October 22, 1996

José L. Fernández, M.D.
160 Ponce de León Ave.
San Juan, Puerto Rico 00901

SUBJECT: NRC MEDICAL CONSULTANT REPORT
(SUPPLEMENT TO NRC INSPECTION REPORT NO. 52-25114-01/95-01)

Dear Dr. Fernández:

In our letter dated March 8, 1996, we advised you that the U. S. Nuclear Regulatory Commission had retained the services of a medical consultant, Daniel Flynn, M.D., to review the events surrounding the brachytherapy misadministrations which occurred at your facility. Dr. Flynn has provided the NRC with a report of his review. A copy of Dr. Flynn's report is enclosed for your information and review. In particular, we call your attention to the discussion of the potential impacts of the misadministrations on patients. You should consider this information when notifying patients as required by 10 CFR 35.33, particularly regarding the written notification of "...consequences as they may affect the individual..." as specified in 10 CFR 35.33(a)(4). By separate correspondence we are forwarding an Immediately Effective Order to you to address our inspection findings.

In light of the seriousness of the possible complications, we are forwarding a copy of Dr. Flynn's report to the Puerto Rico Department of Health and requesting their assistance for long term following up of patients.

Should you have any questions concerning this letter, please call us.

Sincerely,

Bruce S. Mallett, Director
Division of Nuclear Materials Safety

Docket No. 030-31873
License No. 52-25114-01

Enclosure: Medical Consultant Report
dated September 26, 1996

cc w/encl:
Commonwealth of Puerto Rico

Tribunal Examinador de Médicos de Puerto Rico
[Puerto Rico Board of Medical Examiners]
ATTN: Dr. Humberto Vásquez
President
P.O. Box 13969
San Juan, Puerto Rico 00908

Distribution w/encl: (See Page 2)

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DATE	10 / / 96	10 / / 96	10 / 09 / 96	10 / 07 / 96	10 / 23 / 96	10 / 22 / 96	
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(REDACTED COPY)

MEDICAL CONSULTANT REPORT
U.S. NUCLEAR REGULATORY COMMISION
Daniel Flynn, M.D. September 26, 1996

Licensee: Jose Fernandez, M.D.
Puerto Rico Ophthalmic Institute
Mayaguez, Puerto Rico

NRC License No.: 52-25144-01
NRC Docket No.: 030-31873
Date of Incident: Years 1994-1995

BACKGROUND:

Pterygium is a slowly progressive, benign condition where tissue overgrowth in the conjunctiva of the eye may eventually cause visual interferences or cosmetic problems. Surgical excision is sometimes necessary; however, the pterygium may eventually regrow. Recurrences have often been treated with surgery plus immediate (within 24 hours) superficial irradiation with a strontium-90 source. Strontium-90 is a beta emitter with a 28 year half life. It is chosen because the superficial depth dose is ideal for the surface treatment of the eye. A small dose does reach the lens of the eye; however, it does not result in cataracts in most cases, but there is still a risk of cataracts and other complications which appear to be dose dependent.

Strontium-90 ophthalmic applicators are now provided by only one company in the U.S.: Mediphysics-Amersham Health Care, 2636 S. Cleveland Drive, Arlington Heights, IL 60005. Technical or product consultants for this company include Michael Langton, Ph.D., 800-323-0332 or Ms. Lori Bradley, 800-832-4633. This company provides 55 mCi applicators which deliver 50 rads/sec on the surface. Calibration data (N.I.S.T. traceable) is provided to any NRC licensee who purchases the applicator (approx. cost $7,760). There are other older applicators in use from previous manufacturers, including 100 mCi sources. The applicator in this incident was not an Amersham source.

In January 1994, NRC Region II amended Dr. Fernandez' license to include a new place of use in Mayaguez, Puerto Rico. In the process, Dr. Fernandez obtained possession of the strontium 90 eye applicator used by Luis Vazquez, M.D., a former NRC licensee, who had died. At that time, the only reference to dosimetric data available to Dr. Fernandez was a calibration sticker attached to a wooden box that contained the applicator. The sticker had a handwritten dose rate of 24 rads/sec (centigrays/sec) and a note indicating that this dose rate was determined using a Victoreen R-chamber by Daniel Torres, M.S. (medical

consultant to Dr. Vazquez) dated September 1990. The licensee was inspected by an NRC inspector on October 18, 1995. The inspector determined that the licensee had not established a Quality Management Program (QMP). The inspector noted that the eye applicator was stamped with the following information:

"Sr-90 100 mCi 7/76 SN: 0204"

The inspector determined that the dose rate used by the licensee was low compared to the expected dose rate for the age of the applicator. The licensee was not able to provide the inspector evidence of the accuracy of the calibration so that the applicator was sent back to the manufacturer for recalibration. The manufacturer's calibration determined that the actual dose rate was 53 cGy/sec instead of 24 cGy/sec. The licensee record review determined that 87 patients received incorrect doses by more than 100%. Treatments were delivered between January 14, 1994 and October 18, 1995. My table which follows shows the 25 patients receiving the highest doses. Note that O.D. means right eye and O.S. means left eye.

