Sealed Source & Device
Prototype Testing

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Purpose of Prototype Testing

- ❖ Demonstrate that the product design will maintain its integrity under normal operating and likely accident, conditions during installation, use, handling, maintenance, storage, and transportation.

- ❖ Assist users of products to identify products that will suite environmental conditions in the workplace.

- ❖ Give regulatory authorities a standard to classify sources against, approve locations of use and evaluate integrity during emergencies.

- ❖ Appropriate methods:
  - prototype testing;
  - engineering analysis;
  - operational history; or
  - comparison to a similar or equivalent model that is already reviewed and registered.

Summary of Prototype Testing Requirements

Applicable 10 CFR Regulations

	Device	Prototype Test
Exempt	Certain Items (30.15)	32.14(b)(4), 32.40
	Self-Luminous (30.19)	32.22(a)(2)(xi), and (xii)
	Gas & Aerosol (30.20)	32.26(b)(11), and (12)
GL	Detectors (31.5)	32.51(a)(2)
	Luminous Safety Devices (31.7)	32.53(d)(4), 32.101
	Ice Detector (31.10)	32.61(e)(4), 32.103
SL	Radiography	34.20(a)(1) (34.20(a)(2) for Eng. Analysis)
	Well-Logging	39.41(a)(3)
	Irradiator	36.21(a)(5)
	Medical	32.74(a)(2)(iii)

Types of Standards

- ❖ Specific Industry or Consensus Standards
  - American National Standard Institute (ANSI)
  - Nat'l Radiological Protection Board
  - Nat'l Institute of Standards and Technology (was NBS)
  - Defense standards
  - International Organization for Standardization (ISO)
  - Foreign countries national standards (e.g., DIN, BSI)
- ❖ Other Guidance Documents
  - Regulatory Guides/Standard Review Plans
  - NARM guidance
  - State or NRC regulations
  - CRCPD guidance
    (Conference of Radiation Control Program Directors)
  - International Atomic Energy Agency

Typical Guides and Standards

NUREG-1556
Vol. 3, Rev. 1

Consolidated Guidance About Materials Licenses

Applications for
Sealed Source and Device Evaluation and Registration

Final Report

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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INTERNATIONAL STANDARD

ISO 2919

Second edition
1999-02-15

Radiation protection — Sealed radioactive sources — General requirements and classification

Radioprotection — Sources radioactives scellées — Prescriptions générales et classification

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ANSI/HPS N43.6-2007

American National Standard

Sealed Radioactive Sources – Classification

Approved: August 2007

American National Standards Institute, Inc.

