U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 85-01

Docket Nos. 030-12239
030-15070
030-22102

License Nos.		Priority	Category
	20-17131-01	G1	II
	20-17131-03	E	III
	20-17131-04	E	III

Licensee: Brigham and Women's Hospital
75 Francis Stret
Boston, Massachusetts 02115

Facility Name: Brigham and Women's Hospital

Inspection At: Boston, Massachusetts

Inspection Conducted: August 20 and 21, 1985

Inspectors: Jenny M. Johansen 10/3/85
Jenny M. Johansen, M.S. date
Health Physicist

Approved by: for Laurence F. Friedman 10/3/85
John E. Glenn, Ph.D., Chief date
Nuclear Materials Safety Section B

Inspection Summary: Inspection Conducted on August 20, 1985, and August 21, 1985, Combined Report No. 030-12239/85-01, 030-15070/85-01, and 030-22102/85-01

Areas Inspected: Routine unannounced inspection of two irradiator licensed programs and a broad scope program for medical research, diagnosis, and therapy, including licensee actions on previous inspection findings, organization, license audits, training, radiation protection procedures, use of materials, storage of materials, facilities, instruments, receipt and transfer of material, personnel protection (external and internal), waste disposal, transportation, notification and reports, posting, and measurements by the inspector. The inspection involved 20 hours on site by one NRC inspector.

Results: Eight violations and one deviation were identified: Failure to perform adequate internal audits; Failure to train; Failure to assure dose calibrator constancy test within ±5 percent of predicted activity; Failure to perform dose calibrator constancy test with long-lived source on all commonly used settings; Failure to adequately perform molybdenum-99 assays; Failure to secure materials in unrestricted area; Failure to record exposure levels during package opening procedures; Failure to record daily surveys; Deviation of licensee's stated corrective action on seals used for shipment of radioactive packages by common carrier.

DETAILS

1. Persons Contacted

Michael Nowak, Radiopharmacist
Margaret Hunt, Radiopharmacist
*Alun G. Jones, Ph.D., Director, Radiopharmacy
Charles Rosenkranz, DOT carrier (Choice Courier, Inc.)
Michael Melisi, Harvard University Health Services (HUHS)
*David E. Drum, M.D., Ph.D., Radiation Protection Officer and Chairman, Radiation Safety Committee
Vivian Smith, Technical Director, Blood Bank
Jean Kat, Chief Technician, Immunogenetics
Jack Leonard, Ph.D., Researcher, Thyroid Lab
Dr. Silva, Researcher, Thyroid Lab
Dr. Rittenhouse, Researcher, Hematology
Robert English, Nuclear Medicine Technologist
Katy Sobey, Nuclear Medicine Technologist
Joseph Kozlowski, Nuclear Medicine Technologist
Philip D. Cobb, Radiation Safety Officer, Joint Center for Radiation Therapy (JCRT) (via telephone)
Robert Morse, Health Physics Assistant, JCRT (via telephone)
Robert Zimmerman, Electronics Physicist
*B. Leonard Holman, M.D., Chief, Nuclear Medicine Services
Robert U. Johnson, HUHS
Security guard on duty 6:00 A.M., August 20, 1985
*Kristians Veinbergs, Assistant Vice President for Administrative Services
Various other research and clinical personnel

*Present at Exit interview

2. Licensee Action on Previous Inspection Findings

(Closed) Inspection 82-01: Failure to maintain radiation levels in unrestricted areas surrounding brachytherapy implant patients below regulatory limits. The inspector reviewed radiation survey records for unrestricted areas surrounding brachytherapy implant patients. These records indicated no radiation level greater than 2 mR in any one hour. Additionally, licensee obtained exceptance from 10 CFR 20.105(b) limits during license renewal and 20.105(a) limits are stated in license as Condition 18.

(Closed) Inspection 82-01: Inadequate surveys surrounding rooms of brachytherapy implant patients due to movement of patients in room. Licensee submitted information during his renewal and NRC granted exceptance under 20.105(a) for radiation levels. Additionally, survey records show that since 1982 no unrestricted area's radiation levels exceeded 2 mR in any one hour.

