EA No. 95-058

U.S. NUCLEAR REGULATORY COMMISSION

REGION I

Enforcement Conference Report No. 030-29300/95-002

Docket No. 030-29300 License No. 20-12836-01

Licensee: Amersham Corporation
40 North Avenue
Burlington, Massachusetts 01803

Facility Name: Amersham Corporation

Enforcement Conference Conducted: May 15, 1995

Prepared By: Penny Lanzisera
Penny Lanzisera, Health Physicist — 5-26-95 Date

Penny Lanzisera for
Sami Sherbini, Health Physicist — 5-26-95 Date

Approved By: M. Shanbaky
Mohamed M. Shanbaky, Chief
Research and Development Section — 6/1/95 Date

Enforcement Conference Summary: An Enforcement Conference was held on May 15, 1995, to discuss the apparent violations of NRC requirements identified during an NRC inspection conducted on March 29, 1995, and the subsequent issuance of a Confirmatory Action Letter (CAL) on April 6, 1995. The Licensee's preventive and corrective actions to prevent recurrence of the violations were discussed.

RETURN ORIGINAL TO
REGION I

IE 07

(Enclosure 1)

DETAILS

1. Participants

A. Licensee

William McDaniel, Burlington Site Manager
Cathleen Roughan, Radiation Safety Officer
Lori Podolak, Assistant Radiation Safety Officer
Perry Robinson, Legal Counsel

B. Nuclear Regulatory Commission

Charles W. Hehl, Director, Division of Radiation Safety & Safeguards
Mohamed M. Shanbaky, Chief, Research & Development Section
Penny Lanzisera, Health Physicist
Sami Sherbini, Health Physicist
Judy Joustra, Senior Enforcement Specialist
Karla Smith, Regional Counsel

2. Conference Summary

The enforcement conference began at 1:00 p.m. on May 15, 1995. The conference was open to the public and therefore taped. Mr. Hehl described the scope and purpose of the conference and provided the NRC's understanding of the hot particle skin contamination incident and the licensee's three subsequent dose assessments of the exposure. Mr. Hehl also acknowledged receipt of a letter dated May 13, 1995, from Amersham Corporation which outlined their perceived inaccuracies in Inspection Report No. 030-29300/95-001. Mr. Hehl stated that several items provided additional information not originally provided during the inspection and two items (Item 4/3 involving fraction of particle retrieved for dose assessment and Item 5/5 involving cesium-137 versus iridium-192 attenuation through the mylar window of the detector) indicated assumptions made during the licensee's dose assessment and would be discussed at a later date. Ms. Joustra reviewed the purpose and process involved with an enforcement conference. Ms. Lanzisera stated the apparent violations and the licensee was requested to respond to each of these apparent violations.

The licensee's site manager, Mr. McDaniel, presented the agenda to be covered by his staff. Ms. Roughan, the licensee's Radiation Safety Officer (RSO), provided an overview of operations and a discussion on the apparent violations for the failure to perform an appropriate survey and exceeding shallow-dose equivalent limits as described in 10 CFR 20.1201. Ms. Roughan stated that correcting dose assessments for resolving time did not have an effect on whether Amersham was in compliance with applicable limits from Information Notice 90-48 and acknowledged that seven previous hot particle contamination incidents should have been reported in accordance with 10 CFR 20. Mr. Hehl reminded Ms. Roughan that the current limit for skin exposures is in 10 CFR 20.1201 (i.e., 50 rem). Ms. Podolak, the licensee's Assistant RSO

discussed the overexposure event and the licensee's assumptions used in dose assessment (i.e., all of the particle was retrieved during the decontamination process and the Ludlum geiger-mueller detector results should be ignored since the detector was saturated). Mr. McDaniel closed the licensee's presentation with a discussion of CAL actions taken and overall conclusions.

Ms. Joustra then explained the enforcement policy and summarized the enforcement options available to the NRC. Mr. Hehl thanked the licensee personnel and stated that a meeting would be scheduled in the near future to discuss dose assessment assumptions. The conference was adjourned at 5:15 p.m.

APPENDIX

1. Activity Based on the Ludlum 44-40 Probe

Licensee's Analysis

The following information was provided by the licensee on or about March 27, 1995, regarding the use of the Ludlum 44-40 GM thin-window probe connected to a Ludlum 2221 meter:

- The probe at contact with the particle was saturating. Probe moved to a distance of 3" to lower the count rate.
- At 3" from the particle on the shirt, the count rate was measured at 1,530,000 cpm.
- A calibration factor was measured to permit conversion of count rate to activity. The factor was determined using a Cs^{137} source in a geometry identical to that used in counting the particle.
- The conversion factor using the Cs^{137} source was 2×10^{-6} μCi/cpm.
- Based on the count rate and conversion factor, the particle activity was estimated to be,

  $$A = 1{,}530{,}000 \times 2 \times 10^{-6} = 30.6 \ \mu Ci$$

- A transmission factor for the shirt was measured using a Cs^{137} source and was found to be 0.3088. This factor gives the fraction of the beta radiation that penetrates the shirt to reach the skin.

Additional information was provided by the licensee on or about April 12, 1995:

- The beta transmission factor was re-evaluated using more accurate measurements and was raised to 0.4624.
- Ludlum, the probe manufacturer, stated that the probe shows non-paralyzable dead-time behavior. Based on this, the licensee estimated a system dead-time of 80 μsec.
- Ludlum informed the licensee in a telephone discussion that, at 500,000 cpm, the system dead-time losses amount to about 2/3 of the true counts, i.e. the observed counts rate is about 1/3 of the true count rate. The licensee estimated that the losses at 1,500,000 cpm would be such that the observed count rate would be about 1/9 the true count rate.
- On the basis of the above data, the activity was estimated to be:

$A = 1{,}530{,}000 \times 9 \times 2 \times 10^{-5} = 275\ \mu Ci$

- The licensee concluded that, since the dead-time losses cannot be accurately estimated, the results obtained using this instrument are unreliable and will not be used in estimating particle activity.

NRC's Analysis

- The manufacturer stated that the Ludlum GM probe shows non-paralyzable behavior. For such behavior, the maximum count rate that can be observed is given by

$$C_{max} = 1/\tau$$

where τ is the system dead-time. Given the observed count rate of 1,530,000 cpm, and assuming that this is the maximum count rate possible, the maximum system dead-time is,

$$\tau_{max} = 60/1{,}530{,}000 = 39\ \mu sec$$

Since it is known that 1,530,000 cpm is not the maximum rate but is close to it, it is reasonable to assume that the system dead-time is about 30 μsec. This is typical for this type of detector. Using this estimate of the dead-time, the true count rate is given by,

$$C_{true} = 1{,}530000/(1 - 1{,}530{,}000 \times 30 \times 10^{-6}/60) = 6{,}500{,}000\ cpm$$

The activity is then given by,

$$A = 6{,}500{,}000 \times 2 \times 10^{-5} = 130\ \mu Ci$$

NRC regards this as a reasonable estimate of the particle activity, based on the instrument observed count rate corrected for dead time.

- The uncorrected activity is given by the observed count rate not corrected for dead-time, i.e.:

$$A_{uncorr} = 1{,}530{,}000 \times 2 \times 10^{-5} = 30.6\ \mu Ci$$

- Any estimate of particle activity must be consistent with the activity established above and the activity above must be corrected for dead time.

2. Activity Validation Based on the Portal Monitor

Licensee's Analysis

In an attempt to provide support for their estimate of particle activity, the licensee used the fact that the portal monitor alarmed as the contaminated worker exited the monitor. To that end the licensee made the following assumptions and calculations:

- An Ir^{192} particle of 275 μCi activity would produce a field of 1.4 mR/hr at 1 foot.
- The portal monitor alarm setpoint was estimated to be between 80-250 μR/hr.
- If the worker stood in the center of the monitor, the licensee estimated that an activity of about 20 μCi would be needed to trigger the monitor. If the particle was 6" away, the activity would have to be at least 5 μCi to trigger the alarm.
- The licensee did not provide details of the calculations to arrive at the particle activities, nor any assumptions made to complete the calculations.

NRC's Analysis

- A review of vendor data showed that a portal monitor is typically about 24" wide. The particle is assumed to have been in the center of the monitor, and was therefore about 12" from the detectors (30.5 cm).
- The exposure rate constant for Ir^{192} is given by the licensee as 0.48 μR/hr per μCi at 1 m from a point source.
- The activity necessary to set off the portal monitor alarm is given by:

  $A = (S \times l^2)/X$

  where S is the setpoint in μR/hr, X is the exposure rate constant in μR/hr per μCi, and l is the distance from the source to the detector in meters. Substituting,

  $A = 80 \times 0.305^2 / 0.48 = 15.5$ μCi for a set point of 80 μR/hr

  $A = 250 \times 0.305^2 / 0.48 = 48.5$ μCi for a set point of 250 μR/hr

- Based on the above considerations, the particle activity would have to be at least between 15 and 50 μCi.