ANSI/HPS N43.8-2001

Health Physics Society

HEALTH PHYSICS SOCIETY
FOUNDED 1956

An American National Standard

Classification of Industrial Ionizing Radiation Gauging Devices

Supplement 3
HEALTH PHYSICS 2006

Classification Comparison Between ANSI/HPS N43.6-2007 and ISO 2919:1999

	Class									
							5		6	
	N43.6	ISO 2919	N43.6	ISO 2919	N43.6	ISO 2919	N43.6	ISO 2919	N43.6	ISO 2919
Temp.	-40°C (20 min) +80°C (1 hr)	-40°C (20 min) +80°C (1 hr)	-40°C (20 min) +180°C (1 hr)	-40°C (20 min) +180°C (1 hr)	-40°C (20 min) +400°C (1 hr) and thermal shock 400°C to 20°C	-40°C (20 min) +400°C (1 hr) thermal shock to 20°C	-40°C (20 min) +600°C (1 hr) and thermal shock 600°C to 20°C	-40°C (20 min) +600°C (1 hr) thermal shock to 20°C	-40°C (20 min) +800°C (1 hr) and thermal shock 800°C to 20°C	-40°C (20 min) +800°C (1 hr) thermal shock to 20°C
Ex. Pres	25 kPa (3.6 psi) abs to atmosphere	25 kPa (3.6 psi) abs to atmosphere	25 kPa abs to 2 MPa (290 psi) abs	25 kPa abs to 2 MPa abs	25 kPa abs to 7 MPa (1015 psi) abs	25 kPa abs to 7 MPa abs	25 kPa abs to 70 MPa (10153 psi) abs	25 kPa abs to 70 MPa abs	25 kPa abs to 170 MPa (24656 psi) abs	25 kPa abs to 170 MPa abs
Impact	50 g (1.8 oz) from 1 m and	50 g from 1 m or equivalent imparted energy	200 g (7 oz) from 1 m	200 g from 1 m or equivalent imparted energy	2 kg (4.4.lb) from 1 m	2 kg from 1 m or equivalent imparted energy	5 kg (11 lb) from 1 m	5 kg from 1 m or equivalent imparted energy	20 kg (44 lb) from 1 m	20 kg from 1 m or equivalent imparted energy
Vibration	3 times 10 min 25 to 500 Hz at 49 m/s^2 peak amp (5g)	*3 times 10 min* 25 to 500 Hz at 5g peak amp.	3 times 10 min 25 to 50 Hz at 49 m/s^2 (5g) peak amp. and 50 to 90 Hz at 0.635 mm amp. Peak to peak and 90 to 500 Hz at 98 m/s^2 (10g)	*3 time 10 min* 25 to 50 Hz at 5g peak amp. and 50 to 90 Hz at 0.635 mm amp. Peak to peak and 90 to 500 Hz at 10g	3 times 30 min 25 to 80 Hz at 1.5 mm amp. peak to peak and 80 to 2000 Hz at 196 m/s^2 (20g)	*3 time 30 min* 25 to 80 Hz at 1.5 mm amp. peak to peak and 80 to 2000 Hz at 20g	Not Used	Not Used	Not Used	Not Used
Puncture	1 g (15.4 gr) from 1m (3.28 ft)	1 g from 1m or equivalent imparted energy	10 g (154 gr) from 1m (3.28 ft)	10 g from 1m or equivalent imparted energy	50 g (1.76 oz) from 1m (3.28 ft)	50 g from 1m or equivalent imparted energy	300 g (10.6 oz) from 1m (3.28 ft)	300 g from 1m or equivalent imparted energy	1 kg (2.2 lb) from 1m (3.28 ft)	1 kg from 1m or equivalent imparted energy

Common Nuclides in SS&D
(Source Std: ANSI/HPS N43.6-2007, ISO 2919-1999)

Usage	Isotope	Source/Device Standard (R) - Reaffirmed, (W) - Withdrawn
Medical	Cs-137	Brachytherapy; ANSI/HPS N43.6-2007 Teletherapy Device; ANSI N449-1974(W), N499.1-1978(W)
	Co-60	Brachytherapy; ANSI/HPS N43.6-2007 Teletherapy Device; ANSI N449-1974(W), N499.1-1978(W)
	Au-198	Brachytherapy; ISO 2919:1999
	Ir-192	Brachytherapy; ISO 2919:1999
	Sr-90	Brachytherapy; ANSI/HPS N43.6-2007
	Ra-226	Brachytherapy; ANSI/HPS N43.6-2007
	Pd-103	Brachytherapy; ISO 2919:1999
	Id-125	Brachytherapy; ISO 2919:1999
Radiography	Co-60	ANSI N43.9-1991
	Ir-192	ANSI N43.9-1991
Gauge	Cs-137	Density, ANSI N43.8-2001
	Am-241:Be	Moisture (neutron source), ANSI N43.8-2001
Exempt	Am-241	Smoke Detector
	H-3	Self-Luminous, ANSI N43.4-2000
	Kr-85	Self-Luminous, ANSI N43.4-2000
	Pm-145	Self-Luminous, ANSI N43.4-2000
Irradiator	Co-60	Pool, ANSI N43.10 (W) 10 CFR 36.21
	Cs-137	Type I, ANSI N433.1-1977(R1989)

ANSI/HPS N43.6-2007 -Classification

- Based on performance specifications related to radiation safety. Does not consider radiation output.

- Actual testing of two prototype (or dummy) sources for each test in Table 1; or by derivation/comparison to previously tested source (similar design/construction).

- An example of a typical source designation is:
  ANSI 07C43515, where,

ANSI	07	C	4	3	5	1	5
	year of standard	meets max. activity allowed for this isotope	temp.	press.	impact	vibr.	punct.

