

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-04038/86-001(DRSS)

Docket No. 030-04038

License No. 12-00621-03

Category B

Priority I

Licensee: Abbott Laboratories
Diagnostics Division
North Chicago, IL 60064

Inspection At: North Chicago Plant
1400 Sheridan Road
North Chicago, IL

Diagnostic Division Distribution Center
Intersection of U.S. 41 and 22nd Street
North Chicago, IL

Abbott Park
Route 32 and Route 137
Lake County, IL

Inspection Conducted: June 3-5, 1986

Inspectors: *G. L. Shear*
G. L. Shear
Radiation Specialist

7/1/86
Date

C. C. Casey
C. C. Casey
Radiation Specialist

7/1/86
Date

Approved By: *D. J. Sreniawski*
D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2

7/1/86
Date

Inspection Summary

Inspection on June 3-5, 1986 (Report No. 030-04038/86-001(DRSS))

Areas Inspected: Announced, routine safety inspection of activities conducted under License No. 12-00621-03 including: organization; licensee audits; training, retraining and instructions to workers; radiological protection procedures; materials, facilities, and equipment; exposure controls, external, internal, and ALARA program; posting, labeling, and control; surveys; radioactive effluents and waste disposal; notification and reports; quality assurance; environmental monitoring programs; and radiological contingency plan.

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Results: Of the areas inspected, three violations were identified; (1) 10 CFR 20.201(b), failure to adequately evaluate personnel exposures (Section 10); (2) License Condition No. 12(c), failure to maintain records and certification of competency of users (Section 4); (3) 10 CFR 19.11(d), failure to post the required documents, notices, and forms referenced in 10 CFR 19.11 (Section 12).

DETAILS

1. Persons Contacted

- *D. Coleman, Manager of Group Formulation
- *P. Ward, Health Physicist, Assistant RSO
- *D. McCallister, Radiation Monitor, Abbott Park
- B. Steidtman, Radiation Monitor, Abbott Park
- R. Davis, Radiation Monitor, North Chicago Plant
- T. Rosko, Warehouse Supervisor, Radiologic Contingency Plan Team Captain
- T. Wessel, Material Operations Manager, Skokie Warehouse
- *J. Kark, Health Physicist, Illinois Department of Nuclear Safety
- D. Padovani, Health Physicist, Illinois Department of Nuclear Safety
- V. Muzzalupo, Emergency Planner, Illinois Department of Nuclear Safety
- J. Papendorf, Health Physicist, Illinois Department of Nuclear Safety

*Denotes those present at exit meeting on June 5, 1986

2. Licensee Action on Previous Inspection Findings

The March 11-12, 1985 inspection of License No. 12-00621-03 identified one violation of NRC requirements: License Condition No. 13, failure to maintain records of a leak test of a cesium-137 sealed instrument calibrator source. The 1986 inspection showed that corrective action had been taken to correct the identified violation and to prevent recurrence.

3. Organization

The licensee's administrative management organization and Radiation Safety Committee members are identified in Attachments A and B of this report. The licensee has two functioning safety committees, the Corporate Radiation Safety Committee (CRSC) and the Abbott Diagnostics Division Radiation Safety Committee (ADD-RSC), which provide administrative control for the licensed program pursuant to the requirements of 10 CFR 33. The ADD-RSC is comprised of division personnel and provides an "in-house" means of discussing and resolving division problems. This committee acts as an advisory body to the CRSC.

The CRSC members are approved through the Office of the Vice President, Personnel, with the Division Vice Presidents supplying the appointees. The CRSC addresses the major policy and philosophic questions and problems involving radioactive material and serves as a monitor of all activities conducted under all corporate NRC licenses.

No violations were identified.

4. Licensee Audits

Health Physics personnel perform routine audits in restricted areas of all facilities. Problems identified during those audits are either corrected during the audit or presented to the manager of the research group involved for corrective action.

The Abbott Diagnostic Division - Radiation Safety Committee meets bimonthly and reports to the Corporate Radiation Safety Committee at the quarterly meeting. The licensee maintains the required documentation of these meetings.