(Closed) Inspection 82-01: Failure to evaluate dose to the fingers from wrist badges worn for extremity exposure evaluation. The licensee performed three month evaluation with Nuclear Medicine Technologists and Radiopharmacists wearing wrist and ring badges. A multiplication factor of 4.8 times measured wrist dose for Nuclear Medicine and 2 times measured wrist dose for the Radiopharmacy was established. Inspector's review of records indicated no quarter limits for extremity exposures were exceeded and ALARA Level I or II limits were maintained.

(Closed) Inspection 82-01: Use of byproduct materials on human beings for other than medical research, diagnosis or therapy. Licensee has stopped using technetium-99m (Tc-99m) labelled sulfur colloid on human volunteers for contamination removal training in radiological emergencies.

(Closed) Inspection 83-01: Failure to properly prepare package for shipment in accordance with Department of Transportation (DOT) and 10 CFR 71.5 regulation. The inspector observed that all shielding of radioactive materials was secured by tape, and that package marking, labeling, surface radiation level, transportation index, and contamination surveys performed by the Radiopharmicist prepared the packages properly for shipment in accordance with DOT 49 CFR 173.441(a) and 10 CFR 71.5 regulations.

(Closed) Inspection 83-01: Failure to ensure by examination or test that special instructions for filling, closing and preparing packages shipped were followed. The inspector observed that packing material was contained in the packages to ensure proper package geometry and compliance with Type 7A package testing results in accordance with DOT 49 CFR 173.475(e) and 10 CFR 71.5 regulations.

(Closed) Inspection 83-01: Failure to properly label package. The inspector observed that the packages prepared for shipment were properly labelled as to package contents in accordance with DOT 49 CFR 172.403(g) and 10 CFR 71.5. regulations.

(Closed) Inspection 83-01: Failure to describe hazardous material in shipping paper. The inspector reviewed copies of shipping papers and determined that the shipping papers properly described the contents of the package in accordance with DOT 49 CFR 172.200(a) and 10 CFR 71.5 regulations.

(Closed) Inspection 83-01: Failure to have on file test result indicating packaging met Type 7A specifications. The inspector reviewed the test results of the "ammo" container and fiberboard boxes the licensee has used for shipping containers. These test results were on file with the licensee and submitted to the NRC. Packages shipped were properly certified Type 7A in accordance with DOT 49 CFR 173.415(a) and 10 CFR 71.5 regulations.

(Open) Inspection 83-01: Failure to incorporate a seal on packages which, while intact, gives evidence that package has not been opened. The inspector observed that nylon locking Cobe ties were used on all packages shipped by common carrier. However, the licensee stated in his corrective actions contained in a letter dated November 30, 1984, that seals bearing individual code numbers would be used on all packages shipped by common carrier. This appears to be a deviation from licensee's stated corrective action.

(Closed) Inspection 83-01: Failure to supply emergency procedures to drivers transporting packages via a delivery service. The inspector interviewed the DOT carrier. He stated he had a copy of the emergency procedures in his vehicle. Additionally, the inspector observed that a set of emergency procedures was given the driver with the packages to be delivered.

(Closed) Inspection 83-01: Failure to perform daily constancy test on dose calibrator. Inspector reviewed records of dose calibrator constancy checks since 1983. The test had been performed daily.

(Closed) Inspection 83-01: Failure to perform linearity tests quarterly on dose calibrator. Inspector reviewed records of dose calibrators. Linearity had been performed quarterly on all dose calibrators since 1983. The license uses the Calicheck device and decay method to determine linearity.

(Open) Inspection 83-01: Failure to use a long lived standard radionuclide on all commonly used radionuclide settings on the dose calibrator. The inspector observed that while this was done in the Radiopharmacy, a long-lived radionuclide (e.g. Cs-137) was not used as part of the daily constancy test on the Nuclear Medicine dose calibrator. This item is not fully corrected.

(Open) Inspection 83-01: Failure to correctly determine the total molybdenum-99 (Mo-99) activity in technetium-99m on (Tc-99m) eluate from a generator. The inspector discussed the elution of the Mo-99/Tc-99m generator for on-call situations with a nuclear medicine technologist. The technologist indicated he has performed on-call elutions of the generator and performed Mo-99 assays. However, he stated he did not know the reading for Mo-99 on the dose calibrator must be multiplied by 3.5, as stated in the manufacturer's instruction manual, to obtain the correct Mo-99 activity in the eluate. The Radiopharmacy did use the correction factor for their elutions. This item is not fully corrected.

