



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

Q-5

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Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission Region I
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RE: Final Status Survey Report for Federal Building 8
Food and Drug Administration
License No. 19-30771-01
Docket No. 03036120

Dear Ms. Ullrich:

Enclosed is the Final Status Survey Report for the Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN) Federal Building 8 (FB-8), located at 200 C Street SW, Washington DC and other supporting documents related to the final status survey process.

Upon satisfactory review of the information provided, FDA/CFSAN requests an amendment to its license under the provisions specified in Title 10, Code of Federal Regulations, Part 20.1402 to release FB-8 for unrestricted use.

We look forward to hearing from you regarding the Final Status Survey Report. If you have any questions please contact me at 301-436-2429.

Sincerely yours,

Arnold P. Borsetti, Ph.D.
Associate Director for Operations
Center for Food Safety
and Applied Nutrition

Enclosures

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NMSS/RGNI MATERIALS-002

FINAL STATUS SURVEY REPORT

**FEDERAL BUILDING – 8
200 C St., SW Washington, DC**

December 22, 2004

FINAL REPORT

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Abbreviations

CFSAN	Center for Food Safety and Applied Nutrition
CPM	Counts per minute
DCGL	Derived Concentration Guideline Level
DPM	Disintegrations per minute
FDA	Food and Drug Administration
FB8	Federal Building 8
FSS	Final Status Survey
GCPM	Gross counts per minute
GSA	General Services Administration
L_c	Critical level
L_D	Detection limit
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDC	Minimum detectable concentration
MDCR	Minimum Detectable Count Rate
NCPM	Net counts per minute
NRC	Nuclear Regulatory Commission
QA	Quality Assurance

References

1. NUREG-1507, "Minimum Detectable Concentrations With Typical Radiation Survey Instruments for Various Contaminants and Field Conditions", NRC-Washington, DC, June 1998
2. NUREG-1575, "Multi-Agency Radiological Survey and Site Investigation Manual, Revision 1", August 2000
3. NUREG-1757, Vol. 1, "Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licenses", Final Report, NRC-Washington, DC, September 2002
4. NUREG-1757, Vol. 2, "Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licenses", Final Report, NRC-Washington, DC, September 2003
5. NUREG-CR-5512, Vol. 2, SAND2001-0822P, "Residual Radioactive Contamination From Decommissioning, Users Manual DandD, Version 2.1", NRC-Washington, DC, April 2001
6. DandD, Version 2.1 software
7. Title 10, Code of Federal Regulations
8. "Final Status Survey Plan", Center for Food Safety and Applied Nutrition, Food and Drug Administration, October 2004

1. Background

The Food and Drug Administration is part of the Executive Branch of the United States Government within the Department of Health and Human Services. The Food and Drug Administration (FDA) is a Nuclear Regulatory Commission (NRC) radioactive materials licensee. The FDA operated research and testing laboratories at a facility located in Washington, DC. This facility is known as Federal Building 8 (FB-8). This facility has provided primary laboratory and administrative office space for FDA research and administrative personnel for over thirty-eight years. The primary FDA occupant has been the Center for Food Safety and Applied Nutrition (CFSAN). CFSAN is one of six product-oriented centers that carry out the mission of the Food and Drug Administration. Other tenants of FB-8 have included the FDA's Center for Drug Evaluation and Research, Consumer Products Safety Commission and the Environmental Protection Agency's Pesticide Program.

There were research protocols that involved the use of radioactive materials in various forms e.g. unsealed, sealed material from 1965 to 2002. The use of unsealed forms was also incorporated into protocols involving investigative animal research. Unsealed form usage involved the benchtop manipulation of radioactive materials in research. These materials were procured and used at FB-8 under the FDA/CFSAN broad scope radioactive materials license (number 08-00482-03, docket number: 030-03917, expiration date April 30, 2005).

The FDA has relocated research operations and administrative personnel to other facilities in the Washington, DC metropolitan area. The building owner, the General Services Administration (GSA), has designated FB-8 for major renovation. This renovation will require the removal of interior walls, fixed laboratory equipment and mechanical systems.

The FDA/CFSAN, as an NRC licensee, is required to demonstrate that FB-8 located at 200 C St., SW Washington, DC is acceptable for release in accordance with the requirements and conditions specified by the NRC. The FDA/CFSAN has retained the services of Clym Environmental Services, LLC (Clym) to assist in the decommissioning of FB-8. All decommissioning related activities (scoping surveys, characterization surveys, remediation and waste disposal) were conducted under the authority of the current FDA/CFSAN NRC license (number 19-03771-01, docket number 03036120, expiration date April 30, 2005).

