records and facilities," we can see no reason for deleting the statement merely because other factors also will be taken into consideration.

30.32 (V) Note. It would be highly impracticable to require that a user submit a new application each year for unused radiomaterials in his possession. (1) The number of applications each year would increase by several thousand. (2) Half-life of the material and the fact that a person may possess the radioisotope for several years, as opposed to a few days, is taken into consideration in evaluating an application.

C O P Y

J. Wallace Ould, Jr.

- 4 -

January 9, 1953

(3) Our Advisory Field Service Branch continues to inspect users of fairly large quantities of long-lived or hazardous materials after the expiration date of an authorization.

(4) Expiration of an authorization does not exempt a radioisotope user from observing health-safety requirements -- i.e., enforceability of health-safety regulations or orders is not contingent upon the user possessing a valid, current authorization.

The definition of "research and development" has been copied verbatim from the statutory definition. Since Section 5(c)(2) of the Act speaks of "research and development" and "medical therapy" it seems evident that the former does not include the latter. In the interests of clarity, however, we have added a parenthetical statement that research and development as used in the regulations does not include administration of radioisotopes to human beings.

Although our revision necessarily entailed some minute deviations from provisions of the Manual, substantive discrepancies between the revised draft of the criteria and the Manual will be reconciled by changing the Manual.

If your office has no objections to the proposed regulations, as modified, please forward the enclosed draft for approval. In view of the delay already encountered we shall appreciate any action on your part which will expedite clearance of the proposed regulations and place them before the Commission for consideration.

T. R. Jones

Enclosure:

Proposed Regulations (Revised 1/2/53) (2)

1063260

C O P Y*Office Memorandum* • UNITED STATES GOVERNMENT

TO : Harold L. Price, Acting General Counsel,
Washington

DATE: January 14, 1953

FROM : J. W. Ould, Jr., Assistant General Counsel,
Oak Ridge

SUBJECT: PROPOSED AMENDMENTS TO RADIOISOTOPES REGULATIONS AND PROPOSED
STABLE ISOTOPE REGULATIONS

SYMBOL: GC:OSH

Reference memorandum, Lowenstein to Ould, December 10, 1952, commenting on, and suggesting certain revisions of, proposed amendments to and new regulations pertaining to the radioisotope and stable isotope distribution programs earlier submitted by the Manager, ORO.

Attached is a copy of a memorandum prepared by the Isotopes Division answering the above memorandum, and attaching a revised copy of the proposed regulations previously submitted. This revision of the earlier amendments and new material submitted for approval reflect some changes suggested by Lowenstein and the Subcommittee on Human Applications, but does not reflect the general reorganization or revision suggested in Lowenstein's memorandum.

We have reviewed the comments of the Isotopes Division, and the attachments thereto. In our opinion these comments are well taken, and we concur in the revised attachments as submitted. It would seem unnecessary to rearrange the material proposed for publication for clarity or legal effect. We have worked closely with the Isotopes Division in the development of its regulations, and have endeavored to assure compliance with legal authority and clarity in the language used as it affects legal obligations and authorities. Beyond this we had not undertaken to direct the organization of material or the format to be followed. The original regulations, of course, were some time in the making and both Washington and Oak Ridge actively participated in the development of the format and language used. In the absence of important deficiencies it would not seem desirable now to undertake a reorganization of the regulations. This certainly was part of the motivating reason for proposing the amending material in the sequence and at the sections indicated.

From our acquaintance with the objectives and administration of the isotopes program, we are particularly concerned with Lowenstein's suggestion that applications will not be approved "unless it appears on the basis of facts set forth in the application that ..." While this requirement of "facts" in the application could serve a purpose

1063261

Harold L. Price

- 2 -

January 14, 1953

in establishing a prima facie basis for denial, we feel it is more than outweighed by the objections stated by the Isotopes Division. Thus, it is not desired that merely because the application states the applicant meets the criteria an authorization will issue; or that consideration of the application will be necessarily limited to those "facts". The administration of the program, heretofore, has been conducted on a basis which permits - and neither expressly nor by implication would prevent - consideration of information however obtained in determining whether or not the applicant is qualified.

We also are in doubt that AEC may refuse to grant an authorization when it "would not be in the public interest", apart from the criteria specified in the Atomic Energy Act. (Lowenstein's memorandum, page 1). We have previously made several studies on the authorities of AEC under Section 5(c)(2), and had not concluded that a general grant of authority existed to deny applications on such a broad and undefined ground. Moreover, we are concerned that the inclusion of a "public interest" basis of denial, in itself, opens as a matter of routine consideration, an aspect of the licensing function which ought not to be available. A case of "public interest" falling outside other established or evident grounds for denial should be quite rare. The omission of this ground in the published regulations would not appear to leave open an area of general concern; nor does such omission deny the existence of an area in which a general "public interest" test might be available. From our standpoint, we believe it would be preferable not to assert the existence of this general basis of refusal in the regulations (and thereby makes its use available administratively in any case). Should at some future time a situation arise when it is desired to refuse an authorization to an applicant who meets all the statutory and regulatory requirements, further consideration could be given to the "public interest" test.