The inspector reviewed minutes of the ADD-RSC meetings for 1985 and 1986.

No violations were identified.

5. Training, Retraining, and Instructions to Workers

Training is implemented as required by the license application.

The licensee has incorporated video tapes into their training program. A general radiation safety tape is viewed by all new employees and a more comprehensive set of tapes is viewed by new employees who will be radiation workers.

Training is documented through use of an H. P. Training Checklist and satisfactory completion of the training program is determined by the Training Quiz (Attachment C) which is given to both types of workers. Unsatisfactory answers are reviewed with the employee prior to assumption of employment responsibilities.

Retraining is required for all individuals who work in or whose duties may require them to work in restricted areas or in the vicinity of licensed materials on an annual basis. The licensee has implemented a retraining program for individuals described above.

Training and retraining records are maintained in the personnel folders and training files maintained in the Health Physics office.

The licensee is in compliance with 10 CFR 19.12, "Instructions to Workers."

In addition to the above requirements, License Condition No. 12.C. requires that individuals approved by the licensee's Radiation Safety Committee to independently use licensed material shall have (in addition to required Abbott training) as a minimum education, experience, and training equivalent to that outlined in Part 33.15(b), 10 CFR Part 33. Records of training and certification of competency of users by the licensee's committee shall be maintained for review by the NRC. However, on the dates of the inspection, June 3-5, 1986 records of training and certification of competency of users by the licensee's Radiation Safety Committee were not available for review by the inspectors. The failure of the licensee to maintain records of training and certification of competency of users by the licensee's Radiation Safety Committee constitutes a violation of License Condition No. 12.C.

One violation was identified.

6. Radiological Protection Procedures

The licensee has implemented radiological protection programs required by their license conditions. Procedures are provided for both radiation workers and non-radiation workers. The Health Physics Department conducts and implements an overall radiological protection program to assure compliance with established standards and procedures.

(The licensee utilizes three color-coded levels of restricted areas. Red areas are the most restricted (e.g., iodination labs); yellow areas are moderately restricted (e.g., certain hallway corridors); and green areas are minimally restricted (e.g., health physics offices).)

These written procedures appeared to be adequate for the existing programs. The procedures appeared to be properly implemented and utilized by licensee personnel.

No violations were identified.

7. Materials, Facilities and Equipment

Materials

Licensed materials are possessed, used, and distributed in quantity and kind as authorized.

The licensee maintains no formal inventory of materials. This information can be obtained from the existing records of receipt, transfer, disposal and distribution.

Facilities

Inspection of the physical facilities showed that the facilities conform with descriptions in the applications and letters referenced by license conditions.

Methods and systems utilized by the licensee to maintain security of licensed material and prevent unauthorized entry into controlled areas, and/or unauthorized removal of material appear adequate. The licensee is in compliance with license conditions referencing requirements relating to security and access controls.

The licensee is in compliance with 10 CFR 20.207, "Storage of Licensed Material," and 10 CFR 20.203, "Caution Signs, Labels, Signals, and Controls." The licensee is also in compliance with the requirements referenced by the license conditions regarding utilities, services, sewer systems for liquid waste release, storage areas and shielding.

Equipment

Based upon the inspection sampling, the licensee appears to be in compliance with respect to license condition requirements for process and storage systems, and associated equipment. This includes items such as fume hoods, shields and shielding devices, ventilation systems, and retention tanks. The licensee also appears to be in compliance with the requirements for area monitors and air samplers, laboratory counting equipment, portable survey instruments and the appropriate calibration of these instruments.

No violations were identified.

8. Receipt and Transfer of Material

The licensee is in compliance with the requirements of 10 CFR 20.205(a) and (d) (Procedures) and 10 CFR 20.205(b) and (c) (Surveys) for incoming packages.

Material transfers are made in accordance with 10 CFR 30.41, 71.5 and DOT requirements under Title 49 of the Code of Federal Regulations.

Based upon the inspection sampling, material distributed by the licensee appeared to be packaged and labeled in accordance with NRC and DOT requirements.

