


Sandy Perle

Radiation Litigation: an Expert Witness' Perspective

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MIRION TECHNOLOGIES Dosimetry Services Division

Contact Information

Sandy Perle
Mirion Technologies, Dosimetry Services Division
2652 McGaw Avenue
Irvine, CA 92614
sperle@mirion.com
(949) 419-1000

Agenda

- NVLAP and External Dosimetry
- NVLAP Fields of Accreditation
- NVLAP Regulatory Issues and Limitations on Wear Period
- Extremity Monitoring Considerations
- Effective Dose Equivalent Methodologies
- Performing Dose Investigations
- Records Quality Management
- Dosimeter Characteristics
- Film Energy Response Curves and Images, TLD Glow Curves, TLD Anomalies – Tools for Investigations

NVLAP

- The National Institute of Standards and Technology (NIST) administers NVLAP.
- NVLAP accredits public and private laboratories based on evaluation of their technical qualifications and competence to carry out specific calibrations or tests
- Accreditation criteria are established in accordance with the U.S. Code of Federal Regulations (CFR, Title 15, Part 285), NVLAP Procedures and General Requirements, and encompass the requirements of ISO/IEC 17025 and the relevant requirements of ISO 9002. Accreditation is granted following successful resolution of any deficiencies identified during the on-site assessment, participation in proficiency testing, and technical evaluation. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation

NVLAP

- NVLAP provides an unbiased third-party evaluation and recognition of performance, as well as expert technical guidance to upgrade laboratory performance. An On-Site Assessment is required every two years.

- NVLAP accreditation does not imply any guarantee (certification) of laboratory performance or test/calibration data; it is solely a finding of laboratory competence

- Calibration Laboratories
  - Ionizing Radiation

- Dosimetry
  - Ionizing Radiation Dosimetry

NVLAP Accreditation Requirements

- Successful On-Site Assessment
  - Requirements outlined in NIST Handbook 150 (2006), NVLAP Procedures and General Requirements
  - NIST Handbook 150-4 (2005), NVLAP Ionizing Radiation Dosimetry

- Successful Performance
  - ANSI N13.11-2009 (in process of ANSI approval), American National Standard for Dosimetry Personnel Dosimetry Performance

    Criteria for Testing
  - ANSI N13.32-2008 (recently published HPS Standards Committee website for download), American National Standard

    Performance Testing of Extremity Dosimeters

NVLAP On-Site Assessment

- Quality Systems
- Personnel, Training & Competency Qualifications
- Accommodation and environment
- Test and calibration methods
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Test and calibration reports.

Regulatory Requirements and NVLAP

CFR, Title 10, Part 20

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment

Individual monitoring devices (*individual monitoring equipment*) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and person (“lapel”) air sampling devices

Regulatory Requirements

What must be recorded and reported – CFR, Title 10, Part 20

Deep dose equivalent (Hd) applies to the external whole-body exposure, is the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2)

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2)

Shallow-dose equivalent (Hs) applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

How is NVLAP Required

Subpart F—Surveys and Monitoring

§ 20.1501 General.

(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

[56 FR 23398, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

Notifications and reports to individuals

§ 19.13 Notifications and reports to individuals.

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the statement:

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference.

Limitations on Wear Period

- The issue of how long a dosimeter may be worn is both an issue of technical acceptability and regulatory policy. Although the NVLAP is not "voluntary" for ionizing dosimeter testing laboratories providing services to satisfy Nuclear Regulatory Commission (NRC) requirements in 10 CFR 20, NVLAP is not a regulatory agency. It does, however, establish technical acceptability of dosimeter processing through its proficiency testing and on-site assessment programs.

- NRC specifies the exchange frequency for personnel dosimeters processed by an accredited NVLAP processor only in cases where high doses are more likely to occur (irradiators, well loggers, and radiographers). That exchange rate is 1 month for film badges and 3 months for TLDs and other dosimeters. NRC does not specify the dosimeter exchange frequency for other types of licensees. State regulations should be consulted for the monitoring requirements pertaining to x-ray equipment or accelerators and to naturally-occurring or accelerator-produced radioactive materials, which are outside NRC jurisdiction.

Limitations on Wear Period

- If processors pursue extended wear periods, they should be prepared to support the wear period with documentation should litigation arise.

- NVLAP requires that a processor establish and document a quality system appropriate to the scope of its dosimetry processing activities in accordance with the requirements of ISO 17025.

Limitations on Wear Period

The NVLAP General Operations Checklist, which addresses these requirements, contains at least two items relevant to wear periods:

4.1.2 states "It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this handbook and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition." In this regard processors should communicate with clients about their needs and provide advice about the consequences of particular dosimeter use or processing practices (such as wear period length) on the accuracy of dosimetry measurements.

5.4.6.1 states that "Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement." The wear period or exchange frequency could be a major component of the uncertainty of the measurement results.

Limitations on Wear Period

- In addition, NVLAP's Specific Operations Checklist for dosimetry includes two items that must be accommodated:

- 5.1(3) "Fading of TLD materials under normal conditions of use, is documented and accounted for over the intended period of use...."In order to provide good customer service, dosimetry testing facilities should collect data over a period of time beyond the intended period of use because there will be wearers who turn in their dosimeters late. A rule of thumb used by most dosimetry testing labs is to characterize the fading characteristics of their TLDs for twice the intended wear period.

- 8.3 "Protocols for routine processing are defined and can be shown to be consistent with NVLAP testing procedures." NVLAP proficiency testing is only over a 1-month period. Results using a proficiency testing laboratory for the wear/exchange period of interest should be obtained, and the uncertainties compared with the normal NVLAP proficiency testing period, to demonstrate this consistency.

Limitations on Wear Period

- In addition, the requirements of the General Operations Checklist, Section 5.4, Test and calibration methods and method validation, must be defined and documented in the Quality System to justify any dosimeter wear period, be it for 1 month or for 1 year.

Limitations on Wear Period

The most important reasons to approach this issue more conservatively than technically feasible are from the health physics and ALARA aspects. Radiation exposure (individual radiation exposures as well as collective dose equivalent) must be kept As Low As Reasonable Achievable (ALARA principle), not at or just below regulatory limits. As an example, an extended wear/exchange rate would not be appropriate in monitoring pregnant radiation workers to demonstrate compliance with both the total dose to unborn baby and rate of accumulation requirements. A fetus is limited to 500 mrem/gestation period accumulated at a fairly even rate of the course of the gestation period. This implies monitoring of pregnant radiation workers at an increased frequency (i.e. monthly) in order to be an effective radiation protection management tool.

All of this discussion emphasizes the need for NVLAP accredited labs meeting ISO/IEC 17025 to discuss with its client(s) the need for data, measurements, etc. to be in place to ensure that the lab has the capability of providing the requested services.

Extremity Monitoring

Extremity is defined as the hand, elbow, arm below the elbow, foot, knee, or leg below the knee

- Multi-element dosimeter that can be worn in any of the above defined areas
- Single element dosimeter that can be worn on a finger or toe

Multi-Element Dosimeter

- Multiple elements allow for discrimination between photons, beta and possibly neutron (if neutron sensitive element or CR39 is included)
- A multi-element extremity dosimeter is typically a whole body dosimeter with a strap attached
- Even though this is generally a whole body dosimeter with a strap, the standard used to determine performance is ANSI N13.32-2008 and not ANSI N13.11-2001(2009 version)
- If used as an extremity dosimeter, a different phantom is used for dose irradiations

Single Element Dosimeter

- Inability to discriminate between photons, beta and neutron
- Dose is generally based on ^{137}Cs source factor. Therefore, the error in dose reported will be based on the actual type of radiation and energy as compared to a ^{137}Cs irradiation
- The C_x factor applied is applied to the entire elemental response, and not simply a photon, beta or neutron correction factor
- In medical or university environments this error is generally within +/- 20%

Single Element Dosimeter Source Factors Based on Harshaw MeasuRing Chipstrate Irradiations

M150 (73 keV)	1.22
M100 (53 keV)	1.48
M60 (35 keV)	1.42
M100 + Cs137	1.17
Cs137 + Tl204	0.57
M60 + Cs137	1.2
M30 + Cs137	1.1
Am 241	0.8
Cs137 (662 keV)	1
H150 (122 keV)	1.08
M30 (20 keV)	1.26
^{90}Sr/^{90}Y (^{32}P) (2.1 MeV)	0.9
Tl-204 (767 keV)	0.16
Depleted Uranium	0.61

Effective Dose Equivalent Methods

- Gill 1980
- Faulkner 1988
- Webster 1989
- Niklason 1994
- Berger 1995
- ANSI N13.41-1997
- CRCPD 1995 and NCRP 1995

Effective Dose Equivalent Methods

Two of the most well accepted relationships are found in recommendations published by the CRCPD's report titled *"Suggested State Regulations for the Control of Radiation."* (CRCPD, 1995) and NCRP's Report No. 122, titled *"Use of Personal Monitors to Estimate Effective Dose Equivalent to Workers for External Exposure to Low-LET Radiation"* (NCRP, 1995)

NCRP METHODOLOGY

NCRP 122 recommends that "When a single personal monitor worn at the neck outside and above a protective apron is used, dividing the personal dose equivalent (i.e. deep dose equivalent) by 5.6 to obtain a conservatively high estimate of EDE is recommended." These modifications of the personal dose equivalent give appropriate credit for the protection afforded by the lead apron and do not overestimate the value of EDE by more than a factor of three.