You will note the Isotopes Division requests our assistance in expediting clearance of the proposed regulations. If there yet remain differences of opinion, we suggest it would be desirable to call a meeting of the interested divisions to discuss and agree upon the wording to be used. Since the proposed regulations were included as appendices to the Manager's report and suggested staff paper, we do not believe it will be necessary to rewrite either the report or staff paper. There is one change, however, which will be required in the

1063262

C O P Y

Harold L. Price

- 3 -

January 14, 1953

staff paper with reference to the publication date of the Isotope Distribution Information Manual. This manual has not yet been distributed - pending clearance and approval of the proposed regulations on which it is based.

We are advised additional copies of the revised regulatory material are being forwarded through the ORO Manager to the Director of Production, and copies will also be forwarded to the Research Division by the Isotopes Division.

J. W. Ould, Jr.

Enclosure:
Memo, dtd. 1/9/53

Hiestand:ga

1063263

OCT. 27, 1952

Office Memorandum • UNITED STATES GOVERNMENT

TO : R. W. Cook, Director, Division of Production,
Washington

DATE: October 27, 1952

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

SUBJECT: CRITERIA, PROCEDURES FOR PROCUREMENT OF ISOTOPES

SYMBOL: OI:GLH

Enclosed herewith is a staff paper for submission to the Commission providing for amendment of regulations governing radioisotope distribution and promulgation of regulations relative to stable isotope distribution.

In accordance with provisions of the Administrative Procedure Act, subject criteria and procedures should be published in the Federal Register. It is recommended, therefore, that the enclosed staff paper be forwarded to the Commission for approval.

for *H. H. Woodruff*
S. R. Sapirie

Enclosure;
Staff Paper

Cy.: Dr. T. H. Johnson, Washington
Dr. John C. Bugher, Washington
Asst. General Counsel (2 cys.)

Hutton:rmj

ATOMIC ENERGY COMMISSION
CRITERIA, PROCEDURES FOR PROCUREMENT OF ISOTOPES

A Report by the Manager of Oak Ridge Operations

THE PROBLEM

1. To consider amendment of regulations governing radioisotope distribution, and promulgation of regulations pertinent to stable isotope distribution.

BACKGROUND

2. On January 25, 1951, at meeting 522, the Commission approved recommendations of AEC 398. Subsequently, regulations controlling the possession, use, transfer, and disposal of radioisotopes were published in the Federal Register (16 F.R. 3251, April 13, 1951), codified in 10 CFR, 1951 Suppl. 30.

3. These regulations do not include criteria used by the AEC in evaluating applications for radioisotopes, nor procedural requirements for obtaining stable isotopes.

DISCUSSION

4. Applications for radioisotopes present unique problems because of the characteristics of the materials and the different radiation hazards associated with them. The complexity of these problems is further magnified by the wide variety of purposes for which the radioisotopes are to be used. In the past, therefore, it has been necessary to consider each application on an individual basis.

5. Cumulative experience in evaluating applications has made it possible to formulate criteria for reviewing certain types of applications. These criteria are based on recommendations of the Advisory Committee on Isotope Distribution and the Subcommittee on Human Applications of the ACID. These

standards have been included in the Isotopes Division "Information Manual" which is scheduled for distribution to all isotope users and other interested persons on or about November 15, 1952.

6. Section 3 (a) of the Administrative Procedure Act provides that:

"Sec. 3. Except to the extent that there is involved (1) any function of the United States requiring secrecy in the public interest or (2) any matter relating solely to the internal management of an agency--

(a) Rules. Every agency shall separately state and currently publish in the Federal Register (1) descriptions of its central and field organizations including delegations by the agency of final authority and the established places at which, and methods whereby, the public may secure information or make submittals or requests; (2) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal or informal procedures available as well as forms and instructions as to the scope and contents of all papers, reports, or examinations; and (3) substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law. No person shall in any manner be required to resort to organization or procedure not so published."

7. In order to comply with requirements of the Administrative Procedure Act, it would appear that criteria for evaluation of applications for radioisotopes should be published in the Federal Register and incorporated into the present radioisotope distribution regulations. Similarly, regulations should be published with reference to stable isotope distribution. The following drafts, Appendices "A" and "B" are submitted for consideration:

(a) APPENDIX "A" - Proposed Amendment of Part 30 - Radioisotopes Distribution (10 CFR 30). The basic purpose of these amendments is to set forth the criteria which the AEC uses in evaluating applications for radioisotopes. Criteria or standards which cannot be formulated with a sufficient degree of definiteness and completeness to warrant publication for public guidance are not included. Appendix "A" also includes minor modifications of presently established regulations. Illustrative of this

is the amendment of section 30.13(a) so as to prohibit the use of exempt items or quantities in humans except as permitted under a valid Authorization of the Commission. This is in accord with recommendation of the Subcommittee on Human Applications at meeting May 10-11, 1952, that "... the present statement of exempt quantities of radioisotopes in the Federal Register be amended to exclude human use."