2. Radiological Surveys

The Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) assigns a greater level of effort on surveys conducted in areas that have, or had, the highest potential for contamination. The process by which an area is classified is described according to radiological characteristics. Areas that have no

reasonable potential or extremely low probability of residual contamination are classified as non-impacted. Areas with some potential for residual contamination are classified as impacted.

Given the long history of usage at FB-8, it was necessary to assess the current radiological condition of areas. It would be necessary for FDA/CFSAN to conduct surveys of equipment, laboratories and areas within FB-8 in support of relocation activities. A Sampling Plan was developed and approved by the FDA/CFSAN Decommissioning Committee for these activities to additionally provide data on the current radiological condition of all areas at FB-8, regardless of the area's current designation (i.e., administrative, facility operation or laboratory). The Sampling Plan assigned a greater level of effort on surveys conducted in areas that were known to have had a history of usage and thus the highest potential for contamination. The Sampling Plan designated that all items, remaining equipment and areas within the entire building be evaluated for total and removable residual contamination. These surveys, when completed, would afford FDA/CFSAN the information necessary to properly classify areas at FB-8 for Final Status Surveys.

Any area where residual contamination was identified in three- (3) or more distinct locations was designated for 100% evaluation of all surface areas. It should be noted that the release criteria for equipment under the FDA/CFSAN radioactive material license is specified in Regulatory Guide 1.86.

All laboratory effluent systems (e.g., sanitary sewer drain lines, chemical fume hood exhaust ducts) were designated for evaluation. Any system found to have detectable residual activity above MDC were removed and decontaminated as necessary. The process of removing affected system lines continued until such time as it was determined that there was no detectable residual activity above instrument MDC. Early in this evaluation process, activity was detected in the building air handling system (both return and supply ducting) using portable survey instrumentation, in both the "office" and "laboratory" sides of FB-8.

The activity detected in the air handling system ranged from 100 to 500 ncpm with 1,000 ncpm maximum, on average. However, no removable surface activity was detected above the minimum detectable. The uniformity in distribution throughout the building focused attention on the building air intake. Samples of unused influent filters were obtained and evaluated using direct measurement techniques. No activity was detected above the minimum detectable. Surface scans of "in-use" filters obtained positive results. A sample of an air filter assembly was obtained from the influent building air handling system for analysis. This air filter assembly had been changed a year and six months after radioactive materials usage was suspended at FB-8 in September of 2002.

The filter was re-evaluated 2 weeks later in an effort to determine if the detected activity was due to the presence of radon. A positive result was once more obtained. A static count was performed on the bag filter and yielded a net count of

1,000 cpm. The bag filter and contents were sent to Severn Trent Laboratories (license nr. WN-L0146-1) in Richland, WA for radioanalysis. The results of this analysis identified the presence of naturally occurring uranium. A copy of this analysis has been provided as Attachment 1.

Radio-analysis of the filter media identified the presence of natural uranium. It is known that natural uranium was used in research and had been identified as a contaminant. Since the filter had been changed after natural uranium was used at FB-8, it was unlikely that the activity detected in the air handling system was the direct result of licensed activities.

3. Final Status Survey Plan

The FDA/CFSAN used the Alternative Simplified Method as provided for in NUREG-1757, Volume 2, Appendix B, Part B.2 to demonstrate compliance with the provisions specified in Title 10; Code of Federal Regulations, Part 20.1402 for releasing Federal Building 8 for unrestricted use.

FDA/CFSAN obtained screening values for building-surface contamination using the values provided in NUREG-1757, Volume 1, Table B.1 in Appendix B. DandD; Version 2.1 was used to obtain screening values for radionuclides not provided in Table B.1. A copy of the DandD Building Occupancy Scenario reports was provided as Attachment 2 to the Final Status Sampling Plan submitted in correspondence to the NRC dated October 5, 2004 and subsequently approved. A listing of the acceptable screening values has been provided in Table 1.