- We believe that, although the above provides some idea of the minimum level of activity needed, it must be viewed as semi-quantitative because it is critically dependent on the distance assumed for the particle from the detectors, any interposed shielding, and the setpoint, all of which are not known with sufficient accuracy, particularly the distance.

3. Activity Based on the TAN2000 GM Probe

The licensee provided the follcwing data on or about April 13, 1995:

- The particle was surveyed on the shirt with a TAN2000 GM probe and gave a contact reading of 10-12 mR/hr.

- The TAN2000 probe is 3 cm long, 1 cm diameter, with the probe center at 2 cm from the face of the detector.

- Using a gamma ray constant of 0.48 μR/hr per μCi at 1 m, the field at 2 cm, which is the center of the detector, is

  $A = 0.48/0.02^2 = 1200$ μR/hr per μCi

- Assuming the particle to be a point source that gave a field at 2 cm (the center of the detector) of 12,000 μR/hr, the activity is:

  $A = 12{,}000/1200 = 10$ μCi

- The licensee collected the activity flushed from the contaminated shirt on kimwipes, which were kept inside a surgical gloves or gloves. The licensee was unsure if all the particle activity was collected. The activity in the kimwipes was measured in a NaI well counter and gave 2.5 μCi. The glove was also measured on contact with the TAN2000 and gave a reading of 4 mR/hr.

- Since 2.5 μCi gave a contact reading of 4 mR/hr, a reading of 12 mR/hr would correspond to an activity of:

  $A = 12/4 \times 2.5 = 7.5$ μCi

- The licensee used 7.5 μCi as their best estimate of the particle activity. They estimated that such a particle would give a field of 39 μR/hr at 1 foot and 156 μR/hr at 6". They stated that these levels were consistent with the alarming of the portal monitor.

In a subsequent submittal by the licensee on or about May 13, 1995, they provided further data and modified the estimate of 7.5 μCi as follows:

- The original measurement of the particles in the well counter were found to be faulty because of inconsistent geometry effects. A recount, taking these effects into account, gave a total activity of 11.32 μCi. Calculation of the field from such a point source at 2 cm (the center of the probe) gave a filed of 14 mR/hr. Since the particle survey gave 10-12 mR/hr, the licensee concluded that all the original particle activity had been captured on the kimwipes, and 11.32 μCi represents the entire particle activity. The licensee used this as the revised estimate of the particle activity.

NRC's Analysis

A review of the licensee's TAN2000 analysis revealed some weak points that are considered to invalidate the analysis:

- The initial survey result on the hot particle of 10-12 mR/hr must be considered as a qualitative, rather than a quantitative, measurement. This is because the calibration of the meter, which is performed in a field that uniformly irradiates the detector, is not valid when measuring a point source on contact with the detector. The exposure rate in this situation is therefore unknown.

- Use of the center of the detector as representative of the mean effect of a source on detector response is invalid because the change in response of the detector with changes in distance from the source is non-linear. This is due both to the inverse square effect with depth into the active volume of the detector, as well as effects such as wall effect, effective window area, etc., which also change non-linearly with distance from the source at close range. Therefore, calculation of an activity of 10 μCi on the basis of a reading of 12 mR/hr at the center of the detector is invalid.

- Since the probe used is a GM detector, it is subject to the same dead-time effects as those noted with the Ludlum system. the licensee did not indicate what the magnitude of this effect might be and how to correct for it.

- A point source of 11.35 μCi activity at the center of the portal monitor would give a field at the detector of about 50 μR/hr. This is not consistent with the licensee's estimate of the minimum field to trigger an alarm of 80-250 μR/hr.

- The licensee's conclusion that all the activity of the particle was retrieved on the kimwipes because the calculated exposure rate at the center of the detector is 14 mR/hr, which is close to 12 mR/hr, is unwarranted. The reason is that both the value of 12 mR/hr, as well as the calculated value of 14 mR/hr are invalid, the first because of an invalid calibration, and the second because of invalid assumptions in calculating the expected response of the detector.

Conclusions

Based on the above analyses, NRC concludes the following:

- The most reliable information for estimating the hot particle activity is that from the Ludlum 44-40 probe. The reasons for believing this is that use of this information involves the fewest assumptions.

- Use of the portal monitor must be viewed as qualitative and is only useful in verifying that the estimated activity is at least of the correct order of magnitude.

- Use of the TAN2000 is the less reliable source of information because of the large number of assumptions necessary. These assumptions include using the response at the detector center as representative of the overall detector response, assuming that the instrument readout in mR/hr is quantitatively meaningful when measuring a point source, assuming that dead-time effects were negligible (an implicit assumption since no dead-time considerations were included in the assessments), and assuming that the entire particle activity was retrieved. Some of the above assumptions are difficult to justify, and others are incorrect.

- Unless the Ludlum 44-40 system can be demonstrated to have been malfunctioning during counting of the hot particle, the minimum activity of the particle must be substantially above 30.5 μCi.

- If it is assumed that the fractional dead-time losses at 1,530,000 cpm are equal to that at 500,000 cpm, then the particle activity must be at least 90 μCi. NRC's estimate of 130 μCi is not far from that level, and it would be acceptable to use an estimate for the activity of about 100 μCi. Greater accuracy is not justified, due to the uncertainty in the determination of the particle activity.

- The licensee used a beta conversion factor of 3.45 rads/μCi-hr to convert activity to skin dose. The factor includes the attenuation of the beta radiation in the shirt material. NRC used a value of 2.50 rads/μCi-hr.

- A stay time of 2 hours was used by both the Licensee and NRC.

- Using an activity of 100 μCi, a conversion factor of 2.5 rads/μCi-hr, and 2 hours exposure time yields a beta skin dose of 500 rads.

- A further assumption that may reasonably be made is that the worker's shirt was not in contact with his skin (the worker had no tie on) but provided an air gap of about 3 mm between the skin and the particle. The revised skin beta dose would be 220 rads.

- At an activity of 100 μCi, the gamma skin dose was estimated to be approximately 10 rads, leading to a total skin dose of approximately 230 rads.

- The licensee's estimates were 11.35 μCi for the particle activity, with a total skin dose of 74 rems.

NRC believes that the most reliable estimate of the skin dose, given the available information, is approximately 230 rads. This is not viewed as a conservative estimate, because no conservative assumptions were made, but is regarded as the best estimate permitted by the data.

ENFORCEMENT CONFERENCE PRESENTATION

TO THE

NUCLEAR REGULATORY COMMISSION

BY AMERSHAM CORPORATION

MAY 15, 1995

Enclosure (2)