TABLE 1: THE 25 PATIENTS AT HIGHEST COMPLICATION RISK

	NRC Patient # (REDACTED)	Treatment Date	Prescribed Dose	Actual Dose	Eye Treated*
1.	12	4/27/95	1500	3313	OD
	12	4/26/94	2000	4417	OD
	12	2/2/94	N/A	N/A	N/A
2.	16	5/17/95	1500	3313	OS
	16	4/4/95	1500	3313	OS
3.	17	2/24/95	2500	5521	OD
4.	21	4/21/95	1500	3312	OS
	21	4/27/95	1440	3180	OS
5.	22	4/21/95	1500	3313	OD
	22	4/26/95	1440	3180	OD
6.	25	8/9/95	1500	3313	OS
	25	8/12/95	N/A	N/A	OS
7.	30	2/24/95	1500	3313	N/A
	30	3/3/95	1000	2208	OS
8.	33	2/11/95	2400	5300	OD
	33	8/4/95	1500	3313	N/A
9.	42	5/12/94	2500	5520	OS
	42	8/16/94	N/A	N/A	OS
10.	43	2/20/94	2500	5520	OS
11.	45	10/21/94	2500	5520	OD
12.	47	4/21/95	1500	3313	OS
	47	7/28/95	1500	3313	OS
13.	50	1/31/94	1488	3286	OD
	50	2/2/94	1488	3286	OD
	50	8/2/94	1500	3313	OD
14.	51	5/9/95	2880	6360	OS
15.	53	4/21/95	1500	3313	OS
	53	4/25/95	1500	3313	OS
16.	55	12/8/94	N/A	N/A	OS
	55	12/8/94	1000	2208	N/A
17.	57	11/4/94	2500	5520	OS
18.	59	10/25/94	2500	5520	OD
	59	12/2/94	1000	2208	N/A
19.	61	4/27/95	1500	3313	OD
	61	6/2/95	1000	2208	OD
20.	67	10/26/94	2500	5520	OD
21.	70	3/31/95	2500	5520	OS
22.	74	12/21/94	1000	2208	OS
	74	4/20/95	2160	4770	OS
	74	5/18/95	3000	6625	OS
23.	80	8/4/95	N/A	N/A	OS
	80	8/10/95	1500	3313	OS
24.	81	3/6/95	2500	5520	OS
25.	84	8/3/95	2160	4770	OS

*O.D. = Right Eye; O.S. = Left Eye

This table gives the twenty-five patients who received the highest doses of the 87 patients irradiated. These patients would be at higher risk for complications. Of those twenty-five cases, the licensee has provided follow-up on only seven with medical record numbers [REDACTED] which can be correlated with the data as to dose prescribed and actual dose delivered, on the table.

Follow-up data was provided on only seven cases. Most consisted of a one or two sentence note in Spanish and the handwriting is difficult to read even with an interpreter. I do not see evidence of a slit lamp examination, which would be necessary to carefully check the sclera and to carefully check for cataracts. This includes patient [REDACTED] who received the highest total dose (13,603 cGy). In addition, since the patients were treated between January 1994 and October 1995, not enough time has elapsed since cataracts can develop several years after irradiation, and treatment-related infections (panendophthalmitis) can develop ten years after treatment.

In addition to the eleven references at the end of this report (see "References"), two additional references would be helpful to demonstrate that there are serious late complications that may appear in addition to cataracts: scleral ulceration and infection. These complications may appear even ten years after the event. (REFS: [1] Tarr, "Late Complications of Pterygium Treatment," *British Journal of Ophthalmology 1980; 64:496-505; [2] Moriarty*, "Severe Cornea Scleral Infection," *Arch. Ophthalmology* 1993; 947-951)

COMMENTS:

1. The eleven clinical reports in the References on strontium irradiation for pterygia were published in recent years (1979 - 1993) and included both treatments with single applications and treatments fractionated over a number of days/weeks. A dose response relationship for eye surface dose versus complication risk is difficult since some authors noted no serious complications, including one author at 6000 cGy in 6 weekly 1000 cGy fractions, and another author who utilized 3000 cGy in a single fraction. However, other authors reported complications at levels including 1800 to 2200 cGy single dose. Many authors reported an average dose used in their patients but a degree of variability as to the dose presented to different patients.