Table 1

Radionuclide	Symbol	Acceptable Screening Levels (dpm/100cm²)
Hydrogen-3	³ H	1.2E+08
Carbon-14	¹⁴ C	3.7E+06
Nickel-63	⁶³ Ni	1.8E+06
Technetium-99	⁹⁹ Tc	1.3E+06
Uranium- Natural	U-nat	93
Thorium-Natural	Th-nat	58.4

The criteria for determining Impacted Areas at Federal Building 8 required that contamination be identified on the building structure (e.g., casework, chemical fume hood, shelf, etc.) or "permanent" equipment (e.g., refrigerator, walk-in cold room) that is not easily moved. Additionally, any room or area housing a run of contaminated drain line was designated as impacted. The size of each individual survey unit was limited to 100 m². A listing of individual survey units, physical location and known radiological status prior to the commencement of Final Status surveys is provided as Attachment 2.

The Final Status Survey involved a one hundred percent (100%) surface scans of accessible surfaces and the collection of thirty- (30) samples from randomly selected sample points within each survey unit. The types of samples collected from each survey point did include 1) a smear, and 2) an integrated or static measurement.

4. Final Status Survey

The Alternative Simplified Method stipulates the average concentration of residual activity for each survey unit be directly compared to the DCGL. The unity rule applies to survey units exhibiting contamination from multiple radionuclides. The most conservative DCGL will be used for comparison in survey units for which no residual activity is detected above MDC in any sample point. Areas of elevated activity will be considered acceptable if the measured activity does not exceed three times (3x) the DCGL in any sample location. Statistical tests, the Sign or Wilcoxon Rank Sum tests (α and $\beta = 0.05$) will be used to demonstrate whether or not a survey unit passes should any measurement within a survey unit exceed the DCGL.

4.1 Reference Areas

The reference areas for establishing background for the different matrices were identified. Radiological evaluations for total and removable surface contamination were conducted in each location designated as a reference area. No designated reference area was found to contain residual activity above the minimum detectable concentration (MDC). Sample measurements were then made at various locations within each of the reference areas on each type of matrices (e.g. benchtop, floor, casework, etc.). Variations in "background" were encountered for each type of matrices throughout FB-8. A listing of reference areas used has been provided as Attachment 3.

4.2 Field Measurements Methods and Instrumentation

NUREG 1757, Volume 2, Appendix B.2 stipulates the MDC for each survey instrument used to measure residual activity will be 10% to 50% of the DCGL. Surface scans and measurements for beta emitting radionuclides were made using scaler/rate meters equipped with large area gas proportional detectors (Ludlum model 43-68 and 43-37). The Scan MDC (NUREG 1575, 6.7.2.1 (6-9, 6-10)) was determined for each instrument using the reference background for each matrices encountered to ensure compliance. The "worst case" reference background measurement for each detector type was selected. The surveyor efficiency ($P = 0.5$), instrument efficiency 0.2 and source efficiency 0.25. The minimum detectable count rate ($MDCR_{\text{surveyor}}$) was next determined for the ideal surveyor during the first scanning stage using an index of

sensitivity (d') of 2.48 and a 2 second observation interval (NUREG 1575, 6.7.2.1 (6-8, 6-9)). These calculations have been provided in Table 2.

Table 2

Detector	Serial Number	Probe Area (cm ²)	Reference Area Matrices Background (cpm)	Scan MDC (DPM/100cm ²)	MDCR _{surveyor} (CPM)
43-68	122015	126	561	7,200	1,000
43-37	190909	582	2,129	3,000	3,000

The 43-37 was the preferred survey detector. The large surface area afforded the surveyor expanded coverage per pass. The 43-68 detector was used primarily in "hard to reach" areas such as surface areas inside of cabinets or behind laboratory fixtures. A listing of the reference matrices, associated measurement and MDCR_{Surveyor} for each portable survey instrument used has been provided as Attachment 4. Any area found to have detectable activity equal to or greater than the MDCR_{Surveyor} would be designated for further investigation.

The L_C and L_D (NUREG 1575, 6.7.1 (6-6)) including the minimum detectable concentration (MDC) expression (Brodsky & Gallagher 1991) for an integrated static count have been determined and are provided in Table 3. (MDC was calculated for a one-minute static count).

Table 3

Detector	Serial Number	Probe Area (cm ²)	Reference Area Matrices Background (cpm)	L _C (counts)	L _D (counts)	MDC (dpm/100cm ²)
43-68	122015	126	561	55	113	1,750
43-37	190909	582	2,129	108	218	740

The Scan MDC and MDC_{Static} for either probe is significantly less than 10% of the DCGL for any of the beta emitting radionuclide identified as a contaminant.