No violations were identified.

9. Shipping Incidents

No significant shipping incidents have occurred since the last inspection.

No violations were identified.

10. Exposure Controls - External

The licensee employs the services of R. S. Landauer, Jr. and Co. for both weekly and monthly film badge processing. Films are changed monthly or weekly as dictated by the magnitude of the expected exposures, and wrist badges are used to measure extremity exposures when necessary. All persons who regularly work in Red Restricted Areas are provided with film badges. Other persons-visitors, transient workers, etc. are provided with film badges if they are expected to occupy Red Restricted Areas for over eight hours per week.

During the calendar year 1985, the maximum annual exposure levels recorded for weekly badged individuals have been 750 mrem whole body and 6,720 mrem extremity (wrist). For those whose badges are processed monthly, the maximum annual whole body exposure level was 640 mrem.

During the first quarter of 1986, the highest exposure levels were for the production workers who are badged weekly and showed 90 mrem whole body and 1,670 mrem for the extremity (wrist) exposures.

Exposure history Forms NRC-4 and NRC-5, or equivalent are maintained for all personnel who are issued personnel dosimetry badges. All records since the previous inspection were reviewed.

The licensee utilizes low energy gamma scintillation detectors with alarm count rate meters as personnel monitors for iodine-125 contamination. These are strategically located throughout the facilities wherein iodine-125 is used. Individuals are required to check themselves with these instruments when leaving controlled areas and thus control the possible spread of contamination.

Based upon the inspection sampling, the licensee appears to be in compliance with the requirements of 10 CFR 20.101(a) and (b), 20.102, 20.104(c), 20.105(a), 20.202(a), and 20.401(a).

No violations were identified.

11. Exposure Controls - Internal

The licensee's program for internal exposure control consists of surface contamination surveys, airborne radioactivity monitoring, thyroid counting, and urinalysis. Measurements of radioiodine in air (approximate breathing zones) for the evaluations of airborne concentrations are performed in restricted areas on a daily basis. Based upon the inspection sampling, air concentrations of iodine-125 appeared to be well below regulatory limits.

Thyroid counting is required to be performed on individuals working with radioiodine or potentially exposed to airborne radioiodine. The frequency of thyroid counting is based upon the probability of external exposure. Internal policy requires that production workers are monitored weekly; housekeeping personnel-monthly; and nonproduction workers-quarterly. In addition, urine bioassays are required to be performed on individuals working with beta-emitting radionuclides. These urinalyses are to be performed quarterly. 10 CFR 20.201(b) requires that the licensee make such surveys as may be necessary for compliance with all sections of Part 20 and are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a) "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of the dates of the inspection, June 3-5, 1986, the licensee failed to make adequate evaluations of personnel exposure to iodine-125 and beta-emitting radionuclides. Specifically, individuals who work with millicurie quantities of iodine-125 have not had their thyroids monitored for periods of greater than one year. In addition, urinalyses were not performed on several individuals working with beta-emitting

radionuclides, during the third quarter of 1985 and the first quarter of 1986. The failure of the licensee to adequately evaluate personnel exposures constitutes a violation of 10 CFR 20.201(b).

Based upon the inspection sampling the licensee appears to be in compliance with the requirements of 10 CFR 20.103 and 20.106.

One violation was identified.

12. Exposure Controls-ALARA Program

The licensee does not have a formal ALARA and exposure reduction program, however, Health Physics personnel are maintaining cognizance of this through personnel awareness of ALARA concepts.

No violations were identified.

13. Posting, Labeling, and Control

Based upon the inspection tour and observations, the licensee appears to be in compliance with the requirements of 10 CFR 20.203 and 20.207.

10 CFR 19.11(d) requires that documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

Contrary to the above, as of the dates of the inspection, June 3-5, 1986, the licensee failed to post the documents, notices, and forms referenced in this section in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies. Specifically, the licensee failed to post any Notices to Workers in any of the areas inspected and only one NRC Form-3 was posted in the North Chicago facilities inspected. The one NRC Form-3 posted was in the Health Physics office which is not an area frequented by individuals engaged in licensed activities. The failure of the licensee to post the required documents, notices, and forms, referenced in 10 CFR 19.11, in a sufficient number of places constitutes a violation of 10 CFR 19.11(d).