(b) APPENDIX "B" Part 31 - Proposed Rules - Stable Isotope Distribution. This part sets forth instructions and procedures governing the procurement, use, and transfer of Commission distributed stable isotopes. The rules proposed are a statement of the procedures and policy which have been followed for sometime.

RECOMMENDATIONS

8. It is recommended that the Commission:

a. Approve publication in the Federal Register of Proposed Amendment of Part 30 -- Radioisotope Distribution (10 CFR 30) as contained in Appendix "A", and Part 31. Proposed Rules -- Stable Isotope Distribution as set forth in Appendix "B".

b. Note that the General Manager will arrange for such publication in conformity with the procedure which allows for a thirty day period after initial publication for receipt of public comments and objections;

c. Note that, if after the thirty day period, no substantial changes are indicated, the General Manager will arrange for the Regulations to be published in final form. If substantial changes are indicated, they will be submitted to the Commission for approval before revision of the Regulations;

d. Note that the Joint Committee on Atomic Energy will be informed of these actions by appropriate letter and a copy of the Regulations, as presently approved, will be furnished the Committee.

LIST OF ENCLOSURES

APPENDIX "A"

Proposed Amendment of Part 30 -- Radioisotope Distribution (10 CFR 30).

APPENDIX "B"

Part 31. Proposed Rules -- Stable Isotope Distribution

APPENDIX "A"
UNITED STATES
ATOMIC ENERGY COMMISSION

PROPOSED AMENDMENT OF PART 30 - RADIOISOTOPE DISTRIBUTION (10 CFR 30)

Notice is hereby given that adoption of the following rules is contemplated. All interested persons who desire to submit comments and suggestions for consideration by the General Manager of the Atomic Energy Commission in connection with the proposed rules shall send them to the General Manager, United States Atomic Energy Commission, Washington 25, D. C., within 30 days after publication of this notice in the Federal Register.

Part 30 of Radioisotope Distribution Regulations (10 CFR 30) is hereby amended by addition of the following definitions, rules, criteria, instructions, and standards:

30.2 (1) "Research and Development" means theoretical analysis, exploration, and experimentation, and the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. (RESEARCH AND DEVELOPMENT AS USED HEREIN DOES NOT INCLUDE THE INTERNAL OR EXTERNAL ADMINISTRATION OF RADIOISOTOPES, OR THE RADIATION THEREFROM, TO HUMAN BEINGS).

30.23 Experience and Facilities

GENERAL

(a) An Authorization for Radioisotope Procurement, Form AEC-374, will not be issued ~~for research or development activity, industrial uses, processing or making of compounds, or such other useful applications as may be developed, unless~~

DELETED PART OF (a) IS SUPERSEDED - COVERED BY PRESENT REGULATIONS.

* UNITED STATES GOVERNMENT PRINTING OFFICE: 1964 O 341-100

the applicant is equipped to handle safely the quantity of radioisotope requested for the proposed use by having:

- (1) Trained and experienced personnel;
- (2) Suitable equipment and facilities

(handling devices, work areas, shields, measuring and monitoring instruments).

MEDICAL THERAPY (HUMAN USE)

(b) ^A An Authorization for Radioisotope Procurement, Form AEC-374, will not be issued for medical therapy ^{(USE IN HUMANS INVOLVING INTERNAL OR} ~~administra-~~

~~tion~~ of radioisotopes, ^{OR THE RADIATION THEREFROM,} to humans ~~being~~ for research, diagnosis, and treatment) unless the applicant meets the following

standards ^{IN ADDITION TO THOSE SET FORTH IN PARAGRAPH (A) ABOVE :}

(1) ~~Staff or~~ Institutional Use

(i) Isotope Committee. The medical ~~research~~ institution, hospital, clinic, or other medical organization, ^{HAS APPOINTED} ~~shall appoint~~ a local isotope committee of at least three members to evaluate all proposals for research, ^{DIAGNOSTIC} ~~diagnosis~~, and therapeutic use of radioisotopes within that institution. Membership of the Committee should include ^{PHYSICIANS} ~~persons~~ expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations.

(ii) Clinical Facilities. The medical institution shall possess adequate facilities

CHANGES RECOMMENDED BY
SUE... TO MARK
... THAT EXTENSIVE
... FACILITIES...

EXTERNAL ADMINISTRATION

SUE... THAT STAFF...
... MISLEAD...
... TO...
... THE...

for the clinical care of patients, and for assaying, safe handling, and disposal of radioisotopes.

