

This event is closed for the purpose of the AO report to Congress.

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AS 00-6 Brachytherapy Misadministration at Aultman Hospital in Canton, Ohio

Date and Place—August 22, 2000 through October 30, 2000; Aultman Hospital; Canton, Ohio.

Nature and Probable Consequences—As a result of a common error, four patients that were prescribed manual brachytherapy gynecological procedures were administered doses higher than those prescribed.

The first patient was prescribed a total dose of 92.9 Gy (9,290 rad). This dose included brachytherapy treatments of 20 Gy (2,000 rad) and 22.5 Gy (2,250 rad) using Ir-192 sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On September 18, 2000, the patient was administered a brachytherapy dose of 33.3 Gy (3,330 rad) Ir-192 instead of the prescribed dose of 20 Gy (2,000 rad). On October 9, 2000, the same patient was administered a brachytherapy dose of 35 Gy (3,500 rad) Ir-192 instead of the prescribed dose of 22.5 Gy (2,250 rad) Ir-192. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The second patient was prescribed a total dose of 90.7 Gy (9,070 rad). This dose included brachytherapy treatments of 19.8 Gy (1,980 rad) using Ir-192 sources and of 20.5 Gy (2,050 rad) using a combination of Ir-192 and radium-226 (Ra-226) sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On August 22, 2000, the patient was administered a brachytherapy dose of 35.2 Gy (3,520 rad) Ir-192 instead of the prescribed dose of 19.8 Gy (1,980 rad) Ir-192. On September 5, 2000, the same patient was administered the prescribed dose of 20.5 Gy (2,050 rad) using a combination of Ir-192 and Ra-226 implant sources. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The third patient was prescribed a total dose of 63.9 Gy (6,390 rad). This dose included a brachytherapy treatment of 18.9 Gy (1,890 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 30, 2000, the patient was administered a brachytherapy dose of 32.4 Gy (3,240 rad) Ir-192 instead of the prescribed dose of 18.9 Gy (1,890 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad)

from an external beam linear accelerator.

The fourth patient was prescribed a total dose of 79.3 Gy (7,925 rad). This dose included brachytherapy treatments of 20.3 Gy (2,025 rad) and 14 Gy (1,400 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 23, 2000, the patient was administered a brachytherapy dose of 31.5 Gy (3,150 rad) Ir-192 instead of the prescribed dose of 20.3 Gy (2,025 rad) Ir-192. On November 6, 2000, the same patient was administered the prescribed brachytherapy dose of 14 Gy (1,400 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad) from an external beam linear accelerator.

The misadministrations were discovered on November 3, 2000, and November 13, 2000, during an internal audit of the licensee's Quality Management Program (QMP) by the Radiation Safety Officer (RSO) and the Radiation Protection Staff. A telephone report by the licensee's RSO was made to the Ohio Department of Health, Bureau of Radiation Protection, on November 4, 2000, and November 13, 2000.

The first, second, and fourth patients were notified of the misadministrations. The notification of the third patient is pending because the patient was hospitalized for an unrelated infection. The licensee stated that the clinical treatment of these patients has not been affected by the misadministrations.

Cause or Causes—The licensee indicated that this event was primarily caused by an operator error in the data entry of the source strength in the treatment planning computer. The facility obtained a new computer in August 2000, and the operator made a mistake and entered the source strengths in milligram-radium-equivalent instead of millicurie. Also, the quality assurance of the treatment planning was inadequate, and the second checks of treatment plans, to which the licensee committed in its QMP were inadequate.

Actions Taken To Prevent Recurrence

Licensee—As soon as the licensee's management determined that a reportable event had occurred, the licensee took action to provide additional training to the staff involved in brachytherapy procedures. The licensee submitted a written report to the Ohio Department of Health, Bureau of Radiation Protection, within 15 days of discovering the misadministrations.

State Agency—The Ohio Department of Health, Bureau of Radiation

Protection, performed an onsite investigation on November 21 and 22, 2000, to review the procedures and the findings of the licensee's quality management review and to confirm that the licensee's corrective action proposal is adequate to prevent recurrence. Enforcement actions or penalties, if any, will be determined at a later date.