One violation was identified.

14. Surveys

The licensee performs radiation surveys in production areas, receipt areas, and shipping areas in accordance with the frequencies stated in the license.

The licensee also performs routine smear tests of all areas. A review of the smear test data demonstrated that the licensee is decontaminating areas and surfaces showing levels in excess of the licensee's action limits for radioactive contamination.

No violations were identified.

15. Radioactive Effluents and Waste Disposal

Gaseous and volatile byproduct material effluents are monitored by the licensee. Material released from the exhaust stack systems is continuously monitored. The licensee has computerized their stack release data to obtain the unrestricted MPC(a) averages. For the year 1985, the average annual iodine-125 release for the Abbott Park and North Chicago sites was less than eight percent of the annual MPC(a).

Liquid effluents generated from building AP-8 are processed through the licensee's liquid waste concentrator. Radioactive waste liquids (I-125) from Buildings AP-1 and 1A are heat treated to destroy biohazardous organisms. This waste is then drained into 30 gallon drums and transferred to the waste storage area for decay. When sufficiently decayed (less than 100 microcuries per barrel) the material is discharged into the sanitary sewer system. During 1985, a total of 48.941 millicuries of iodine-125 was released to the sanitary sewer. The inspectors obtained water samples from the bio-waste tank in AP-1A and a ground water sample from a sampling point near the liquid waste concentrator. The analysis of these samples was not completed at the time this report was written. The licensee's other waste products (consisting primarily of both solid and liquid carbon-14 and hydrogen-3 compounds) are collected in drums and, after being packaged in accordance with DOT regulations, are shipped to a commercial waste burial site. During 1985, the licensee shipped forty 55-gallon drums of waste to their waste handler for burial. A total of 650.01 millicuries of mixed radioactive material was disposed of in these shipments.

No violations were identified.

16. Notifications and Reports

The licensee is in compliance with the requirements of 10 CFR 19.13, 20.402, 20.403, 20.405, 20.407, 20.408, and 20.409.

No violations were identified.

17. Quality Assurance

Quality assurance of licensed materials and products manufactured is performed as required by various agencies such as the NRC, FDA, DOT, etc.

No violations were identified.

18. Environmental Monitoring Program

In accordance with this license, the licensee's environmental monitoring program presently consists of monitoring two groundwater sampling points at the Abbott Park facility liquid waste concentrator, usually on a monthly frequency. Results of these samplings are within the restricted MPC (w) concentration limits.

No violations were identified.

19. Radiological Contingency Plan

The licensee has submitted and implemented a Radiological Contingency Plan in accordance with the NRC order dated May 22, 1981. That Contingency Plan and the licensee's last annual drill were reviewed by the inspectors.

The plan currently covers one building, AP-15A, which is the waste storage area. Building AP-15A has an occupancy rate of 15 to 25% with three to five individuals present.

Written procedures for actions to be taken in the event of a radiation accident were available. All emergency numbers were verified and corrected in March 1986.

The emergency procedures identify the Libertyville Fire Department Rescue Squad as the carrier to be used for medical transport.

The designated response center is identified as Victory Memorial Hospital, Waukegan, Illinois. Annual contact with hospital personnel is maintained by Abbott Laboratories. Victory Memorial Hospital is currently under contract with Zion Nuclear Power Plant and has the capability to respond to the type of accident postulated for Abbott Laboratories.

Onsite emergency policies identify common assembly points for building evacuation and a method for assessing personnel accountability.

An annual emergency drill is conducted by the licensee and generally coincides with the annual fire drill conducted at the facility. The last drill, conducted June 19, 1985, did not identify any deficiencies in the plan. All listed response agencies are notified of the drills and respond according to the disaster scenario. Several of the listed agencies were contacted by the inspectors to verify the licensee's agreements with the agencies. All agencies contacted were aware of the agreements and their role in response to a radiologic emergency.