3. License No. 20-17131-03. (Self-Contained Irradiator) The inspector observed the Chief Technician in Immunogenetics operate the J. L. Shepherd irradiator. The technician had a copy of the operating instructions available and had been instructed in the use of the irradiator. The inspector surveyed the radiation levels on the surface of the irradiator

in the "on" and "off" positions. These radiation levels were equivalent to the external readings submitted to the NRC upon installation of the irradiator (<2mR/hr at any point). The inspector observed that the log book containing the use record of the irradiator had initials of the users rather than their last names. The licensee, at the close of the inspection, agreed to identify the users by either having them write their last name in the log book or incorporate a key which identifies a set of initials to a users full name. (See Section 21)

No violations of Commission rules, regulations or license conditions were identified.

4. License No. 20-17131-04 (Self-Contained Irradiator) The inspector informed the licensee's Radiation Protection Officer (RPO) that the AECL Gammacell 1000D could not be moved to its new location without amendment of the license. The RPO showed the inspector a copy of the amendment request dated August 5, 1985, and the Amendment Fee check dated August 16, 1985. The RPO contacted USNRC Region I to ascertain whether the move could be made if the letter were express-mailed to the Region. Region I immediately issued an amendment to the license in order not to delay the riggers and AECL's representatives from moving the irradiator unit on August 20, 1985. The inspector monitored the move of the irradiator and performed radiation surveys before and after the move. Radiation levels measured were equivalent to those performed by AECL and the licensee upon initial installation (<2mR/hr at various points on the irradiator surface in on and off position). The amendment dated August 20, 1985, was delivered to the RPO by the inspector on August 21, 1985.

No violations of Commission rules, regulations, or license conditions were identified.

5. License No. 20-17131-01 (Broadscope)

Organization

Since February 1982 the Radiation Safety Committee has met once each quarter. The Committee consists of representatives from Administration, Nursing, selected areas of where radionuclides are used and the Radiation Protection Officer. Representatives from Harvard University Health Services (HUHS) and the Joint Center for Radiation Therapy (JCRT) who provide radiation safety services for the research, waste disposal, survey meter calibration, and branchytherapy implant services, etc., are also represented on the committee. The inspector's review of the committee minutes indicated that human use research is reviewed and performed only by physicians. The training and experience of physicians involved in clinical human use is compared to Appendix A of Regulatory Guide 10.8 for minimal acceptable experience. ALARA levels are reviewed during the quarterly meetings. This committee is also registered as the Radioactive Drug Research Committee (RDRC) with the Food and Drug Administration (FDA).

No violations of Commission rules, regulations, or license conditions were identified.

6. Licensee Internal Audits

The license made commitments in his letter dated June 16, 1983, that detailed audits including radiation surveys, contamination surveys, inventories, review of records and procedures, and verification of user training would be conducted twice annually for all users and quarterly for the Thyroid Unit, Nuclear Medicine, the Radiopharmacy and Radiation Therapy. The licensee's records showed that internal audits were performed for each quarter since August 1983, however, the inspector noted that these audits did not identify a violation in the dose calibrator constancy procedures in Nuclear Medicine that was the same as identified during the NRC's August 16-17, 1983, inspection of the Radiopharmacy nor did the audits identify a deviation from licensee's stated corrective action in the Radiopharmacy (See Open Items in Section 2 of this report). Additionally the quarterly audits did not identify that in Nuclear Medicine an individual was not properly trained in performing the total assay for Mo-99 in Tc-99m generator eluates.

The finding that the scope of the quarterly internal audits performed by the licensee in Nuclear Medicine since August 1983 was inadequate to identify violations similar to those found by the NRC during its August 16-17, 1983 inspection, that the audits did not identify that constancy procedures were not followed as required, that an individual was not trained in Mo99 assay procedures, and that audits in the Radiopharmacy did not identify a deviation from licensee's stated corrective action, is an apparent violation of Condition 27 of License No. 20-17131-01.

7. Training

The inspector discussed the receipt of radioactive materials packages during off hours with the security guard on duty at 6:00 AM on August 20, 1985. The guard stated that the delivery persons are escorted to the Nuclear Pharmacy by a security guard. He further stated that sometimes the second guard was not available to escort the delivery person. In this case the package was left at the information desk under his observation until the security guard on rounds returned. The second security guard then took the package to the radiopharmacy and locked it up. The licensee, in Item 13e. of a letter dated June 16, 1983, stated that "Security personnel do not themselves handle packages".

