ENVIRONMENTAL REPORT

POLYMER TRACK ETCH MEMBRANE
10 C.F.R. § 30.15

Summary

a. GE Osmonics Inc. (GE) produces Polymer (either polycarbonate or polyester) Track Etch (PCTE or polymer) 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). For the purposes of this report, PCTE refers to either polycarbonate or polyester films.

The PCTE membrane is irradiated at the Texas A&M reactor to produce the desired ion tracks and then shipped to GE's facility at Bryan, Texas. From there, the membranes are shipped to GE's facilities in Westborough, Massachusetts and Minnetonka, Minnesota, where they are stored and finally fabricated into the various products in response to specific orders from GE's customers.

b. An alternative to irradiation of the polymer membrane entails bombardment with accelerated ions. Some of the bombarded product, however, requires ultraviolet pretreatment prior to further processing. This ultraviolet pretreatment contributes to longer cycle times and quality concerns related to additional material handling of very sensitive product, and thus significantly lower yields. There are no significant environmental impacts associated with the

use of PCTE membrane as discussed further below.

This Environmental Report follows the general format and content of NRC Reg. Guide 6.7 (May 2010, Rev. 2) to the extent reasonably applicable.

Chapter 1. Introduction

1.1 The Petition for Rulemaking

GE proposes to amend 10 C.F.R. § 30.15(a) to add, as a new product which is exempt from NRC licensing requirements, irradiated Polymer (polycarbonate or polyester) Track Etch membranes. These membranes 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).

The polymer membranes are initially irradiated to create the desired ion tracks, and, although most of the byproduct material passes through (and is not captured within the membrane) or otherwise decays during the period in which the irradiated membrane is stored prior to distribution, some byproduct material remains fixed and embedded in the membrane. Nevertheless, the quantity of this residual radioactivity is so low that the product provided to GE's customers contains quantities of radionuclides below the exempt quantities set forth in 10 C.F.R. § 30.18, Schedule B. Because of this, the dose analyses discussed herein, and the beneficial characteristics of the product, 10 C.F.R. § 30.15(a) should be amended to include irradiated PCTE membrane.

1.2 The Petitioner

1.2.1 GE Osmonics (GE), the petitioner, is an affiliate of the General Electric Company, and is a business unit of GE Water and Process Technologies. Its principal offices are located in Minnetonka, Minnesota. GE is engaged in the production of filtration products.

1.2.2 GE's PCTE membranes are irradiated under a contract with Texas A&M University, at the Texas A&M reactor, an NRC-licensed facility, using a GE owned and operated irradiator system. After irradiation, the membranes are shipped to GE's Bryan, Texas facility, where they are etched, packaged, and stored before distribution to GE's facilities in Westborough, Massachusetts and Minnetonka, Minnesota for storage, final fabrication into ordered filter products, and shipment to GE's customers.

Chapter 2. Description of the PCTE Membrane Manufacturing and Distribution Process

2.1 Description

2.1.1

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.

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. Dependent 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 TX Radioactive Materials License, the wastewater is analyzed for adherence to release limits as set forth in 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.

2.1.2 Description of Radionuclides

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.

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

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

Nuclide	Yield %	Half-life	goes to	
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 fate 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.

2.2 Operations

GE has discussed above how the PCTE membrane product functions and its uses in scientific, medical and other applications. Additional information on such uses and operating conditions is provided in various Sections below.

2.3 Uses

PCTE membranes are used worldwide 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). As a general matter, users are commercial and industrial or other large institutional organizations and not private individuals. GE is not aware of any uses other than those for which the product is intended.

As noted above, PCTE membranes are not irradiated or used because of their radioactive properties. Rather, the membranes are irradiated to achieve specified ion track sizes and porosities which make the membranes well-suited as filter media and for other applications. The byproduct material remaining in the membranes after irradiation and decay is composed of fixed and embedded residual radioisotopes.

PCTE membranes function as a particle exclusion device due to the pores formed by the irradiation and etching process. From 0.01 micron to large pore sizes, the membrane is specified based upon the level of filtration required for the specific application. PCTE membranes are also employed as substrate materials in applications such cell culture and skin graft applications.

