Attachment 1

Atomic Energy of Canada Limited
L'Énergie Atomique du Canada, Limitée

Commercial Products
Produits Commerciaux

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File: Q2.9.2
RA81.1.373

1981 January 23

Mr. Samuel Pettijohn,
United States Nuclear Regulatory
Commission,
Office of Analysis & Evaluation
of Operational Data,
Washington, D.C.
U.S.A. 20555

Dear Mr. Pettijohn:

AECL-CP TYPE IR 96 CAT IV IRRADIATOR
BECTON-DICKINSON, BROKEN BOW, NEBRASKA

This relates to our telephone conversation of 20 January, 1981, during which we discussed the circumstances surrounding the jamming of the source rack in the IR 96 irradiator in October, 1980.

A full report, describing our assessment of the cause of the incident, its consequences and the corrective action taken, was forwarded to Mr. Simmons (Nebraska State Licensing Authority) on 12 November, 1980. It is my understanding that you now have a copy of this Report.

As a participating member in the ANSI Committee N43-3.4, dealing with standards for Category I, II, III and IV gamma irradiators, I reported the conditions which occurred in Broken Bow for Committee consideration at its November, 1980 meeting. The case was debated at some length and it was concluded that, insofar as the Standard was concerned, no additional design requirements were desirable since certain safety devices were already specified to relieve this problem, (e.g. provision of a source guard, etcetera).

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Also, it was acknowledged that product pass systems, product totes, boxes and carriers vary considerably between installations and the imposition of a specific safety device requirement in the Standard (which may be very suitable for the IR 96 irradiator) is likely to be completely incompatable with some other designs.

However, the Committee did agree that it was reasonable to impose an administrative control for irradiators in general to reduce the possibility of a recurrence of this type of malfunction.

The ANSI Category IV Irradiator Standard is currently in draft form although we expect it to be ratified and issued within the next year or so. As requested, I am enclosing a copy of the Preface, Clause 8.3.11 (Source Guard) and Clause 8.3.16 (Product Pass System) for your information. Clause 8.3.16 was expanded (paragraph 3) in December, 1980, to address this particular problem. I have also included a list of Category IV irradiators currently in use in the USA which are of AECL-CP manufacture.

We would recommend that this administrative control become a mandatory instruction in the manufacturers operating manual for such a facility and, as is currently the case, the authorization to receive, possess, use and store radioactive materials in a Category IV Irradiator be conditional on strict adherence to the manual.

If we can be of further assistance to you in this regard, please do not hesitate to contact me at your convenience.

Yours sincerely,

E.F. Ridout

E.F. Ridout, Manager
Regulatory Affairs
Quality Assurance

encl.

c.c. Mr. E.K. Curnow
Chairman
ANSI N43-3.4

PREFACE

(This preface is not a part of American National Standard N433.4, Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators.)

The 1950's and 1960's can be characterized as the research era for radioisotope applications. Based on this research, a number of commercial gamma irradiators started operation in the early 1960's. Their number has been increasing with source storage capacity of individual irradiators reaching the multi-megacurie range by the mid-1970's.

Gamma irradiators are used for a variety of purposes in research, industry and other fields. Typical uses are:

1. Sterilization or microbiological reduction in medical and pharmaceutical supplies.
2. Preservation of foodstuffs.
3. Radiation effects studies.
4. Chemical and polymer synthesis and modifications.
5. Insect eradication through sterile male release programs.

The number and types of irradiators supporting these and other applications are continually growing. Source requirements for any particular irradiator may vary from a few curies to several million curies. Irradiator designs can be many and varied to suit individual needs; therefore, it is essential to establish basic criteria to ensure a high standard of radiation safety in the design and use of irradiators, but in a way which does not unnecessarily restrict the logical use and growth of radioisotope applications.

REFACE (Cont'd)

This standard sets forth basic safety requirements which shall e met in irradiator design and use. Its use by Regulatory Authorties, relative to the review of radioisotope applications, is encouraged.

Because of the variety of designs, four general categories of rradiators have been established to facilitate preparation of standards. A separate standard establishes the criteria to be used in he design, fabrication, installation, use and maintenance for each rradiator category.