(iii) Experience. The physician designated on the application as the individual user shall have ^{SUBSTANTIAL} experience in the ^{PROPOSED} ~~clinical~~ use of radioisotopes ^{IN HUMANS;} ~~for the~~ ~~uses proposed~~, the handling and administration of radioisotopes; and the ^{WHERE APPLICABLE} ~~management~~ of ^{CLINICAL} ~~such~~ ^{RADIOACTIVE PATIENTS.} ~~clinical cases~~. The physician shall be licensed by a state or territory of the United States to dispense drugs in the practice of medicine.

(2) Individual Use or Private Practice

(i) Clinical Facilities. The physician shall have access to a hospital possessing adequate facilities to hospitalize and monitor ^{THE PHYSICIAN'S} radioactive patients whenever it is advisable.

(ii) Experience. The physician shall have ~~SUBSTANTIAL~~ ^{PROPOSED} experience in the ~~clinical~~ ^{IN HUMANS;} use of radioisotopes ^{for the} ~~uses proposed~~, the handling and administration of radioisotopes; and the ^{WHERE APPLICABLE} ~~management~~ of ^{CLINICAL} ~~such~~ ^{RADIOACTIVE PATIENTS.} ~~clinical cases~~. The physician shall furnish suitable evidence of such experience { ~~a~~ statement from the local isotope committee in the institution where he acquired his experience, indicating its amount

and nature, may be submitted as evidence of such experience). The physician shall be licensed by a state or territory of the United States to dispense drugs in the practice of medicine.

(3) Medical Use of Sealed Sources. The physician shall have specialized training in the therapeutic use of the radioactive device considered (teletherapy units, beta applicators, etc.), or shall have experience equivalent to such training, AND SHALL BE LICENSED BY A STATE OR TERRITORY OF THE UNITED STATES TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE -

30.35 General Authorizations. Most authorizations are issued for the procurement of a specified quantity of a single radioisotope for a specific use. Under certain circumstances, however, "General" authorizations are issued to hospitals, institutions, universities, ^{MEDICAL SCHOOLS, GOVERNMENT AGENCIES,} laboratories, and commercial firms for the procurement of any quantity of any radioisotope of atomic number 3 to 83 inclusive:

(a) General Authorizations for Research and Development.

A General Authorization for research and development permits the applicant to use radioisotopes at a specified location for any research and development activity. To qualify for such a general authorization the applicant shall have:

- (1) Received a ^{REASONABLE} substantial number of Authorizations for Radioisotope Procurement for a variety of radioisotopes for a variety of research and development uses.

(2) Established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and approve, in advance of purchase of radioisotopes, proposals for use of radioisotopes.

(3) Appointed a radiological safety officer who will ^{ADVISE ON OR BE AVAILABLE FOR ADVICE AND ASSISTANCE ON RADIOLOGICAL SAFETY PROBLEMS.} ~~be responsible for safe handling of radioisotopes.~~

(b) General Authorizations for Medical ~~Uses~~ THERAPY (HUMAN USE)

Radioisotopes. A General Authorization for medical ~~use~~ ^{THERAPY} of radioisotopes permits the applicant to use radioisotopes at a specified location for any clinical use ^{IN HUMANS} approved by the ^{LOCAL MEDICAL} isotope committee. ~~specified in § 30.23(b)(1) above.~~

To qualify for such a general authorization, the applicant shall have:

(1) Received a ^{REASONABLE} ~~substantial~~ number of Authorizations for Radioisotope Procurement for a variety of radioisotopes for a variety of ~~uses~~ ^{USES} ~~clinical studies~~ in humans.

(2) Established ^{A MEDICAL ISOTOPE} ~~an isotope~~ committee on ~~human uses, as stated in~~ ⁽ⁱ⁾ ~~(§ 30.23(b)(1) above)~~ ^(SEC)

APPLICANT IS <
PROBABLE FOR SAFE
HANDLING - HE CAN
DO THIS - HE HAS
STILL HELDS APPOINTMENT
AS A P.I.C.

which will review and approve, in advance of purchase of radioisotopes, proposals for ~~clinical~~ use of radioisotopes in ^{HUMANS.} ~~the institution.~~

(3) Appointed a radiological safety

officer ^{WHO WILL ADVISE ON OR BE AVAILABLE FOR ADVICE AND ASSISTANCE ON RADIOLOGICAL SAFETY PROBLEMS.}

(c) General Authorizations for Processing. A General

Authorization for processing radioisotopes permits the applicant to purchase any quantity of any radioisotope for processing, resale and distribution to other authorized persons. To qualify for such a general authorization the applicant shall have:

(1) Received a ^{REASONABLE} ~~substantial~~ number of Authorizations for Radioisotope Procurement for processing, resale, and distribution of a variety of radioisotopes.