2.4 Methods of Use

In these applications, PCTE membranes may be used in sheet or disc form. More commonly, the material is incorporated into a filtration device such as a capsule or cartridge filters, or plate device. The membranes are used in research, scientific and commercial laboratories throughout the U.S. Expected useful life is discussed in Section 2.6 below.

2.5 Distribution

2.5.1 Distribution Packaging

The PCTE membranes as initially irradiated, while stored and processed at Bryan,Texas and when shipped to Minnetonka and Westborough are typically 6-20 um thick, 500 mm wide and 2000-4000 m long. They are stored at Bryan in the controlled areas, in a polymer film wrap. Labeling includes Lot numbers, quantity, and Material numbers. Rolls are shipped to Minnetonka and Westborough in boxes containing individual rolls. Shipment size could be several thousand square feet.

The membrane is then processed at Minnetonka and Westborough to create a variety of product configurations including discs, sheets and rolls. Product is sold in large and small quantities, ranging from 3,000 sq ft rolls to 1 sq ft sheets. These are then packed in boxes and shipped to our customers.

2.5.2 Distribution Sites

The etched roll stock material from the Bryan facility will be shipped to Minnetonka and Westborough for further processing to end customers, including distributors. Information about these sites is provided in Section 2.1.1 above.

2.5.3 Transport

The etched roll stock material will be transported to the Minnetonka and Westborough facilities via standard 3rd party common carriers (typically trucks but planes are sometimes used for rush shipments), with no special handling requirements. The same is true for shipments to customers from the Minnetonka and Westborough facilities. Individual shipments to customers range in size from approximately 1000 sqft rolls to individual sheets. Most shipments are domestic within the US but there are some shipments to both Europe and Asia.

2.6 Installation, Maintenance, and Repair

PCTE membranes are intended for disposal following use, and are not repaired or maintained. PCTE membranes are single use products. When used in a cartridge or capsule device, the material functions as the primary filtration media, and is at the end of its useful life when flow is reduced to unacceptable levels, due to particle absorption. When used as a substrate, the membrane is discarded when the cell growth or other biological operation is completed.

2.7 <u>Disposal</u>

Spent filter media are removed and replaced, and are generally disposed of in a landfill as municipal waste.

Chapter 3. Market for PCTE Membranes

3.1 <u>Need for PCTE</u>

PCTE membranes are used in a variety of specialized products utilized for very beneficial scientific and medical purposes. As noted above, they are 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). PCTE membranes produced by *irradiation* are better suited for use in these areas because they are unique in structure compared to all other membrane types. All other membrane structures utilize a tortuous path or depth filtration to accomplish the required filtration. PCTE produced through the irradiation process is the only product which utilizes a defined single pore size, which can be measured with a scanning electon microscope, and has uniformity in pore size everywhere along the membrane.

GE PCTE membranes are marketed under the brand names Memtrex and GE.

3.2 The Product Industry

PCTE membranes are manufactured by a small number of manufacturers including GE, using the accelerated ion process. PCTE membranes manufactured by irradiation to produce track-etched pores, however, are uniquely a GE product.

3.3 Demand for GE PCTE

PCTE membranes are used in a variety of specialized products as discussed above. The need for finer filtration is increasing in the industry (down to 0.01 micron), primarily as a result of operational needs of the microelectronics industry. PCTE membranes are being recognized as one of the only available technologies to achieve, and verify, the required level of filtration. This is due to the unique structure of the PCTE membrane. Biological applications utilizing PCTE membranes as a substrate are also increasing due to the purity (low extractables) and the structure of the membrane. GE production volume in polycarbonate membrane has grown at an increasing rate over the past several years. In 2011, production volume around roll stock to OEMs grew in excess of 20%. The market growth rate is expected to be in the 10 – 12% range annually over the next 10 year. The growth rate in these products has caused lead times on the membrane to increase to unacceptable levels, due to capacity issues around beaming and other factors.