Surface scans and integrated static measurements for alpha emitting radionuclides were conducted using the 43-37 large area gas proportional detectors. The high voltage was adjusted for each instrument, as specified by the calibration certification, to discriminate all beta pulses. The averaged ambient background for this detector in the alpha mode was found to be 4 cpm. The ratio of Th-natural to U-natural was obtained from radio-analysis data. The results of this analysis is provided as Attachment 5. The gross alpha DCGL was determined to be 63 dpm/100cm². One half of a gross alpha DCGL was found to be 31 dpm/100cm² or 5cpm using a total efficiency of 0.15 c/dis. The probability of detecting two or more counts

when passing over 31 dpm/100cm² was determined to be 13% (NUREG-1575, 6.7.2.2 (6-14)) using a probe dimension of 15cm and a scan rate of 4cm/s. The time interval a surveyor should hold over a suspect area was determined to be 4 seconds (NUREG 1575, 6.7.2.2 (6-13)). Any area found to have two or more counts above background would be designated for further evaluation.

The L_C and L_D (NUREG 1575, 6.7.1 (6-6)) including the minimum detectable concentration (MDC) expression (Brodsky & Gallagher 1991) for an integrated count have been determined and are provided in Table 4. (MDC was calculated for a two-minute static count.)

Table 4

Detector	Probe Area (cm ²)	Background (cpm)	Efficiency (cpm/dpm)	L _C (counts)	L _D (counts)	MDC (dpm/100cm ²)
43-37	582	4	0.2	5	12	20

The levels of naturally occurring radioactivity observed on certain reference matrices reduced the effectiveness of surface scans to meet the required minimum detectable concentration. Surface scans were augmented with static measurements on surfaces having a reference background greater than 8 cpm. Static count times were increased for certain matrices from 2 to 5 minutes to ensure adherence to the MDC requirements.

The detectors were employed on the scanned surface at no greater than the prescribed speed as indicated below;

43-68, alpha/beta mode ½ a probe width per second (2inches/sec)

43-37, alpha/beta mode ½ a probe width per second (3inches/sec)

43-37, alpha mode ¼ a probe width per second (1.5inches/sec)

The minimum observational interval or hold time over a suspect area is as specified for the first stage scan; Beta - 2 seconds, Alpha - 4 seconds. Surface scans were systematically conducted on accessible surfaces in each survey area as to ensure the 100% coverage in all areas. Special attention was made to joints, cracks, seams, etc. in any accessible survey area.

All accessible surfaces of each survey unit were designated for surface scans. The building air handling system, laboratory drain line clean-outs and traps are not designated for evaluation, however accessible surfaces directly beneath drain lines were designated for surface scans.

4.3 Laboratory Analysis

The evaluation of removable surface activity was conducted using a dry paper wipe, wetted with alcohol and covering an area of 100 cm² while applying moderate pressure. Smear samples were analyzed by Clym Environmental Services, LLC (license nr. MD-21-035-01) for gross alpha and beta. Samples were analyzed for gross alpha/beta using a liquid scintillation counter. Any activity detected above the minimum detectable would designate the sample for quantitative analysis.

4.3.1 Amendment to the Count Times for Smear Samples

The count time for the analysis of smear samples was reduced in an effort to expedite the turn around time. The count time for the analysis of smear samples for gross alpha was reduced from 60 minutes to 30 minutes. The typical MDC of 5 dpm/100cm² as originally stated in the Final Status Survey Plan was maintained.

Whenever possible the gross beta count time of 4 minutes per sample was maintained. A reduction to a 1 minute count time produced a typical MDC of 60 dpm/100cm², using a conservative Tritium efficiency. This amended MDC is significantly below the worst case MDC requirement of 13,000 dpm/100cm² for 99Tc.

4.4 Survey Unit Evaluation

A total of 109 survey units were designated for evaluation using Final Status Survey techniques. A one meter square grid system was constructed in each survey unit, to include the floor, walls (upper and lower) and ceiling area.

The ceiling area was defined as all surfaces located on the same horizontal plane as the suspended ceiling. In survey units where ceiling tiles were missing, the ceiling area was defined as all surfaces located directly above the area occupied by the missing ceiling tile.

In survey units where residual contamination was identified in the ceiling area or the potential for residual contamination exists in the ceiling area (i.e., where contaminated drain lines were removed), the ceiling area was defined as all surfaces located in the interstitial space that existed when the suspended ceiling was in place.

Random sample points were next identified for each survey unit. The sample point corresponds to an actual grid coordinate in the survey unit.