   Presumably, the variation in the published reports is due in part to the span in years over which the patients were treated, and to the fact that different radiation oncologist and ophthalmologists were involved. The estimate of dose to the anterior surface of the lens was frequently given as 4% of the surface dose, with the average depth of the lens at 4 mm. There would be some variability due to the amount of local anesthetic placed in the eye and the amount of tearing in the eye, which would vary from patient to patient. The lens dose would also vary, depending on the location of the eye surface

irradiated. There was great variability as to how patients were followed among the eleven references, including the length of time and the degree of recognizing the more subtle complications. There was also presumed variability as to the accuracy of source calibrations between different licensees (see Dusenberry reference).

Cataracts may not be clinically significant in that they are not symptomatic and do not require surgery. There is data to suggest that 12% of radiotherapy patients who receive doses between 220 cGy to 650 cGy to the eye develop progressive opacities (cataracts) with an average latent period of eight years. (Ref. Hall, *Radiology for the Radiologist*, 4th edition, Lippincott, 1994.) The figure on page 6 demonstrates the relationship of dose to treatment time to risk of cataracts. It is important data relevant to this misadministration.

2. Using the estimate that 4% of the surface dose (actual dose delivered as per Table 1) is delivered to the anterior surface of the lens, data is available on 17 of the 25 patients at highest risk.

Med. Rec. Number	Eye Treated	Actual Dose (Surface)	Actual Lens Dose (Max.)
(REDACTED)	OS	6626 cGy	265 cGy
	OD	5521 cGy	221 cGy
	OS	6492 cGy	260 cGy
	OD	6493 cGy	260 cGy
	OS	6626 cGy	265 cGy
	OD	9885 cGy	395 cGy
	OS	6626 cGy	265 cGy
	OD	5521 cGy	221 cGy
	OS	13,603 cGy	544 cGy
	OS	5520 cGy	221 cGy
	OD	5520 cGy	221 cGy
	OS	6360 cGy	254 cGy
	OS	5520 cGy	221 cGy
	OD	5520 cGy	221 cGy
	OS	5520 cGy	221 cGy
	OS	5520 cGy	221 cGy
	OS	4770 cGy	191 cGy

The remaining eight patients also received higher lens doses; however, the data provided is incomplete:

(a) Patients with [REDACTED] did not have records showing which eye was treated for one of the treatments. Presumably, it was the same eye that was identified for one of the other treatment(s). When data was not available to distinguish which eye was treated, the entry in Table 1 was "N/A."