IE 07

RETURN ORIGINAL TO
REGION I

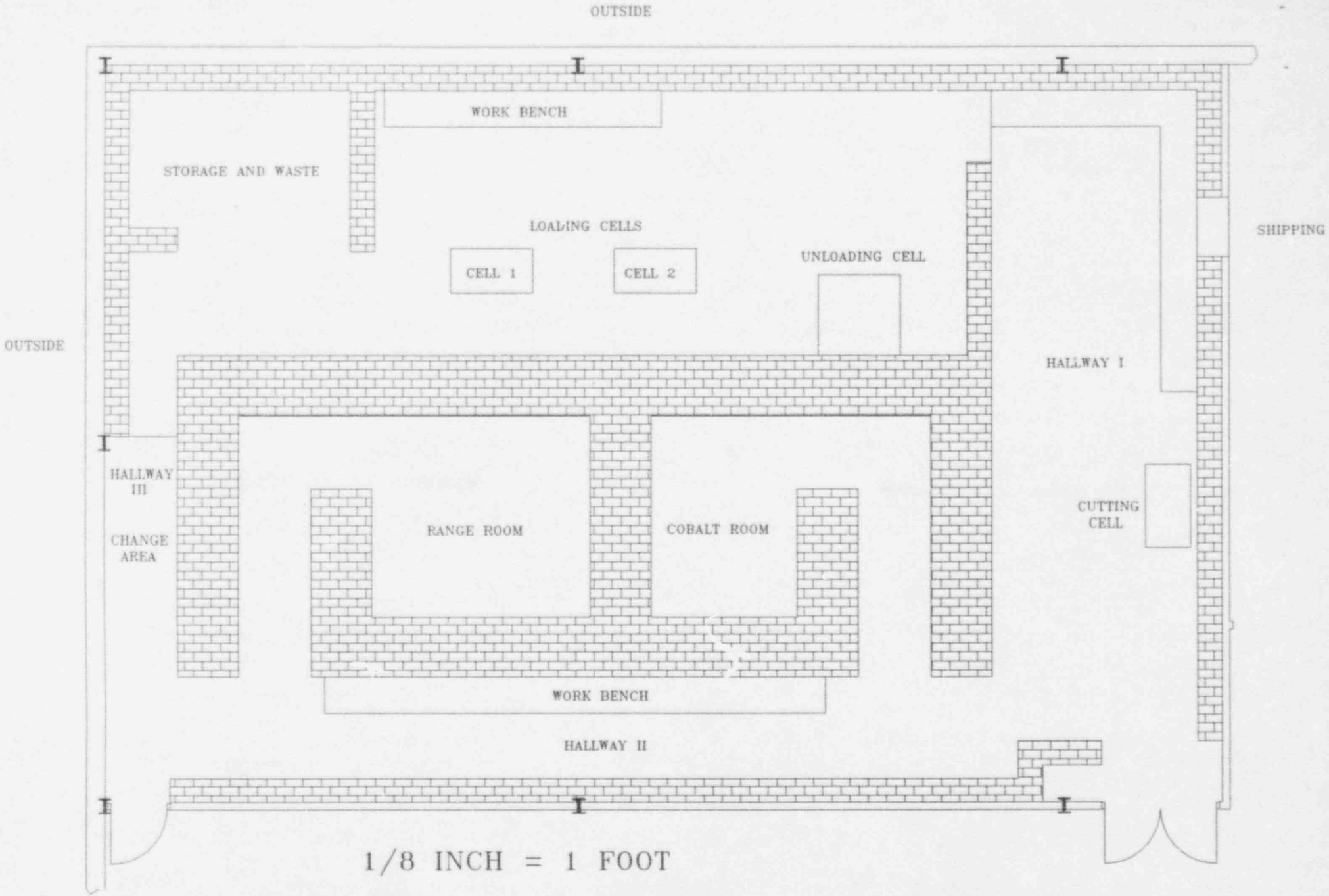
AGENDA

I.	INTRODUCTION	W. McDANIEL
II.	OVERVIEW OF OPERATIONS	C. ROUGHAN
	A. SLIDE PRESENTATION	
	B. DISCUSSION OF NRC's PROGRAMMATIC CONCERNS	
III.	DISCUSSION OF TWO APPARENT VIOLATIONS	
	A. FAILURE TO SURVEY ISSUE	C. ROUGHAN
	B. OVEREXPOSURE EVENTS	L. PODOLAK
IV.	HISTORICAL CORRECTIVE ACTIONS & CAL STATUS UPDATE	W. McDANIEL
V.	CLOSING REMARKS AND OVERALL CONCLUSIONS	W. McDANIEL

SLIDE PRESENTATION

- 35 mm SLIDES PROVIDED OVERVIEW OF LOADING AND UNLOADING OPERATIONS

- 35 mm SLIDES PROVIDED OVERVIEW OF STANDARD HEALTH PHYSICS CONTROLS IN PLACE BETWEEN 1991 TO DATE, INCLUDING CERTAIN RECENT ENHANCEMENTS


OUTSIDE
WORK BENCH
STORAGE AND WASTE
LOADING CELLS
CELL 1
CELL 2
UNLOADING CELL
SHIPPING
OUTSIDE
HALLWAY I
HALLWAY III
CHANGE AREA
RANGE ROOM
COBALT ROOM
CUTTING CELL
WORK BENCH
HALLWAY II
1/8 INCH = 1 FOOT

DISCUSSION OF NRC's APPARENT CONCERN

NRC APPARENT CONCERN:

FIVE SPECIFIC ISSUES NOTED IN INSPECTION REPORT SUGGEST PROGRAMMATIC WEAKNESSES IN LICENSEE's HOT PARTICLE CONTROLS:

- SOURCE OF HOT PARTICLES MAINLY ATTRIBUTED TO CERTAIN SUPPLIERS
- CONTAMINATION IN UNLOADING CELL HAS REACHED A SIGNIFICANT LEVEL
- LIKELY ROOT CAUSE OF HOT PARTICLE EXPOSURES DUE TO THE LICENSEE's FORMER POLICY OF REUSING PROTECTIVE CLOTHING
- NO FORMAL TRAINING ON USE OF PROTECTIVE CLOTHING
- FRISK-OUT PROCEDURES AND PORTAL MONITOR DO NOT APPEAR TO ASSURE A COMPREHENSIVE MEANS TO IDENTIFY HOT PARTICLES

AMERSHAM POSITION:

ALTHOUGH CERTAIN AREAS CAN AND HAVE BEEN ENHANCED, A REVIEW OF THE ENTIRE CONTAMINATION CONTROL PROGRAM DOES NOT INDICATE A PROGRAMMATIC BREAKDOWN

EVALUATION OF AMERSHAM's CONTAMINATION CONTROL PROGRAM

ADEQUATE PROGRAM ESTABLISHED AND MAINTAINED

- KEY PROCEDURES IN PLACE
  - ROUTINE REQUIREMENTS:
    HEALTH PHYSICS SURVEYS
    CONTAMINATION CONTROL
  - CONTAMINATION OCCURRENCE REPORTING
  - RADIATION SAFETY MANUAL REQUIREMENTS
- TRAINING CONDUCTED AND DOCUMENTED
  - INITIAL AND ONGOING
- MONITORING AND TRENDING ROUTINELY PERFORMED
  - DAILY SURVEYS
  - MONTHLY SURVEYS/AUDITS
  - RPGSC REVIEWS
  - ANNUAL REVIEW

INDEPENDENT ASSESSMENTS
DEMONSTRATE ADEQUATE PROGRAM

- AMERSHAM INTERNATIONAL AUDIT IN 1994
- INSURANCE AUDIT (HEALTH PHYSICS) IN 1993
- INTERNAL ANNUAL REVIEW

CONCLUSION

- AMERSHAM HAS AN APPROPRIATE CONTAMINATION CONTROL PROGRAM IN PLACE

RETROSPECTIVE ANALYSIS OF HOT PARTICLE EXPOSURE EVENTS

- IN 1991 AMERSHAM HAD A CONTAMINATION EVENT WHICH WAS EVALUATED AGAINST THE NCRP GUIDANCE TO ESTABLISH OVERALL SAFETY SIGNIFICANCE

- IN 1992 AMERSHAM, LIKE INDUSTRY IN GENERAL, WAS GAINING A MORE DETAILED UNDERSTANDING OF HOT PARTICLES -- THUS, DOCUMENTATION LIMITED

- IN 1992, AMERSHAM BEGAN TO INCREASE ITS SCRUTINY AND DOCUMENTATION OF HOT PARTICLE EVENTS

- IN 1993, THERE WERE MORE CONTAMINATION EVENTS REPORTED, WE ALSO SAW AN INCREASE IN THE UNLOADING CELL CONTAMINATION

- DUE TO THIS INCREASE, AMERSHAM INITIATED A NUMBER OF KEY INITIATIVES IN 1993 TO ADDRESS THE CONTAMINATION PROBLEM THROUGH ITS PROCESS EVALUATION FORMS

  - WAFER CLEANING SYSTEM
  - RECONFIGURATION OF CONTAMINATION CONTROL AREA
  - UNLOADING CELL DECONTAMINATION

- IN 1994 THERE CONTINUED TO BE AN INCREASE IN EVENTS AND THESE ARE DUE IN PART TO SEVERAL FACTORS: AN INCREASE IN THE AMOUNT OF HANDLING IN THE UNLOADING CELL, INCREASED CONTAMINATION LEVELS IN THE UNLOADING CELL AND USE OF DIFFERENT SUPPLIERS

- 1995 WILL PROBABLY HAVE SIMILAR NUMBER AS 1994, BUT WITH THE DECONTAMINATION OF THE UNLOADING CELL IN 1995, AND OTHER CONTAMINATION CONTROL INITIATIVES WE ANTICIPATE A DECREASE IN 1996

SUMMARY OF HOT PARTICLE CONTROL PROGRAM

- IN HINDSIGHT, AMERSHAM ACKNOWLEDGES CERTAIN ASPECTS THAT COULD HAVE BEEN MORE EFFECTIVELY ADDRESSED IN ASSESSING HOT PARTICLE EXPOSURE SITUATIONS

- HOWEVER, WHEN ALL ASPECTS OF AMERSHAM's CONTAMINATION CONTROL PROGRAM ARE CONSIDERED, THERE IS NO INDICATION OF A PROGRAMMATIC BREAKDOWN

- AS SHOWN IN SUBSEQUENT SLIDES, THIS OVERALL CONCLUSION IS FURTHER SUPPORTED BY THE TREND RESULTS

  - ALL HOT PARTICLE DOSES BUT ONE ARE BELOW THE RELEVANT CRITERION ESTABLISHED IN NRC REGULATORY GUIDANCE

  - TREND DATA FOR ROUTINE SURVEYS OF OPERATIONS PERFORMED IN THE RADIOISOTOPE LABORATORY DO NOT SHOW UNACCEPTABLE CONTAMINATION I.EVELS