Random sample points were selected by first assigning each point in the survey unit a sequential numerical value. This numerical value was represented using pre-numbered paper discs. The discs were placed in a vessel and the vessel agitated. Single discs were next drawn from the vessel and arranged in sequential order. The sample point corresponding to the number on each disc was recorded.

A map of the survey unit and thirty sample points was given to the surveyor. The surveyor used the following methodology to acquire the appropriate sample location in the grid system. Floor Area— Locate the lower right hand corner in the grid coordinate with your back to the entrance way. Wall Area - Facing the wall surface, locate the lower right hand corner in the grid coordinate, Ceiling Area – The ceiling and floor grid coordinates area are the same. Locate the designated sample grid coordinate in the floor area with your back to the entrance way. Acquire the lower right hand corner in the floor grid coordinate. The sample area in the designated ceiling grid coordinate will be directly above the “sample area” acquired in the floor area.

The sample area for a grid coordinate having, 1) a numerical designation of “6” and 2) a laboratory bench-top residing in the grid coordinate; will be the laboratory bench-top.

A map of each survey unit, including static measurement and smear sample results has been provided as Attachment 6.

4.5 Activity Detected At or Above Investigative Levels

Survey units had previously been evaluated and decontaminated as necessary to meet the release criteria as designated in the FDA/CFSAN’s radioactive materials license. The acceptable release levels under FDA/CFSAN’s radioactive materials license for Th-natural and U-natural exceed the DCGL. Logic dictated that residual contamination could reside in concentrations above the investigative level in survey units where these radionuclides were identified.

Surface scans identified alpha contamination on areas of two walls in survey unit 5-26 (the radioactive waste storage and processing area). The static measurements confirmed 5 hot spots, 2 on the “B” wall and 3 on the “C” wall. The highest measurement was 35 dpm/100cm². No removable surface activity was detected above the instrument’s minimum detectable concentration (20 dpm/100cm²). These areas were decontaminated to below the minimum detectable using wet method techniques.

Surface scans and static measurements identified 2 additional areas of alpha contamination in survey unit 3-67 (laboratory 3830, where samples

for electron microscopy had been prepared). The static measurements confirmed 3 hot spots, 2 on a laminated benchtop surface and 1 on the concrete floor. The highest measurement was 33 dpm/100cm². No removable surface activity was detected above the instrument's minimum detectable concentration (20 dpm/100cm²). These areas were decontaminated to below the minimum detectable using wet method techniques.

The majority of residual beta contamination remaining in survey units at the commencement of FSS was found to be at or below the MDCR_{surveyor}. A case in point involves a laminated benchtop located in survey unit 6-2 (laboratory 6046A). The area of residual contamination, 1,100 gcpm, was not reported by the surveyor conducting the Final Status Survey. The MDCR_{surveyor} for the instrument used in evaluating the laminated benchtop was 1,200 gcpm. It should be noted that Quality Assurance (QA) surface scans did identify the area. The QA surveyor's MDCR_{surveyor} was 1,100 cpm.

There were however, certain areas where residual beta contamination is known to exist in areas of survey units not accessible to surveyors conducting Final Status Surveys. This was due to the physical location of the contamination. Certain sections of casework had been removed from laboratories for decontamination. Upon successful completion of decontamination efforts, these sections were returned to their original laboratory locations for the Final Status Survey. Repositioning these sections in the original laboratory setting meant restricting access to surveyors as certain areas of residual activity were known to reside on footers or sides of the section that abutted a wall or other section of casework. It should be noted that these areas, having been identified during previous surveys, were released under FDA/CFSAN's radioactive materials license. A copy of residual activity detected during surface scans is provided as Attachment 7.

5. Quality Assurance

The performance of decommissioning activities has been managed within a framework of policies and procedures, which assure the validity and quality of data. Procedures were established for activities requiring the application of standard and approved methods to ensure regulatory requirements were met. These procedures document the technical competence of the survey approach thus ensuring the use of effective processes. Procedures utilized by Clym are documented using program-specific applications.

5.1 Daily Operational Checks for Portable Survey Instruments

The purpose of these procedures was to ensure portable scaler/rate meters equipped with gas proportional detectors were in proper working condition prior to placement into service.

When an instrument failed an operational check, both the instrument and detector were removed from service until the discrepancy could be resolved.

Both source and background measurements must fall within the acceptable range established for the site and were performed as follows:

Prior to beginning the performance of data measurements and/or scanning for the day,

After the lunch or noon break,

Any time the detector is suspected of being contaminated and

Any time instrument operation is in question.