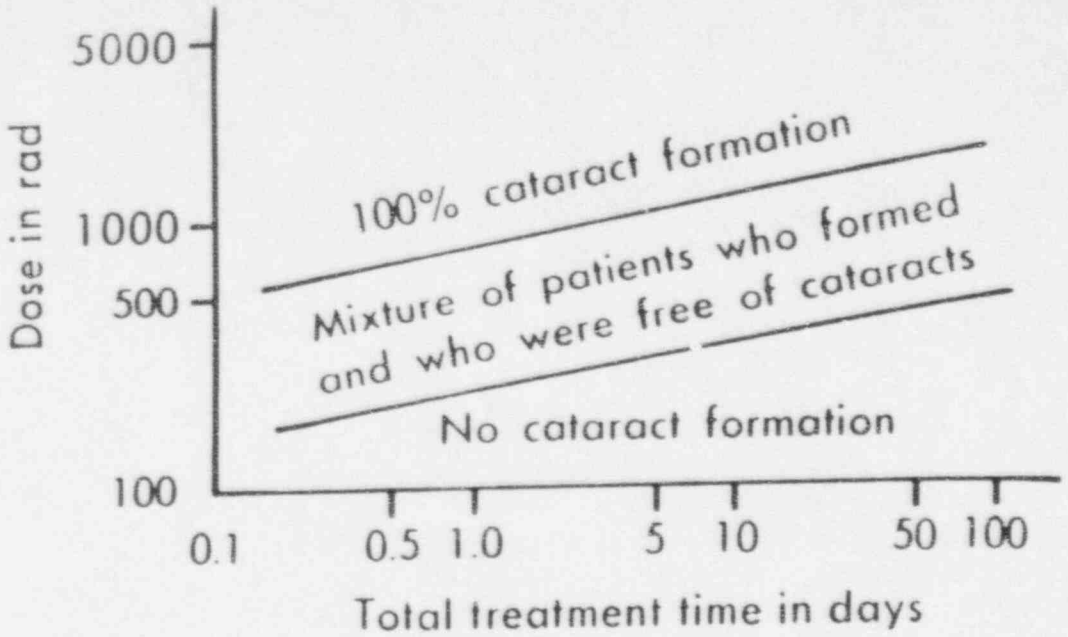

Fig. 10-2. Plot on logarithmic scale of the dose-time relationships for production of radiation-induced cataracts. (Modified from Merriam GR, Szechter A, Focht EF. In Vaeth JM, editor: *Radiation effects and tolerance, normal tissue*, Baltimore, 1970, University Park Press.)

(b) Patients with [REDACTED] did not have data on the prescribed dose or the actual dose delivered for one of the treatments. When data was not available as to the dose, the entry in Table 1 was "N/A."

3. In addition to cataracts, there are other serious complications. Most notable would be severe thinning of the sclera or cornea which sometimes is characterized by ulceration. These cases are at higher risk for severe infections (panendopthalmitis) years after treatment and could result in blindness.

4. The eleven reports in the References demonstrate a wide range of therapeutic doses and a variable complication rate. In general, higher doses and re-treatment are associated with a higher complication rate. The data is somewhat scattered in terms of correlating risk of complication with dose for the following reasons:

   (a) The follow-up period is highly variable in the eleven published reports. Some complications are not seen until years after treatment.

   (b) The effort in carefully evaluating each patient for complications is highly variable in the eleven published reports. Some authors looked at every patient periodically with slit lamp exams and scored patients carefully in terms of lens and scleral changes. Other authors did not carefully study each patient and reported complications only if the patient brought it to their attention. However, some patients may not recognize a complication as being associated with the treatment, and other patients who may be unhappy due to a complication may be lost to follow-up because they switched to another physician.

   (c) The difference in calibration between different applicators is highly variable and may easily approach 50% in some cases (see the Dusenberry article in the References).

5. I spoke by telephone [REDACTED] with Victor Marcial, M.D., in Puerto Rico. Dr. Marcial is Professor of Radiation Oncology at U. of Puerto Rico School of Medicine and retired as Department Chairman of Radiation Oncology. He is a graduate of Harvard Medical School and is board certified in Radiation Oncology. He is the most prominent radiation oncologist in Puerto Rico and is well known in the U.S. as a clinical researcher who has chaired a number of national studies. He currently has an active private practice in Puerto Rico. I did not identify the licensee or the location of the licensee in Puerto Rico or the details. I sought his opinion in reference to follow-up of patients. He stated that it may be easier to follow patients in Puerto Rico and, since it is an island with limited population, he has not experienced difficulty in follow-up of patients treated. He indicated that patients treated in 1994 and

1995 could all be located if enough effort were made.

6. Calibration of a strontium-90 source, which is a beta emitter, should not be done using a Victoreen R-chamber. It will result in false low measurements due to absorption in the cap. This is a serious error by the licensee and indicates that appropriate qualified physics support was not available.

SUMMARY:

1. The misadministrations with the substantial overdose involving a large number of patients is very serious. The doses received were over 100 % of what were prescribed and are outside the therapeutic range in the clinical literature (see References). I conclude that some of these patients are likely to develop serious complications and since the follow-up is currently inadequate, that these complications may go unrecognized and serious consequences will result—consequences which, if recognized, could be treated.

2. The licensee failed to establish any Quality Management Program. In some cases, according to the table provided to me by the NRC, the eye (left vs. right) treated was not recorded. In some other cases, the dose prescribed was not carefully documented. Both are serious violations of licensee requirements.

3. Of the 87 patients overdosed, 25 are at high risk. The licensee provided follow-up on only seven, which is inadequate. The follow-up exam report on the seven was also not adequate since it was often illegible, and a careful slit lamp exam of the lens (for cataracts) and the sclera (for scleromalacia or thinning) was not provided. Finally, the follow-up period of 1 to 2 years is inadequate since severe complications may develop years after treatment.