This event is closed for the purpose of the AO report to Congress.

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Dated at Rockville, Maryland this 25th day of April, 2001.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01-10821 Filed 4-30-01; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

Plan for Updating and Consolidating the Decommissioning Policy and Guidance of the Nuclear Regulatory Commission's Office Nuclear Material Safety and Safeguards, and Notice of Public Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Publication of plan and notice of public meeting.

SUMMARY: The Office of Nuclear Material Safety and Safeguards (NMSS) intends to consolidate and update the policy and guidance for NMSS's decommissioning program. This endeavor is in response to the NMSS performance goals, in the NRC's Strategic Plan, of: (1) Making NRC activities and decisions more effective, efficient, and realistic; and (2) reducing unnecessary regulatory burden on stakeholders.

DATES: Comments on this plan should be submitted by June 15, 2001. The comments will be considered by NRC in the process of updating and consolidating the policy and guidance for NMSS's decommissioning program.

ADDRESSES: Submit written comments to: Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T-7F27, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand-deliver comments to: 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 11555 Rockville Pike, Room O-1F21, Rockville, MD 20852. The NRC Public Document Room is open from 7:45 a.m.

to 4:15 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jack D. Parrott, Mail Stop T-7F27, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-6700; Internet: JDP1@NRC.GOV.

SUPPLEMENTARY INFORMATION: The initial scope of this effort covers all of the decommissioning policies and guidance that implement the NMSS decommissioning regulations. Three NUREG volumes have been identified for development which would update/consolidate all existing NMSS decommissioning guidance documents to the extent practicable. Also reviewed will be decommissioning technical assistance requests, decommissioning licensing conditions, and all decommissioning generic communications issued over the past several years. For the purposes of this project, the NMSS decommissioning policy and guidance documents will be grouped into the functional categories of: (1) The General Materials Decommissioning Process, (2) Characterization, Survey, and Determination of Radiological Criteria, and (3) Financial Assurance, Recordkeeping, and Timeliness. The three NUREG volumes will follow these functional categories. The documents that will be considered in this consolidation/updating project are identified in Table 1.

Table I.—Documents for Consideration in the Decommissioning Guidance Consolidation Project

Guidance Documents To Be Consolidated

NUREG-1727, "NMSS Decommissioning Standard Review Plan," September 2000
 NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuels Cycle and Materials Licensees," March 1997
 Information Notice 90-16, "Compliance with New Decommissioning Rule," March 1990
 "Draft Branch Technical Position on Site Characterization for Decommissioning," November 1994
 NRC Regulatory Issue Summary 2000-09, "Standard Review Plan for Licensee Requests to Extend the Time Periods Established for Initiation of Decommissioning Activities," June 2000
 NRC Administrative Letter 96-05, Revision 1, "Compliance with the Rule 'Timeliness in Decommissioning of Material Facilities'" July 1998

Information Notice 96-47, "Record-keeping and Decommissioning Notifications for Disposals of Radioactive Waste by Land Burial Authorized under Former 10 CFR 20.304, 20.302, and Current 20.2002," August 1996
 Information Notice 90-38, Supplement 1, "License and Fee Requirements For Processing Financial Assurance Submittals for Decommissioning," November 1990
 Information Notice 90-38, "Requirements for Processing Financial Assurance Submittals for Decommissioning," May 1990
 Information Notice 90-16, "Compliance with New Decommissioning Rule," March 1990
 Records Management Guide 93-03, "Final Criteria for Determining That Records Should be Retained Permanently Because of Significant Historical Value," 1993
 Records Management Guide 92-01, "Plan for Decommissioning Records," 1992

