POLYMER TRACK ETCH MEMBRANE
10 C.F.R. § 32.14 – MANUFACTURE AND DISTRIBUTION
PRODUCT SAFETY INFORMATION

GE Osmonics Inc. (GE) produces Polymer (either polycarbonate or polyester) Track Etch (PCTE) membranes which are widely used in pharmaceutical, medical device, water filtration, oceanography, water analyses, surface capture for analysis, microscopy, particulate separation of samples, epifluorescense, microbiology, air analysis, and other applications. This includes cytopathological studies, cell collection and examination for pathology (especially cancer), cancer drug research, and chemotaxis studies (cellular movement in response to chemical exposures).

This assessment addresses product safety in connection with the manufacture and distribution of PCTE membranes at the Bryan, Texas; Westborough, Massachusetts and Minnetonka, Minnesota facilities. As discussed in more detail below, as well as in its application (previously submitted) and Environmental Report, GE has demonstrated, as required by 10 C.F.R. § 32.14, that the PCTE membranes it manufactures and distributes are for a purpose authorized by the Atomic Energy Act of 1954, as amended, that its equipment and facilities are adequate to protect health and minimize danger to life and property, and that it is qualified to use the material for the purpose requested. In addition, the following information describes the chemical and physical form as well as quantities of byproduct material in the PCTE membranes, the design, manufacturing and distribution processes as well as product use, including byproduct containment, quality control measures employed, and product labeling. This information further demonstrates that the PCTE membranes manufactured and distributed by GE are suitable for inclusion and listing as exempt products in 10 C.F.R. § 30.15.[1]

I. Manufacturing, Transportation and Fabrication Processes

The PCTE membrane is manufactured and distributed via the following process:

A. *Ion Track Exposure at Texas A&M Reactor*

A GE owned and operated encased irradiator system is in place in the Thermal Column port of the 1 MW reactor at the Texas A&M University reactor facility. The reactor is operated by Texas A&M under NRC License No. R-83. The activities discussed below are performed by the University under contract to GE. The reactor can be positioned such that through a graphite coupler, neutrons from the reactor are moderated and able to react with the irradiator system U-235 oxide fission plates. Collimators are in place adjacent to the plates to minimize the approach angle of the resultant fission products, as they interact with the polymer film. The irradiator utilizes a moving web process, with the (6-20um thickness, 500mm wide x 2000-4000m long) polymer pulled through the system at a line speed necessary to achieve the desired number of ion tracks/sq-cm. The desired outcome is that the Mixed Fission Products (MFP) pass through the material to create an ion track. However, due to the varying energies of the MFP some become embedded in the film. The nominal tracks per/sq-cm ranges from 4E4 to 6E8.

After exposure, the film is rewound in a controlled environment, and stored within the Texas A&M facility for decay until the activity meets license requirements for release to the Bryan, Texas facility. The entrained activity in the roll is measured using a high resolution gamma spectrometer. The required decay time is directly related to the number of tracks/sq-cm, and ranges from approximately 1-300 days.

---

1 To the extent applicable, GE has also followed the guidance provided in NUREG-1556, Consolidated Guidance About Materials Licenses, Vol. 8, Program-Specific Guidance About Exempt Distribution Licenses, and Vol. 12, Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.

B. *Etching at Bryan, Texas Facility*

Following appropriate decay times and analysis, the rolls are transferred by Texas A&M's staff, and received at the GE site in Bryan, Texas, pursuant to the terms of a Texas Agreement State License.

For the etching process, the material is exposed to a heated sodium hydroxide solution via a moving web process. Depending on time, temperature, and solution strength, the ion tracks are etched into the desired cylindrical pore size. The thickness of the material is reduced proportional to final pore size, resulting in removal of any surface contamination. Material removed through the etching process becomes part of the controlled facility wastewater. In compliance with the Texas Radioactive Materials License, the wastewater is analyzed for adherence to release limits as set forth in the State of Texas' regulations, 25 TAC 289.202.(ggg), prior to any release. The material is then stored on-site, per documented procedures.

Samples of the completed rolls of etched material are beta and gamma counted using gamma/beta sensitive detectors with known efficiencies. To release product from the Bryan, Texas facility, the measurements must show radioactivity levels less than 1000 disintegrations per minute on a 100 sq-cm sample basis, and the rolls themselves are surveyed for contact dose rate less than 0.5 mR using a calibrated ion chamber.