4. I strongly recommend that since the licensee has not been able, perhaps through lack of resources and staff, to adequately follow these patients that alternative follow-up be provided. For example, the Department of Ophthalmology at the University of Puerto Rico Medical School in San Juan could follow at least the 25 high risk patients annually for ten years. The other patients in the total group should be contacted to offer them the program. One must remember that the doses delivered are outside the general therapeutic range and that there is important scientific data to be gained as to the tissue tolerance. The NRC staff might obtain advice through the NRC Office of General Counsel at headquarters. Perhaps the NRC needs to notify the Department of Public Health in Puerto Rico to discuss an arrangement as to how these patients could be offered careful annual eye exams by an ophthalmologist.

5. The NRC should carefully review training and experience criteria for therapeutic levels of isotope as distinctly different and more stringent than for diagnostic levels of isotope, such as with diagnostic nuclear medicine.

6. The NRC should review how many licensees possess strontium-90 ophthalmic applicators and whether there should be a requirement for a N.I.S.T.-traceable calibration and 30 years' decay data with average dose rate for each quarter (4 data points per year).

7. The NRC could request that Amersham Corp. voluntarily supply 30 years of decay data with each source they sell. Amersham evidently supplies, as the sole source in the U.S., five to ten new strontium-90 ophthalmic applicators per year. Given the approximate 28-year half-life for strontium-90, only 4 data points per year or 120 data points total for 30 years would be necessary. This could be provided on one or two pieces of paper at little or no cost to the manufacturer. It would prevent other errors of improper decay data, such as in this case and another recent case in Hawaii currently under NRC investigation. Alternatively, the NRC should contact the FDA, which may require Amersham to provide the data. However, I am confident that Amersham would do this voluntarily. Although the strontium-90 applicator in this incident was apparently <u>not</u> a source provided by Amersham, the potential for decay calculation errors is real regardless of the manufacturer.

8. The calibration method (Victoreen R-chamber) used by the licensee is an improper method to calibrate strontium-90, which is a beta emitter. The licensee has evidently had inadequate training and did not recognize the appropriate calibration necessary. I expect that this may be a problem among other licensees. Strontium-90 ophthalmic applicator source calibration should be an issue readdressed by the NRC.

REFERENCES:

The following eleven clinical reports give a wide range of therapeutic doses used to treat pterygia with a strontium-90 ophthalmic applicator. Treatment was with either single doses or fractionated doses. The most common treatment schemes are:

SINGLE DOSE:

850 cGy
1500 to 2000 cGy
1800 to 2000 cGy
2200 cGy
3000 cGy

FRACTIONATED DOSE:

700 cGy x 4 over 5 days = 2800 cGy
800 cGy x 3 over 2 weeks = 2400 cGy
1000 cGy x 5 over 5 weeks = 5000 cGy
1000 cGy x 6 over 6 weeks = 6000 cGy

The most common or representative single surface dose would be approx. 2000 cGy, and the most common fractionated schemes would be 2400 cGy: 800 cGy x 3 over two weeks, or 5000 cGy: 1000 cGy x 5 over 5 weeks. Note that the higher total doses are fractionated presumably to allow for normal tissue repair between treatment fractions. In radiation oncology, a higher complication rate is generally associated with higher doses given over shorter periods of time. Therefore, when higher total doses are prescribed in written directives, this dose is given with a number of fractions over a period of weeks rather than days.

1. Alaniz-Camino. "Use of Postoperative Beta Radiation in the Treatment of Pterygia." *Ophthalmic Surgery* 1982; 13:1022-1025.

   483 patients treated. 2800 cGy FRACTIONATED

   Treatment: 700 cGy x 4 fractions over 4 to 5 days. Complications: "No serious complications." However, reference was made to a few patients with occasional corneal opacity which did not interfere enough with normal vision to require surgery, and reference was made to a report of "scleral telangiectasia" in one patient.

2. Bahrassa, *et. al.*, "Postoperative Beta Radiation Treatment of Pterygium." *International Journal of Rad. Onc. Biol. Phys.* 1983; 9:679-684.

   67 patients (83 eyes) 1800 to 2000 cGy SINGLE DOSE

   Complications: Three patients had corneal ulceration with one serious secondary infection. In 19% of the irradiated patients, cataracts were detected

as opposed to 10% of the patients who received surgery without radiation. The cataracts counted included those that did not interfere with vision and did not require surgical removal of the lens. Corneal ulceration was seen in three patients, with one of these resulting in infection (panendophthalmitis as a result of a non-healing ulcer). Complication rate was judged by the authors to be within acceptable range.