The finding that a security guard was not aware that security guards were not handling and transporting packages of radioactive materials to the Nuclear Pharmacy left by the delivery person at the information desk on those occasions when a security guard escort was not available is an apparent violation of 10 CFR 19.12.

The inspector discussed the Mo-99 assay procedures for eluates from the Mo-99/Tc-99m generator during on-call and weekends for emergency scans. In discussing the procedure used, the technologist stated he was unaware of the dose calibrator manufacturer's Mo-99 assay procedure, which requires that the displayed value on the dose calibrator be multiplied by 3.5 to obtain the total Mo-99 activity in the eluate. He further stated that he had received no training in the dose calibrator procedures for Mo-99 assay, linearity tests, or accuracy tests. The inspector was informed that the linearity and accuracy tests were performed by the Chief Technologist and the Electronics Physicist.

The finding that an individual was not trained to conduct testing for molybdenum-99 activity in technetium-99m eluates from a generator is an apparent violation of 10 CFR 35.14(b)(4)(ii).

8. Radiation Protection Procedures

Discussions with the Health Physics Assistant from the JCRT confirmed that closeout surveys on brachytherapy patients and source counts were performed prior to the discharge of the patients receiving treatment.

The licensee has procedures for handling patients receiving therapeutic doses and handling of radioactive cadavers.

An emergency call list for spills and other radiation safety problems is posted in radioactive material use areas. Review of medical records and survey records for patients treated with iodine-131 for thyroid carcinoma indicated that there was no verification that the patient remained hospitalized until the residual activity in the patient was 30 millicuries or less. The inspector discussed this finding with the RPO and he agreed that the medical record or the patient survey record would, in the future, show the residual activity at the time of the patient's discharge (See Section 21).

No violations of Commission rules, regulations or license conditions were identified.

9. Use of Materials

From discussions with the licensee's RPO, a review of records, and observations by the inspector, the inspector determined that all leak tests of sealed sources had been performed and recorded at the required 6-month frequency.

The licensee, in Block 10 of his application dated November 30, 1981, requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8. The inspector reviewed the use of the dose calibrator with individuals in the Radiopharmacy and in Nuclear Medicine. The inspector determined that

the linearity, accuracy and geometry tests were performed as required. However, records indicated that since July 25, 1985, for the cesium-137 source and since August 4, 1985, for the cobalt-57 source, the results of the daily constancy test had not been plotted on semilog graph paper to determine that the measured reading did not deviate more than ±5 percent from the decay-corrected activity of the sources in the Radiopharmacy. In Nuclear Medicine, the daily constancy test had not been plotted on semilog graph paper to assure the measured value for the colbalt-57 source was within ±5 percent of the decay corrected activity since the previous inspection.

The finding that constancy test readings were not plotted to determine whether the reading was within ±5 percent of the decayed value of the cesium-137 source and the cobalt-57 source in accordance with Item C.4 and C.8 of Appendix D, Section 2, of Regulatory Guide 10.8 is an apparent violation of Condition 27 of License No. 20-17131-01.

The inspector additionally determined by discussions with the nuclear medicine technologists that a cesium-137 source was not used as part of the daily constancy test on the cesium-137 setting and on all commonly used radionuclide settings.

The finding that a cesium source was not used at the cesium-137 and all other commonly used radioclide settings in accordance with Item C.7. of Appendix D, Section 2 of Regulatory Guide 10.8 is an apparent violation of Condition 27 of License No. 20-17131.01.

The inspector asked a nuclear medicine technologist whether a Mo-99/Tc-99m generator was eluted for on-call and weekend emergency scans. The technologist stated he had performed generator elutions for on-call and weekend emergency scans since the time that he was hired five years previously. The inspector asked the technologist to describe how he performed the Mo-99 assay test. The technologist indicated the Tc-99m eluate was placed in a lead pig, which was then placed in the dose calibrator measurement chamber with the indicator set on Mo-99 assay. The reading directly from the dose calibrator was then recorded in the Mo-99 assay book for the elution. The inspector asked if there was any correction factor applied to the number recorded from the dose calibrator readout. The technologist said "no". The inspector obtained the manufacturer's instruction book for the CRC-5 Model dose calibrator and showed the technologist that the Mo-99 assay instructions stated that the Mo-99 assay reading had to be multiplied by 3.5, in order to obtain the total Mo-99 activity in the eluate. The technologist stated he had not been trained to use the correction factor and therefore had not used this number in determining the total Mo-99 activity or concentration in the eluate on those dates since August 17, 1983, that he eluated the generator for on-call and weekend emergency scans.