C. *Activities at Minnetonka, Minnesota Facility*

The PCTE membranes shipped to Minnetonka are received in the warehouse and stored in the pleated production area. PCTE membranes are not stored in the warehouse. By procedure, operators are required to wear lab coats, and hair nets. When the PCTE membrane is moved from the warehouse, it is left in the plastic shipping bag and placed on shelves in the pleated production area.

When the PCTE membrane is needed for an order, the operator (with the same personal protective equipment (PPE) as above) takes the roll out of the plastic bag and places it on the pleating unwind shaft. The membrane is then unwound with several other types of non-radioactive material and compressed together. The compressed material is then folded (pleated), exits the pleating equipment, is cut by the operator to width, and placed in a metal bin. The operator then removes the membrane from the bin, cuts it to appropriate length, and returns it to a metal bin. Another operator takes the "pleat pack" and ultrasonically welds the two ends together. The pleat pack is then wrapped around a core and inserted into a plastic sleeve. At this point, the operators no longer have any direct contact with the membrane. End caps are melted onto both ends of the sleeve, and the membrane is completely enclosed. Operators rotate jobs so that one employee is not always handling all of the membrane. Operators do not work in the immediate area where the membrane is stored.

D. *Activities at Westborough, Massachusetts*

At Westborough, the PCTE membranes are received in the warehouse and then taken to the production area, where they are stored in cabinets. In accordance with procedures, operators handling the membranes are required to wear gowns, hairnets, and gloves or finger cots. Two operations occur in Westborough. In the slitting operation, the operator places the membrane roll onto the slitting equipment. The membrane travels through the slitter, is cut into narrower widths, and is wound onto cores. When complete, the operator removes the slit membrane cores from the machine, places a protective wrap around the cores, and labels and bags the cores.

In the second operation, the operator cuts and layers a predetermined number of membrane sheets, protected at the top and bottom with parchment paper. These "wraps" are stapled together and moved to the cutting equipment (roller). A die is placed over the wrap and the roller is cycled to cut the material. The operator removes and inspects the cut disks and places them in appropriate packaging. At the end of each of these two operations, operators no longer have any direct contact with the membrane.

The PCTE membranes themselves are fabricated into a variety of products of varied sizes and configurations. These configurations include pleated cartridge filters, membrane rolls and sheets, and discs.

II. Compliance with Exempt Quantity Limits

The PCTE products contain exempt quantities of byproduct material. The point of compliance for providing reasonable assurance that the exempt quantity limits of 10 C.F.R. § 30.71 Schedule B will not be exceeded is at the point of transfer from the Minnetonka and Westborough facilities to unlicensed and exempt GE customers. As discussed above, GE cuts or slits the membrane off of the rolls into much smaller product sizes for distribution to customers. Standard methods of tracking the radionuclide quantities in the irradiated membrane (such as isotopic spectrum analysis) will be used to provide reasonable assurance that quantities released to GE customers will be below Section 30.71, Schedule B limits. Specifically the activities measured at the Texas A&M reactor will be tracked and maximum mass or surface area of products that can be released is calculated based on 10 C.F.R. § 30.71 Schedule B quantities. How this is accomplished is discussed next.

During the manufacture of the membranes, ideally all fission products would pass through the film, and none would stop part way and remain embedded. However, because the fission products are multiply charged and present large interaction cross sections, their range in air is only a few centimeters and their range in uranium is only a few tens of microns. The uranium coating on the fission plates used to produce fission products in the GE process is very thin, but still thick enough to lower and smear out the kinetic energy spectrum of some of the products. Those fission products that are captured in the membrane are those that start from the fission plates with their energy already degraded by the uranium coating or other materials, so that they lack sufficient kinetic energy to fully penetrate the film. During the etching process, that part of these stopped fission products near the front or back surface of the membrane will be released.

Equations of conservation of energy and momentum show that during the fission process, more kinetic energy is given to the light fission products. In addition, the lighter products have a greater range than the heavier products, so fewer of the light products will be captured in the membrane compared to the heavier products. Analytical analysis of the embedded radionuclides confirms this.

In modeling the quantity of radionuclides in the membrane, there are well over 500 such radionuclides produced during the fission of uranium-235 that could be embedded in the membranes. The production of fission products as a function of mass number for thermal fission of U-235 is well known. See http://www-nds.iaea.org/sgnucdat/c1.htm, for example.

