PRM-30-65

GE Energy Infrastructure
Water & Process Technologies

Annette User
EHS Leader

5951 Clearwater Drive
Minetonka, MN 55343
USA

T 952-988-6470
F 952-988-6056

April 18, 2011

Secretary
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Petition for Rulemaking Pursuant to 10 C.F.R. § 2.802 On Behalf of GE Osmonics Inc.

I. INTRODUCTION

GE Osmonics Inc. (GE) hereby petitions for a rulemaking pursuant to the U.S. Nuclear Regulatory Commission (NRC) regulation at 10 C.F.R. § 2.802. Under 10 C.F.R. § 2.802(a), "[a]ny interested person may petition the Commission to issue, amend or rescind any regulation." This Petition specifically requests that the NRC modify its regulations in 10 C.F.R. Parts 30 and 32 with respect to the commercial distribution of a particular product – polymer (polycarbonate or polyester) track etch (PCTE) membranes that have been irradiated with mixed fission products (MFP), and that contain such MFPs in quantities below the exempt quantity limits for byproduct material set forth in 10 C.F.R. § 30.71, Schedule B.

GE has separately applied for a specific license, pursuant to 10 C.F.R. § 32.18, to authorize it to distribute exempt quantities of byproduct material (which remains as fixed MFP in PCTE membranes). In that connection, GE recognizes that while such license, if

Template = SECY-051

DS 10

granted, would authorize it to distribute such material only to recipients who do not intend to redistribute it, there are some number of customers who wish to commercially redistribute the PCTE to others. The purpose of the rulemaking request is to permit those persons to whom GE commercially distributes the PCTE/MFP membranes (and who are already generally exempt from NRC licensing with respect to the receipt, possession, use, transfer, ownership, and acquisition of the PCTE/MFP membranes pursuant to 10 C.F.R. § 30.18), to commercially *re*distribute the PCTE/MFP membranes without a license. The Petition also requests that any person who subsequently receives the PCTE/MFP membranes be permitted to commercially redistribute without a license. For the reasons discussed below, GE respectfully requests that the NRC amend its regulations as requested in this Petition at the earliest possible time. And we believe the rulemaking can and should proceed as a direct final rule.

II. BACKGROUND

GE is the manufacturer of PCTE/MFP membranes. PCTE/MFP membranes are thin polymer (polycarbonate or polyester) rolls that have been exposed to nuclear fission fragments in an encased irradiation system housed in the Thermal Column of a small research and test reactor. The exposure to the fission fragments creates an ion track in the polymer film. A subsequent chemical etching process, performed at another location, etches the ion tracks into the desired cylindrical pore size for use in multiple applications.

The PCTE/MFP membranes are utilized in a very wide variety of valuable research, medical, academic, scientific and industrial applications. In particular, PCTE/MFP membranes are widely used in, among other things, pharmaceutical, medical device, and

water filtration applications. PCTE/MFP membranes have a unique pore structure that make them preferred for pharmaceutical and medical applications. The uniform, cylindrical pores allow for the collection of samples on one plane of the membrane surface. Cells and other samples are captured on the flat, smooth, glass-like surface. The precisely sized pores in a very narrow distribution ensure accurate separation or fractionation of samples by size.

Cytopathological studies are a common use of the PCTE/MFP membranes. A primary use is in cell collection and examination for pathology (especially cancer) where the samples are collected on the membrane surface and examined for pathology. Cancer drug research is another major use, utilizing the unique pore structure for cell extrusion and processing. Chemotaxis (cellular movement in response to chemical exposures) studies are another important application, where the smooth surface and cylindrical pores of the membrane allow rapid cell migration and reduced incubation time. Cells are easily removed from the surface of the membrane without damage to the organism.

In addition to the life sciences applications, the PCTE/MFP membranes are also widely used in water analysis, oceanography, surface capture for analysis, microscopy, particle separation of samples by size, epifluoroscence, microbiology (capture bacteria, yeasts and molds), and air analysis.