The finding that, since August 17, 1983, technetium-99m eluted from a

generator in Nuclear Medicine was not adequately tested for total molybdenum-99 activity or concentration, in that the calculation of the total molybdenum-99 activity was performed incorrectly, is an apparent violation of 10 CFR 35.14(b)(4)(ii).

10. Storage of Materials

The inspector visited various restricted and unrestricted areas of the hospital. The inspector found five waste disposal receptacles containing waste material labeled "Caution Radioactive Material, Ca45, H3, C14, and P32" in a hallway outside of the Thyroid Research Laboratory. There were doors at both ends of the hallway, however, these doors were not locked to restrict access to the radioactive materials in the waste receptacles. The inspector measured the radiation levels on the receptacles and found no radiation levels greater than 0.01 mR/hr (background). Additionally, the inspector found that the door to the Thyroid Uptake Laboratory, where three containers labeled, iodine-123, were located, was also unsecured and no one was present in the laboratory. The inspector was informed by an individual that iodine-131 uptakes are occasionally performed in this laboratory.

The finding that radioactive materials in an unrestricted area were not either secured or under an individual's constant supervision is an apparent violation of 10 CFR 20.207.

11. Facilities

The facilities agreed with those described as part of the license application, letters, and support documents.

No violations of Commission rules, regulations, or license conditions were identified.

12. Instruments

License Condition 27. requires that survey meters be calibrated annually. The inspector noted that all survey meters observed had been calibrated within the last year. Calibrations are performed by HUHS.

No violations of Commission rules, regulations, or license conditions were identified.

13. Receipt and Transfer of Material

The inspector observed the opening of packages containing radioactive material in the Radiopharmacy. Radiation level surveys at 3 feet from the package surface and the surface of the package were performed. Wipe tests were also performed. The inspector reviewed the records for the surveys and found that, while the contamination wipe tests were recorded, the

radiation levels measured were not recorded. Records of the package opening procedures for the generators indicated that the measured radiation level at the surface of the package was also not recorded. The licensee, stated in Block 14 of his application dated November 30, 1981, that the procedures in Appendix F of Regulatory Guide 10.8 were adhere to for safe opening procedures for all radioactive packages. These safe opening procedures require that for all packages, radiation exposure levels be measured and recorded.

The finding that radiation levels which were measured as part of safe opening procedures were not recorded for packages containing radioactive materials, in accordance with Items 2.c. and 2.d.of Appendix F of Regulatory Guide 10.8, is an apparent violation of Condition 27. of License No. 20-17131-01.

14. Personnel Protection - External

The inspector observed the drawing up of doses of thallium-201 in the Nuclear Pharmacy and technetium-99m MDP in Nuclear Medicine. In both cases, the individual had to hold the vial containing the radioactive material in the vial shield by use of the tips of the gloved index finger and thumb. (See drawing Exhibit 1). The inspector stated that the use of screw-top shielded vial containers for the vials would eliminate the majority of this unnecessary exposure and discussed this need with the RPO (See commitment in Section 21).

The inspector reviewed the records of monthly and weekly surveys performed by HUHS. All laboratories were surveyed at the required frequency and, when contamination was found, decontamination was performed. The licensee stated in Items 10. and 11.6. of a letter dated June 16, 1985, that daily surveys will be performed with results recorded in Nuclear Medicine and the Radiopharmacy. The inspector reviewed the daily surveys in the Nuclear Medicine Department in the elution, preparation and injection areas. A survey had been performed for each regular working day and each non-regular (Saturday or Sunday on-call) working day since August 16-17, 1983.

The inspector discussed the absence of records for daily surveys on August 15, 1985, and August 19, 1985, with the Radiopharmacist. He stated he had performed the survey but did not record the results.