DISCUSSION OF APPARENT VIOLATIONS

FAILURE TO SURVEY ISSUE

RESTATEMENT OF NRC POSITION

"FAILURE TO PERFORM AN ADEQUATE ASSESSMENT OF RADIOLOGICAL CONDITIONS TO MINIMIZE HOT PARTICLE INCIDENTS AND FAILURE TO ACCOUNT FOR RESOLVING TIME LOSSES"

AMERSHAM's POSITIONS

- AMERSHAM PERFORMED ASSESSMENTS CONSISTENT WITH ALARA AND ADEQUATE TO ENSURE OCCUPATIONAL EXPOSURES WERE MAINTAINED WITHIN REQUIREMENTS OF THE NRC INFORMATION NOTICE 90-48

- CERTAIN PAST HOT PARTICLE ASSESSMENTS DID NOT ACCOUNT FOR RESOLVING TIME - HOWEVER, DOSE REASSESSMENTS PERFORMED ACCOUNTING FOR RESOLVING TIME DID NOT HAVE AN EFFECT ON WHETHER WE WERE IN COMPLIANCE WITH APPLICABLE LIMITS FROM IN-90-48

- AMERSHAM ACKNOWLEDGES THAT A FEW OF THESE PAST EVENTS SHOULD HAVE BEEN REPORTED - EVEN THOUGH THE EXPOSURES WERE OF MINIMAL SAFETY SIGNIFICANCE

"MINIMIZE HOT PARTICLE INCIDENTS" DISCUSSION

APPLICABLE NRC REGULATIONS
COVERING HOT PARTICLE EXPOSURES

- 10 CFR 20.1201(a)
  OCCUPATIONAL EXPOSURE

- 10 CFR 20.1101(b)
  ALARA REQUIREMENT

- NRC INFORMATION NOTICE 90-48
  ENFORCEMENT POLICY FOR HOT PARTICLE EXPOSURES

AMERSHAM's PROGRAM
SATISFIES REGULATIONS AND GUIDANCE

- ADEQUATE CONTAMINATION CONTROL PROGRAM
  - ROUTINE SURVEYS
  - TRAINING
  - MONTHLY AUDITS
  - INDEPENDENT AUDITS

- HISTORICAL DATA RESULTS
  - DATA FROM ROUTINE SURVEYS SHOW MINIMAL CONTAMINATION
  - PRIOR CONTAMINATION EVENTS SIGNIFICANTLY BELOW APPLICABLE LIMITS
  - DID NOT DEMONSTRATE THE NEED FOR ADDITIONAL MONITORING
  - NO CONTAMINATION IN UNRESTRICTED AREAS
  - REVIEW OF PAST CONTAMINATION EVENTS DID NOT SHOW THAT REUSE OF PROTECTIVE CLOTHING CONTRIBUTED TO THE CONTAMINATION EVENT

ROUTINE SURVEY DATA

PERCENT OF DAILY WIPES ABOVE INTERNAL ACTION LEVEL FOR EACH OPERATION:

YEAR	LOADING	UNLOADING
1992	0	0.2
1993	0.4	1.3
1994	0.2	1.3
1995	0.3	1.3

PERCENT OF MONTHLY SURVEY WIPES IN RESTRICTED AREA ABOVE INTERNAL ACTION LIMIT:

YEAR	MONTHLY SURVEY
1992	1.5
1993	0.5
1994	0.7
1995	0.7

PERCENT OF MONTHLY SURVEY WIPES IN UNRESTRICTED AREAS ABOVE INTERNAL ACTION LIMIT OVER 1992-1995:

0%

"MINIMIZE HOT PARTICLE INCIDENTS"
SUMMARY

- AMERSHAM's RETROSPECTIVE ANALYSIS OF THE HOT PARTICLE EVENTS BETWEEN 1991 - 1995 SHOW THAT ALL BUT ONE OF THE EXPOSURES WERE BELOW THE LIMITS SET FORTH IN THE NRC ENFORCEMENT POLICY - THUS, ASSESSMENT APPROACH ADEQUATE

- NEVERTHELESS, AMERSHAM HAS MADE RECENT ENHANCEMENTS TO PROVIDE AN EVEN GREATER MARGIN OF SAFETY

  - TWO PERSON FRISKING
  - FRISKING OF PROTECTIVE CLOTHING
  - INCREASED FREQUENCY OF FRISKING WHEN WORKING IN CONTAMINATION CONTROL AREA

- IN ADDITION, THROUGH OUR RETROSPECTIVE DOSE ASSESSMENT, WE HAVE DETERMINED THAT THE SEVEN INSTANCES WHERE THE NRC ENFORCEMENT EMISSION CRITERIA WAS NOT EXCEEDED SHOULD HAVE BEEN REPORTED UNDER THE REQUIREMENTS OF 10 CFR 20.

"RESOLVING TIME" DISCUSSION

- AMERSHAM DID NOT ACCOUNT FOR RESOLVING TIME ISSUE WHEN CALCULATING SKIN DOSE FOR CERTAIN HOT PARTICLE EXPOSURE EVENTS - HOWEVER THIS HAS NO SIGNIFICANT EFFECT ON WHETHER WE WERE IN COMPLIANCE WITH APPLICABLE LIMITS

- IN ALL CASES, AMERSHAM APPLIED THE MOST CONSERVATIVE ASSUMPTIONS IN THE CALCULATIONS - RESULTING IN OVERESTIMATES OF DOSES

- DOSE REASSESSMENTS SHOWED EXPOSURES BELOW THE NRC CRITERION SET FORTH IN THE ENFORCEMENT POLICY (EXCEPT FOR THE ONE OCCURRENCE REPORTED)

- ENHANCEMENTS OF CALCULATIONAL METHODS

  - RESOLVING TIME LOSSES DETERMINED FOR ALL APPLICABLE MEASURING INSTRUMENTATION.

    (I) EXPERIMENTAL TECHNIQUES

    (ii) VALIDATION WITH MANUFACTURERS

  - DETERMINED ALTERNATIVE METHODS TO COUNT HIGH COUNT RATE PARTICLES, MINIMIZING RESOLVING TIME LOSSES

  - DOSE CALCULATIONS ALL INCLUDE RESOLVING TIME LOSSES

SUMMARY OF FAILURE TO SURVEY

- ADEQUATE ASSESSMENTS WERE PERFORMED
- MINIMAL SAFETY SIGNIFICANCE
- ENHANCEMENTS MADE TO SURVEY PROCEDURES AND DOSE CALCULATIONS
- SEVERAL HOT PARTICLE EVENTS SHOULD HAVE BEEN REPORTED AND THESE WILL BE PROVIDED WITH THE RESPONSE TO THE CAL

DISCUSSION OF OVEREXPOSURE EVENTS

1994 OVEREXPOSURE EVENT

- NRC POSITION: ANNUAL SKIN DOSE TO WORKER EXCEEDED 50 REMS SPECIFIED IN 10 CFR 20.1201(a)(2)(ii)

- HOT PARTICLE IDENTIFIED ON WORKER's SKIN -- APPROPRIATE STANDARD BASED ON IN-90-48 IS 75 uCi-Hr PARTICLE EMISSION

- INITIAL uCi-hr ESTIMATED AT 3 uCi-Hr, WITH ASSOCIATED DOSE OF 21 RAD

- INITIAL ESTIMATE DID NOT TAKE INTO ACCOUNT:

  - MOST CONSERVATIVE ESTIMATE OF ACTIVITY (BASED ON SUBSEQUENT ANALYSIS OF GENERAL HP POPULATION, WORST CASE ACTIVITY FOR A SINGLE PARTICLE EQUALS 7 uCi)

  - RESOLVING TIME LOSSES OF DETECTOR

- DOSE REASSESSMENT, WHICH INCLUDED ABOVE CONSIDERATIONS ESTIMATED EMISSION AT 28 uCi-Hr, WITH ASSOCIATED WORST CASE DOSE OF 180 RAD

- SUMMARY:

  - REVISED DOSE EXCEEDED ANNUAL SKIN DOSE (i.e., 50 REMS), BUT DID NOT EXCEED THE APPLICABLE SKIN DOSE CRITERION OF 75 uCi-Hr SET FORTH IN NRC's ENFORCEMENT POLICY

  - AMERSHAM ACKNOWLEDGES THIS EVENT SHOULD HAVE BEEN REPORTED

DISCUSSION OF OVEREXPOSURE EVENTS (cont'd)