Other Documents for Reference/Consideration

NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Rev. 1," August 2000
 NUREG/CR-5512, Volume 1, "Residual Radioactive Contamination from Decommissioning: Technical Basis for Translating Contamination Levels to Annual Total Effective Dose Equivalent," October 1992
 Draft NUREG/CR-5512, Volume 2, "Residual Radioactive Contamination from Decommissioning: User's Manual," May 1999
 Draft NUREG/CR-5512, Volume 3, "Residual Radioactive Contamination From Decommissioning: Parameter Analysis," October 1999
 Draft NUREG/CR-5512, Volume 4, "Comparison of the Models and Assumptions used in the DandD 1.0, RESRAD 5.61, and RESRAD-Build Computer Codes with Respect to the Residential Farmer and Industrial Occupant Scenarios Provided in NUREG/CR-5512," October 1999
 NUREG/CR-5621, "Groundwater Models in Support of NUREG/CR-5512," December 1998
 Draft NUREG-1549, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination," July 1998
 NUREG/CR-6692, "Probabilistic Modules for the RESRAD and RESRAD-Build Computer Codes," November 2000
 Draft NUREG-1505, Rev. 1, "A Nonparametric Statistical Methodology for the Design and

Analysis of Final Status Decommissioning Surveys," June 1998
 NUREG-1506, "Measurement Methods for Radiological Surveys in Support of New Decommissioning Criteria," August 1995
 NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions," August 1995
 Manual Chapter 2605, "Decommissioning Procedures for Fuel Cycle and Materials Licensees," November 1996
 Manual Chapter 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees," June 1997
 Inspection Procedure 87104, "Decommissioning Inspection Procedure for Materials Licensees," June 1997
 Inspection Procedure 88104, "Decommissioning Inspection Procedure for Fuel Cycle Facilities," June 1997
 Inspection Procedure 83890, "Closeout Inspection and Survey," March 1994
 Temporary Instruction 2800/026, "Follow-up Inspection of Formerly Licensed Sites Identified as Potentially Contaminated", July 2000

Background/Bases Documents

Atomic Energy Act of 1954, as amended
 National Environmental Policy Act
 10 CFR 20, Subpart E—Radiological Criteria for License Termination
 10 CFR 30.35—Financial assurance and recordkeeping for decommissioning
 10 CFR 30.36—Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas
 10 CFR part 30, Appendix A—Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning
 10 CFR part 30, Appendix C—Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning
 10 CFR part 30, Appendix D—Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds
 10 CFR part 30, Appendix E—Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