(2) Appointed a radiological safety

officer ^{WHO WILL ADVISE ON OR BE AVAILABLE FOR ADVICE AND ASSISTANCE ON RADIOLOGICAL SAFETY PROBLEMS.}

(d) Renewal of General Authorizations. ~~Annual~~ ~~Renewal~~

of a general authorization is subject to review of the applicant's records and facilities by the Commission.

Section 30.2 (a) is hereby amended by deletion of the clause, "or its duly authorized representative," and substituting therefor the following:

"or any official to whom the Commission delegates a function, power, or authority referred to in this regulation, and includes any official to whom all or any part of such function, power, or authority is delegated by a proper order."

Section 30.13 is hereby amended by deletion of sub-section 30.13 (a) and substituting therefor the following sub-section:

"30.13 Items and Quantities (a) Sections 30.20 through 30.53, inclusive, do not apply to any item listed in 30.70 (Schedule A) nor to any quantity listed in 30.71 (Schedule B): Provided, that no person shall, except as otherwise permitted by the regulations contained in this Part, effect an increase in the radioactivity of said scheduled items or quantities by adding other radioactive material thereto, by combining the radioisotopes from two or more such items or quantities, or by altering them in any other manner so as to increase thereby the rate of radiation exposure of himself or others above the original rate therefrom; provided further, that no person shall administer externally or internally, or direct the administration of, said scheduled items or quantities to a human being for any purpose, including but not limited to diagnostic, therapeutic, and research purposes, except as permitted by a valid authorization."

Sections 30.32, 30.40, and 30.54 are hereby amended by deletion of said sections in their entirety and substituting therefor the following:

"30.32 Expiration. For purposes of procurement of radioisotopes, an Authorization shall be valid only for the period stated thereon and it shall expire at the end of such period without the necessity of notice or warning from the Commission. The holder thereof shall neither order nor receive radioisotopes after the expiration date

of said Authorization and no person shall transfer radioisotopes to another person after the expiration date of said transferee's authorization."

"30.40 Limitations. No person shall possess, use, or transfer radioisotopes except as permitted by a valid Authorization from the Commission or as otherwise permitted by the regulations in this Part. This limitation, however, does not negate or nullify the right of possession and use of radioisotopes duly and timely ordered and received under authority of a valid Authorization. When transferring any nonexempt items or quantities of radioisotopes, the transferor shall limit delivery to the locations, materials, and quantities stated in the transferee's Authorization."

"30.54 Inspections and Tests. Each person who possesses or uses radioisotopes shall permit the Commission, at all reasonable times, to make such inspections and tests as the Commission deems *APPROPRIATE* necessary for enforcement of the regulations in this Part, including but not limited to inspections and tests of (a) radioisotopes being used, (b) facilities wherein radioisotopes are used or stored, (c) radiation detection, and personnel monitoring instruments, (d) equipment or devices utilizing radioisotopes or used in connection with the utilization of radioisotopes, and (e) radioisotope waste disposal methods."

APPENDIX "B"

UNITED STATES

ATOMIC ENERGY COMMISSION

PART 31. PROPOSED RULES - STABLE ISOTOPE DISTRIBUTION

Notice is hereby given that adoption of the following rules is contemplated. All interested persons who desire to submit comments and suggestions for consideration by the General Manager of the Atomic Energy Commission in connection with the proposed rules shall send them to the General Manager, United States Atomic Energy Commission, Washington 25, D. C., within 30 days after publication of this notice in the Federal Register.

PART 31 - STABLE ISOTOPE DISTRIBUTION

GENERAL PROVISIONS

- 31.1 Scope
- 31.2 Definitions
- 31.3 Amendment
- 31.4 Communications

EXEMPTIONS

- 31.10 Persons Operating Commission-owned Facilities
- 31.11 Transfer to the Commission
- 31.12 Carriers

PROCUREMENT OF STABLE ISOTOPES

- 31.20 Available Stable Isotopes
- 31.21 Filing Application

POSSESSION, TRANSFER, USE

31.30 Limitations

DISTRIBUTION POLICY

31.40 General

GENERAL PROVISIONS

31.1 Scope. The regulations in this part establish instructions and procedures governing the procurement, delivery, possession, use, and transfer of stable isotopes originating in or procured from facilities of the Commission.

31.2 Definitions. As used in this part:

(a) Commission. "Commission" means the United States Atomic Energy Commission created by the Atomic Energy Act of 1946, or any official to whom the Commission delegates a function, power, or authority referred to in this regulation, and includes any official to whom all or any part of such function, power, or authority is delegated by a proper order.

Use of term Distributor in the Commission's regulations
~~(b) Distributor. "Distributor" means any person to the extent that such person is engaged in operating Commission-owned laboratories, plants, or other facilities under a contract with the Commission and is engaged in the distribution of stable isotopes for the Commission.~~

(c) Stable Isotope. "Stable Isotope" means a naturally occurring isotope of an element of atomic number 82 or less.