1995 OVEREXPOSURE EVENT

- NRC POSITION: ANNUAL SKIN DOSE TO WORKER EXCEEDED 50 REMS SPECIFIED IN 10 CFR 20.1201(a)(2)(ii)
- HOT PARTICLE IDENTIFIED ON WORKER's CLOTHING
- INITIAL DOSE ESTIMATED AT 145 RADS
- INITIAL DOSE ESTIMATE DID NOT TAKE INTO ACCOUNT:
  - RESOLVING TIME LOSSES OF DETECTION INSTRUMENTATION
  - REDUCTION IN DOSE RATE DUE TO PARTICLE OFF SKIN, ASSUMED WORST CASE - ON SKIN
  - VARIANCE IN BETA ATTENUATION THROUGH SHIRT
- INITIAL DOSE REASSESSMENT, WHICH INCLUDED ABOVE PARAMETERS ESTIMATED DOSE AT 51.75 RADS. THIS VALUE THEN INCREASED TO 73.7 RAD DUE TO ACTIVITY REASSESSMENT ACCOUNTING FOR DETECTOR GEOMETRY VARIANCES
- SUMMARY:
  - REVISED DOSE EXCEEDED ANNUAL SKIN DOSE (i.e., 50 REMS), BUT DID NOT EXCEED 3 TIMES THE APPLICABLE SKIN DOSE CRITERION SET FORTH IN NRC's ENFORCEMENT POLICY. THIS EVENT WAS REPORTED AS REQUIRED BY 10 CFR 20

HISTORICAL CORRECTIVE ACTIONS

○ CHRONOLOGY

- APRIL 1993
  - WAFER CLEANING SYSTEM INSTALLED
- MAY 1993
  - RECONFIGURE CONTAMINATION CONTROL AREA
  - RECONFIGURE VENTILATION (TO SPECIFICALLY DIRECT AIR FLOW)
  - PORTAL MONITOR INSTALLED
  - PEF INITIATED FOR UNLOADING CELL ACTIONS
- APRIL 1994
  - HIGHER RANGE METERS IN LOADING CELLS
- SEPTEMBER 1994
  - REVIEW BY VENTILATION CONSULTANTS
- OCTOBER 1994
  - HOT PARTICLE DOSE ASSESSMENT PROCEDURE INITIATED

HISTORICAL CORRECTIVE ACTIONS (Cont.)

- NOVEMBER 1994

  - VENTILATION REVIEW PERFORMED:
    - ENHANCED FILTRATION
    - REBALANCE AIR FLOW
    - BLOWER SYSTEM

- DECEMBER 1994

  - WASTE CONSOLIDATION FROM UNLOADING CELL

- JANUARY 1995

  - VENTILATION CONSULTANTS PROVIDE QUOTE.
    - ENGINEERING PLANS IN PROCESS

  -NEW WAFER CLEANING SYSTEM DESIGNED. CURRENTLY IN DEVELOPMENT AND TESTING STAGE

  -TGR (Tooling and Gauge Review) SYSTEM IN PLACE

- FEBRUARY 1995

  - AMERSHAM TECHNICIAN TRAINED IN MANIPULATOR MAINTENANCE

  - NEW BOOT ORDERED

- A NUMBER OF OTHER ENHANCEMENTS ARE ALSO IN PROCESS

CAL STATUS

- FRISKING OUT PROCEDURE ALREADY IN PLACE, REVISED PROCEDURE FOR SECOND TECHNICIAN TO MONITOR INACCESSIBLE AREAS OF BODY IN PLACE 7 APR 95, SENT TO NRC 2 MAY 1995.

- FRISKING OUT PROTECTIVE CLOTHING PRIOR TO REUSE, IMPLEMENTED 5 APR 95.

  • PROCEDURE REVISED TO INCLUDE THESE REQUIREMENTS 7 APR 95.

- EMPLOYEES HAD PREVIOUSLY RECEIVED INITIAL TRAINING FOR WORKING IN CONTAMINATION CONTROL AREA.

  • FORMAL RETRAINING IN REVISED PROCEDURE 7 APR 95.

- ACTION PLAN FOR DECONTAMINATION OF UNLOADING CELL TO BE SUBMITTED BY 1 JUN 95.

  • MANY OTHER RELATED ACTIONS AS WE DESCRIBED EARLIER ARE IN PROGRESS.

- DOSE REASSESSMENT FOR 24 MAR 95 EVENT SUBMITTED TO NRC 12 APR 95.

  • ALL OTHER DOSE REASSESSMENTS TO BE SUBMITTED BY 1 JUN 95.

  • THESE WILL CONSIDER RESOLVING TIME LOSSES FOR INSTRUMENT AND ANY OTHER ADJUSTMENTS FOR ACCURACY.

CLOSING

○ NRC APPARENT CONCERNS ADDRESSED:

- AMERSHAM AGREES THAT SOME INCREASE IN HOT PARTICLES MAY BE CONNECTED TO UNLOADING CELL OPERATIONS. HOWEVER, IT IS MORE COMPLEX THAN DUE TO CERTAIN SUPPLIERS.

- AMERSHAM HAS BEEN AND WILL CONTINUE TO PURSUE CONTAMINATION CONTROL INITIATIVES TO ENSURE LEVELS IN CONTAMINATION CONTROL AREAS AND THE UNLOADING CELL ARE MAINTAINED AS LOW AS REASONABLY ACHIEVABLE CONSIDERING THE SAFETY SIGNIFICANCE OF ALL RELATED PERSONNEL EXPOSURES.

- REUSE OF PROTECTIVE CLOTHING DOES NOT APPEAR TO BE A MAJOR MECHANISM FOR CAUSING HOT PARTICLE EXPOSURES. REGARDLESS, INCREASED SURVEYS OF PROTECTIVE CLOTHING IS EXPECTED TO REDUCE THE POTENTIAL FOR CROSS CONTAMINATION.

- AMERSHAM HAS MAINTAINED AN ADEQUATE TRAINING PROGRAM FOR PERSONNEL ACCESSING THE CONTAMINATION CONTROL AREA.

- AMERSHAM ACKNOWLEDGES THAT ENHANCEMENTS IN IT'S HOT PARTICLE ASSESSMENTS MAY HAVE IDENTIFIED OTHER EVENTS. HOWEVER, RETROSPECTIVE ANALYSIS DEMONSTRATES OUR ASSESSMENT APPROACH WAS ADEQUATE TO ENSURE COMPLIANCE WITH THE APPLICABLE INFORMATION NOTICE 90-48 CRITERIA.

OVERALL CONCLUSIONS

- AMERSHAM HAS ALWAYS MAINTAINED AN ADEQUATE AND CONTINUOUSLY IMPROVING CONTAMINATION CONTROL PROGRAM

  • AMERSHAM HAS TAKEN PROMPT STEPS TO IMPROVE ITS PROGRAM

  • AMERSHAM WAS IN THE PROCESS OF SYSTEMATICALLY UPGRADING ITS CONTAMINATION CONTROL PROGRAM AND FACILITIES

- WHILE SEVERAL HOT PARTICLE EVENTS HAVE OCCURRED, THEY ARE OF MINIMAL SAFETY SIGNIFICANCE

  • AMERSHAM AGREES THAT MORE COMPREHENSIVE SURVEYS MAY HAVE IDENTIFIED OTHER HOT PARTICLE CONTAMINATION EVENTS.

    - HOWEVER, OUR RETROSPECTIVE ANALYSIS INDICATES THESE TOO WOULD HAVE RESULTED IN EXPOSURES OF MINIMAL SAFETY SIGNIFICANCE