Fire Protection

Existing fire protection consists of extinguishers, alarms, sprinkler system, onsite fire brigade, and local fire departments.

Training

In addition to the training identified in Section 5 of this report additional training is provided, by department heads, regarding evacuation, alarm systems, assembly areas, etc.

No violations were identified.

20. Confirmatory Measurements

During the course of this inspection, direct reading survey measurements were made by the inspectors using the following portable survey instruments:

<u>Type</u>	<u>NRC NO.</u>	<u>Calibration Date</u>
Eberline E-520	9573	May 22, 1986
Ludlum 19	10617	May 6, 1986

The results of all surveys agreed with those of the licensee. Of the areas surveyed, readings varied from .02 mr/hr to .5 mr/hr.

21. Exit Interview

The results of the inspection were discussed during an exit interview conducted June 5, 1986 and in telephone conversations with Mr. Paul Ward on June 12 and 13, 1986. Attendance at the exit interview is identified in the Persons Contacted section of this report.

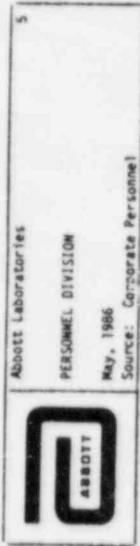
NRC inspectors reviewed inspection findings with the licensee and discussed the apparent violations identified during the course of the inspection. In addition, to the apparent violations, the inspectors noted and discussed with the licensee two potential areas of concern:

- a. the lack of an up-to-date byproduct material inventory
- b. insufficiently controlled fiber drums containing potentially contaminated protective clothing.

The licensee agreed to review these areas for possible implementation of improvements.

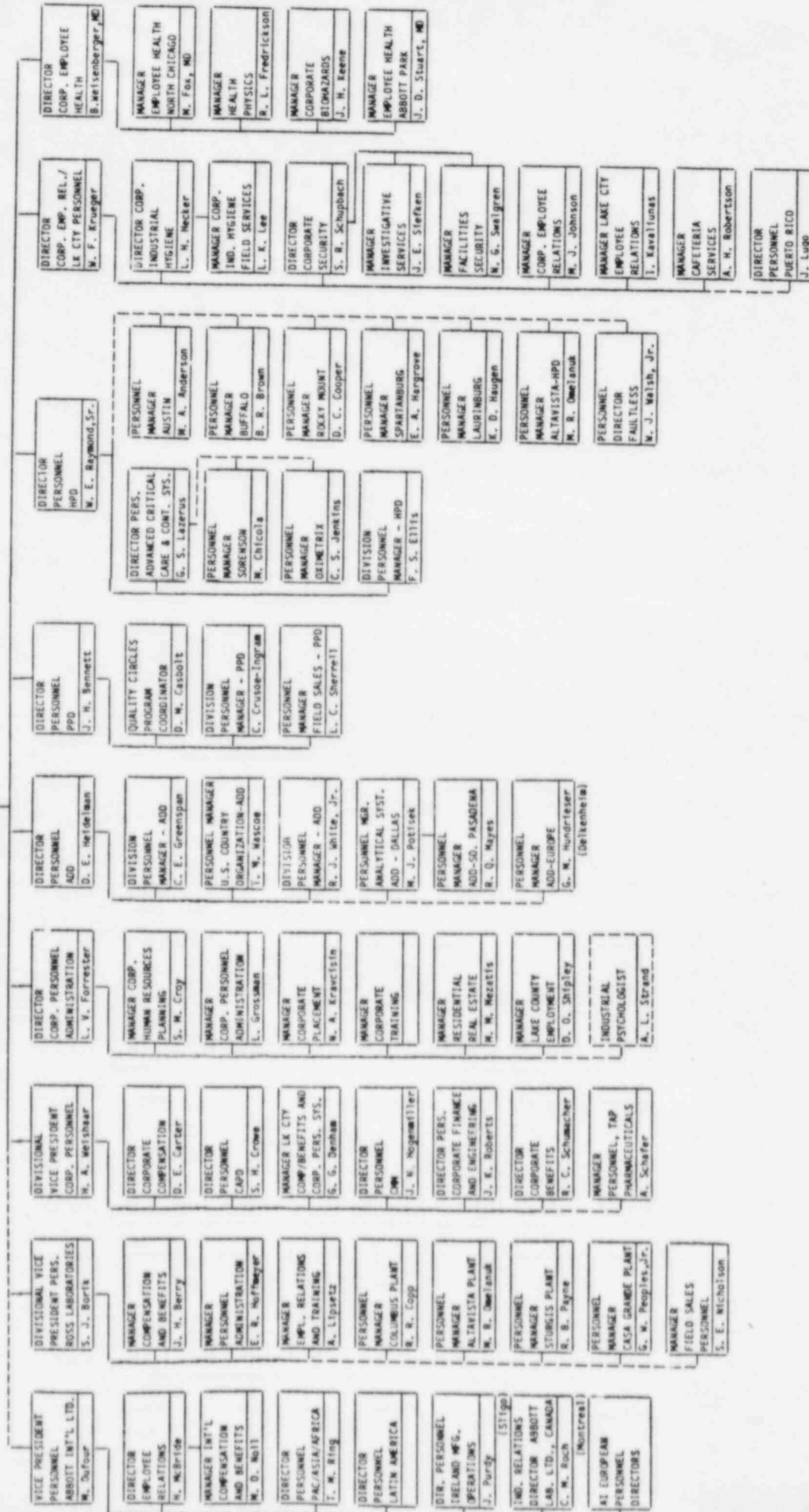
Attachments:

1. Abbott Laboratories
Organizational Chart
2. Abbott Laboratories
Radiation Safety
Committee Members
3. Abbott Laboratories
Radiological Safety
Training Quiz



CHAIRMAN AND CHIEF EXECUTIVE OFFICER

VICE PRESIDENT
PERSONNEL
D. R. Edwards, Jr.



Attachment B

Corporate Radiation Safety Committee Members

Dr. Carl Bodo, Project Manager, Sterilization

Mr. Robert Dal Bello, Operations Manager, Physiologic Diagnostics

Mr. Ronald Fredrickson, Secretary, Corporate Radiation Protection Officer

Mr. George Kinsley, Director, Corporate Loss Prevention

Mr. Ralph Robinson, Chairman, Operations Manager, PPD Production

Dr. Robert Sonders, Manager, PPD Drug Metabolism

Mr. Paul Ward, ADD Health Physicist

Dr. Brockton Weisenberger, Director, Corporate Employee Health Services

Name _____

Dept. _____ Bldg. _____

Date _____

RADIOLOGICAL SAFETYTRAINING QUIZ

INSTRUCTIONS: Answer all the questions. There is at least one right answer.
There may be more than one right answer.

1. Who regulates the possession and use of radioactive materials?
 - a. The Bureau of Radiological Health (BRH).
 - b. The Food and Drug Administration (FDA).
 - c. The Nuclear Regulatory Commission (NRC).
 - d. Federal Bureau of Investigation (FBI).
 - e. Central Intelligence Agency (CIA).
2. How many people have ever been injured by radiation at Abbott's?
 - a. NONE
 - b. 1 - 10
 - c. 11 - 15
 - d. 16 - 20
 - e. 21 or more
3. Who has to wear film badges in restricted areas?
 - a. Production Personnel
 - b. Security Personnel
 - c. Visitors
 - d. Maintenance Personnel
 - e. All of the above
4. If you have to take a visitor into a restricted area you should:
 - a. Sign them in at a visitors station.
 - b. Issue them a visitors film badge.
 - c. Escort them while they are in the restricted area.
 - d. Monitor them and yourself when leaving the restricted area.
 - e. All of the above.
5. Which scale should the radiation monitor be set on when you are using it to monitor yourself for contamination?
 - a. Off
 - b. Batt.
 - c. X1000
 - d. X100
 - e. X10
 - f. X1