CRCPD METHODOLOGY

- This document contains model regulations for voluntary use by state authorities. The applicable provisions are the following: "When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified, the EDE for external radiation shall be determined as follows:
  - When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent shall be the EDE for external radiation; or
  - When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified, the reported deep dose equivalent value multiplied by 0.3 shall be the EDE for external radiation"

CRCPD VS. NCRP METHODOLOGIES

Even though both the CRCPD and NCRP recommendations give appropriate credit for the protection afforded by the lead apron and do not overestimate the value of EDE, NCRP's approach seems more reasonable. NCRP's relationship is not as conservative as the one proposed by the CRCPD, but still assures that the value of EDE is not overestimated. Also NCRP's recommendation does not include the provision that the proposed relationship should only be applied when the deep dose equivalent exceeds 25 percent of the specified limit, which makes dose assessment process more difficult by using a double standard

Gill Methodology

J.R. Gill was one of the first individuals to propose the application of correction factors based on weighting factors applied to the dose from two dosimeters. Gill proposed using the equation shown below to estimate the effective dose equivalent (EDE). EDE ~ $0.6H_u + 0.4H_o$

where H_u is the under-apron dose equivalent, and H_o is the over-apron dose equivalent

Webster Methodology

The most popular and commonly used dose weighting methodology in personnel dosimetry is the one proposed by E. W. Webster. Webster proposed using the following equation to estimate EDE:

$$EDE \sim 1.5H_u + 0.04H_o$$

where H_u is the under-apron dose equivalent and H_o is the over-apron dose equivalent.

Niklason Methodology

L.T. Niklason proposed one of the latest methods for the estimation of effective dose (E) from the radiation dose to two dosimeters. The following equations provide a methodology to estimate effective dose and accounts for the use of a thyroid shield:

$$E = 0.06\,(H_{os} - H_u) + H_u \quad \text{Without a thyroid shield}$$

$$E = 0.02\,(H_{os} - H_u) + H_u \quad \text{With a thyroid shield}$$

where H_u is the under-apron dose equivalent

and H_{os} is the over-apron dose equivalent.

ANSI N13.41-1997 Methodology

$$(0.89 * H_o) + (0.11 * H_u) = EDE$$

- Where H_o is the torso dosimeter and H_u is the dosimeter worn on the collar
- The 0.89 factor was determined using all organ dose weighting factors

Considerations for Effective Dose Equivalent

All three of the recommendations mentioned provide appropriate credit for the protection afforded by the lead apron and do not overestimate the occupational dose. Nevertheless, the use of methodologies proposed by Gill and Webster will result in substantial errors because of the different weighting factors associated with EDE and because the use of thyroid shields are not considered in their proposed methodologies. Niklason's methodology provides accurate Occupational dose estimates and provides a correction for the use of thyroid shields.

Agreement States and NRC Recommendations

Most Agreement States as well as the NRC, agree that, in many external exposure situations, dose estimates obtained from personal dosimeters significantly overestimate occupational doses, particularly when the body is not uniformly irradiated due to the use of aprons. As consequence, regulatory agencies have published advisory letters or Notices recommending the use of accepted numerical relationships to demonstrate compliance with occupational dose limits. The logistics of implementing of a numerical Relationship are relatively simple, and besides assisting in the assignment of more accurate occupational doses, their use also helps reduce the number of unnecessary dosimetry investigations when investigational dose limits are exceeded.

Capabilities for each type of dosimeter

- Radiation environment
- Ability to measure and report the desired radiation environment
- Measures undesired radiation environment

GDS FILM BADGE

Who <u>can</u> wear a film badge:

- Occupational workers who are exposed to X-Rays (medical practitioners and technologists, veterinarians, chiropractors, diagnostic and therapeutic X-Rays)
- Occupational workers who are exposed to gamma, X-Rays and high energy beta (nuclear medicine facilities)
- Occupational workers who are exposed to X-Rays from industrial equipment

GDS FILM BADGE

Who should NOT wear a film badge:

- Any occupational worker who is exposed to low energy beta
- Any occupational worker who is exposed to various complicated radiation mixtures and, highly non-uniform geometry of exposure
- Any occupational worker who is exposed to neutron (unless there is a CR39 included)
- If the facility has low energy neutrons, < 150 keV, the CR39 is not effective

GDS TLD 760 BADGE
3 Li-700 and 1 Li-600 element

Who can wear a TLD 760 (7776) Badge:

- Any occupational worker
- The TLD 760 is appropriate for gamma, X-Rays, beta and neutron exposures

GDS TLD 760 BADGE
3 Li-700 and 1 Li-600 element

Who should NOT wear a TLD 760 (7776) Badge:

- There are no limitations
- If an occupational worker is exposed to neutron energies that exceed 5 MeV, there must be a CR39 included to detect and report neutron exposure

GDS TLD 760 BADGE
3 Li-700 and 1 Li-600 element

Who <u>can</u> wear a TLD 100 (1110) Badge:

- Occupational workers who are exposed to X-Rays (medical practitioners and technologists, veterinarians, chiropractors, diagnostic and therapeutic X-Rays)
- Occupational workers who are exposed to gamma, X-Rays and high energy beta (nuclear medicine facilities)
- Occupational workers who are exposed to X-Rays from industrial equipment
- Occupational workers who are exposed to various complicated radiation mixtures and, highly non-uniform geometry of exposure, except where there is neutron and low energy beta

GDS TLD 100 BADGE 3 Li-100 elements

Who should <u>NOT</u> wear a TLD 100 (1110) Badge:

- Any occupational worker who is exposed to low energy beta
- Any occupational worker who is exposed to neutron

GDS TLD 802 BADGE
2 LiBO and 2 CaSO elements

Who can wear a TLD 802 Badge:

- Any occupational worker
- The TLD 802 is appropriate for gamma, X-Rays, beta and neutron exposures

GDS TLD 802 BADGE
2 LiBO and 2 CaSO elements

Who should NOT wear a TLD 802 Badge:

- There are no limitations
- If an occupational worker is exposed to neutron energies that exceed 5 MeV, there must be a CR39 included to detect and report neutron exposure

GDS CR39 Polycarbonate Plastic

Who <u>should</u> wear a CR39 Badge:

- Any occupational worker who is exposed to neutron energies >5 MeV

GDS CR39 Polycarbonate Plastic

Who ***should not*** *wear a CR39 Badge:*

- Any occupational worker who is exposed to neutron energies <150keV
- Any occupational worker who is exposed to neutron energies > 10 MeV must have a site specific calibration performed

When Investigations Are Needed

- Questionable Readings

- Recreate how the badge got its element readings
- Find out what the algorithm did to those readings
    - Is the exposure real?
    - If so, can you help your facility clarify the situation?
    - Is the dosimeter reading what the person actually received?
    - Is the exposure questionable?

When Investigations Are Needed

- A lost dosimeter
- A dosimeter is worn by more than one individual during the same wear period
- A dosimeter is inadvertently irradiated while not worn
- A dosimeter is damaged within the facility, during transportation or processing
- A dosimeter is environmentally degraded
- A dosimeter is worn incorrectly (such as not in the proper geometry with respect to the source of irradiation, film worn not in the holder or worn in the wrong body location). This is especially important if two dosimeters are worn for the purpose of calculating Effective Dose Equivalent

Performing The Investigation

- A review of the dosimetry history of the affected individual and his co-workers
- Interview the monitored individual and co-workers
- A review of the inventory records for that particular laboratory
- Types of isotopes used compared with previous dosimetry periods
- Isotope amounts used compared with previous dosimetry periods
- Types of procedures performed compared with previous dosimetry periods
- Number of procedures performed compared with previous dosimetry periods
- Occurrences of unusual events during the dosimetry period in question
- Surveys performed in the work areas
- Security in the lab
- If a TLD, annealing data prior to being shipped to the facility.
- If a TLD, copies of the various elemental glow curves.
- Reader calibration data.
- Quality Control dosimeter verifications read during the processing of the dosimeter being investigated.