Using this information the source rate of individual fission product isobaric chains can be predicted very accurately. The fission products very seldom divide symmetrically and essentially all fission products are bounded between mass numbers 70 to 164. Many of these radionuclides have such a low yields (>0.01%) that any activity embedded in the membrane will be negligible and undetectable using industry standard equipment. Also, the overwhelming majority of the fission products have half-lives between a few seconds and a few days. Therefore, these radionuclides do not contribute to the activity embedded in the membrane after 30 days. Nuclide half-lives are widely available; See for example:

http://www.nndc.bnl.gov/chart or Nuclides and Isotopes, 16th ed., published by Lockheed Martin, 2002.

Some of the radionuclides at the top of a particular isobaric chain are stable and all the precursor radionuclides below it are short-lived. Consider isobaric chain 80 shown below, for example.

$$ {}^{80}_{30}Zn \xrightarrow{0.54s} {}^{80}_{31}Ga \xrightarrow{1.7s} {}^{80}_{32}Ge \xrightarrow{29.5s} {}^{80}_{33}As \xrightarrow{16s} {}^{80}_{34}Se \qquad \text{Eq. 1} $$

This isobaric chain is produced 0.1285% of the time after thermal-neutron induced fission of U-235. Although some mass-80 nuclides are produced below Zn-80, their half-lives are so short that they have not been measured. Another way to say this is that, of all the fission products produced, 0.1285% of them will end up as Se-80 which is stable (not radioactive). The numbers above the arrows are the half-lives of the nuclides. Zn-80 has a 0.54 second half-life, for example. Clearly all the nuclides along this chain end up as Se-80 within a few minutes. These chains need not be considered in the exempt quantity analysis because they produce negligible radioactive emissions after 30 days.

Some of the isobaric chains have one or more relatively longer-lived isotopes along the chain. These are provided in Table 1 below. See, for example, isobaric chain 90. All precursor nuclides quickly decay to Sr-90 (28.78 year half-life) which then decays to Y-90 (2.67 day half-life). The Y-90 decays to Zr-90 which is stable.

$$ {}^{90}_{35}Br \xrightarrow{1.9s} {}^{90}_{36}Kr \xrightarrow{32.3s} {}^{90}_{37}Rb \xrightarrow{2.6m} {}^{90}_{38}Sr \xrightarrow{28.78y} {}^{90}_{39}Y \xrightarrow{2.67d} {}^{90}_{40}Zr \qquad \text{Eq. 2} $$

Considering all isobaric chains produced by the fission of U-235, the production and half-life for those radionuclides that provide 99% of the membrane activity after 30 days is provided in Table 1 below.

Table 1. Nuclides and daughters that produce PCTE membrane activity after 30 days.

Nuclide	Yield %	Half-life	goes to	
Kr-85	1.31	10.76 y	Rb-85	stable
Sr-89	4.69	50.52 d	Y-89	stable
Sr-90	5.73	28.78 y	Y-90	↓
Y-90	D	2.67 d	Zr-90	stable
Y-91	5.849	58.5 d	Zr-91	stable
Zr-95	6.502	64.02 d	Nb-95	↓
Nb-95	D	34.99 d	Mo-95	stable
Mo-99	6.132	2.7476 d	Tc-99m	↓
Tc-99m	D	6.01 h	Tc-99	↓
Tc-99	D	2.13E5 y	Ru-99	stable
Ru-103	3.103	39.27 d	Rh-103	stable
Ru-106	0.41	1.020 y	Rh-106	↓
Rh-106	D	2.18 h + 29.9 s	Pd-106	stable
Sb-127	0.1202	3.84 d	Te-127	↓
Te-127m	D	109 d (10.21%)	Te-127	↓
Te-127	D	9.4 h (89.79%)	I-127	stable
I-131	2.878	8.020 d	Xe-131	stable
Xe-133	6.6	5.243 d	Cs-133	stable
Cs-137	6.221	30.07 y	Ba-137	stable
Ba-140	6.315	12.75 d	La-140	↓
La-140	D	1.678 d	Ce-140	stable
Ce-141	5.86	32.50 d	Pr-141	stable
Ce-143	5.954	1.377 d	Pr-143	↓
Pr-143	D	13.57 d	Nd-143	stable
Ce-144	5.475	284.6 d	Nd-144	stable
Nd-147	2.232	10.98 d	Pm-147	↓
Pm-147	D	2.623 y	Sm-147	stable
Pm-151	0.4204	1.183 d	Sm-151	↓
Sm-151	D	90 y	Eu-151	stable
Eu-155	0.0308	4.75 y	Gd-155	stable

This table was generated considering those isobars that have at least a 0.06% yield (100 times less than the main chains that have on the order of 6% yields) and, in particular, those chains that produce measurable amounts of gamma activity from the single nuclide at the top of chain, or those chains that produce measurable amounts of gamma activity along the chain (including parents and daughters that are present after 30 days) and finally, those chains that produce significant beta activity after 30 days (e.g., Sr/Y-90). Following the decay of these 30 radionuclides permits the prediction of the activity embedded in the PCTE membrane to a few percent using conservative assumptions as described below.