ANSI/HPS N43.6-2007 - Tables

- "C" or "E" - tied to source activity allowed in each source
- Table 1 - environmental test conditions
- Table 2 - applicable toxicity group
- Table 3 - maximum activity level
- Table 4 - performance requirements for typical usage

Table 2. Classification of Radionuclides According to Radiotoxicity
(An Adaptation Based on ICRP Publications 5 and 6)

High Toxicity Group A				
^{227}Ac	^{254}Cf	^{254}Es	^{208}Po	^{226}Ra
^{241}Am	^{241}Cm	^{255}Es	^{209}Po	^{228}Ra
^{242m}Am	^{242}Cm	^{257}Fm	^{210}Po	^{228}Th
^{243}Am	^{243}Cm	^{258}Md	^{236}Pu	^{229}Th
^{247}Bk	^{244}Cm	^{235}Np	^{237}Pu	^{230}Th
^{249}Bk	^{245}Cm	^{236}Np	^{238}Pu	^{232}U
^{248}Cf	^{246}Cm	^{237}Np	^{239}Pu	^{233}U
^{249}Cf	^{247}Cm	^{231}Pa	^{240}Pu	^{234}U
^{250}Cf	^{248}Cm	^{202}Pb	^{241}Pu	^{236}U
^{251}Cf	^{250}Cm	^{205}Pb	^{242}Pu	
^{252}Cf	^{252}Es	^{210}Pb	^{244}Pu	
Medium Toxicity Group B-1				
^{108m}Ag	^{144}Ce	^{178m}Hf	^{106}Ru	^{204}Tl
^{110m}Ag	^{36}Cl	^{181}Hf	^{124}Sb	^{168}Tm
^{133}Ba	^{56}Co	^{182}Hf	^{125}Sb	^{170}Tm
^{207}Bi	^{60}Co	^{125}I	^{46}Sc	^{88}Y
^{208}Bi	^{134}Cs	^{114m}In	^{89}Sr	^{91}Y
^{210m}Bi	^{137}Cs	^{192}Ir	^{90}Sr-Y	^{88}Zr
^{41}Ca	^{150}Eu	^{53}Mn	^{179}Ta	^{95}Zr
^{45}Ca	^{154}Eu	^{54}Mn	^{102}Ta	
^{115m}Cd	^{172}Hf	^{22}Na	^{127m}Te	
^{141}Ce	^{175}Hf	^{103}Ru	^{129m}Te	
Medium Toxicity Group B-2				
^{105}Ag	^{59}Fe	^{91}Nb	^{183}Re	^{95m}Tc
^{26}Al	^{60}Fe	^{91m}Nb	^{184}Re	^{97}Tc
^{73}As	^{146}Gd	^{92}Nb	^{184m}Re	^{97m}Tc
^{195}Au	^{148}Gd	^{94}Nb	^{186m}Re	^{98}Tc
^{7}Be	^{151}Gd	^{95}Nb	^{35}S	^{99}Tc
^{10}Be	^{153}Gd	^{63}NI	^{75}Se	^{123m}Tc
^{14}C	^{194}Hg	^{185}Os	^{79}Se	^{121m}Te
^{109}Cd	^{203}Hg	^{194}Os	^{32}SI	^{125m}Te
^{113m}Cd	^{166m}Ho	^{107}Pd	^{113}Sn	^{44}Tl
^{139}Ce	^{192m}Ir	^{143}Pm	^{119m}Sn	^{171}Tm
^{57}Co	^{194m}Ir	^{144}Pm	^{121m}Sn	^{49}V
^{58}Co	^{79}Kr	^{145}Pm	^{123}Sn	^{181}W
^{159}Dy	^{137}La	^{146}Pm	^{126}Sn	^{185}W
^{148}Eu	^{173}Lu	^{147}Pm	^{145}Sm	^{188}W
^{149}Eu	^{174}Lu	^{148m}Pm	^{151}Sm	^{169}Yb
^{152}Eu	^{174m}Lu	^{193}Pt	^{157}Tb	^{65}Zn
^{155}Eu	^{177m}Lu	^{83}Rb	^{158}Tb	
^{55}Fe	^{93}Mo	^{84}Rb	^{160}Tb	
Low Toxicity Group C				
^{37}Ar	^{135}Cs	^{129}I	^{101}Rh	^{146}Sm
^{39}Ar	^{68}Ge	^{85}Kr	^{102}Rh	^{85}Sr
^{42}Ar	^{3}H	^{59}Ni	^{102m}Rh	^{93}Zr