The categories are as follows:

ategory I - Self-contained, dry source storage irradiator.
ANSI Document N433.1.

An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed ource(s) is shielded at all times, and human access to the sealed ource(s) and the volume(s) undergoing irradiation is not physically ossible in its designed configuration.

ategory II - Panoramic, dry source storage irradiator.
ANSI Document N433.2.

A controlled human access irradiator in which the sealed source(s, s contained in a dry container constructed of solid materials, and the

sealed source(s) is fully shielded when not in use; the sealed source(s) is exposed within a radiation volume(s) that is maintained inaccessible during use by an entry control system.

Category III - Self-contained, wet source storage irradiator.
ANSI Document N433.3.

An irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

Category IV - Panoramic, wet source storage irradiator.
ANSI Document N433.4.

A controlled human access irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), and the sealed source(s) is fully shielded when not in use; the sealed source(s) is exposed within a radiation volume(s) that is maintained inaccessible during use by an entry control system.

This standard applies to Category IV irradiators only. Category I standard (ANSI Document N433.1) has been published, Categories II and III standards will be published as they are completed.

8.3.11 Source guard

The radiation source shall be provided with adequate mechanical protection to prevent interference from the product boxes or carriers. This may take the form of guide bars on the product pass mechanism or floor guides for suspended product carriers.

Product movement mechanisms shall not be able to apply force directly or indirectly to the radiation source.

8.3.16 Product Pass System

It is detrimental to the irradiator and product to continue operations when a malfunction of the product pass system occurs.

The product pass system shall be provided with controls that will detect a malfunction of the system, which will cause the source to be lowered into the fully shielded (safe) position and the irradiator to shut down.

It is the responsibility of the user to ensure that all product pass system components, product boxes or carriers continue to meet design specifications. For example, it is important to ensure that the correct product boxes or carriers are used and that they are maintained in a condition that will not cause an irradiator malfunction.

CATEGORY IV - WET SOURCE STORAGE

MEDICAL PRODUCTS IRRADIATORS

INSTALLED IN U.S.A.

IR NO.	UNIT	COMPANY
20	Carrier Type	Ethicon Inc. U.S. Route 67 San Angelo, Texas 76901
21	Tote Type	Becton-Dickinson Rt. #44, Church St. Canaan, Connecticut
47	Tote Type Batch & Automatic	Radiation Technology Lake Denmark Road Rockaway, New Jersey 07866
68	J6300 Tote Type (Batch)	Isomedix Inc. 7828 Nagle Avenue Morton Grove, Illinois 60053
70	J6700 Carrier Type	Johnson & Johnson Highway 75S. Sherman, Texas 75090
78	Carrier Type	Ethicon Inc. U.S. Highway 22 Somerville, New Jersey 08876
85	J6500 Tote Type	Isomedix Inc. P.O. Box 2044 Industrial Park Square Columbus, Mississippi 39701
89	Carrier Type	American Convertors One Butterfield Trail El Paso, Texas 79906
90	J7500 Tote Type	Surgikos 2500 Arbrook Blvd. P.O. Box 130 Arlington, Texas 76010
93	J7500 Tote Type	Sherwood Medical Industries Inc. P.O. Box 1169 Norfolk, Nebraska 68701
96	J7500 Tote Type	Becton-Dickinson P.O. 686 Broken Bow, Nebraska 68822
97	Carrier Type	Isomedix Inc. P.O. Box 3408 Spartanburg, S.C. 29304

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IR NO.	UNIT	COMPANY
100	J7500 Tote Type	3M Company Surgical Products Engineering
104	J8500 Tote Type	Becton-Dickinson Falcon Labware Division 1950 Williams Drive Oxnard, California 93030
107	Carrier Type (to be installed)	Isomedix Inc. Puerto Rico
110	Carrier Type	E.M. Watkins & Company The Buckeye Cellulose Project Industrial Development Board of Huntsville Highway 72 and Moores Mill Road Huntsville, Alabama
116	Carrier Type (to be installed)	Becton-Dickinson Vacutainer Systems Division Airport Road Sumter, South Carolina

E.F. Ridout
AECL-CP
1981 January 20