The PCTE membranes are irradiated in a GE-owned irradiator housed inside the Texas A&M University reactor. The irradiation is performed by Texas A&M, under contract to GE and under Texas A&M NRC License No. R-83 , to produce an ion track. After irradiation and a period of storage for decay, Texas A&M ships the PCTE/MFP membranes to GE's Bryan, Texas facility, which receives and possesses the membranes under a Texas Agreement State

license. Byproduct material which remains after decay is embedded/tightly bound in the membrane. At the Bryan, Texas facility, GE chemically etches the membranes.

Until February 2010, GE transferred the PCTE/MFP membranes to two GE redistribution facilities in Westborough, Massachusetts, and Minnetonka, Minnesota. However, as part of the Bryan, Texas license renewal process, the Texas Department of State Health Services advised GE that it could no longer transfer the PCTE/MFP membranes to those two facilities for commercial distribution without a specific exempt distribution license from the NRC. GE is submitting such a license application to the NRC.

As discussed below, under the applicable NRC regulations, licenses, (and license application if approved), GE will be able to manufacture and commercially distribute PCTE/MFP membranes to that segment of its customers that will not be further distributing the product for commercial purposes. However, under the existing regulations, any *further* commercial redistribution is prohibited. A substantial portion of GE's customer base would redistribute commercially if authorized to do so.

The relevant existing NRC regulation is 10 C.F.R. §§ 30.18. Section 30.18(c) states:

> This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

Section 30.18(d) states:

> No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued

> under § 32.18 of this chapter which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

Thus, a change to the existing regulations is needed.

III. TEXT OF THE NEW OR REVISED REGULATIONS

10 C.F.R. § 2.802(c)(i) states that each rulemaking petition shall "[s]et forth . . . the . . . text of any proposed regulation or amendment . . . ." GE proposes the following changes to the relevant regulations to accomplish the purposes of this rulemaking.

A. Modify 10 C.F.R. § 30.18

GE proposes that 10 C.F.R. § 30.18 be modified as follows:

> (c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution, except as provided in § 30.18(f).
>
> (d) Except as provided in § 30.18(f), no person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.
>
> (f) Polymer track etch membrane containing mixed fission products in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71 Schedule B, may be redistributed commercially to any person without the redistributor obtaining a specific license under § 32.18, so long as the person who initially manufactures, processes, produces, packages, repackages, or transfers quantities of byproduct

material for commercial distribution obtains a specific license under § 32.18.

GE is open to alternative approaches for modifying the NRC regulations that will achieve the desired purposes in an efficient manner. It is GE's judgment, however, that amending 10 CFR § 30.18 is the most direct and efficient approach, because the fundamental basis for the rulemaking request is the need to permit additional commercial distribution by GE customers of exempt quantities of byproduct material.

IV. GE'S GROUNDS FOR AND INTEREST IN THE ACTION REQUESTED

A. Grounds for the Action Requested

Once GE obtains an exempt quantity distribution license from the NRC, there will be no significant health, safety or common defense and security rationale that should preclude its customers from further redistribution without a license. First and foremost, as discussed below, the quantities of byproduct material in the PCTE/MFP membranes upon transfer from GE's licensed facilities in Massachusetts and Minnesota are in all cases below the exempt quantity limits set forth in 10 C.F.R. § 30.71, Schedule B. In order to obtain the § 32.18 license, GE will have to demonstrate, among other things, that: (1) it has the facilities and equipment and qualified and experienced personnel to ensure those exempt quantity limits are not exceeded (see 10 C.F.R. §§ 32.18(a), 30.33); (2) the byproduct material is not contained in any items designed for human ingestion, inhalation or application (see 10 C.F.R. § 32.18(b); and (3) appropriate prototype labels and brochures will be used (see 10 C.F.R. § 32.18(d)).

Second, the MFPs in the PCTE/MFP membranes are fixed in the matrix of the material and there is no removable radioactivity.

Third, GE's customers, including those that would commercially redistribute under

this rulemaking, do not, to GE's knowledge, incorporate the membranes into any consumer products. Fourth, under § 30.18 (even as amended by this rulemaking), GE's customers are exempt from licensing only to the extent they receive *and transfer* byproduct material "in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B" (see 10 C.F.R. § 30.18(a)). This places an important restriction on any further repackaging or redistribution by any subsequent user of the membranes.