3.4 Supply

The current supply of PCTE membranes is limited by two factors – increasing demand and limited sources of beaming facilities. As mentioned above, the demand for PCTE membrane is increasing, driven by PCTE's unique properties. Facilities for beaming or irradiation are extremely limited, and in all cases are operated by governmental agencies such as universities or research labs. As such, the commercial production of PCTE membranes is almost always a secondary operation, and production time is dependent upon time that is free from the primary operation of the facility.

Chapter 4. Environmental Effects of Normal Distribution, Use and Disposal of GE PCTE

4.1 Environments and Populations Affected

4.1.1 Environments and Populations Affected During Distribution

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 are trained, follow 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.

4.2 Radiological Impacts

4.2.1 Radiological Impacts on People

This section provides an assessment of the radiation doses to individuals and the public from routine distribution and transport, use, and disposal. Chapter 5 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.

While the vast majority of the fission fragments pass through the film, some residual radioactivity remains fixed in the film as embedded fission products. 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[1]. 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

[1] 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.

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 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.

4.2.1.1 <u>Radiological Impacts During Transportation</u>

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 and its associated entrained activity are shipped to customers. (Assuming 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 easily calculated. The dose factor can be found for Zr-95, Nb-95, Ce-144, and Ce-141 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.

4.2.1.2 <u>Radiological Impacts During Manufacturing</u>

Individuals who handle and fabricate the final product for distribution to customers are appropriately trained, follow appropriate procedures and wear personal protective equipment. Because of the foregoing, 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. 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.

4.2.1.3 Radiological Impacts During Use

Because of the intended, specialized use of the filter membranes, they are not routinely handled after receipt and installation by the customer. 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 ashed outside 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, 10CFR20, Table 2. Even if thousands of these filters were ashed in air, the collective dose is 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.

4.2.1.4 Radiological Impacts During Installation, Maintenance, and Repair

The filters are used for approximately one day to one year. 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 – they do not require any maintenance, nor are persons otherwise exposed to them.

4.2.1.5 Radiological Impacts Due to Disposal

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 Section 5 below.)

4.2.2 Radiological Impacts on Terrestrial and Aquatic Ecology

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 by landfill depending upon the material filtered or cultured. No radiological effect is anticipated based upon residual radiation amounts.

4.2.3 Radiation Impacts on Land, Air, and Water Use

Because of the nature of the radioactive material, which remains embedded in the PCTE membrane, the radiological impacts on land, air, and water use 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 by landfill or some other municipal facility. No radiological impact is anticipated based upon residual radioactive material.

4.3 Nonradiological Impacts

There are no nonradiological impacts associated with the production, distribution or use of PCTE membrane that are significantly different than those that might be associated with the use of conventional filter media.

4.4 Social and Economic Impacts

PCTE membranes are increasingly used in pharmaceutical, medical device, microelectronics and other leading edge technology 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), and sub-micron filtration applications in microelectronics. As the requirements for purity and finer filtration increase, researchers have discovered that PCTE membranes are unique in the properties necessary to perform the advanced research in these areas. No other membrane or mechanical separation device offers the same benefits as PCTE.

4.5 Resources Committed

GE has invested in facilities, quality control and production equipment, at multiple sites in North America (Bryan, TX, Minnetonka, MN and Westborough, MA). Personnel at the manufacturing sites have been trained in the production and handling of the PCTE materials. The sites in North America are used to fulfill the global demand for the product.

Chapter 5. Environmental Effects of Postulated Accidents or Misuse

5.1 Radiological Impacts of Accidents

Analysis of accidents during transportation, manufacture, and use was performed using the methodology of NUREG-1717. The results of these calculations are given in Table 2 above.

5.1.1 Radiological Impacts of Accidents During Distribution

The doses to the general public and to firefighters are very small (See Table 2 above). Even these doses are calculated using extremely conservative assumptions. For example, we assume that the whole radioactive inventory is made airborne by the fire, when in actuality, the film will burn only if fueled by other materials. Otherwise the rolls of film would melt and still contain a large fraction of their radioactive inventory. The doses were calculated using NUREG-1717, Table A.1.15 dose factors.