(d) Person. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, the United States or any agency thereof, any government other than the United States, any political subdivision of any such government, and any legal successor, representative, agent, or agency of the foregoing, or other entity, but shall not include the Commission or officers or employees of the Commission in the exercise of duly authorized functions.

31.3 Amendment. Nothing in this part shall limit the authority of the Commission to issue or amend its regulations in accordance with law.

31.4 Communications. All communications about the regulations in this part or any approved request issued under them should be addressed to the United States Atomic Energy Commission, Post Office Box E, Oak Ridge, Tennessee, Attention: Isotopes Division.

EXEMPTIONS

31.10 Persons Operating Commission-owned Facilities. The regulations in this part do not apply to persons to the extent that such persons operate Commission-owned facilities in carrying out programs on behalf of the Commission. In such cases the acquisition, transfer, use, and disposal of stable isotopes are governed by the contracts between such persons and the Commission and internal bulletins, instructions, and directives issued by the Commission.

31.11 Transfer to the Commission. The actions of any person in transferring or delivering stable isotopes to the Commission are not subject to the regulations in this part.

31.12 Carriers. Common and contract carriers transporting stable isotopes in the normal course of business are exempt from the regulations in this part.

PROCUREMENT OF STABLE ISOTOPES

31.20 Available Stable Isotopes. Concentrated stable isotopes prepared in Commission facilities are generally available, upon approval by the Commission, as follows: Deuterium, Oxygen 18, Helium 3, Boron 10, Boron 11, Argon 38, and electromagnetically-concentrated stable isotopes.

31.21 Filing Application. Any person who desires to procure stable isotopes, as defined in this part, shall file Stable Isotope Request, Form

AEC-100, with the Isotopes Division of the Commission specifying the use to be made of the isotope and giving all other information called for by the form. A separate request shall be completed for each isotope. Copies of the form will be furnished upon request to the United States Atomic Energy Commission, Post Office Box E, Oak Ridge, Tennessee, Attention: Isotopes Division.

POSSESSION, TRANSFER, USE

31.30 Limitations. (a) No person shall possess, use, or transfer stable isotopes ^{ORIGINATING IN OR PROCURED FROM FACILITIES OF THE COMMISSION} except as permitted by a Stable Isotope Request approved by the Commission, or as otherwise permitted by the regulations in this part.

(b) Each person authorized by the Commission to procure stable isotopes shall confine his use to the locations and purposes approved by the Commission on his Stable Isotope Request, and such use is subject to all applicable laws, regulations of the Commission, and terms and conditions stated in the application or made a part thereof.

DISTRIBUTION POLICY

31.40 General. Approval of a Stable Isotope Request is based upon availability of the requested isotope and feasibility of the proposed use.

APPENDIX "A"

UNITED STATESATOMIC ENERGY COMMISSION

PROPOSED AMENDMENT OF PART 30 - RADIOISOTOPE DISTRIBUTION (10 CFR 30)

Notice is hereby given that adoption of the following rules is contemplated. All interested persons who desire to submit comments and suggestions for consideration by the General Manager of the Atomic Energy Commission in connection with the proposed rules shall send them to the General Manager, United States Atomic Energy Commission, Washington 25, D. C., within 30 days after publication of this notice in the Federal Register.

Part 30 of Radioisotope Distribution Regulations (10 CFR 30) is hereby amended by addition of the following definitions, rules, criteria, instructions, and standards:

30.2 (1) "Research and Development" means theoretical analysis, exploration, and experimentation, and the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. (Research and Development as used herein does not include the internal or external administration of radioisotopes, or the radiation therefrom, to human beings).

30.23 Experience and Facilities

(a) General. An Authorization for Radioisotope Procurement, Form AEC-374, will not be issued unless the applicant is equipped

to handle safely the quantity of radioisotope requested for the proposed use by having:

(1) Trained and experienced personnel;

(2) Suitable equipment and facilities

(handling devices, work areas, shields, measuring and monitoring instruments).

(b) Medical Therapy (human use). An Authorization for Radioisotope Procurement, Form AEC-374, will not be issued for medical therapy (use in humans involving internal or external administration of radioisotopes, or the radiation therefrom, to humans for research, diagnosis, and treatment) unless the applicant meets the following standards in addition to those set forth in paragraph (a) above:

(1) Institutional Use

(i) Medical Isotope Committee. The medical institution, hospital, clinic, or other medical organization, has appointed a local isotope committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations.

(ii) Clinical Facilities. The medical institution shall possess adequate facilities for the clinical care of patients.

(iii) Experience. The physician designated on the application as the individual user shall have substantial experience in the proposed use of radioisotopes in humans; the handling and administration of radioisotopes; and, where applicable, the clinical management of radioactive patients. The physician shall be licensed by a state or territory of the United States to dispense drugs in the practice of medicine.