GE assumes that the irradiation of the membrane is well-approximated as instantaneous, so that burnout of the fission products already embedded in the membrane is negligible. GE also assumes that the isobaric chains decay instantly to the first long-lived nuclide in the chain rather than the few minutes to few days that it actually takes. Rather than try to predict quantities of individual nuclides embedded in the membrane, a nuclide of interest, usually Ce-144 or Cs-137 will be measured by GE, and using appropriate models of nuclide capture in the membrane as a function of mass number, GE will calculate and record all the other nuclides using the production ratios and the individual radionuclide's half-life.

GE assumes that all nuclides are deposited in the film with the same capture ratio as Cs-137 or Ce-144. This model is conservative because, as discussed above, the heavier fission fragment receives less kinetic energy during its production by fission and it is more easily stopped than the lighter fragment as it traverses the film. This has been confirmed by radiochemical measurements of the film in which the Sr/Y-90 capture ratio was 5 times smaller than the Cs-137 capture ratio. By measuring the activity of Cs-137 or some other heavy fission fragment and assuming all fragments have the same capture ratio, then the source terms for all fragments are known. This coupled with decay data allows calculation of activities any time into the future using equations widely published in nuclear physics textbooks. See for example, F. H. Attix, *Introduction to Radiological Physics and Radiation Dosimetry*, Wiley & Sons, 1986 or R. D. Evans, *The Atomic Nucleus, McGraw-Hill, 1955*. The activities per gram of the 30 nuclides given in Table 1 are calculated for a given time and these activities are divided by the quantities listed in Section 30.71, Schedule B limits for each nuclide. The sum of these ratios gives the fraction of a Schedule B formula quantity in a gram of film, and the inverse of this sum is the number of grams that can be released that contain exactly one formula quantity. Thus by tracking the individual rolls, the initial measurement of entrained radionuclides can be used to control releases anytime in the future. Written quality control measures will be implemented at both Westborough and Minnetonka to ensure that the quantity of nuclides in a package is below the quantities listed in Section 30.71, Schedule B.

III. Dose Assessment

As described above, following irradiation at the Texas A&M reactor and initial storage to allow for decay, PCTE membranes are sent to GE's Bryan, Texas facility for chemical etching into a porous membrane, initial packaging, and further storage. Individuals who handle and fabricate the product for distribution are appropriately trained, follow appropriate procedures and wear personal protective equipment that minimizes the potential for any worker exposure as well as assures product cleanliness. Because of the foregoing, there is at most only limited ingestion or inhalation concern for the radionuclides during normal handling or shipping at Bryan. Historical records for the last 20 years of weekly samples show no activity above 1% of limits (TAC 289.202.pp).

The PCTE membranes shipped to Minnetonka and Westborough are received in the warehouse and stored in areas controlled by the operators who handle that material. Individuals at these facilities likewise are trained, follow written procedures and wear appropriate personal protective equipment. Therefore, there would be at most only limited ingestion and inhalation concern during normal handling and processing. Since production with these membranes is not a daily occurrence, and much less frequent than at the Bryan facility, the resultant ingestion and inhalation risks are much less.

After processing the PCTE membrane at Minnetonka and Westborough, operators no longer have any direct contact with the membrane. This holds true as the membrane is transported to the customer. When the product is received by our customers, most customers incorporate the PCTE membrane in to their products which may require some additional mechanical processing (i.e. further cutting and slitting), after which, their products are packaged and ready for transport to their end use customers.

Disposal of scrap material is assumed to be ultimately handled in municipal waste facilities. Doses from such disposal are very small.

The following discussion provides an assessment of the radiation doses to individuals and the public from routine distribution and transport, use, and disposal. Chapter 5 of the Polymer Track Etch Environmental Report assesses radiation doses from postulated accidents associated with such activities. The results for all of these assessments are included in Table 2 in this section. All dose calculations in this and the following section use the methodology presented in NUREG-1717.