5.1.2 Radiological Impacts of Accidents During Use

For even large area (and therefore high inventory) applications of the film, the contact dose rates are well below 0.015 mrem/hr. This level precludes any serious injury. If we assume a 24 hour contact exposure after removing the film from the product, the dose to the whole body is 0.36 mrem. Other hypothetical *misuses* of the film include removing the film from its package and using it as a filter for water, beer, or wine. However, even if the whole film inventory ended up in the filtrate, the doses would be less than 0.003 mrem for someone drinking the entire filtrate. Since expected leach rates from the film are much less than 0.1% clearly external dose from the film is worse.

5.1.3 Radiological Impacts of Accidents During Installation, Maintenance, and Repair

All accidents occurring during installation, maintenance, or repair are bounded by the analysis performed for accidents during use above (Section 5.1.2).

5.1.4 Radiological Impacts of Accidents During Disposal

All accidents during disposal are bounded by the transportation accident doses.

5.2 Nonradiological Impacts of Accidents

There are no nonradiological impacts unique to PCTE film.

Chapter 6. Alternatives

Alternatives to the PCTE product are possible for a small segment of the PCTE demand. Filtration devices utilizing conventional membranes may be rinsed to high purity for some of the applications where purity is the primary concern. This post treatment is a costly, less effective means of production. An alternative to irradiation of the polymer membrane entails bombardment with accelerated ions. Some of the bombarded product, however, requires ultraviolet pretreatment prior to further processing. This ultraviolet pretreatment contributes to longer cycle times and quality concerns related to additional material handling of very sensitive product, and thus significantly lower yields. For the application dependent upon the unique PCTE design there is no clear alternative.

6.1.1 Alternative Radionuclides

.Alternative radionuclides are not an option, due to the needed release of the energetic U-235 MFP utilized in the bombardment phase of the membrane production.

6.1.2 Alternative Products or Designs

For the application dependent upon the unique PCTE pore design there is no clear alternative.

6.1.3 Alternative Means of Distribution, Use and Disposal

The extremely low levels of radioactivity associated with the finished products do not require any special handling in terms of distribution, use or disposal.

6.2 Alternatives Related to Licensing Requirements for PCTE Membranes

6.2.1 General License

GE considered, as an alternative licensing scheme, requesting a specific license authorizing the manufacturing and distribution of irradiated PCTE membrane as exempt quantities pursuant to 10 C.F.R. § 32.18. In conjunction with that approach, GE initially proposed to amend 10 C.F.R. § 30.18 to allow persons who initially purchased PCTE membranes from GE to repackage and redistribute such PCTE membranes to others under a general license. Overall, however, GE does not believe there is a particular benefit or preference for one licensing approach versus the other.

6.2.2 Specific License

The alternative of requiring each user of PCTE membranes to obtain a specific license is unnecessarily burdensome, commercially impracticable, and provides no regulatory benefit. Whether added to the specifically identified products enumerated in 10 C.F.R. § 30.15, or permitted as an exempt quantity under 10 C.F.R. § 30.18, the quantities of radionuclides remaining fixed within the membranes will be below the exempt quantities under 10 C.F.R. § 30.71, Schedule B, and do not warrant the very significant additional burdens that would be created if a specific license for all such customers was required. This is especially evident given the nature of the consumers who typically use this product and the circumstances under which it is used.

Chapter 7. Summary of Potential Benefits and Possible Costs

The market for PCTE membranes is approximately $200 million worldwide. The forecast for the market growth rate is 10 – 12 % annually over the next decade. Applications in the pharmaceutical, medical device, microelectronics and other leading edge technology areas continue to grow, and alternative uses for PCTE membranes are identified consistent with their unique properties . These are highly beneficial activities from a societal benefit perspective. This is true for the production of legacy drugs and materials as well as the new applications. PCTE membrane is unique in performance for these applications, and the production of uniform, quality PCTE membrane products is essential.