Daily checks included 1) a determination of operational readiness, 2) ambient background determination and verification that each reading is within $\pm 20\%$ of the average in beta mode and 50% of the average in alpha mode and 3) check source reproducibility determination.

The check source reproducibility determination involved obtaining the data necessary to calculate the average source count and verify that each section of the detector face was reading within $\pm 10\%$ of the average. Additionally, the 2σ and 3σ values for the background and check source counts were calculated. The acceptable value for 3σ was established at $\pm 10\%$ of the mean.

A copy of these daily checks and calibration certificates has been provided as Attachment 8.

5.2 Internal Quality Assurance Checks

Quality assurance evaluations were conducted in each survey unit. These evaluations involved verification measurements to confirm Final Status Survey measurements for total and removable surface contamination. Measurements were made at three- (3) randomly selected Final Status Survey sample points by two- (2) designated surveyors. QA surveyors used procedures and techniques identical to those used in the FSS. Additionally, surface scans were conducted on what were deemed "high

risk" surfaces in each survey unit. "High risk" surfaces included laboratory benchtops, chemical fume hoods, fixtures, including door knobs and light switches.

The results of these evaluations are provided as Attachment 9. An additional Quality Assurance evaluation included assessing the measured values for each survey point both verification and FSS, to determine if overlap occurred, at the 95% confidence level.

On four occasions the verification and FSS measured values did not demonstrate the 95% confidence level overlap. Two of these occurrences were able to exhibit overlap when 1.96 standard deviations were applied to either the verification or FSS reference value.

The third instance involved removable surface activity in survey unit 4-36. Removable surface activity was detected during the FSS, (80 ± 26 dpm/100cm² - 63Ni). The verification measurement was not able to reproduce the result obtained from the FSS measurement.

The fourth instance involved removable surface activity in survey unit 3-60. Removable surface activity was detected during the verification measurement, (88 ± 7 dpm/100cm² - 63Ni). The verification measurement was not able to reproduce the result obtained from the FSS measurement.

There are many factors that could have contributed to the inability to obtain reproducible results in these last two instances. However, the final outcome is the level of removable surface contamination obtained in each instance is negligible, less than 100 dpm/100cm² and is well below the prescribed DCGL. The results of the evaluation of verification measurements are provided as Attachment 10.

5.3 External Quality Assurance Review

An external quality assurance review was conducted by an independent outside firm, Chesapeake Nuclear Services, Inc. The purpose of this audit was to, 1) verify the appropriate application of site characterization to the specified surveys, 2) confirm the appropriate use of instruments, detectors, laboratory analysis and calibrations, correlations to characterized radionuclides, detection capabilities and use in the field 3) perform direct measurement verifications in survey units and 4) review records for completeness.

A copy of the audit findings has been provided as Attachment 11.

6. Disposition of Materials and Waste

All radioactive materials were either returned or transferred to the appropriate licensees. All radioactive waste, including wastes generated as a result of decommissioning activities, was disposed of in accordance with FDA/CFSAN's radioactive materials license. A completed copy of NRC Form 314, "Certificate of Disposition of Materials" including copies of disposal and transfer manifests have been provided as Attachment 12.

7. Findings

The average concentration of residual activity for each survey unit was compared to the DCGL. The average concentration in each survey unit was found to be less than the DCGL. The unity rule determination was found to be less than 1 in survey units exhibiting contamination from multiple radionuclides. No area of elevated activity was found to be greater than 1% of the DCGL in any sample location. The evaluation of FSS measurements are provided in Attachment 13.

8. Conclusion

The Final Status Surveys conducted by the FDA/CFSAN demonstrate compliance with the provisions specified in the Code of Federal Regulations, Title 10, Part 20, Subpart E for releasing Federal Building 8 for unrestricted use.

This is to acknowledge the receipt of your letter/application dated

11/31/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 19-30771-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136303.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN: : (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
License Fee Management Branch, ARM : Program Code: 03611
and : Status Code: 0
Regional Licensing Sections : Fee Category: EX 3L
: Exp. Date: 20050430
: Fee Comments: _____
: Decom Fin Assur Req'd: Y
:

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: HEALTH & HUMAN SERVICES, DEPT. OF
Received Date: 20050131
Docket No: 3036120
Control No.: 136383
License No.: 19-30771-01
Action Type: Amendment

2. FEE ATTACHED

Amount: /
Check No.:

3. COMMENTS

Signed *Ruben Pineda*
Date 2/2/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____