Table 3. Activity Levels

Radionuclide group (from Table 2)	Maximum activity, TBq (Ci)	
	Leachable[1] and/or reactive[3]	Non-leachable[2] and non-reactive[4]
A	0.01 (0.3)	0.1 (3)
B1	1.11 (30)	11.1 (300)
B2	11.1 (300)	111 (3,000)
C	18.5 (500)	185 (5,000)

[1]Leachable—greater than 0.1 mg per gram in 100 mL still H_2O at 50°C in 4 h (ref. ISO 9978, 5.1.1).
[2]Non-leachable—less than 0.1 mg per gram in 100 mL still H_2O at 50°C in 4 h (ref. ISO 9978, 5.1.1).
[3]Reactive – reactive in ordinary atmosphere or water (e.g., sodium, potassium, etc.)
[4]Non-reactive – non-reactive in ordinary atmosphere or water (e.g., aluminum, gold, krypton, ceramics, etc.)
Note: In the expression "milligram per gram," the "milligram" refers to the dissolved or removed radionuclide, and the "gram" to the total weight of radioactive material present, without the capsule.

Table 4. Sealed Source Performance Requirements for Typical Usage

Sealed Source Usage		Sealed Source Test and Class				
		Temperature	Pressure	Impact	Vibration	Puncture
Radiography—Industrial	Unprotected source Source in device	4 4	3 3	5 3	1 1	5 3
Medical[1]	Radiography Gamma teletherapy	3 5	2 3	3 5	1 2	2 4
Gamma gauges (medium- and high-energy)	Unprotected source Source in device	4 4	3 3	3 2	3 3	3 2
Beta gauges and sources for low-energy gamma gauges or x-ray fluorescence analysis (excluding gas-filled sources)		3	3	2	2	2
Oil Well logging		5	6	5	2	2
Portable moisture and density gauge (including handheld or dolly-transported)		4	3	3	3	3
General neutron source application (excluding reactor startup)		4	3	3	2	3
Calibration sources—Activity greater than 1.11 MBq (30 μCi)		2	2	2	1	2
Gamma Irradiators[2]	Category I Categories II, III, Category IV	4 5 5	3 3 3	3 4 4	2 2 2	3 4 4
Ion generators[3]	Chromatography Static eliminators Smoke detectors	3 2 3	2 2 2	2 2 2	1 2 2	1 2 2

[1]Brachytherapy sources, which involve highly specialized and miniaturized sources, are not specified in the usage table. Due to the nature of these sources, when approving them for inclusion in the U.S. Registry of Sealed Sources and Devices, the USNRC and Agreement States accept alternative performance tests as appropriate and indicative of the sealed sources' "fitness for their intended purposes."

[2]For this standard, gamma irradiators have been divided into four distinct categories:

Category I: Self-Contained – Dry Source Storage
Category II: Panoramic – Dry Source Storage
Category III: Self-Contained – Wet Source Storage
Category IV: Panoramic – Wet Source Storage.

[3]Source–device combination may be tested.

Note: Bending test requirements may also need to be considered for some sources as specified in Sections 4.1.4 and 7.7.

ANSI/HPS N43.6-2007 - The “1" Classification

- Indicates that source was not subjected to a particular test.

- Certain sources with the “1" classification may still be allowed for distribution provided that the device provides additional protection in source area.

ANSI/HPS N43.6-2007 - The “X" Classification

- ❖ Designates tests conducted by the manufacturer for specific environments including fire, explosion, corrosion, or other environmental or chemical extremes which exceed the standard tests.
- ❖ Factors which should be considered in determining the need for special tests include:
  - consequence of loss of activity;
  - quantity of active material contained in the source;
  - radiotoxicity;
  - chemical and physical form, and the geometrical shape of the radioactive material;
  - environment in which it is used; and
  - protection afforded the source or source-device combination

Considerations in Testing

- ❖ Should require actual prototype testing of the sealed source (not engineering analysis), since sealed source is the primary containment of the radioactive material.
- ❖ Passing = source must maintain containment integrity.
- ❖ Engraving may have a detrimental effect on the source integrity for thin walled capsules. Test after engraving.
- ❖ Should be tested in accordance with ANSI/HPS N43.6-2007, or ISO 2919-1999, and any variances must be evaluated.
- ❖ Registration certificate for the source should include its ANSI (or ISO) classification.