Performing The Investigation

- Control dosimeter results. This could identify that the dosimeter in question may have been irradiated in transit, or, in some area where there was a continual, or intermittent exposure situation.
- Algorithm path used for determining the dosimeter dose as reported. This step identifies the type of radiation and energy the algorithm determined that the dosimeter was exposed to.
- If a film dosimeter, chemical QC information such as temperature and stability
- Evaluation of the filter OD readings and ratios
- Visually inspect the film to determine static exposure or geometry irradiation issues
- Inspect the film holder for filters missing or damaged
- Evaluate reader background data
- Evaluate any fading issues
- Evaluate initial film base fog data
- Evaluate film dosimeter in an area where there is excessive heat
- Evaluate potential contamination of the work area and the dosimeter
- If dosimeter is taken home, evaluate the home environment and transit area between the home and work place

Assigning the Dose

- After completing a thorough investigation, a dose must be assigned
- Unless there is absolute evidence that the reported dose is incorrect, do not change it
- If there is evidence that the reported dose may be accurate, but that it is not an accurate reflection of the true dose received by the individual, then a dose adjustment is appropriate
- Dose can be assigned based on other workers in the same work area for the same time period
- Dose can be assigned based on work time studies
- Dose can be assigned averaging the previously accepted dose over a 3 month period (if monthly dosimetry is worn), or based on 3 quarters of data (if quarterly dosimetry is worn)

Assigning the Dose

- ALWAYS discuss the evaluation with the monitored individual
- ALWAYS have the monitored individual AND the individual assigning the dose, sign the dose adjustment request
- This is CRITICAL in the event of potential litigation

- **DOCUMENT EVERYTHING!!!!!**

Records Quality Assurance

- Essential for any litigation disposition and mitigation
- Legal documentation of what actions were taken which contributed to the establishment of a dose record

Why is it Important

- Identifies positive or negative trends which determine if a change to the operating process has occurred
- Facilitates a “paying attention to details” attitude among dosimetry processing and records management staff members
- Facilitates dose reconstruction

Types of Records

- TLD Life-Cycle History
- Receipt Acceptance Testing of new TLDs
- Calibration Records; Irradiator and Readers
- Linearity Determinations
- Filter/Material Verifications
- Response Characteristics of the dosimeter
- Type Testing Data for the Dosimeter
- Staff Qualifications and Certifications
- TLD Processing Follower Forms
- Reader, Irradiator & Computer Log Books
- Quality Assurance Processing Followers
- Exception and Discrepancy Reports
- Film Acceptance Testing
- Retention of Films Processed

Types of Records

- Film Optical Density Response
- Film Developer Parameter Tracking
- CR39 Acceptance Testing
- Retention of CR39 Foils
- Glow Curve Analysis Evaluations
- Error Report Evaluations
- ECC Generation Reports
- Software Quality Assurance Records - Development and Change Control
- Deviations to Procedures
- Index and Copy of ALL historical Procedures (required to identify how a badge was processed at any point in time)
- Documentation on ALL modifications to a "dose of record"

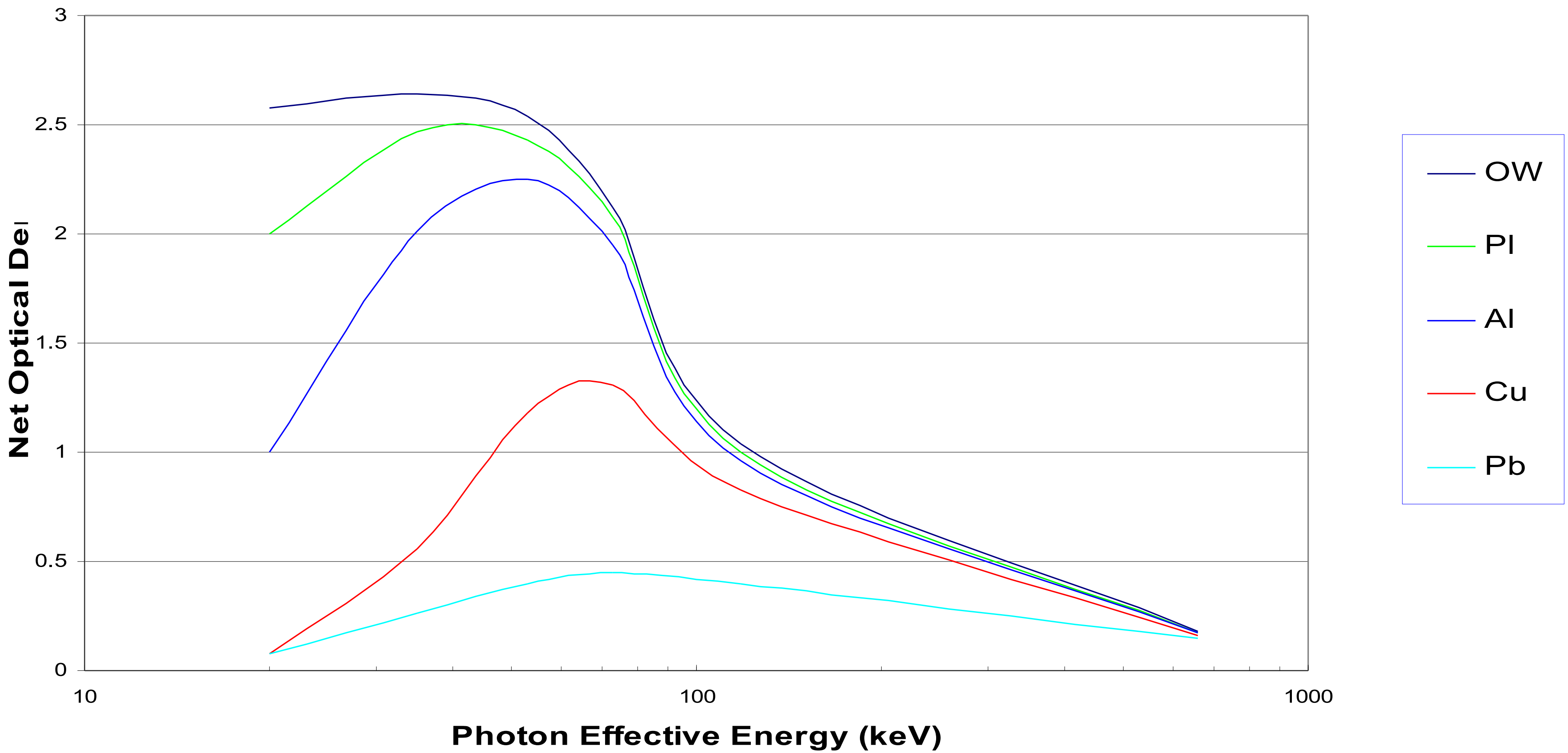
Security of Records

- Procedures and Quality Instructions which cover:
  - Change Control
  - Procedural Deviation
  - Records Retention
  - Records Storage
  - Approval and Authorization Requirements
  - Access to Records

Maintenance of Records

- Hard Disk
- Back-up cartridges, off-site copies
- Optical Systems (original <u>NOT</u> modified)
- Microfiche
- Viable index and retrieval system established and tested periodically

GDS Film Dosimeter Energy Response - 100 mrem Dose



Film Dosimeter Filters

PHOTON FILM PATTERNS

^{137}CS
(662 keV)

H150
(118 keV)

M150
(73 keV)

M100
(53 keV)

M60
(35 keV)

M30
(20 keV)