3. Beyer, *et. al.* "Pterygia: Single Fraction Postoperative Beta Irradiation." *Radiology* 1991; 178:569-571.

128 patients (146 eyes) 3000 cGy SINGLE DOSE

No serious complications; however, it is not clear that patients received follow-up exams looking for cataracts. It was noted that one patient complained of poor vision, five had severe conjunctivitis, and one had a local granuloma requiring surgical removal.

4. Campbell, *et. al.* "Recurrent Pterygia: Result of Postoperative Treatment with Sr-90 Applicators." *Radiology* 1990; 174:565-566.

42 patients (48 eyes) 1000 to 7000 cGy FRACTIONATED

Most common treatment: 5000 cGy: 1000 cGy x 5 fractions over 5 weeks. "No serious complications." However several symptomatic complications were noted, including telangiectasia (2 pts.), conjunctival scar (3 pts.), granuloma (1 pt.).

5. Dusenberry, *et. al.* "Beta Irradiation of Recurrent Pterygia: Results and Complications." *International Journal of Rad. Onc. Biol. Phys.* 1992; 24:315-320

36 patients 1500 to 5300 cGY FRACTIONATED

Most common treatment: 800 cGy x 3 fractions over 2 weeks. Complications were noted in 13 pts. (36%) to include corneal thinning (3), symblepharon (5), cataract (4), corneal ulceration (1). Of the four patients with cataracts, only one interfered with vision sufficiently to require surgical removal.

Four out of five patients who were retreated with a second course of irradiation were among the thirteen patients with complications. It should be noted that the physicists in this group subsequently found their calibration (by TLD) was 36% higher than that provided by the manufacturer and subsequently NIST found it to be higher by 30%. The authors concluded that the doses for all patients were 30-36% higher and that this might be one factor in the complication rate.

6. MacKenzie, *et. al.* "Recurrence Rate and Complications After Beta Irradiation for Pterygia." *Ophthalmology* 1991; 98:1776-1781

503 patients (with follow-up) 2200 cGy average SINGLE DOSE

Complications: severe scleromalacia (scleral thinning) was seen in 34 cases, which constituted 4.5% of the patients who had adequate follow-up. A total of 1102 patients were treated; however, the rest were not seen in follow-up. The 503 patients were closely followed in regards to scleromalacia (scleral thinning), which the authors categorized in five grades or levels of severity. Grades 1 and 2 totaled 65 and were not considered severe; grades 3, 4, 5 totaled 34. Five cases were incomplete grades. Of those patients with severe scleromalacia or severe thinning (ulceration), two cases subsequently developed endophthalmitis (severe intraocular infection). This infection may develop up to ten years or more after the irradiation. The authors of this study did not address the cataract rate or other possible complications.

7. Nowell, *et. al.* "Management of Pterygia 20 Years Later." *South Med. Journal* 1986; 79:1382-1384

205 patients 500 to 1000 cGy SINGLE DOSE

No complications noted with 800-900 cGy average single dose. However, this does is at the low end of a range of therapeutic doses in clinical practice.

8. Paryani, *et. al.* "Management of Pterygium with Surgery and Radiation Therapy." *International Journal of Rad. Onc. Biol. Phys.* 1993; 28:101-103.

690 patients (825 eyes) 6000 cGy FRACTIONATED

No major complications noted; however, follow-up period in some cases short and scheme of actively looking for complications absent from the report.

9. Pinkerton. "Surgical and Strontium Treatment of Pterygium." *Ophthalmic Surgery* 1979; 10:45-47.

975 eyes 3000 cGy (max.) SINGLE DOSE

Two cataracts requiring surgery with lens changes noted in 7% of the cases. Scleral atrophy described as a complication but it was not quantified in this study.

10. Wesberry, *et. al.* "Optimal Use of Beta Irradiation in the Treatment of Pterygia." *South Med. Journal* 1993; 86:633-637.

    140 patients (171 eyes) 1500 to 2000 cGy SINGLE DOSE

    Complications were seen in 3% of the eyes treated and all were described as "minor" except for one case of scleral thinning.

11. Wilder, *et. al.* "Pterygium Treated with Excision and Postoperative Beta Irradiation." *International Journal of Rad. Onc. Biol. Phys.* 1992; 22:533-537.

    338 patients 2400 cGy FRACTIONATED

    Treatment given was 800 cGy x 3 fractions over 3 weeks.

    No serious complications. A number of "non-serious" complications: decreased visual acuity (11), scleral telangiectasia (6), photophobia (1), granuloma formation (3), scleral atrophy (2). There was one additional cataract noted in the irradiated eyes (3 cases) versus the non-irradiated eyes (2 cases).