B. Interest in the Action Requested

The rulemaking is necessary to allow GE to distribute the PCTE/MFP membranes to the full range of its customers. This is not only a significant commercial issue for GE, but it will also allow for the fullest use of the membranes in the broad range of beneficial applications discussed earlier. For example, laboratory supply companies may redistribute either pre-cut filter disks or sheets for custom laboratory equipment. Common applications include blood analysis, chemotaxy, environmental monitoring, and basic research. Specific examples include chemotaxis (study of cellular migration toward chemical stimulus), erythrocyte deformability (study of the ability of red blood cells to pass through pores smaller than their diameter), and the general study of diagnostic samples including biopsy and tumors, blood cells and platelets, pap smear, and cerebrospinal fluids.

V. FURTHER STATEMENT IN SUPPORT OF RULEMAKING AND BURDEN OF THE EXISTING RULES

A. Further Statement of Support

GE has separately requested an NRC exempt distribution license under 10 CFR § 32.18 to authorize it to commercially distribute the PCTE/MFP membranes to its customers. The analysis in the license application demonstrates that the amounts of radionuclides that

are to be transferred from GE's licensed facilities to exempt persons: (1) will be below the applicable exempt quantity limits; and that (2) the radionuclides are fixed in the matrix of the membrane and non-removable. Provided below is the analysis presented in the license application applicable to the PCTE/MFP membranes at the time of transfer from GE's licensed facilities. As GE customers receive, possess and potentially retransfer the membranes, further decay will occur and the quantities of radionuclides will continue to decrease. Given the particular characteristics of this specific product, the requested rule is reasonable and will result in no undue risk to public health and safety or the common defense and security.

The analysis set forth in the license application is as follows:

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, making a comprehensive theoretical model of the captured fraction difficult to formulate. Therefore, GE will determine compliance with the exempt quantity limits on the basis of actual measurements as

addressed below.

Nevertheless there are still general conclusions that can be drawn. 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 heavy products so fewer of the light products will be captured in the membrane compared to the heavy 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.

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 very short half-lives when considering a 30 day decay. These radionuclides do not contribute to the activity embedded in the membrane after 30 days.

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 no radioactive emissions after 30 days. Thus it is necessary to concentrate only on the final radionuclide or two at the top of a particular isobaric chain.

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.

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

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/MFP 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 fate of these 30 radionuclides permits the prediction of the activity embedded in the PCTE/MFP membrane to a few percent using certain conditions and assumptions.

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 assumes that the isobaric chains decay instantly to the first long-lived parent 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 all the other nuclides using the production ratios and the individual radionuclide's half-life.

B. Burden of the Existing Rule

As discussed in Section IV.B above, without changes in the rule, GE cannot distribute the PCTE/MFP membrane to the full range of its customers, creating both a significant commercial issue and limiting the fullest use of the membranes in the broadest range of beneficial applications. The only alternative to the rulemaking would be for GE's individual customers, as necessary, to apply for their own individual commercial distribution licenses, as well as either NRC or Agreement State possession and use authority. This would be a much more burdensome, costly and time-consuming process than a single generic rulemaking.

VI. ENVIRONMENTAL IMPACTS UNDER NEPA

This Petition does not involve a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

In particular, because of the manufacturing processes employed to produce PCTE/MFP membranes, the residual byproduct material (MFP) remaining in the membrane when distributed and redistributed will be within the allowable limits for exempt quantities specified in 10 C.F.R. § 30.71, Schedule B. Moreover, the MFP remaining in the membrane when distributed and redistributed is fixed and non-removable. Thus, the rule changes addressed in this Petition do not have the potential to result in environmentally significant increases in the types or quantities of radiological effluents that may be released offsite, nor a significant increase in public or occupational radiation exposure.

With regard to non-radiological impacts, the rule amendments addressed in this Petition involve neither changes to non-radiological effluents, nor changes in activities that would adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with the Petition.

VII. CONCLUSION

For the reasons discussed above, GE believes that the requested rulemaking will create no undue risk to public health and safety or the common defense and security, will enable a broad range of societally-beneficial uses of PCTE/MFP membranes, and should be granted as expeditiously as possible.

Respectfully Submitted,

Annette User
Vice President, Environmental Health and Safety