BETA PARTICLE RESPONSE PATTERNS

^{90}Sr


ANGULAR IRRADIATION PATTERNS
M150
TOP
BOTTOM
SIDE

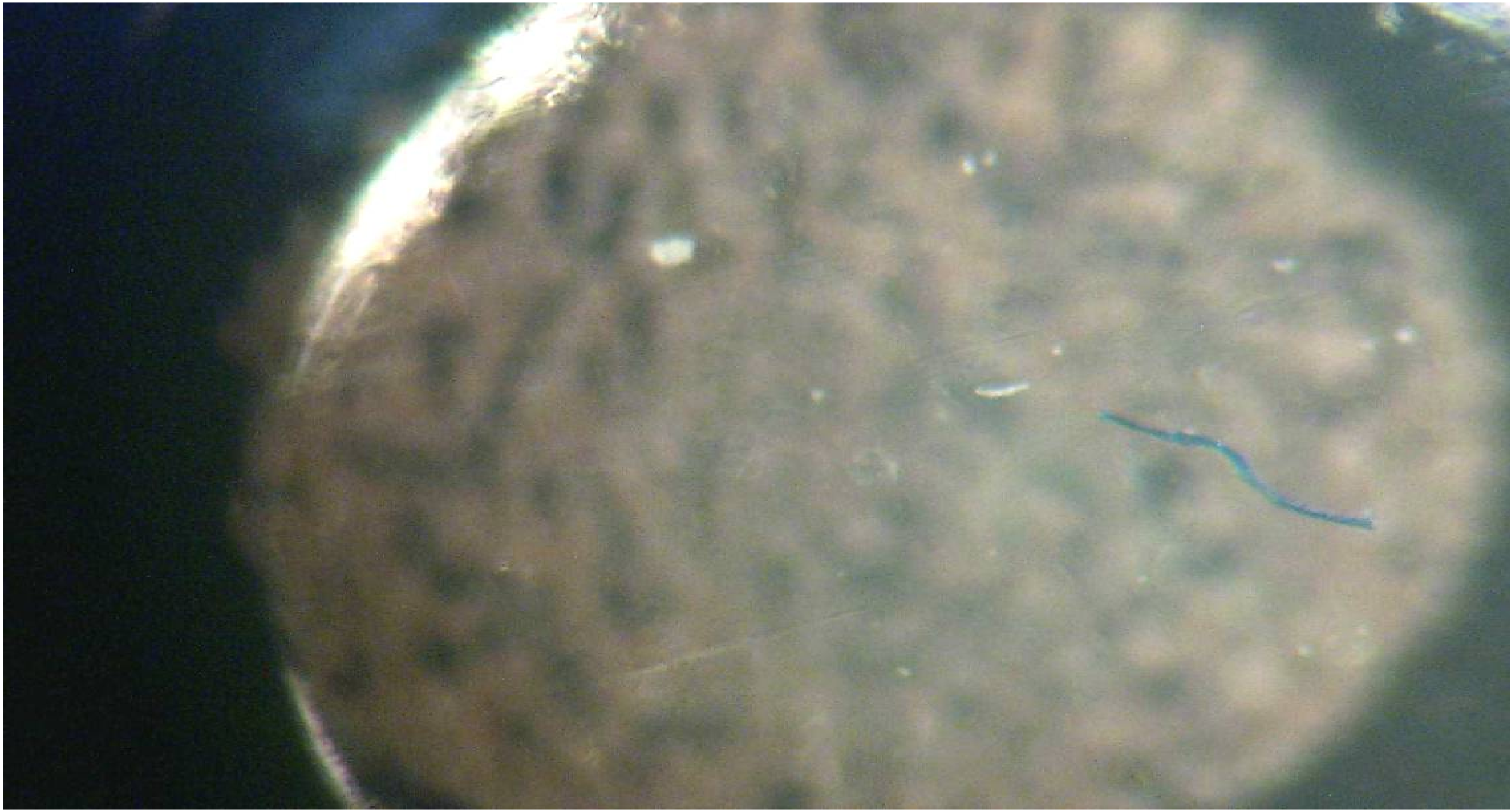
Dosimeters Requiring Investigation

Images Courtesy of Mike Lantz, Arizona Public Service Company, Palo Verde Nuclear Plant