- 10 CFR 40.36—Financial assurance and recordkeeping for decommissioning
- 10 CFR 40.42—Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas
- 10 CFR 70.25—Financial assurance and recordkeeping for decommissioning
- 10 CFR 70.38—Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas
- 10 CFR 72.30—Financial assurance and recordkeeping for decommissioning
- 10 CFR 72.54—Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas
- 10 CFR 72.130—Criteria for decommissioning
- 62 FR 39058, “Radiological Criteria for License Termination,” July 1997
- 53 FR 24018, “General Requirements for Decommissioning Nuclear Facilities,” June 1988
- 64 FR 68395, “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” December 1999
- 63 FR 64132, “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” November 1998
- 62 FR 39058, “Radiological Criteria for License Termination,” July 1997
- 53 FR 24018, “General Requirements for Decommissioning Nuclear Facilities,” June 1988
- 61 FR 24669, “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” May 1996
- 60 FR 38235, “Clarification of Decommissioning Funding Requirements,” July 1995
- 59 FR 36026, “Timeliness in Decommissioning of Materials Facilities,” July 1994
- 58 FR 39628, “Decommissioning Recordkeeping and License Termination: Documentation Additions,” July 1993
- 53 FR 24018, “General Requirements for Decommissioning Nuclear Facilities,” June 1988
- NUREG-1496, “Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities,” July 1997
- NUREG-0586, “Final Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities,” August 1988
- NUREG/CR-1754, “Technology, Safety and Costs of Decommissioning Reference Non-Fuel-Cycle Nuclear Facilities,” February 1981
- NUREG/CR-1754, “Technology, Safety and Costs of Decommissioning Reference Non-Fuel Cycle Nuclear Facilities,” Addendum 1, October 1989
- NUREG/CR-0129, “Technology, Safety and Costs of Decommissioning a Reference Small Mixed Oxide Fuel Fabrication Plant,” February 1979
- NUREG/CR-1266, “Technology, Safety and Costs of Decommissioning a Reference Uranium Fuel Fabrication Plant,” October 1980
- NUREG/CR-1757, “Technology, Safety and Costs of Decommissioning a Reference Uranium Hexafluoride Conversion Plant,” October 1981
- NUREG/CR-2210, “Technology, Safety and Costs of Decommissioning a Reference Independent Spent Fuel Storage Installation,” January 1984
- NUREG/CR-2241, “Technology and Costs of Termination Surveys Associated with Decommissioning of Nuclear Facilities,” February 1982
- NUREG/CR-3293, “Technology, Safety and Costs of Decommissioning Reference Nuclear Fuel Cycle and Non Fuel Cycle Facilities Following Postulated Accidents,” May 1985
- NUREG/CR-6280, “Technology, Safety, and Costs of Decommissioning a Reference Large Irradiator and Reference Sealed Sources,” January 1996
- NUREG/CR-6477, “Revised Analyses of Decommissioning Reference Non-Fuel-Cycle Facilities,” July 1998
- NUREG/CR-6656, “Information on Hydrologic Conceptual Models, Parameters, Uncertainty Analysis, and Data Sources for Dose Assessments at Decommissioning Sites,” November 1999
- Licensing Documents To Be Considered*
- Post License Termination Rule decommissioning technical assistance requests
- Post License Termination Rule license amendments
- Site specific decommissioning Environmental Assessments/Environmental Impact Statements
- Site specific decommissioning Safety Evaluation Reports
- Results of decommissioning financial assurance reviews
- Site specific submittals of Form NRC-314, “Certificate of Disposition of Materials”
- Other Documents for Possible Reference*
- Other agencies’ documents—e.g., U.S. Department of Energy, U.S. Environmental Protection Agency, U.S. Geological Survey, Council on Environmental Quality
- Consensus standards—American Nuclear Society, American Society of Mechanical Engineers, American Society for Testing and Materials, Health Physics Society
- International guidance—International Atomic Energy Agency, Nuclear Energy Agency
- The implementation of the consolidation and updating of the decommissioning policy and guidance documents will be conducted using the Business Process Reengineering (BPR) techniques established for the NRC’s materials licensing policy and guidance consolidation and updating efforts (NUREG-1556 series). The BPR approach will be used to both develop the product, and manage the review and concurrence process, using self-managed teams consisting of NRC headquarters and regional resources. The goal is to produce consolidated NMSS decommissioning guidance that allows the NRC staff to evaluate information submitted by licensees in a timely, efficient, and consistent manner that protects public health and safety.
- The development of each NUREG volume will follow a standardized BPR team model to facilitate overall project management. Teams will consist of a team leader and three or four team members, representing headquarters and regional staff, and possibly Agreement State participation.
- The goal is to commence the first NUREG volume project in the June/July 2001 time frame, the second NUREG volume in the January 2002 time frame, and the third NUREG volume in the June/July 2002 time frame. The BPR model uses a one year schedule that contains two periods of document production for each volume. The first phase of document production lasts five months during which the teams work together at NRC headquarters during much of this time to focus their efforts on the guidance document, and to take advantage of the facilitation services provided by the NRC’s Regulatory Product Development Center. At the end of the first phase a draft NUREG volume is produced which is released to the public for review and to solicit public input. After a 90-day comment period, the teams reconvene periodically over approximately four months to consider public input and revise the document. The NUREG volume is then published in final.
- The overall project is scheduled to be completed by the end of fiscal year 2003 with the publication of the final version of the third NUREG volume. The end result will be a streamlined multi-volume NUREG grouped into the decommissioning functional categories described above, with the goal of

making decommissioning activities licensed by NRC more effective and efficient while reducing unnecessary regulatory burden on stakeholders. Further ease of use will be realized by making this a web-based document. Note also that the BPR model establishes a 3-year review cycle for updating the guidance.

The updated, consolidated guidance will be provided to all users, both NRC and licensee, in hardcopy and/or electronic media. Since each group will have access to the same guidance, the expected results are more complete license documents that will expedite the approval process for both applicants and reviewers. As a result, the resource expenditure for this project will serve to improve the overall decommissioning process. Successful completion of this project is an integral component of the effort to meet NMSS' performance goals in the NRC's Strategic Plan. This will be done by developing decommissioning guidance that ensures that NRC's decommissioning activities and decisions are more effective, efficient, and realistic; and that they reduce unnecessary regulatory burden on stakeholders through, for example, the application of risk insights and performance-based methods, and the use of a consistent decommissioning regulatory basis.