The finding that daily surveys performed August 15 and 19, 1985, were not recorded is an apparent violation of Condition 27 of License No. 20-17131-01.

The inspector reviewed personnel exposure records and found exposures well under 10 CFR 20.101 limits and ALARA I and II limits. Unrestricted area surveys surrounding brachytherapy implant patients rooms were within limits stated in License Condition 18 and 10 CFR 20.105(a); Review of

survey records for thyroid cancer patients treated with iodine-131 indicated that the stated unrestricted area limits were not exceeded.

15. Personnel Protection - Internal

The inspector reviewed iodination records and records of thyroid monitoring. The RPO explained that each individual performing iodinations with one millicurie or more of iodine-125 or iodine-131 must have a thyroid scan within two weeks of performing the iodination. Additionally, a personnel air monitor is worn.

From discussions with the RPO and the review of records, the inspector found that thyroid monitoring had been completed as required.

From discussions with a HUHS representative and review of air monitoring records for environmental releases the inspector found that airborne concentrations of licensed material were less then 10% of 10 CFR Part 20 limits for monitoring periods in 1983, 1984 and 1985.

No violations of the Commission rules, regulations or license conditions were identified.

16. Effluent Controls, Waste Disposal

The inspector reviewed the waste disposal records and procedures with the RPO.

The licensee holds material for decay in storage or ships waste for disposal through HUHS to the State of Washington.

The inspector visited the waste disposal facility and observed that the facility had ventilation and that materials in the waste barrels were properly identified and stored.

No violations of Commission rules, regulations, or license conditions were identified.

17. Transportation

The inspector observed the preparation of "ammo" type shipping boxes for shipment by DOT carrier. All surveys, labeling, marking, shipping papers, and packaging were completed and recorded in accordance with DOT regulations, except that the seals placed in the packages shipped by DOT carrier did not have individual code numbers. However, they were sealed with nylon locking Cobe ties. The licensee, in his letter dated November 30, 1983, as a result of violations identified during the NRC's August 16-17, 1983, inspection stated that part of his corrective action would include the placement of seals bearings individual code numbers on all packages shipped by common (DOT) carrier.

The finding that seals bearing individual code numbers were not used on packages shipped by common carrier is an apparent deviation from the licensee's corrective action stated in his letter dated November 30, 1983, in response to Violation II.A.3. of the NRC's Notice of Violation enclosed in the NRC's letter dated November 8, 1983.

18. Notification and Reports

Licensee representatives stated that no incidents which required reporting to the NRC have occurred since August 16-17, 1983.

No violations of Commission rules, regulations, or license conditions were identified.

19. Posting

The inspector observed that all required notices were posted.

No violations of Commission rules, regulations, or license conditions were identified.

20. Independent Measurements

The inspector performed surveys independently and concurrently with licensee's representatives using a Eberline Model E120 thin-end window G-M Survey meter last calibrated May 16, 1985. All surveys in the unrestricted areas were <0.01 mR in any one hour (background). All package surveys for shipping packages indicated correct DOT labeling and transportation index. All restricted areas had radiation levels of less than 2mR/hr.

21. Exit Interview

The inspector met with the individuals identified in Section 1 and discussed the results of the inspection. The inspector requested and obtained commitments from the license's representatives to (1) provide lead shields with screw-on shield tops for Nuclear Medicine and the Radiopharmacy in order to reduce the exposure to fingertips (See Section 13); (2) identify the users of the J. L. Shepherd irradiator by either last name in the log book or provide a key which will identify the initials of the user (See Section 3); and (3) place either on the radiation survey record or medical record of iodine-131 therapy patients a verification that the residual activity of iodine-131 was 30 millicuries or less upon the patients release from the hospital (see Section 13).

Mr. T. T. Martin, Director, Division of Radiation Safety and Safeguards, USNRC, Region I, expressed his concern that the licensee had failed through its internal audit process to identify in Nuclear Medicine the same types of violations that occurred in the NRC's 1983 inspection of

the Radiopharmacy. He further stated that the NRC looks closely at repeat violations that are not fully corrected from previous inspections in selecting its enforcement options.

At no time during the inspection was written material given to the licensee by the inspector.

EXHIBIT 1

Region I Combined Report No. 030-12239/985-01
030-15070/85-01
030-22102/85-01