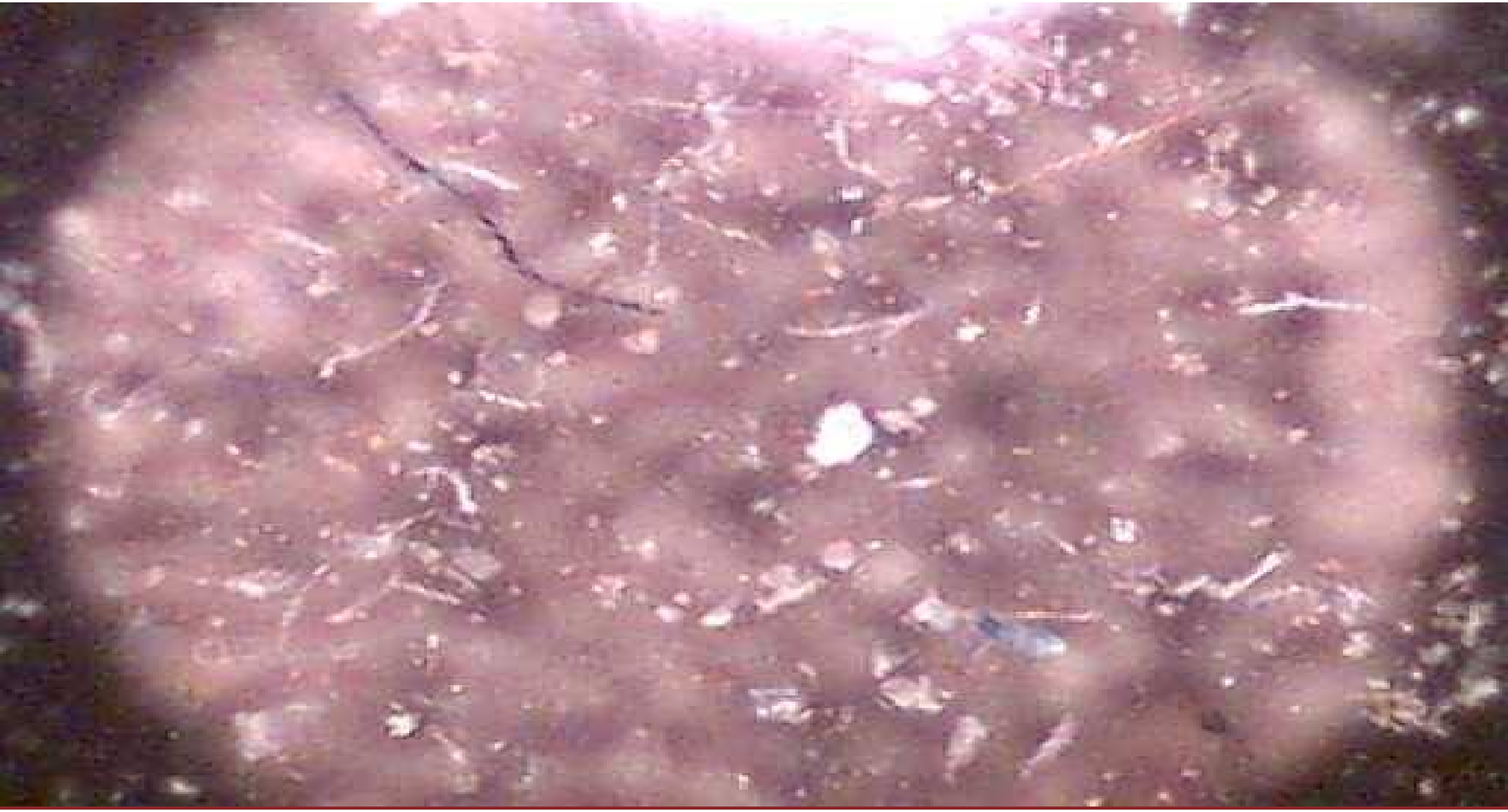
Panasonic TLD Element

Cut caused a 177 mrem dose

Panasonic TLD Element
Blue thread caused 120 mrem dose



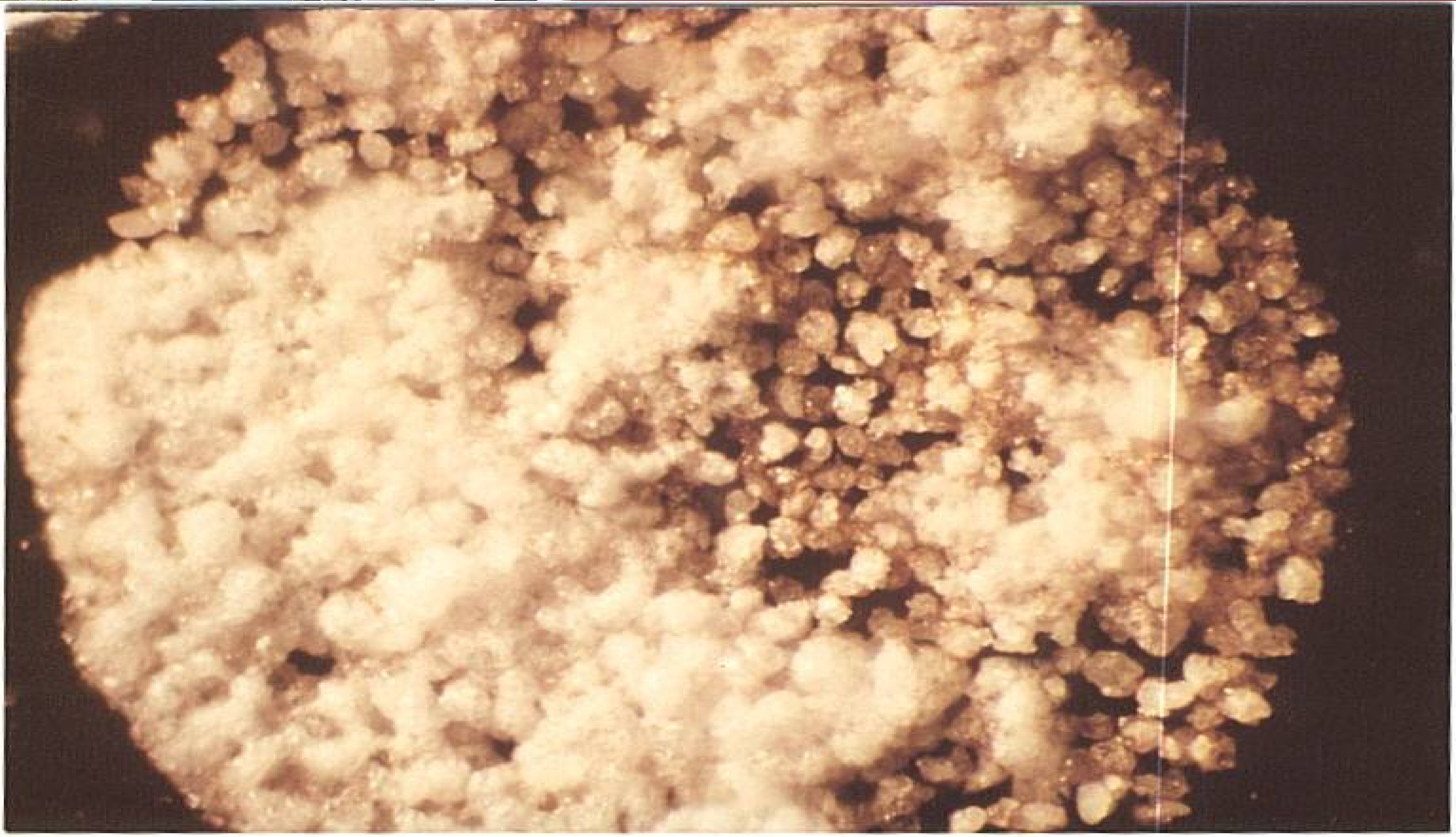
Panasonic TLD Phosphor