Multiple Encapsulations

ANSI/HPS N43.6-2007

- A source with more than one encapsulation shall be deemed to have complied with a test if it can be demonstrated that at least one encapsulation has maintained its integrity after the test.
- The outer encapsulation of a source may be totally destroyed during testing, but as long as one of the encapsulations passes the test, the source may be approved.

NRC 10 CFR Regulations

- 36.21(a)(2): must be doubly encapsulated
- 36.21(a)(5): leak-free after each of tests described in ¶ (b) - (g)
- 39.41(a)(1): is doubly encapsulated
- 39.41(a)(3): maintain its integrity after each of tests in ¶ (i) - (v)
- CsCl sources not allowed for irradiator (II - IV) and well-logging

Testing of Source/Device Combinations

- As a rule, source testing should be independent of the device. Consideration of the holder or device is allowed in some cases, such as devices where the manufacturer has committed to a limited distribution, ion generators (e.g., foil sources in gas chromatography), or custom sources.

- In all cases, the manufacturer must provide justification for consideration of the holder as protection, including the reason that the source cannot pass the test without the holder or device.

Using Standards for Custom Designs

- As a rule, try to hold custom designs to the specified ANSI, or ISO, standard for that use. If some ANSI, or ISO, tests are not applicable, the applicant should justify why the tests are not applicable or why different parameters should be used in the testing. License conditions may be used to limit the conditions under which the source or device can be used.

- For custom sources, if the applicant is licensed to handle unsealed material for the isotope, activity, and form in question, testing is not required and a registry sheet should not be issued. This is typically involves research or broad scope licensees.

Evaluation of Integrity

- ❖ Source cleaned to ensure that all contamination is removed from the surface before the first test
- ❖ Source examined visually, and leak tested after each test
- ❖ Radioactive and non-radioactive means refer to ISO 9978-1992(E) now:

Radioactive	Non-Radioactive
Wet wipe	Vacuum bubble
Dry wipe	Hot liquid bubble
Immersion (hot)	Helium pressurization bubble
Immersion (boiling) Gaseous emanation	Liquid nitrogen-alcohol bubble Helium sealing
Kr-85	Helium pressurization Water pressurization

Leak Test Method Selection

❖ Not all of the leak test methods are applicable to all sources. Selection of a leak test method should be based on:

- source design
- source technology
- source configuration

Leak Test Method Selection (cont.)

- Non-radioactive means using a dummy source are particularly effective when:
  - testing a new source configuration that you don't know how it will react to testing, prevents possible contamination
  - the testing facility may not be authorized to work with radioactive materials
  - under certain conditions, a non-radioactive means may be more efficient in detecting leakage in a particular type of source (helium)

Leak Test Method Selection (cont.)

- When evaluating testing that uses a dummy source, look carefully at their physical characteristics as compared to the actual source. Dummy sources may not perform the same under testing as a source with radioactive material inside.

  For example, some isotopes in certain forms change matrix forms with temperature change, resulting in swelling.

Leak Test Method Selection (cont.)

- ❖ Internal void space of less than 0.10 mL - not appropriate to use one of the vacuum or pressure tests. Use:
  - Wet wipe test,
  - Dry wipe test,
  - Immersion with boiling test
- ❖ Immersion with boiling test may not be appropriate for a sources where the construction involves adhesives with low temperature or solubility tolerances.

ISO 9978:1992(E) - Recommended Leak Test Method

Source type		Production sources		Prototype sources	
		1st choice	2nd choice	1st choice	2nd choice
A A1 A2	radioactive sealed sources Thin single integral window (smoke det.) Low-act. ref. sources (encamp. in plastic)	Immersion	Wipe	Immersion	Wipe
A3	SNG or dbl. encamp. sources (except H-3, Ra-226) for gauge, r'graphy, & brachy.	Immersion Helium	Bubble	Immersion Helium	Bubble
A4	SNG or dbl. encamp. Ra-226 & other gases sources	Gaseous emanation	Immersion	Gaseous emanation	Immersion
A5	dbl. encamp. sources for teletherapy & high activity irradiation sources	Helium	Wipe (dry)	Immersion Helium	Bubble
B	simulated sealed sources of Types A3, A4 & A5			Immersion Helium	Bubble
C	dummy sealed sources			Helium	Bubble

Certificate of Radioactive Source Integrity

Title	: Static Eliminator Foil
Assembly Code	: None
Assembly Drawing	: 2A 10277
Nuclide	: Polonium-210 (PO-210)
Radiotoxicity Group	: A
Maximum Activity	: 10 GBq (270)