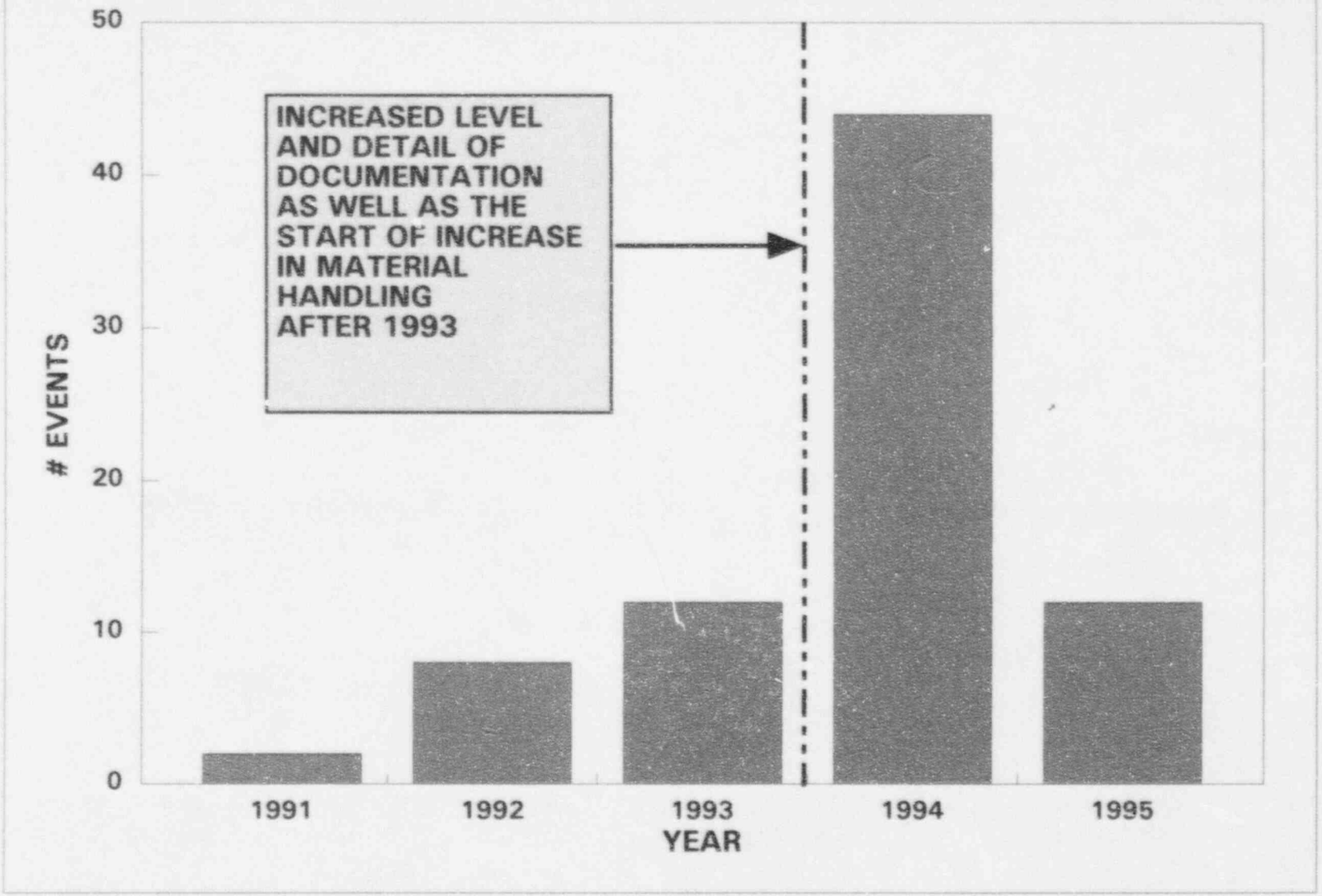
  • UNDER NRC's ENFORCEMENT POLICY, THE HOT PARTICLE EVENTS DO NOT WARRANT ESCALATED ENFORCEMENT ACTION

- AMERSHAM's CONTAMINATION CONTROL ACTIVITIES HAS BEEN IN COMPLIANCE WITH APPLICABLE GUIDANCE IN THE NRC ENFORCEMENT POLICY

  • THEREFORE, NO PROGRAMMATIC BREAKDOWN IN AMERSHAM's CONTAMINATION CONTROL PROGRAM EXISTS

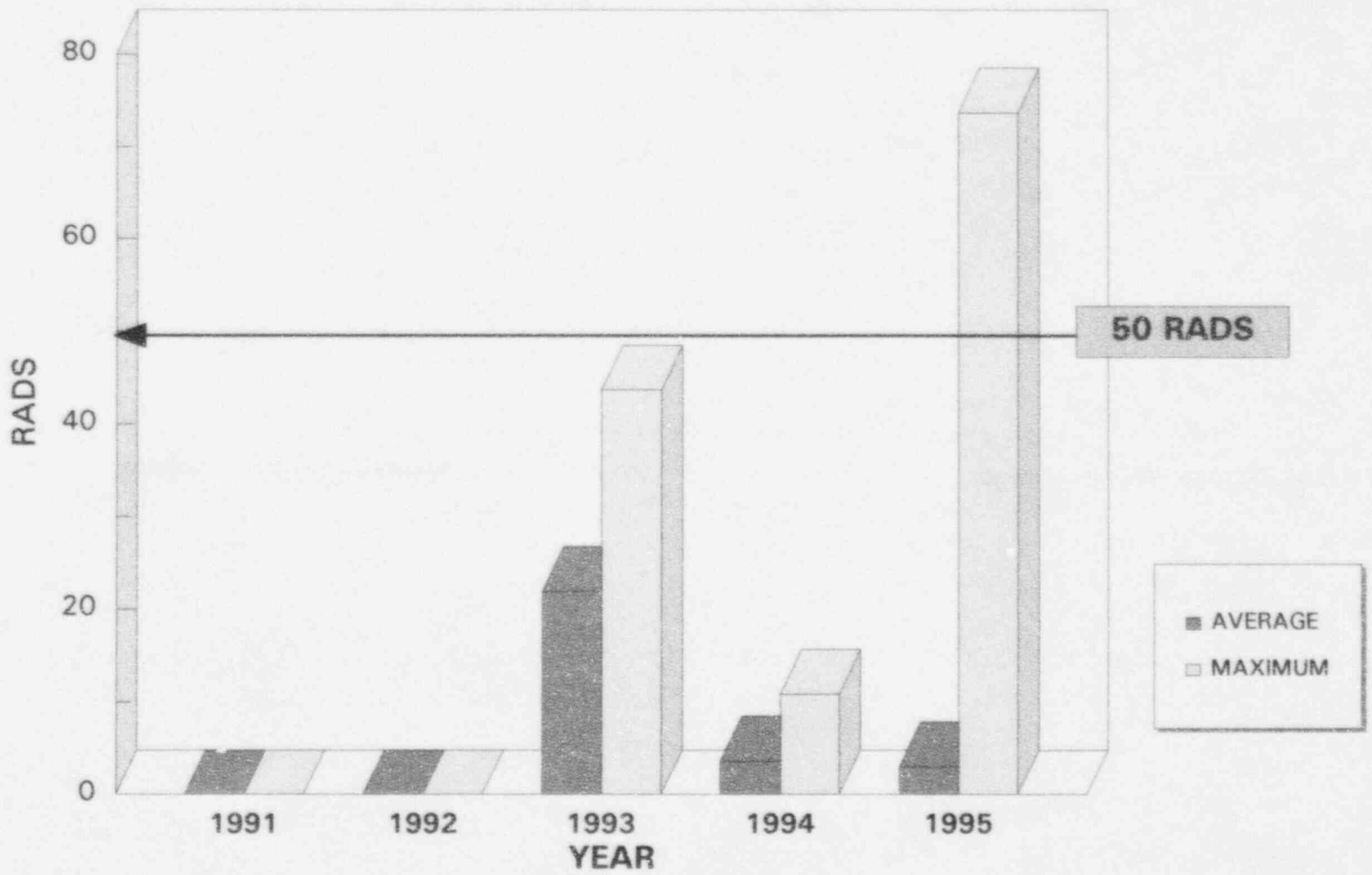
- OVERALL CONCLUSION: ESCALATED ENFORCEMENT IS NOT WARRANTED

OF DOCUMENTED CONTAMINATION EVENTS PER YEAR (1991 - 24 MAR 95)