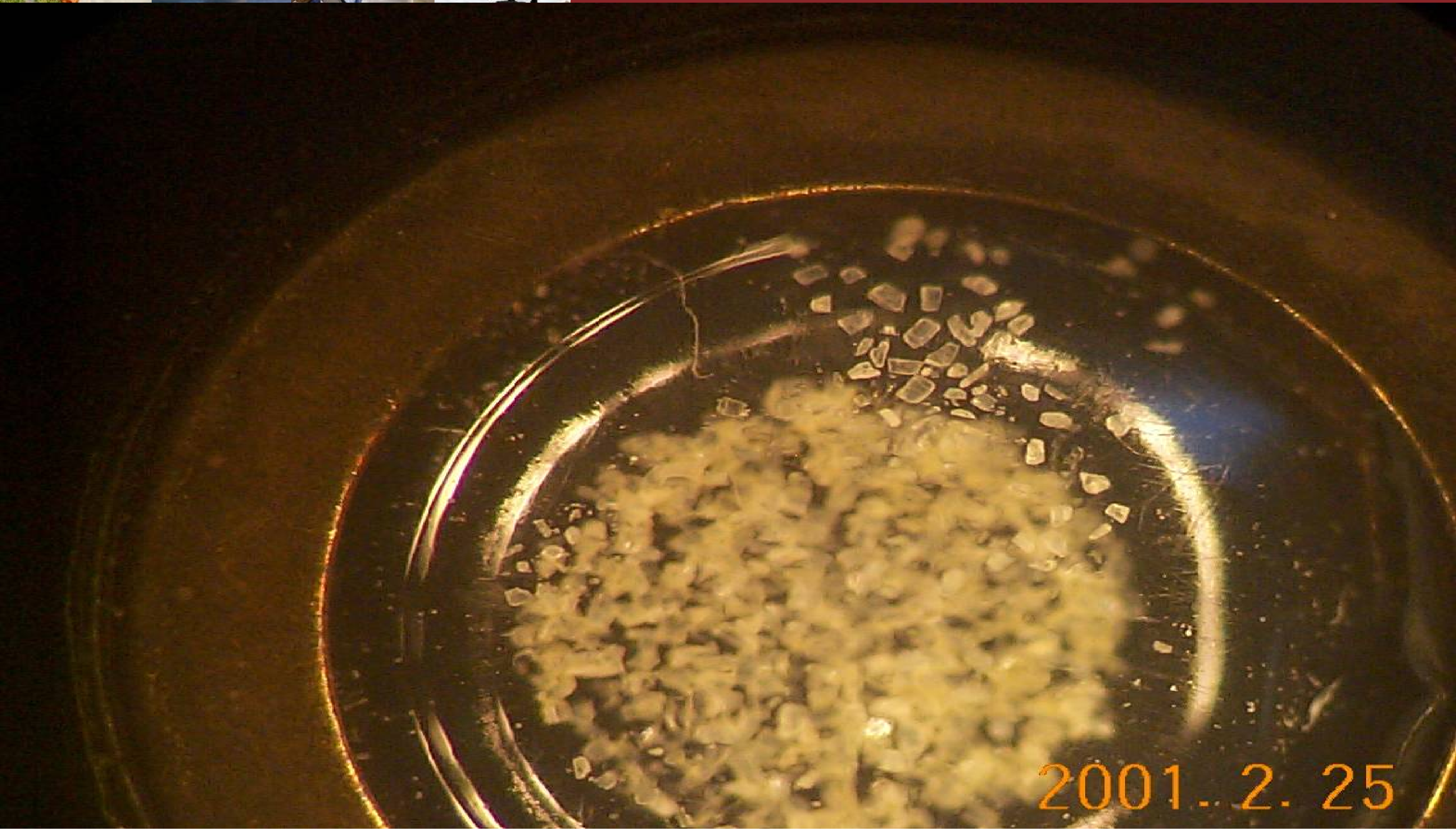
Panasonic TLD Phosphor

Panasonic TLD Phosphor

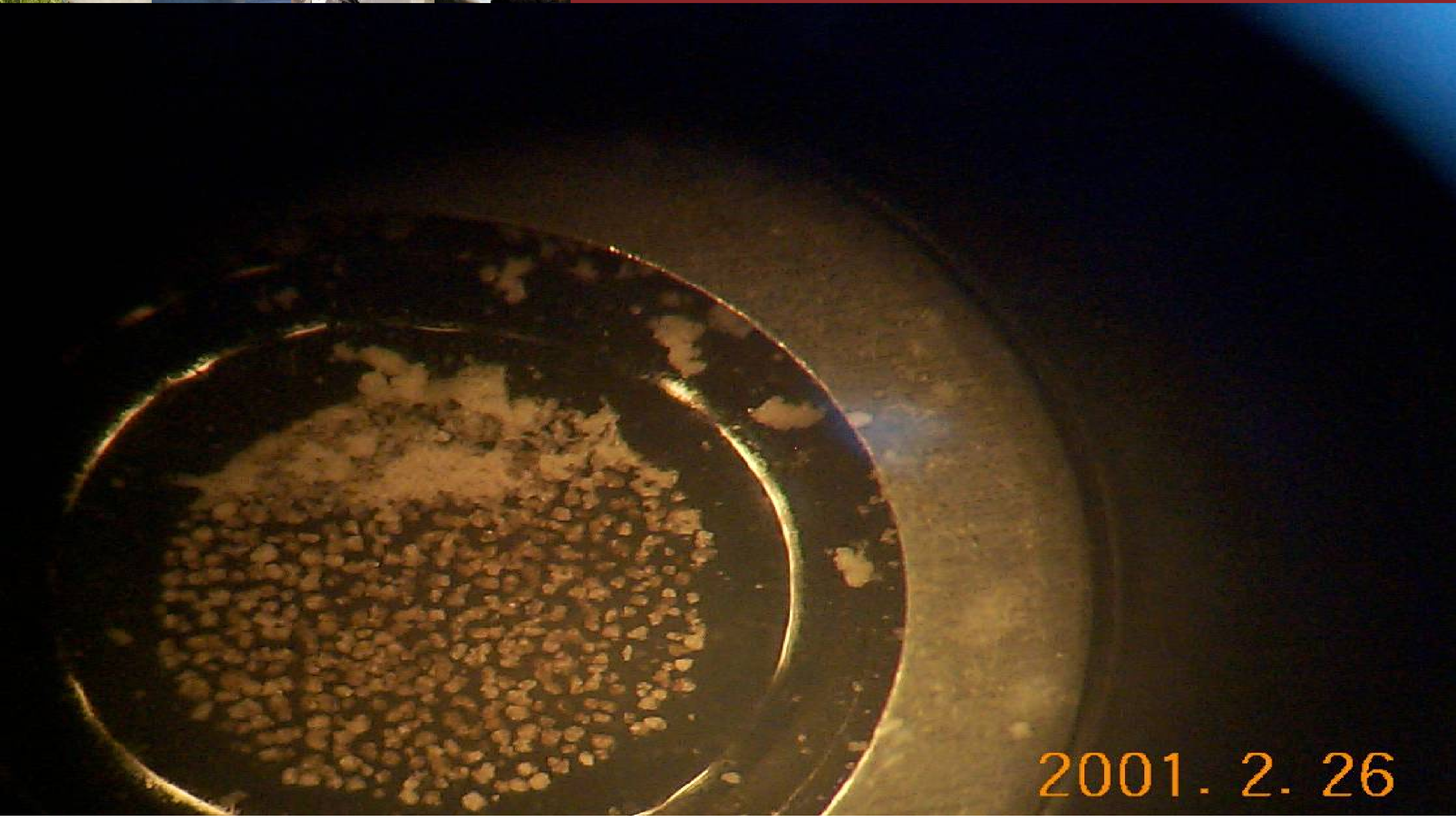
Panasonic TLD Phosphor



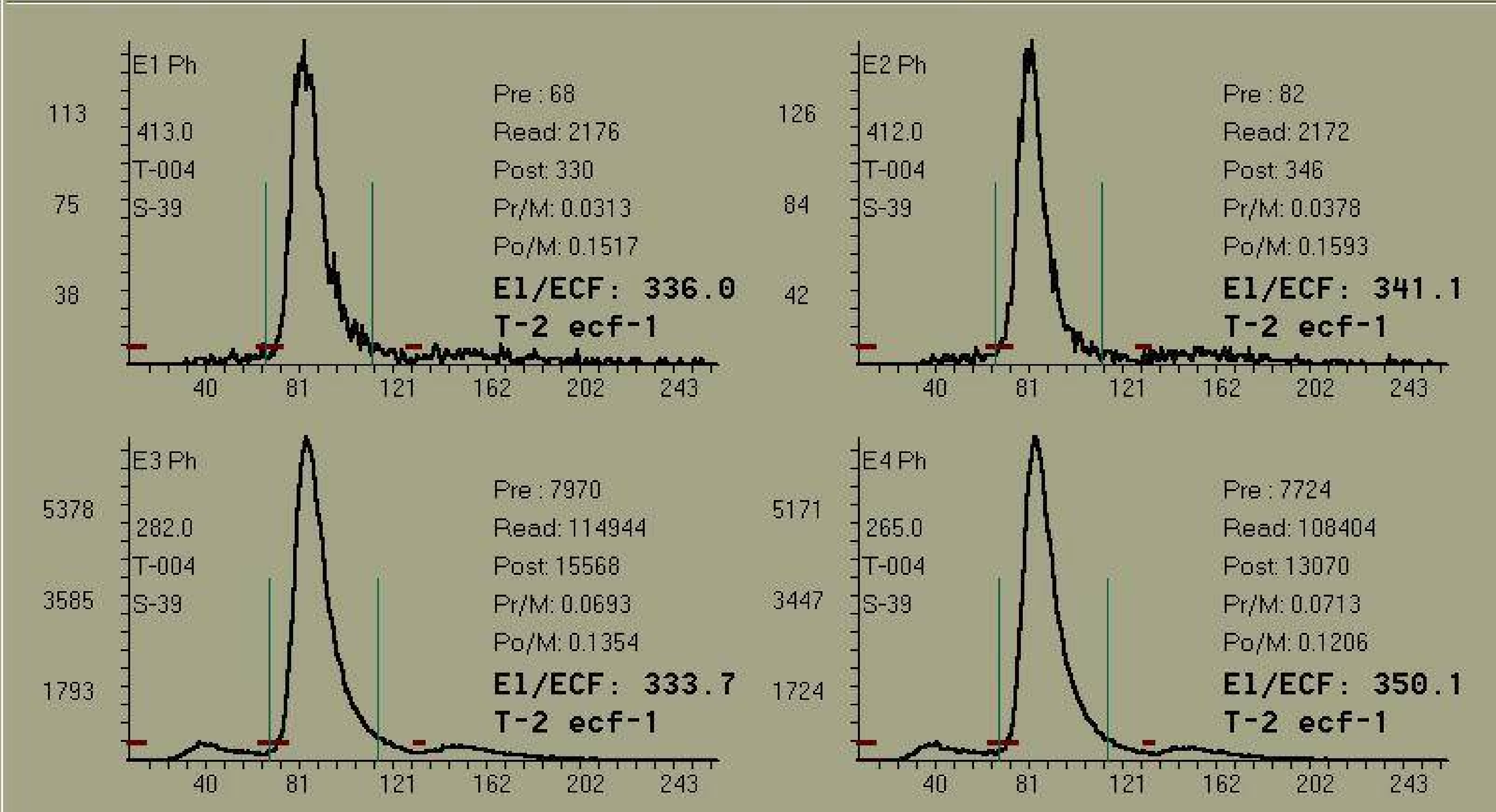
Panasonic TLD Phosphor



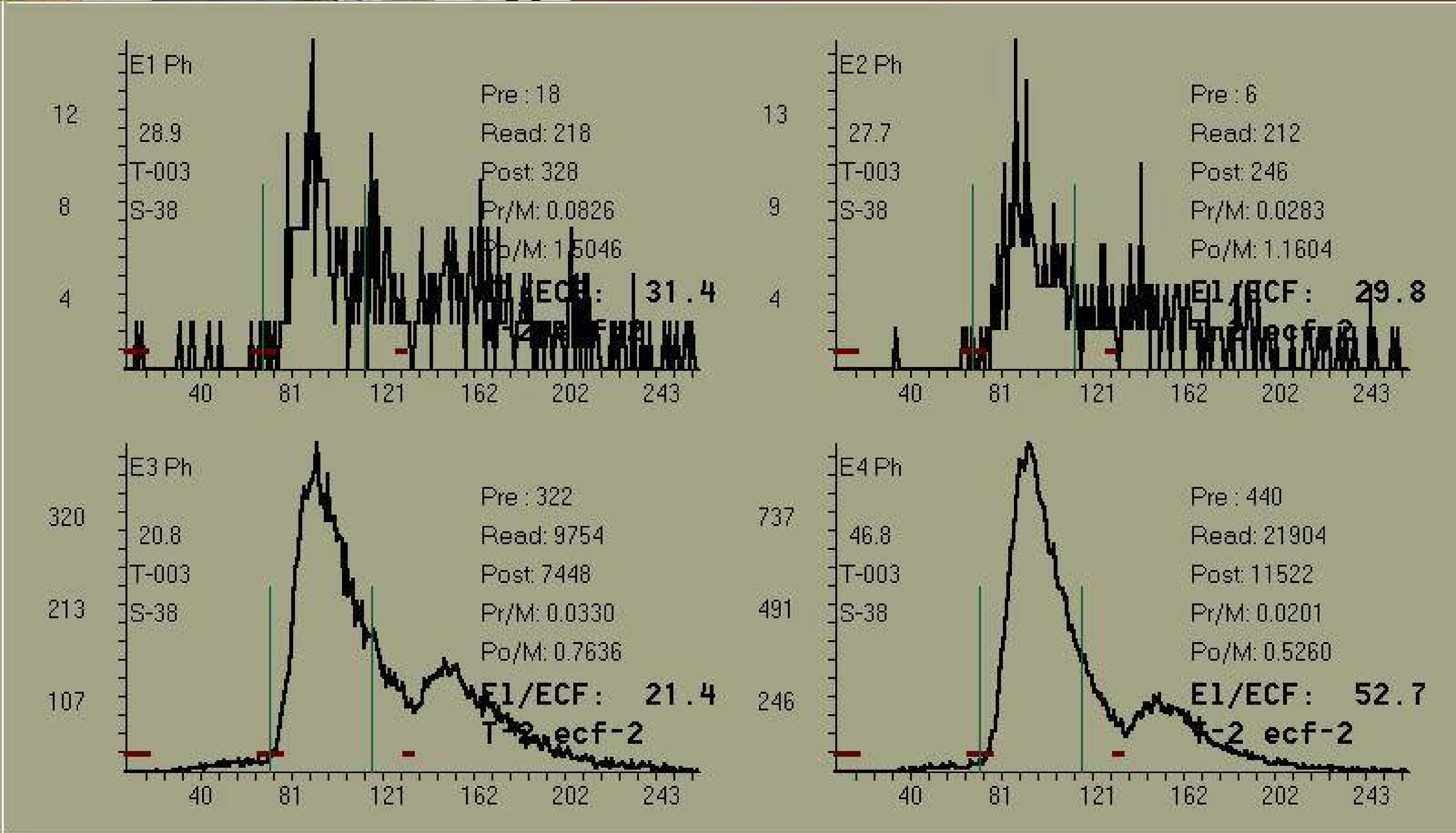
