

8-1-63

DBH

R. Lowenstein
Director
Division of Licensing
and Regulation

For your information.

A meeting was held with Ethicon, Inc., to discuss preliminary plans for construction of a 750,000 curie Cobalt 60 irradiator. The irradiator will be located at Somerville, New Jersey, and used for sterilization of sutures. The tentative completion date is July 1964. Ethicon presented preliminary specifications of the facility to determine areas in which revisions or clarifications of design may be required.

AECL is the designer of the facility and will install the sources, perform related check-out of the facility operation, and subsequent servicing of the facility. We would plan to license AECL to install the source and perform the check-outs prior to authorizing Ethicon to operate the facility. The design will be such that it can be operated by personnel with essentially no training in radiation. We plan to meet with AECL for a preliminary review of the firm-up design specifications prior to their submitting a formal application.

R. E. Cunningham
Chief, Isotopes Br.
DLAR

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August 5, 1963

Subject: JULY 31, 1963, VISIT OF DR. CHARLES ARTANDI, MR. NORMAN KEMPSON, AND MR. ANTHONY ABBURZZE OF ETHICON, INCORPORATED, SOMERVILLE, NEW JERSEY, WITH D. B. HOWELL AND R. E. CUNNINGHAM IN THE ST. ELMO STREET BUILDING, BETHESDA.

The purpose of the visit was to discuss licensing requirements in regard to a proposed 750,000 curie Cobalt 60 suture irradiator (this is similar to the irradiator proposed for use at San Angelo, Texas, which was described in an application submitted to the AEC and subsequently transferred to the Texas licensing authorities). Dr. Artandi acted as spokesman for Ethicon. ~~It is expected that a contract will be let to AECL in the near future for construction of the facility.~~ Operation is planned for July 1964. The Somerville facility will be essentially the same as the San Angelo facility except for the shielding ^{CONTAINMENT & SOURCE ACTIV.} ~~container~~ (See July 24, 1963, letter from Artandi). Artandi went through the specifications prepared by AECL dated June 25, 1963, for the San Angelo facility to determine our reaction to the design. The facility is proposed for twenty-four hour a day operation with technicians as operators. Artandi was advised that operational procedures and safety features could serve in lieu of

having highly-trained radiation personnel as operators. Ethicon proposes ^{to let out a} ~~to contract with AECL for construction services, also AECL would perform~~ ^{in the near future and source installation and check facility check-out} ~~all servicing associated with the use of sources or safety mechanisms.~~

Ethicon would service only those parts of the facility not effecting radiation safety. ^{formed} ~~Consequently,~~ the procedure for a hazardous or emergency situation would be to shut-down operation and await arrival of AECL personnel. Ethicon also plans to have AECL perform semi-annual inspections of the facility ^{after they} ~~(Ethicon) have assumed responsibility for the facility under their AEC license.~~

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at
Visit July 31, 1963, ~~with~~ ^{to} Dr. Charles Artandi, Mr. Norman Kempson, and Mr. Anthony
Abburzze of Ethicon, Incorporated, Somerville, New Jersey. ^{with} D. B. Howell and R. E.
Cunningham ^{at the} for the Atomic Energy Commission. ~~4~~ ¹ St. Elmo Street Bldg ~~Ethicon~~

the purpose of the visit was

To discuss licensing requirements in regard to their proposed 750,000 curie Cobalt 60
suture irradiator (this is similar to the irradiator proposed for use in San Angelo,
Texas, which was ^{described} ~~submitted~~ ^{to the AEC and subsequently transferred to Texas}).

^{to Ethicon} Dr. Artandi acted as spokesman. ^{stated that} He briefly outlined the purpose of his visit ~~was to discuss the requirements for the facility and the use of the facility.~~ ^{above} and the use of the facility. The facility is planned for operation in July
of 1964. It is expected that a contract will be let to AECL in the near future.

The Somerville facility will essentially be the same as the San Angelo facility
except for the shielding containment (see July 24, 1963, letter from Artandi).

Artandi went through the specifications prepared by AECL (dated June 25, 1963) for ~~the~~
San Angelo facility to determine our reaction to the design. Discussion of the
possibility that the source array would bind or otherwise stick in the irradiate
position was discussed at length. Ethicon was advised that this ^{aspect} would be critically
evaluated in our formal review. We also ^{discussed} ~~asked about~~ ^{the} provisions for protection of
sources from impact damage if it was necessary to cut the cable drive to the source
array ^{should} ~~the~~ the cable should bind ^{caused by} causing the array to ^{of the source} free fall into the storage
pool. ~~There were no major problems with the facility specifications as presented~~

The facility is proposed for 24 hour a day operation with technicians as operators.

We advised Artandi that operational procedures and safety features ^{could} ~~would~~ serve in

lieu of having highly trained radiation type personnel as operators, ^{since they proposed}
^{to} ~~would~~ contract with AECL for ~~service and consultant services - that is~~ ^{also} AECL would

perform all servicing of ~~equipment~~^{use of} associated with the sources or safety mechanisms.

Ethicon would only service those parts of the facility not directly effecting radiation safety. (Also Ethicon intends having AECL perform semi-annual inspections of the facility.) ^{Consequently} Their procedure in a hazardous or emergency situation would be to shut down and await arrival of AECL people. AECL will also install sources and source mechanisms and safety devices and check-out facility operation. Ethicon was advised that AECL would have to obtain a license in this regard and that, in fact, ^{it appeared} the major burden of licensing would be on AECL.

Mr. Kempson told of preliminary plans to use dry fill^{in concrete design} for shielding between concrete walls, and asked our opinion. We said that while such a facility involving these ^{large} quantities of activity had not been previously licensed as an above-ground installation, we would consider such a proposal provided they show the method of controlling density of fill, compacting to eliminate voids, and other factors that would cause loss or shifting of shield material. When asked what we thought of ^{the adequacy} an 18 inch concrete ^{ceiling} ~~ceiling as adequate~~ for shielding, we advised that it appeared that excessive levels of radiation would be created and ^{further} that 200-300 mr/hr levels were considered ^{not} advisable levels in such areas. Dr. Artandi was advised that the following should be included or clarified in his application:

1. Routine tests to be made to determine operating condition of safety devices and interlocks;
2. Detailed operational procedures;
3. Delineation of services to be supplied by AECL;
4. Detailed techniques of leak testing ^{through} water samples^{etc.} if performed by their people.

Since AECL will provide bulk of design data on facility to obtain license for start up and check out of facility, it ^{is felt} ~~was decided~~ ^{formal} that initial communication regarding facility license would be with AECL and that Ethicon would keep informed of status through AECL.

Ethicon expressed interest in later operating their facility in a semi-unattended condition. We said that ^{with a roving operator} ~~request for such an operation~~ should be documented with a history of safe operation over a period of time and ^{that} ~~with~~ additional signals ^{would be needed in case of a} ~~warning~~ ^{should be strategically located} cognizant people, ^{so that} ~~that the system has malfunctioned~~. They agreed to hold such a request pending until they could so document ^{the safety of} ~~their~~ operation.