6. What should you do if the alarm goes off while you are monitoring yourself for contamination?
- a. Run out of the building.
 - b. Scream and shout for help.
 - c. Turn off the alarm and sneak out before anybody sees you.
 - d. Turn off the alarm and stay where you are.
 - e. Ask somebody else to call health physics for assistance.
7. When you are in a Green Restricted Area, can you:
- | | YES | NO |
|-----------------------------------|-------|-------|
| a. Eat | _____ | _____ |
| b. Drink | _____ | _____ |
| c. Smoke | _____ | _____ |
| d. Carry food or beverage through | _____ | _____ |
8. When you are in a Yellow Restricted Area, can you:
- | | YES | NO |
|-----------------------------------|-------|-------|
| a. Eat | _____ | _____ |
| b. Drink | _____ | _____ |
| c. Smoke | _____ | _____ |
| d. Carry food or beverage through | _____ | _____ |
9. When you are in a Red Restricted Area, can you:
- | | YES | NO |
|-----------------------------------|-------|-------|
| a. Eat | _____ | _____ |
| b. Drink | _____ | _____ |
| c. Smoke | _____ | _____ |
| d. Carry food or beverage through | _____ | _____ |
10. How can you tell which type of restricted area you are in?
- a. By the size of the sign on the door.
 - b. By the color of the door.
 - c. By the color of the floor.
 - d. By the color of the restricted sign on the door.
 - e. By the color of the restricted sign on the wall, by the yellow stripe on the floor.

11. What are some health effects that could be caused by excessive exposure to radiation?
 - a) genetic defects in later generations
 - b) skin cancer
 - c) cataracts in the lense of the eye
 - d) leukemia
 - e) all of the above
12. Is there a safe level of exposure? That is, is there a level of radiation exposure below which it can be proven there is no effect?
 - a) yes, it's about 4 rem/yr
 - b) yes, it's about 12 rem/yr
 - c) no, there is no level of exposure that is absolutely safe
13. What is the "natural" incidence of cancer in the general population?
 - a) 1 person in every 20 (5%)
 - b) 1 person in every 10 (10%)
 - c) 1 person in every 5 (20%)
 - d) 1 person in every 4 (25%)
14. How much of an increase in this "natural" incidence will exposure to 1 rem (1000 millirem) of ionizing radiation cause?
 - a) one more per hundred (1%)
 - b) one more per thousand (0.1%)
 - c) five more per ten thousand (0.05%)
 - d) three more per ten thousand (0.03%)
 - e) one more per ten thousand (0.01%)
15. How low are you required (by law) to keep your own exposure to radiation?
 - a) 3 rems/quarter
 - b) up to 5 rems per year for each year at your age over 18
 - c) 100 millirem per week
 - d) 1 rem per month
 - e) a and b above.
16. How low should you keep your own exposure to radiation?
 - a) 1 rem per quarter
 - b) up to 2 rem per year
 - c) 50 millirem per week
 - d) as low as is reasonably achievable

17. How can you control your exposure to radiation?

- a) limit the amount of time you are exposed to the radiation source.
- b) keep as much distance between the source and yourself as is possible.
- c) keep as much shielding between the source and yourself as is possible.
- d) wear lab coat, gloves, respirator, etc., as necessary to keep internal contamination controlled.
- e) all of the above.

18. What should you do if you are working at a hood and the hood alarm sounds?

- a) close the hood
- b) hold your breath
- c) leave the lab and close the door behind you
- d) call Health Physics
- e) all of the above

19. What should you do if you accidentally spill some radioactive material?

- a) cover it with absorbent paper
- b) leave the room quickly and shut the door behind you
- c) clearly mark the door and control access to the area
- d) call Health Physics
- e) it depends on what you spilled. for example; a, c & d above for Co-57 and Fe-59, or b, c & d above for I-125.

20. What should you do if you detect an unsafe situation involving the transportation, use or storage of radioactive material?

- a) immediately call the police, fire department or other government agency
- b) notify Health Physics and tell them what the situation is.
- c) notify the Corporate Radiation Protection Officer.
- d) notify the chairman of the Corporate Radiation Safety Committee.
- e) notify the Nuclear Regulatory Commission