Panasonic TLD Phosphor



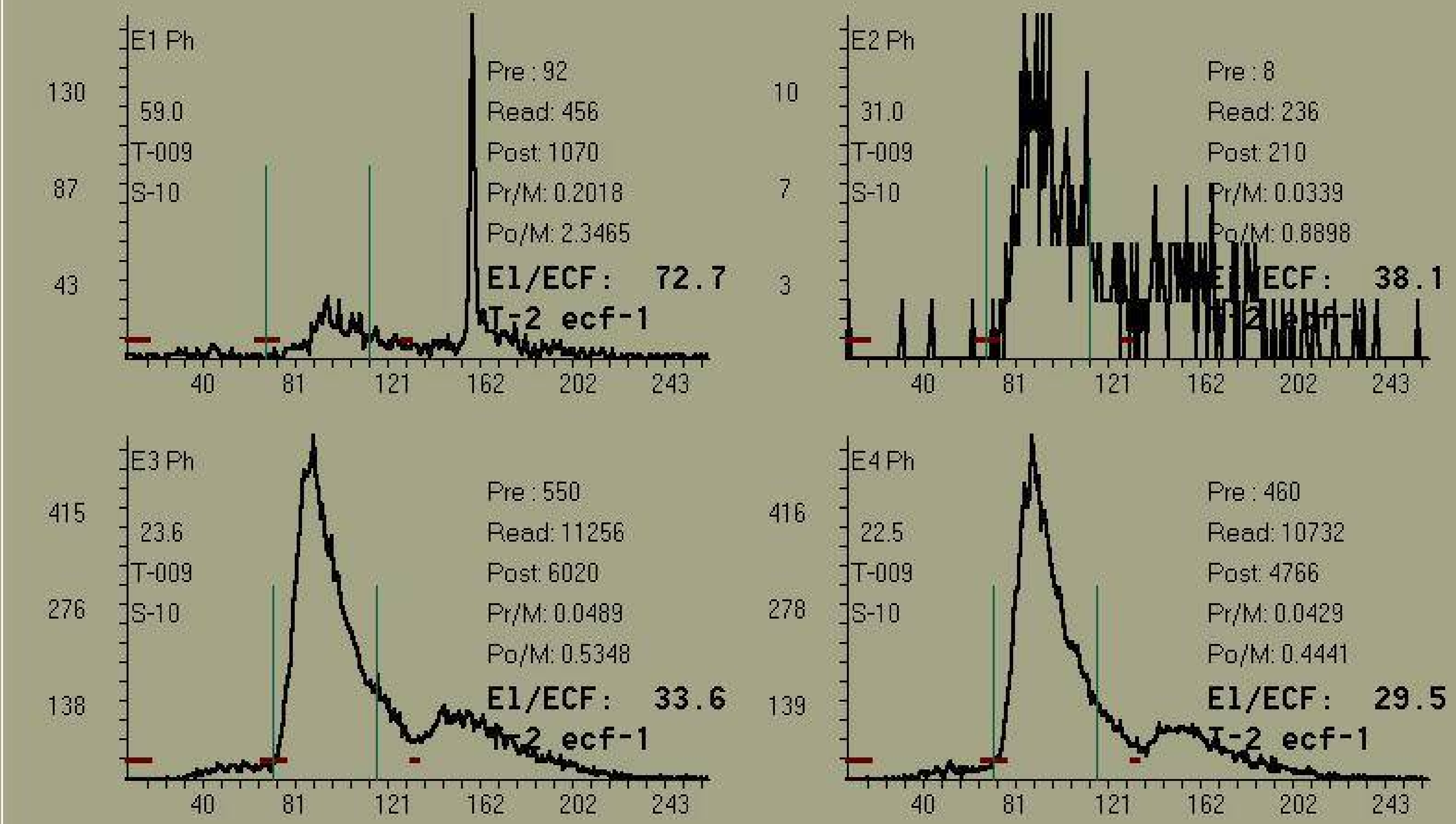
Panasonic Good Glow Curve



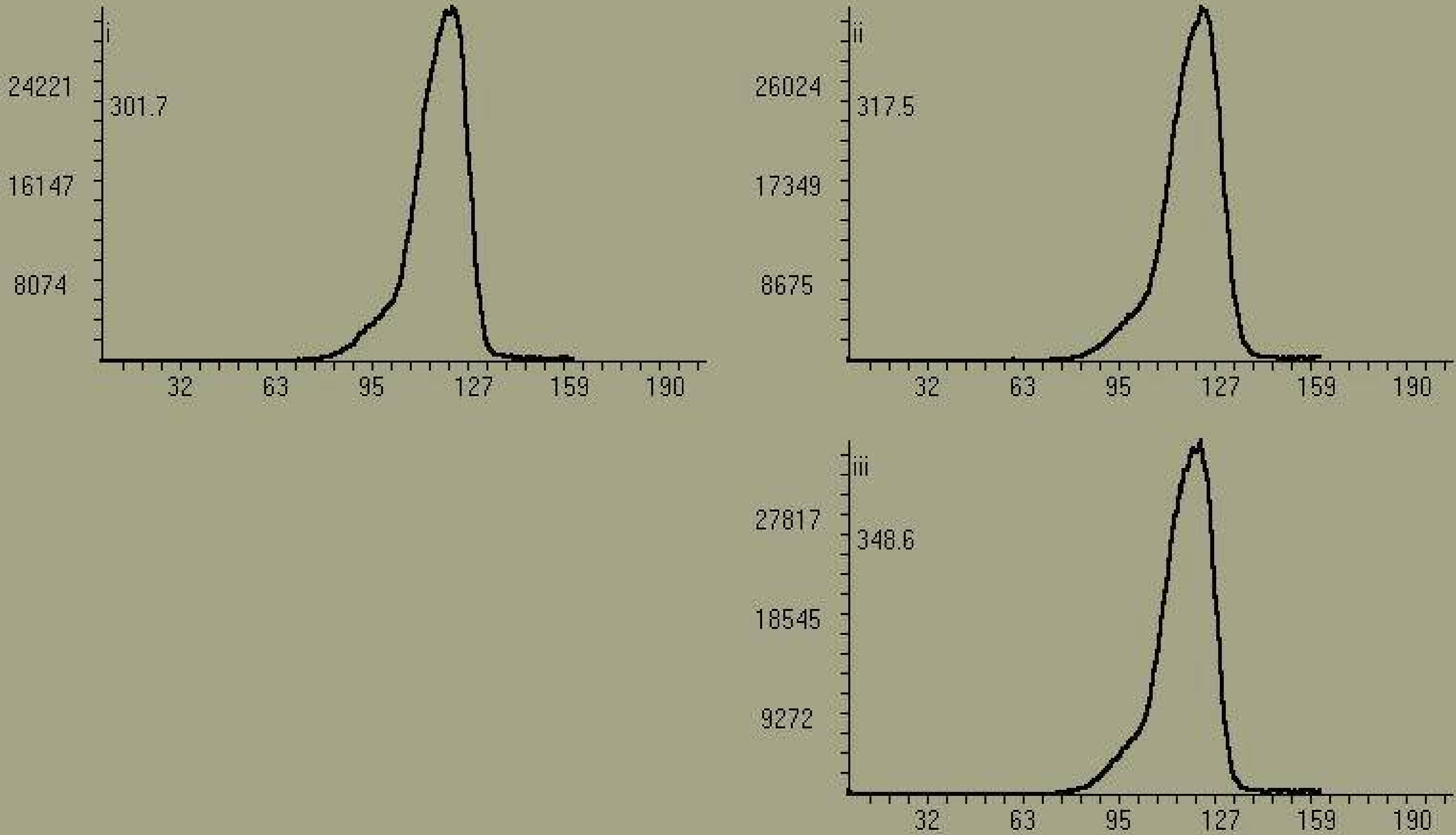
Panasonic Heating Problem



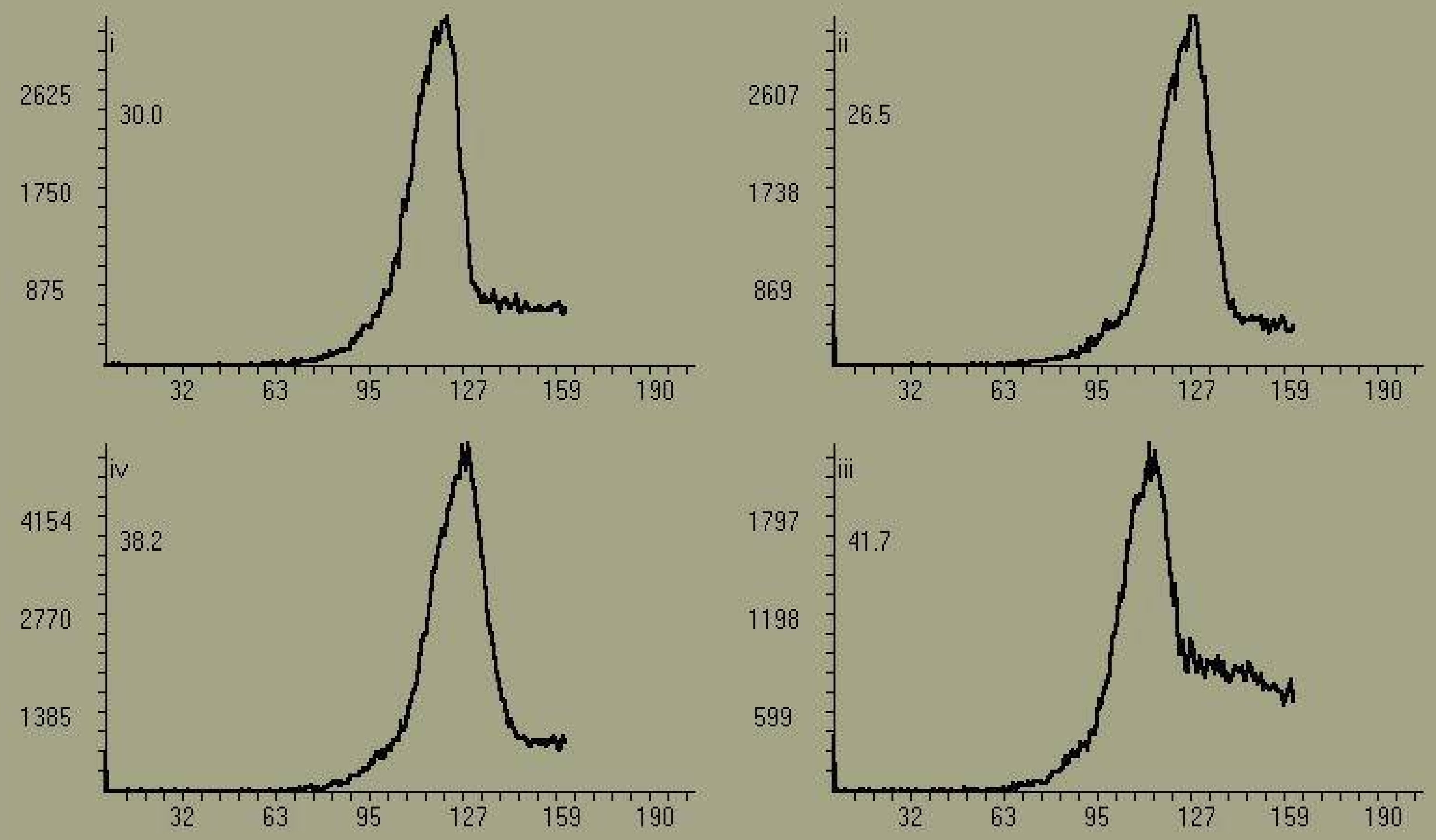
Panasonic Spike