Doses associated with distribution and transportation

While the vast majority of the fission fragments pass through the film, some residual radioactivity remains fixed in the film as embedded mixed fission products (MFP). The MFP remains fixed in the PCTE after fabrication into filter media, as well as during storage, distribution, and use, with few exceptions (membrane combustion or solvent dissolution). Moreover, PCTE membranes are not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being.[2] Rather, PCTE membranes are used in specialty products which are not designed or intended for consumer uses or incorporation into consumer products. The safety of the PCTE membranes is assured by the nature of the residual byproduct material – it is embedded and fixed in the membrane – and the fact that the initially-irradiated membrane is stored to allow for decay before the final consumer product is fabricated and distributed.

The source term for the dose calculations is based on current production levels. These levels cannot be increased significantly because of limitations of irradiation time at the reactor, limits in the capacity of the processing facility in Bryan, Texas, and the overall demand for the product. The sum of the activities of all entrained nuclides for a year's production is around 4 mCi, calculated at the time of earliest release from the Bryan, Texas facility. The gamma-emitting radionuclides that dominate the external dose calculations have the following total activities: Cs-137 (27 uCi), Zr-95 (790 uCi), Nb-95 (1362 uCi), Ce-144 (619 uCi), and Ce-141 (238 uCi). These activities are conservatively used in dose calculations, in that we assume: all films are released from the Bryan, Texas facility immediately upon meeting the release criteria; they are instantly transported to the warehouses; they are instantly used in manufacturing; and

2 PCTE membranes are used in the production of several chemotherapy drugs. In this application, the membrane is used purely as a separation device to ensure that only the materials of a desired range are included in the pharmaceutical production. At no time is the PCTE degraded or modified in any way that would permit the inclusion of the PCTE material in the final product.

are immediately released to the public. For calculations concerning disposal, we assume that the film products are immediately sent to disposal at release from the warehouse facilities.

The etched films are transported by common carrier to the Minnetonka and Westborough plants, and, after fabrication into the final products, approximately 80% of the film mass (including its associated entrained activity) is shipped to customers (this assumes 20% scrap loss during manufacturing). Using the Cs-137 activity-to-dose factor (dose factor or DF) given in NUREG- 1717 for individual and collective dose, Tables A.3.2 and A.3.3, respectively, the individual and collective doses from transportation are readily calculated. The dose factor for Zr-95, Nb-95, Ce-144, and Ce-141 can be found by multiplying the Cs-137 dose factor by the ratio of the specific gamma constant of the nuclide of interest divided by the specific gamma constant of Cs-137. The specific gamma constants used in these calculations was taken from *Specific Gamma-Ray Dose Constants for Nuclides Important to Dosimetry and Radiological Assessment,* L. A. Unger and D. K. Turbey, ORNL/RSIC-45/R1, 1982. Using these dose factors the total dose for transportation to Minnetonka and Westborough from Bryan, Texas and transportation out to GE customers for all five isotopes listed above is calculated to be 3.6E-6 mrem for individual dose and 4.5E-6 person-mrem for collective dose.

As noted earlier, individuals who handle and fabricate the final product for distribution to customers are appropriately trained, follow appropriate written procedures and wear personal protective equipment. Because of this, there is at most only limited ingestion or inhalation concern for the radionuclides during handling and shipping at the Bryan, Westborough and Minnetonka facilities. The activities at these facilities are subject to the terms of specific licenses issued by the NRC under 10 C.F.R. Part 32, and by the State of Texas under analogous provisions which permit the possession and use of the byproduct material at these facilities and the manufacture and distribution of products fabricated from the irradiated polymer membrane if authorized as exempt products, by 10 C.F.R. § 30.15.

For purposes of compliance with 10 C.F.R. § 30.15, the product provided by GE to specialized consumers is described in GE Product Sheet "PCTE Membrane". This product is supplied to customers in various stock sizes and shapes, as well as in custom configurations. As previously discussed, the fabrication of the product for customers is only performed at the Westborough and Minnetonka facilities. The product is packaged at each facility in plastic boxes with heat shrink, or plastic bags with cardboard boxes for shipment. In this process, the product is handled by material handlers and distribution personnel. The total exposure to the GE workers from this process is estimated to be 6 mrem per year to an individual and 24 person-mrem per year for the collective dose. These calculations are based on 4 people working to make pleat packs, 2 minute contact with 0.5 mrem/hr rolls once a day to start the process, processing 50 units a day in contact with each for 30 seconds at a dose rate of 0.015 mrem/hr. The packaged filters are then shipped to customers using standard 3rd party common carriers with no special handling requirements. Products shipped to customers will comply with the limits set forth in 10 C.F.R. § 30.71, Schedule B.