HPSTAT.WK4

AVERAGE & MAXIMUM SKIN DOSE BY YEAR FOR HOT PARTICLES NOT ON THE SKIN



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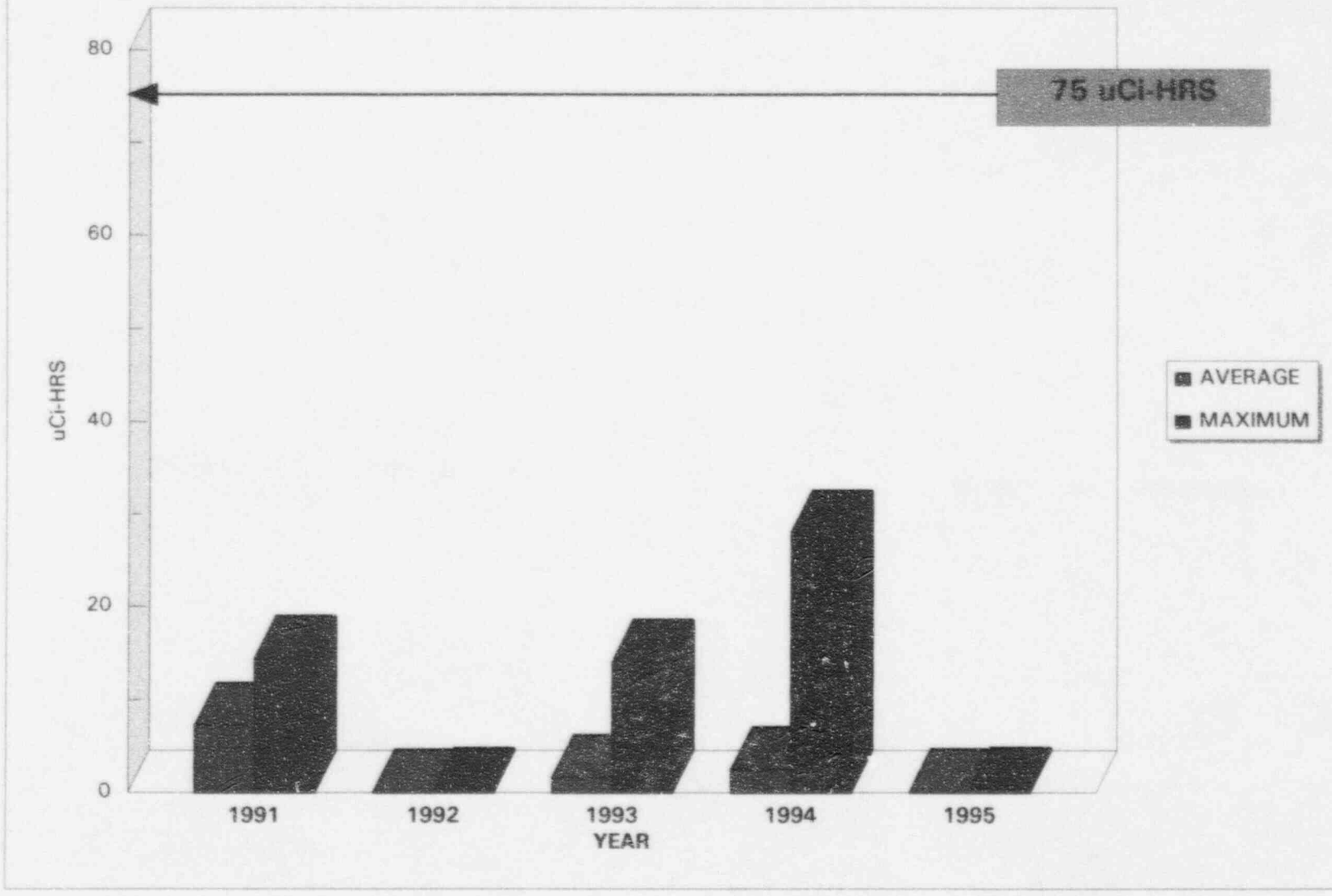
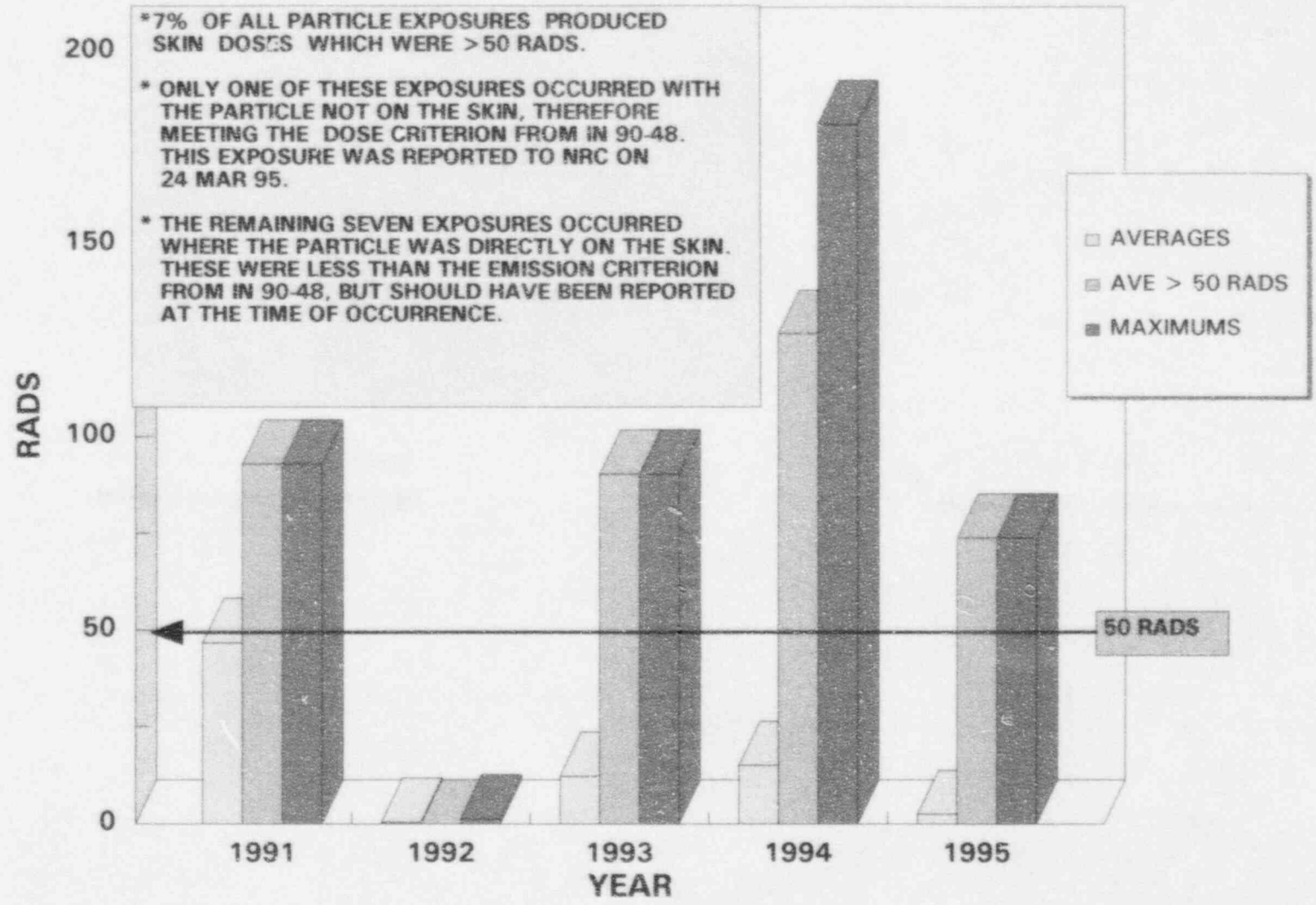
AVERAGE & MAXIMUM uCi-HRS BY YEAR FOR HOT PARTICLES ON THE SKIN