(2) Individual Use or Private Practice

(i) Clinical Facilities. The physician shall have access to a hospital possessing adequate facilities to hospitalize and monitor the physician's radioactive patients whenever it is advisable.

(ii) Experience. The physician shall have substantial experience in the proposed use of radioisotopes in humans; the handling and administration of radioisotopes; and, where applicable, the clinical management of radioactive patients. The physician shall furnish suitable evidence of such experience (a statement from the local isotope committee in the institution where he acquired his experience, indicating its amount and nature, may be submitted as evidence of such experience). The physician shall be licensed by a state or territory of the United States to dispense drugs in the practice of medicine.

(3) Medical Use of Sealed Sources. The physician shall have specialized training in the therapeutic use of the radioactive device considered (teletherapy unit, beta applicator, etc.), or shall have experience equivalent to such training, and shall be licensed by a state or territory of the United States to dispense drugs in the practice of medicine.

30.35 General Authorizations. Most authorizations are issued for the procurement of a specified quantity of a single radioisotope for a specific use. Under certain circumstances, however, "General" authorizations are issued to hospitals, institutions, universities, laboratories, medical schools, government agencies, and commercial firms for the procurement of any quantity of any radioisotope of atomic number 3 to 83 inclusive:

(a) General Authorizations for Research and Development.

A General Authorization for research and development permits the applicant to use radioisotopes at a specified location for any research and development activity. To qualify for such a general authorization the applicant shall have:

(1) Received a reasonable number of Authorizations for Radioisotope Procurement for a variety of radioisotopes for a variety of research and development uses.

(2) Established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and approve, in

advance of purchase of radioisotopes, proposals for use of radioisotopes.

(3) Appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

(b) General Authorizations for Medical Therapy (human use).

A General Authorization for medical therapy permits the applicant to use radioisotopes at a specified location for any use in humans approved by the local medical isotope committee. To qualify for such a general authorization, the applicant shall have:

(1) Received a reasonable number of Authorizations for Radioisotope Procurement for a variety of radioisotopes for a variety of uses in humans.

(2) Established a medical isotope committee (see § 30.23 (b)(1)(i) above) which will review and approve, in advance of purchase of radioisotopes, proposals for use of radioisotopes in humans.

(3) Appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

(c) General Authorizations for Processing. A General Authorization for processing radioisotopes permits the applicant to purchase any quantity of any radioisotope for processing, resale and distribution to other authorized persons. To qualify for such a general authorization the applicant shall have:

(1) Received a reasonable number of Authorizations for Radioisotope Procurement for processing, resale, and distribution of a variety of radioisotopes.

(2) Appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

(d) Renewal of General Authorizations. Renewal of a general authorization is subject to review of the applicant's records and facilities by the Commission.

Section 30.2 (a) is hereby amended by deletion of the clause, "or its duly authorized representative." and substituting therefor the following:

"or any official to whom the Commission delegates a function, power, or authority referred to in this regulation, and includes any official to whom all or any part of such function, power, or authority is delegated by a proper order."

Section 30.13 is hereby amended by deletion of sub-section 30.13 (a) and substituting therefor the following sub-section:

"30.13 Items and Quantities (a) Sections 30.20 through 30.53, inclusive, do not apply to any item listed in 30.70 (Schedule A) nor to any quantity listed in 30.71 (Schedule B): Provided, that no person shall, except as otherwise permitted by the regulations contained in this Part, effect an increase in the radioactivity of said scheduled items or quantities by adding other radioactive material thereto, by combining the radioisotopes from two or more such items or quantities, or by altering them in any other manner so as to increase thereby the rate of radiation exposure of himself or others above the original rate therefrom; provided further,

that no person shall administer externally or internally, or direct the administration of, said scheduled items or quantities to a human being for any purpose, including but not limited to diagnostic, therapeutic, and research purposes, except as permitted by a valid authorization."

Section 30.32, 30.40, and 30.54 are hereby amended by deletion of said sections in their entirety and substituting therefor the following:

"30.32 Expiration. For purposes of procurement of radioisotopes, an Authorization shall be valid only for the period stated thereon and it shall expire at the end of such period without the necessity of notice or warning from the Commission. The holder thereof shall neither order nor receive radioisotopes after the expiration date of said Authorization and no person shall transfer radioisotopes to another person after the expiration date of said transferee's authorization."

"30.40 Limitations. No person shall possess, use, or transfer radioisotopes except as permitted by a valid Authorization from the Commission or as otherwise permitted by the regulations in this Part. This limitation, however, does not negate or nullify the right of possession and use of radioisotopes duly and timely ordered and received under authority of a valid Authorization. When transferring any nonexempt items or quantities of radioisotopes, the transferor shall limit delivery to the locations, materials, and quantities stated in the transferee's Authorization."