CLASSIFICATION	: AS/ISO/ANSI 77 C34444
RECOMMENDED WORKING LIFE	: 1 YEAR

Test Sources : 6 off active foils Serial Numbers S10-S13 inclusive & S17-S18 each containing 5 mCi of Polonium-210 oxide sandwiched between copper and end capped. As per drawing 2A 10277 Issue J

Tests carried out in accordance with Recommendation of:

BS.5288: 1976 ISO.2919: 1980 (E) ANSIN542: 1977

Leak test Method	Temperature	Pressure	Impact	Vibration	Puncture	Units
	3	4	4	4	4	
Wipe Test (QCP 130)	Pass 0.02 0.03	Pass 0.85 0.07	Pass 0.02 0.14	Pass 0.07 0.24	Pass 0.07 0.24	Nanocuries
Immersion Test (QCP 131)	Pass 0.89 1.97	Pass 0.36 0.29	Pass 0.69 1.07	Pass 0.59 0.83	Pass 0.36 0.99	Nanocuries

Devices

- ❖ Verify that the sealed source incorporated in the device has achieved the appropriate ANSI or ISO classification consistent with the device's intended use.
- ❖ Use applicable industry and consensus standards.
- ❖ If there is no applicable standard,
  - must ensure, using professional judgment, that the testing performed sufficiently simulate the conditions during use, handling, storage, and transportation.
  - can obtain useful general guidance from a standard for a comparable device.

Devices (cont.)

- Passing =
  - radioactive material is not dispersed
  - source capsule remains within the protective source housing
  - shielding integrity not compromised
  - radiation levels not increase more than 20%
  - does NOT need to operate/perform its intended function after being subjected to accident condition testing.
- The registration certificate for the device, you should include either:
  - the ranges for the normal use conditions in the "Conditions of Normal Use" section, or
  - the prototype tests' ranges

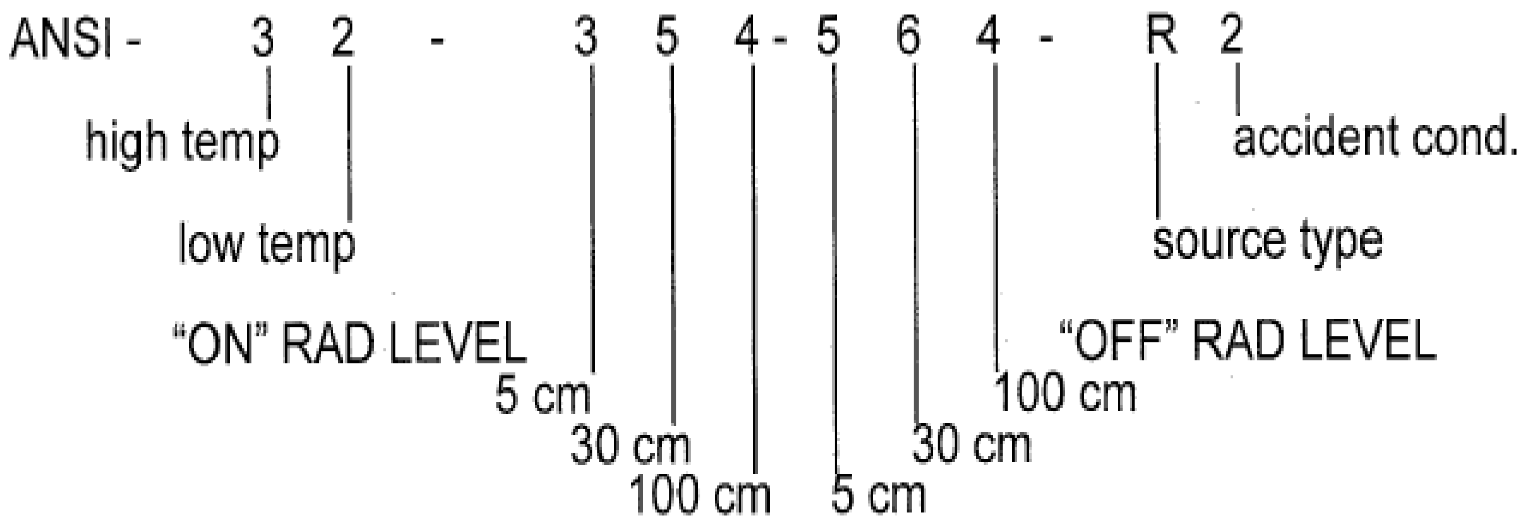
ANSI N43.8-2008 - Classification of Device

- ❖ For gauging devices (gauges) using ionizing radiation to measure thickness, density, level, interface location (i.e., liquids), and qualitative or quantitative chemical composition. Applies to devices containing radioactive or X-ray tube source.