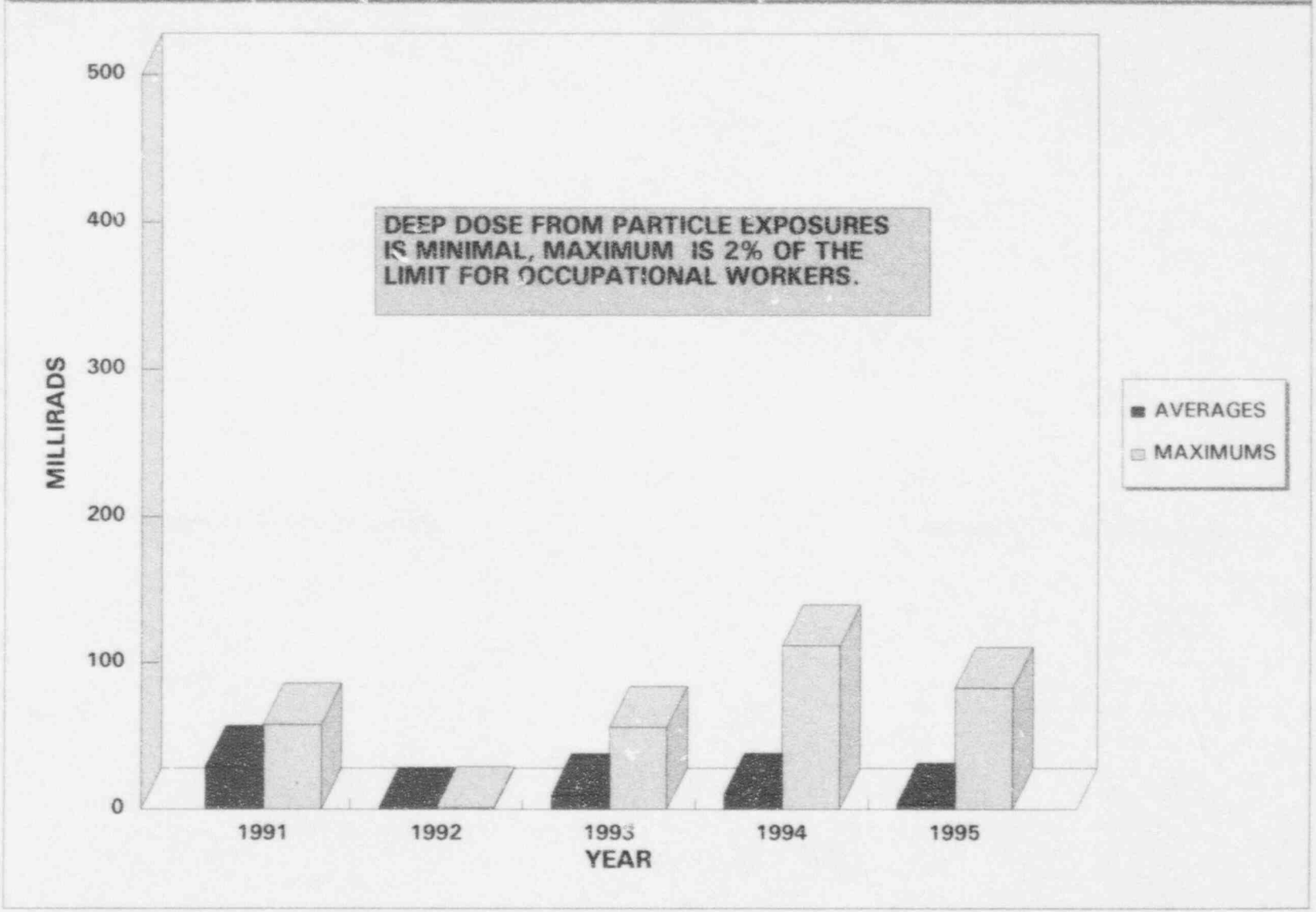
HPSTAT.WK4

AVERAGE & MAXIMUM SKIN DOSE IN RADS FROM 1991 - 1995



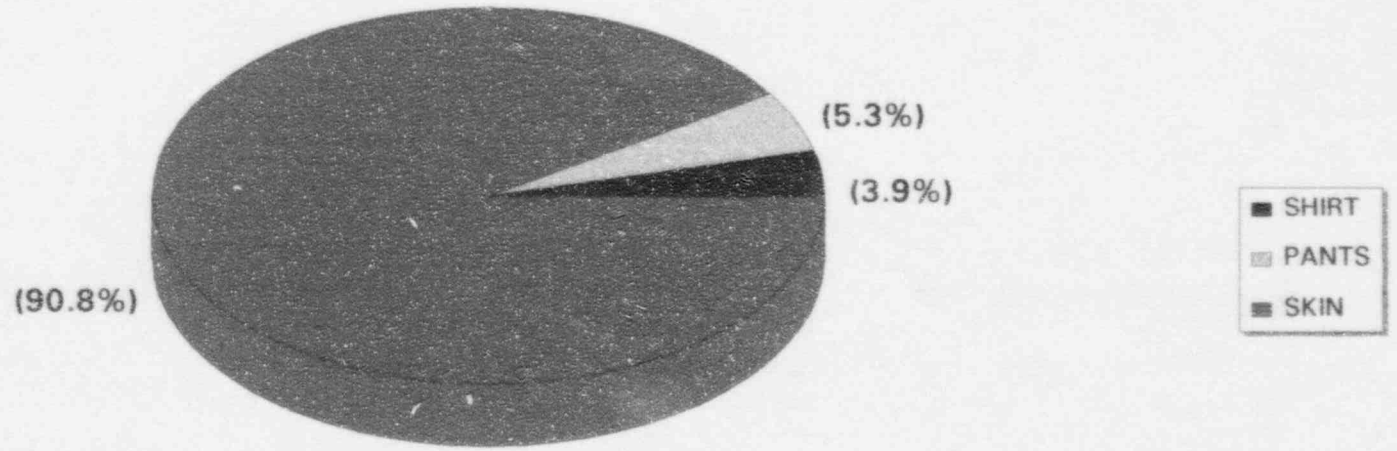
HPSTAT.WK4

AVERAGE & MAXIMUM WHOLE BODY DOSE IN MILLIRADS FOR EACH YEAR



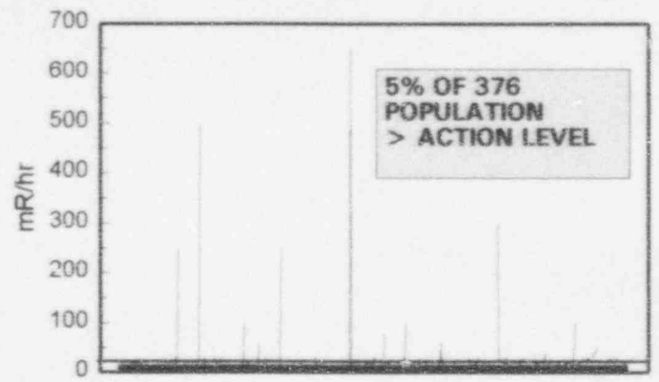
HPSTAT.WK4

HOT PARTICLE LOCATION
PRIOR TO 24 MAR 95



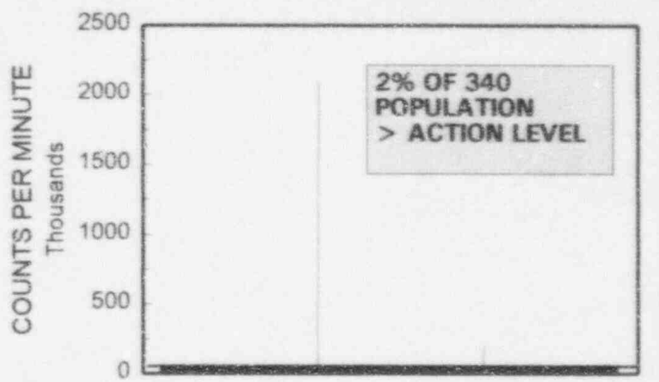
PRELOCAL.WK4

LOADING CELL #2 START OF DAY BACKGROUND READINGS IN mR/hr



ACTION LEVEL OF 30 mR/hr INDICATES LEVEL FOR CELL DECONTAMINATION PRIOR TO ADDITIONAL SOURCE LOADING OPERATIONS.

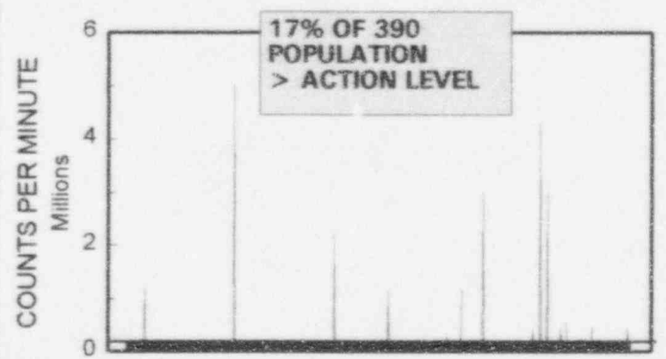
END OF DAY STEP OFF STICKY MAT READINGS IN COUNTS PER MINUTE



ACTION LEVEL OF 10,000 COUNTS PER MINUTE INDICATES UNUSUAL CONTAMINATION LEVELS AND INITIATES COMPARISON WITH OTHER CONTAMINATION CONTROL INDICATORS.

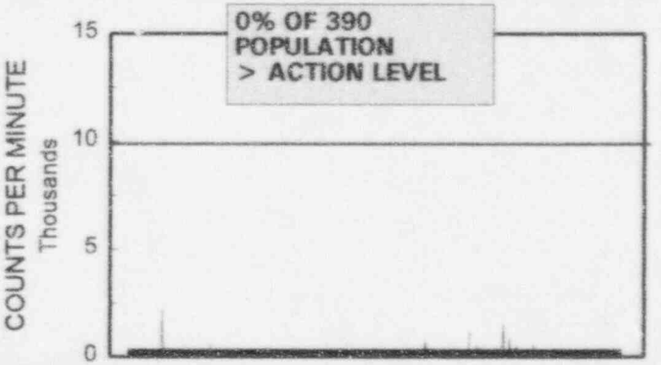
DATA FROM 01 JAN 94 THROUGH 30 APR 95

END OF DAY CONTROL AREA MASSLINS READINGS IN COUNTS PER MINUTE



ACTION LEVEL OF 10,000 COUNTS PER MINUTE INDICATES UNUSUAL CONTAMINATION LEVELS AND INITIATES COMPARISON WITH OTHER CONTAMINATION CONTROL INDICATORS.

END OF DAY LAB DOOR STICKY MAT READINGS IN COUNTS PER MINUTE



ACTION LEVEL OF 10,000 COUNTS PER MINUTE INDICATES UNUSUAL CONTAMINATION LEVELS AND INITIATES COMPARISON WITH OTHER CONTAMINATION CONTROL INDICATORS.