Public Meeting: NRC will conduct a public meeting in the auditorium of the NRC's headquarters office, Two White Flint North, 11545 Rockville Pike, Rockville, MD, on June 1, 2001, to discuss this plan for updating and consolidating the decommissioning policy and guidance of the NRC's Office Nuclear Material Safety and Safeguards with interested members of the public. The meeting is scheduled for 9 a.m. to 2 p.m. There will be an opportunity for members of the public to ask questions of NRC staff and make comments related to the plan. The meeting will be transcribed. For more information on the public meeting, please contact Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T-7F27, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; 301-415-6700; Internet: JDP1@NRC.GOV.

Dated at Rockville, MD, this 20th day of April, 2001.

For the Nuclear Regulatory Commission.

Larry W. Camper,

Chief, Decommissioning Branch Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 01-10823 Filed 4-30-01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-44217; File No. SR-EMCC-00-04]

Self-Regulatory Organizations; Emerging Markets Clearing Corporation; Order Approving a Proposed Rule Change Relating to Membership Criteria for Inter-Dealer Brokers Regulated by the Securities and Futures Authority Limited

April 24, 2001.

On July 3, 2000, the Emerging Markets Clearing Corporation ("EMCC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-EMCC-00-04) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").¹ Notice of the proposal was published in the **Federal Register** on December 13, 2000.² No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The rule change establishes admission criteria for brokers or dealers who are regulated by the Securities and Futures Authority Limited ("SFA")³ and act as inter-dealer brokers ("IDBs"). EMCC's membership criteria for IDBs that are registered by the SFA will mirror the requirements of U.S. registered broker-dealers acting as IDBs⁴ except SFA regulated IDBs will be required to maintain "excess financial resources" of \$10,000,000 US as opposed to excess net capital of \$10,000,000.

II. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to promote the

¹ 15 U.S.C. 78s(b)(1).

² Securities Exchange Act Release No. 43680 (December 6, 2000), 65 FR 77947.

³ SFA is the United Kingdom financial services regulator.

⁴ EMCC's Rules define an IDB as "a broker-dealer that conducts securities trading which matches buyers and sellers who are banks or dealers, and who is designated as such by the Corporation." EMCC's membership criteria for broker-dealers acting as IDBs require an applicant to demonstrate to the EMCC Board or Membership and Risk Committee that: (1) The applicant has the operational capacity to perform its membership functions in a satisfactory manner; (2) the applicant has an established business history of at least three years or personnel with sufficient operational background and experience to ensure the ability of the applicant to conduct its business; (3) the applicant has the financial ability to make all anticipated payments required by EMCC; (4) the applicant is in compliance with the capital requirements imposed by its appropriate regulatory authority; and (5) no adverse conditions exist which might prohibit applicant's membership in EMCC.

prompt and accurate clearance and settlement of securities transactions.⁵ Since the Commission's approval of EMCC Rule 2, EMCC has been informed that brokers or dealers who are regulated by the SFA also act as IDBs and, in fact, that there are broker-dealers who are regulated by the SFA who would like to be IDB members of EMCC. The Commission believes it is prudent for EMCC to establish criteria for broker-dealers that act as IDBs and that are regulated by the SFA because it will encourage IDBs regulated by the SFA to become participants in EMCC and therefore should facilitate the prompt and accurate clearance and settlement of emerging market securities transactions.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR-EMCC-00-04) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.⁶

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 01-10748 Filed 4-30-01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-44219; File No. SR-OCC-00-02]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Approving a Proposed Rule Change Relating to OCC Clearing Members Pledging Long Options Positions

April 25, 2001.

On March 6, 2000, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-OCC-00-02) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").¹ Notice of the proposal was published in the **Federal Register** on July 19, 2000.² No comment letters

⁵ 15 U.S.C. 78q-1(b)(3)(F).

⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² Securities Exchange Act Release No. 43029 (July 12, 2000), 65 FR 44844.