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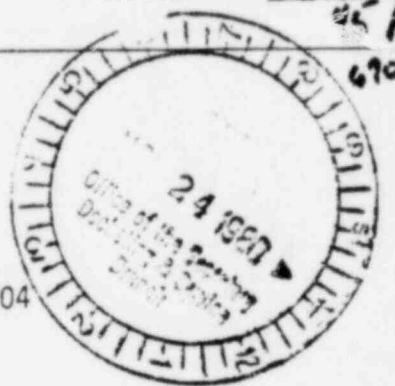
PROPOSED RULE PR 20
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**BECTON
DICKINSON**

November 17, 1980

Secretary to the Commission
U. S. Nuclear Regulatory Commission
Washington D. C. 20555

Ref: RD80-004



Subject: Proposed Rulemaking for 10CFR20,
45FR67018 (October 8, 1980)

Dear Secretary:

We are pleased to submit this comment on the subject proposed rules. We fully support the immediate adoption of the rules since we agree with the rationale for the change as outlined in the Supplementary Information section of the preamble.

Johnston Laboratories manufactures the BACTEC blood culture system for use as an in vitro diagnostic tool by clinical laboratories and hospitals. Over 600 hospitals presently use BACTEC as part of their standard blood culture protocol. BACTEC culture vials contain 2 micro curies of C-14 labelled substrate in 30 ml of culture media. Microbes metabolize the media, or produce a bio-chemical reaction, which generates C-14O₂ gas. Should microbes be present, this radioactive gas will be produced and detected by a radio-activity monitor. We estimate that most microbiology laboratories in U. S. hospitals will be using BACTEC by the end of 1981.

The advantages of this well established and proven "Radiometric Detection" method are:

1. Detection of viable organisms in a much shorter period of time than with traditional methods. This allows for early identification of microbes so that effective therapy may be begun quickly.
2. Reduction in the amount of time required by the laboratory for performing routine cultures, since the detection method can be, and for BACTEC is, automated. This allows personnel to be utilized for other important laboratory tasks.
3. Potential savings in materials costs since the laboratory may eliminate certain sub-culture samples, because the early detection of "positives" will allow the sub-culturing of known positives only in many circumstances.



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Administrated by 4/24/80

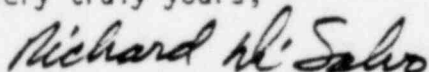
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Therefore, the radiometric method provides a better, more cost effective method for blood culturing. The method can also be applied, and has been so used, for testing sterility of any medium. So the benefits provided by BACTEC are similar to those of other medical, research and diagnostic uses of C-14.

We estimate that about 20% of BACTEC users are presently using the material under a specific license, and are restricted to the waste disposal criteria of 10CFR20.301. (Other users are general licensees per 10CFR31.11 or are exempt per 10CFR30.18). These specific licensees generate about 1.5 million used culture vials per year. (Approx. 3 curies C-14). Although we have no estimate of the total number of BACTEC vials sent to licensed burial sites per year, the change in the sewer disposal limit for C-14 will certainly benefit these users, since the disposal of BACTEC will have a negligible effect on a licensee's total sewer disposal of C-14, and no effect on the sewer disposal of other nuclides. This will allow the licensee to take full advantage of sewer disposal for those nuclides which may be properly disposed of in that manner, thus reducing the use of licensed burial sites and saving burial space for significantly radioactive wastes.

These changes will hopefully be adopted in all Agreement States so that all licensees may take advantage of the sewer disposal method as may be required for their particular use.

Very truly yours,



Richard DiSalvo
Radiation Specialist

RD/ew

CC: John Waters, Glenn Bucklin, Doug Bloomberg