Doses associated with use

Because of the intended, specialized use of the filter membranes, they are not routinely handled by the customer after receipt and installation. Experience has shown that the product is stored in its original packaging and then only handled during installation into the operating system, installed and used for short periods of time. One product made from PCTE material is filters used in chemical analysis. Typically, these filters are approximately 50 mm in diameter. If one of these filters were ignited and combusted outside of a fumehood, the dose to an individual would be very small. This 50-mm filter would contain 0.44 pCi of Cs-137, 9.9 pCi of Cd-144, 0.97 pCi of Nb-95, 0.25 pCi of Zr-95, and 0.13 pCi of Ce-141. If there was a 1% uptake by inhalation, the committed dose would be 3.3E-6 mrem based on the Annual Limits for Intake, 10 C.F.R. Part 20, Table 2. Even if thousands of these filters were ashed in air, the collective dose would be very small. If the filters were dissolved and disposed in the sewer, these inventories would constitute a tiny fraction of the Table 2 values for sewer disposal.

Doses to personnel during installation are estimated to be less than 0.025 mrem per year and usually much less. This calculation assumes that an individual is in contact with a filter for 2 minutes with a contact dose rate of 0.015 mrem/hr and replaces 50 filters per year. Assuming 200 such persons, the collective dose would be 5 person-mrem/year. After installation, the product is not handled by anyone – the filters do not require any maintenance, nor are persons otherwise exposed to them.

The filters are used for approximately one day to one year. The filters are then removed and disposed of. Disposal of the material is assumed to be ultimately handled in municipal waste facilities. Doses from such disposal are very small. Using the methodology described in NUREG-1717 (Tables A.2.1, through A.2.4), a year's material discarded as waste would lead to doses of less than 5×10^{-6} person-mrem for both the waste collectors and employees at the waste facilities. Individual doses are below 0.001 mrem. The collective EDE to the general public corresponding to a year's disposal is 0.001 person-rem due primarily to exposure from Cs-137 to future on-site residents over a 1000 years after loss of institutional control of the landfill. Offsite doses from incineration of a year's worth of material gives a collective dose of 0.002 person-mrem (NUREG-1717, Table A.2.14). Estimated doses above are summarized in Table 2 below.

Table 2 Estimated Effective Dose Equivalents From Distribution, Use, and Disposal of PCTE Membranes

Exposure Pathway	Individual Annual Effective Dose Equivalent (mrem)	Collective Effective Dose Equivalent (person-rem)
Manufacturing	6	0.024
Distribution and Transport	0.004	0.005
Installation and Use	0.025	0.005
Disposal as ordinary trash	<0.001	0.005
Accidents or Misuse:		
Transportation Fire	<0.0003	
Warehouse Fire	<0.001	
Misuse of product	0.36	

The doses in this Table both for the normal product flow and for accidents are extremely conservative. Individual doses are calculated using high-activity material with minimum decay times. The doses in accident calculations assume: a full truckload of film for a transportation fire, a full year's inventory in the warehouse, and the misuse of the product assumes multiple high-inventory films in contact with the body for a day. (See Chapter 5 in the Polymer Track Etch Environmental Report for more details.)

Because of the nature of the radioactive material which remains embedded in the PCTE membrane, the radiological impacts on the terrestrial and aquatic ecology during distribution and use are essentially zero. As noted above, PCTE membranes do not require maintenance or repair, and, therefore, these activities do not have the potential to cause any impact. Disposal of spent PCTE membranes is generally in landfill depending upon the material filtered or cultured. No radiological effect is anticipated based upon residual radiation amounts.

IV. Summary

In summary, GE has demonstrated that the PCTE membranes it manufactures and distributes are for a purpose authorized by the Atomic Energy Act of 1954, as amended, that its equipment and facilities are adequate to protect health and minimize danger to life and property, and that it is qualified to use the material for the purpose requested. In addition, the information provided by GE describes the chemical and physical form as well as quantities of byproduct material in the PCTE membranes, the design, manufacturing and distribution processes as well as product use, including byproduct containment, quality control measures employed, and product labeling. This information further demonstrates that the PCTE membranes manufactured and distributed by GE are suitable for inclusion and listing as exempt products in 10 C.F.R. § 30.15.