"30.54 Inspections and Tests. Each person who possesses or uses radioisotopes shall permit the Commission, at all reasonable times, to make such inspections and tests as the Commission deems appropriate or necessary for enforcement of the regulations in this Part, including, but not limited to, inspections and tests of (a) radioisotopes being

used, (b) facilities wherein radioisotopes are used or stored, (c) radiation detection and personnel monitoring instruments, (d) equipment or devices utilizing radioisotopes or used in connection with the utilization of radioisotopes, and (e) radioisotope waste disposal methods."

APPENDIX "B"

UNITED STATES

ATOMIC ENERGY COMMISSION

PART 31. PROPOSED RULES - STABLE ISOTOPE DISTRIBUTION

Notice is hereby given that adoption of the following rules is contemplated. All interested persons who desire to submit comments and suggestions for consideration by the General Manager of the Atomic Energy Commission in connection with the proposed rules shall send them to the General Manager, United States Atomic Energy Commission, Washington 25, D. C., within 30 days after publication of this notice in the Federal Register.

PART 31 - STABLE ISOTOPE DISTRIBUTION

GENERAL PROVISIONS

- 31.1 Scope
- 31.2 Definitions
- 31.3 Amendment
- 31.4 Communications

EXEMPTIONS

- 31.10 Persons Operating Commission-owned Facilities
- 31.11 Transfer to the Commission
- 31.12 Carriers

PROCUREMENT OF STABLE ISOTOPES

- 31.20 Available Stable Isotopes
- 31.21 Filing Application

POSSESSION, TRANSFER, USE

31.30 Limitations

DISTRIBUTION POLICY

31.40 General

GENERAL PROVISIONS

31.1 Scope. The regulations in this part establish instructions and procedures governing the procurement, delivery, possession, use, and transfer of stable isotopes originating in or procured from facilities of the Commission.

31.2 Definitions. As used in this part:

(a) Commission. "Commission" means the United States Atomic Energy Commission created by the Atomic Energy Act of 1946, or any official to whom the Commission delegates a function, power, or authority referred to in this regulation, and includes any official to whom all or any part of such function, power, or authority is delegated by a proper order.

(b) Stable Isotope. "Stable Isotope" means a naturally occurring isotope of an element of atomic number 82 or less.

(c) Person. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, the United States or any agency thereof, any government other than the United States, any political subdivision of any such government, and any legal successor, representative, agent, or agency of the foregoing, or other entity, but shall not include the Commission or officers or employees of the Commission in the exercise of duly authorized functions.

31.3 Amendment. Nothing in this part shall limit the authority of the Commission to issue or amend its regulations in accordance with law.

31.4 Communications. All communications about the regulations in this part or any approved request issued under them should be addressed to the United States Atomic Energy Commission, Post Office Box E, Oak Ridge, Tennessee, Attention: Isotopes Division.

EXEMPTIONS

31.10 Persons Operating Commission-owned Facilities. The regulations in this part do not apply to persons to the extent that such persons operate Commission-owned facilities in carrying out programs on behalf of the Commission. In such cases the acquisition, transfer, use, and disposal of stable isotopes are governed by the contracts between such persons and the Commission and internal bulletins, instructions, and directives issued by the Commission.

31.11 Transfer to the Commission. The actions of any person in transferring or delivering stable isotopes to the Commission are not subject to the regulations in this part.

31.12 Carriers. Common and contract carriers transporting stable isotopes in the normal course of business are exempt from the regulations in this part.

PROCUREMENT OF STABLE ISOTOPES

31.20 Available Stable Isotopes. Concentrated stable isotopes prepared in Commission facilities are generally available, upon approval by the Commission, as follows: Deuterium, Oxygen 18, Helium 3, Boron 10, Boron 11, Argon 38, and electromagnetically-concentrated stable isotopes.

31.21 Filing Application. Any person who desires to procure stable isotopes, as defined in this part, shall file Stable Isotope Request, Form AEC-100, with the Isotopes Division of the Commission specifying the use to be made of the isotope and giving all other information called for by the form. A separate request shall be completed for each isotope. Copies of the form will be furnished upon request to the United States Atomic Energy Commission, Post Office Box E, Oak Ridge, Tennessee, Attention: Isotopes Division.

POSSESSION, TRANSFER, USE

31.30 Limitations. (a) No person shall possess, use, or transfer stable isotopes originating in or procured from facilities of the Commission except as permitted by a Stable Isotope Request approved by the Commission, or as otherwise permitted by the regulations in this part. (b) Each person authorized by the Commission to procure stable isotopes shall confine his use to the locations and purposes approved by the Commission on his Stable Isotope Request, and such use is subject to all applicable laws, regulations of the Commission, and terms and conditions stated in the application or made a part thereof.

DISTRIBUTION POLICY

31.40 General. Approval of a Stable Isotope Request is based upon availability of the requested isotope and feasibility of the proposed use.