- ❖ Actual testing of a prototype device; or by derivation/comparison to previously tested device.

ANSI N43.8-2008 - Classification

- An example of a device classification is:
  (for a typical beta radiation transmission gauge used to measure the thickness of a plastic film)



ANSI N43.8-2008 - Source Type/Performance Tests

- ❖ Source Type - “R” for radioactive, blank for X-ray
- ❖ Table I lists the test conditions and respective classification designation.
- ❖ Desired classification is selected by manufacturer or person specifying the testing. (Cf. ANSI/HPS N43.6-2007 specifies performance levels for specific uses.)
- ❖ Tests include:
  - high and low temperature (normal use)
  - stray radiation (external radiation levels)
  - fire accident condition

Table 1. Classification of device safety performance standards

Use conditions	Test/class 1	2	3	4	5	6	7	8	9	S
High temperature	No Test	50°C (122°F)	60°C (140°F)	85°C (185°F)	105°C (221 °F)	200°C (392°F)	300°C (572°F)	400°C (752°F)	600°C (1112°F)	Special
Low temperature	No Test	20°C (68°F)	0°C (32°F)	−40°C (−40°F)	−79°C (−110°F)	−100°C (−148°F)	−196°C (−320°F)			Special
Stray radiation at 5 cm[a,b]	No Test	2 mSv h^{-1} (200 mrem h^{-1})	1 mSv h^{-1} (100 mrem h^{-1})	0.5 mSv h^{-1} (50 mrem h^{-1})	0.2 mSv h^{-1} (20 mrem h^{-1})	50 µSv h^{-1} (5 mrem h^{-1})	20 µSv h^{-1} (2 mrem h^{-1})	7.5 µSv h^{-1} (0.75 mrem h^{-1})	5 µSv h^{-1} (0.5 mrem h^{-1})	Special
Stray radiation at 30 cm[a]	No Test	1 mSv h^{-1} (100 mrem h^{-1})	0.5 mSv h^{-1} (50 mrem h^{-1})	0.2 mSv h^{-1} (20 mrem h^{-1})	50 µSv h^{-1} (5 mrem h^{-1})	20 µSv h^{-1} (2 mrem h^{-1})	7.5 µSv h^{-1} (0.75 mrem h^{-1})	2.5 µSv h^{-1} (0.25 mrem h^{-1})		Special
Stray radiation at 100 cm[a]	No Test	100 µSv h^{-1} (10 mrem h^{-1})	20 µSv h^{-1} (2 mrem h^{-1})	7.5 µSv h^{-1} (0.75 mrem h^{-1})	2.5 µSv h^{-1} (0.25 mrem h^{-1})					Special
Accident condition										
Fire[c]	No Test	5 min 538°C (1,000°F)	20 min 800°C (1,472°F)	1 h 927°C (1,700°F)	2 h 1,010°C (1,850°F)	4 h 1,093°C (2,000°F)				

[a]Distance measured from the nearest accessible surface of the device or as specified in Section 7.3.2 and Figures 1 and 2.
[b]Due to the large dimensions of neutron detectors, it is impractical to make measurements at 5 cm from the surface of a gauging device containing a neutron source and hence Class 1 will be specified.
[c]Standard U.L. fire rating (time temperature curve). This test does not apply to devices containing machine-generated sources of radiation (provided the conditions of Section 3.1.2 are met)

ANSI N43.8-2008 - High and Low Temperature (cont.)

❖ Evaluation Criteria

- no failure causing loss of function of safety features during temperature cycle.

- stray radiation at the conclusion of test shall not exceed the value recorded prior to the test.

ANSI N43.8-2008 - Fire Accident

- Performance Test Parameters
  - subject to temperatures specified for time specified.
- Evaluation Criteria
  - retain source in source housing.
  - no release or leakage of radioactive material.
  - safety features need not function.