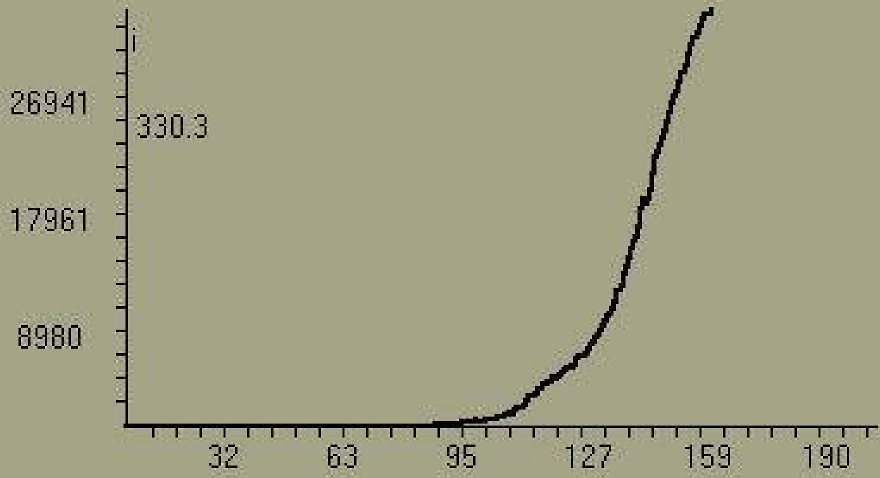
Harshaw Good Glow Curve

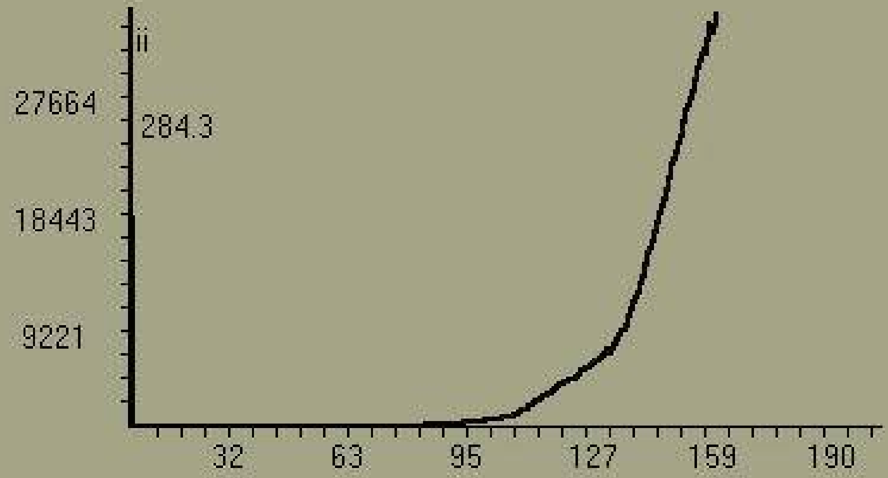


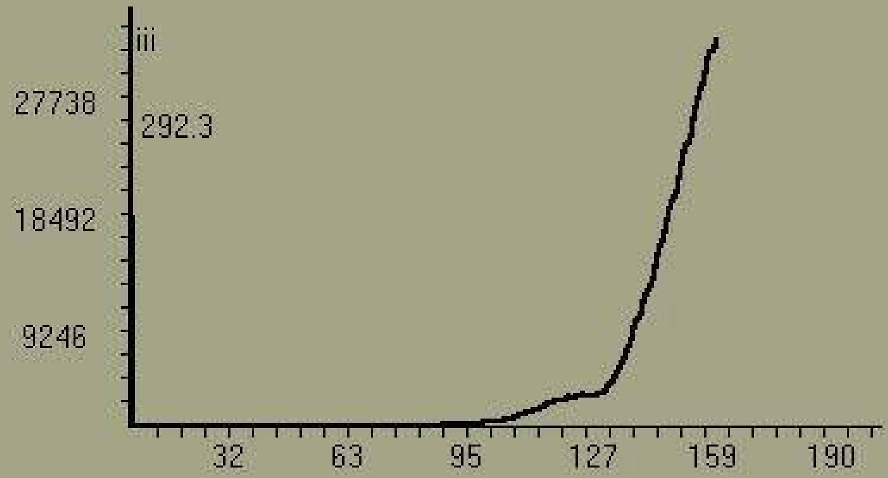
Harshaw Residual



Harshaw High Dose







Thank you for your attention!

Questions?