ANSI N43.8-2008 - “1" & “S” Performance Test Classifications

❖ “1" indicates either:

- device was not subjected to the test; or
- @ 5 cm, stray radiation contains neutron

❖ “S" indicates custom test (outside the parameters for the maximum classification)

Example:

High temp > 600°C,

Low temp < -196°C,

Stray radiation > 200 mrem/hr.

ANSI N43.8-2008 - Other Requirements

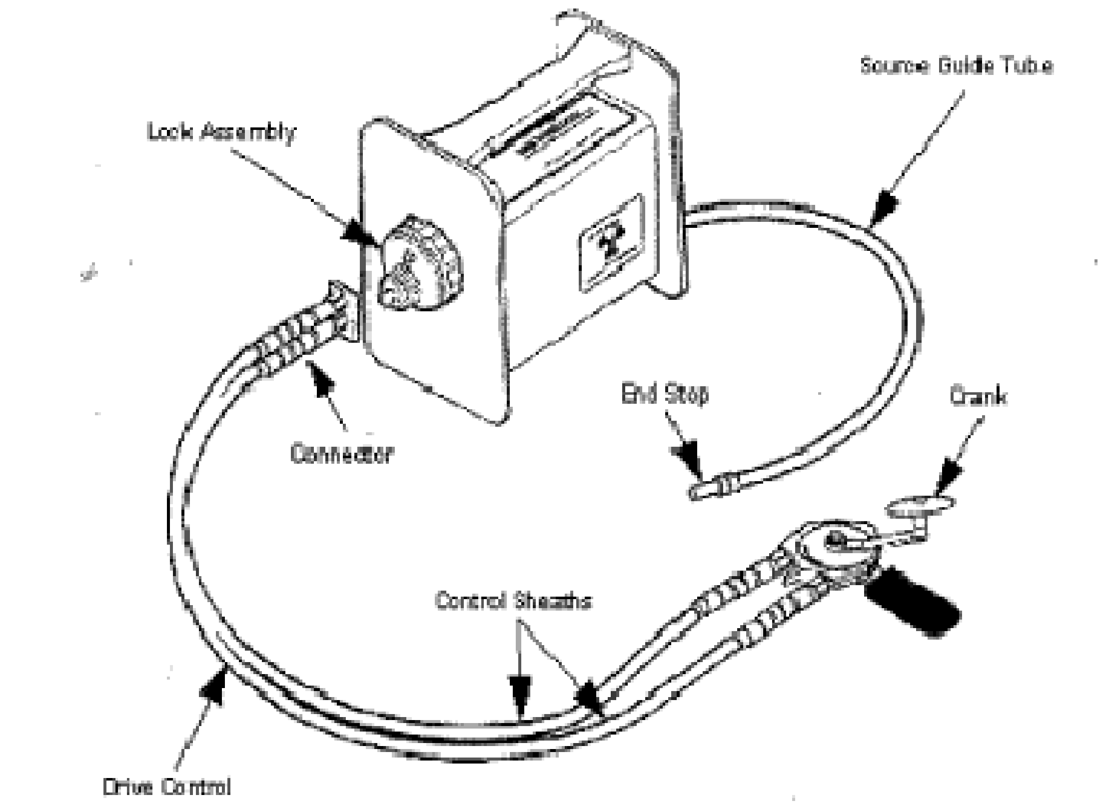
- Safety Features
  - source encapsulation/ANSI/HPS N43.6-2007 classification
  - restrictions to source access
  - radiation shielding
  - useful beam controls (shutter)
  - life cycle testing sufficient to indicate reliability
  - on-off indicators
  - interlocks
  - labeling
  - instructions to users

ANSI N43.8-2008 - Other Requirements (cont.)

- ❖ Conditions of Use - Design
  - corrosion
  - vibration
  - impact
  - compressive loads
  - explosion
  - flooding

- ❖ Conditions of Use -Radiation Safety/Licensing
  - distance to workstations
  - personnel occupancy times
  - maintenance (gauge and nearby equipment)

General Arrangement of Radiography Section



N43.9-1991 - Radiography Test Requirements

- Prototype apparatus by qualified organization
- Shielding efficiency for all production units by manufacturer
- Strength of source holder connection for all production units by manufacturer

Other References on Radiography Equipment:

NUREG/CR-6652, “Safety Testing of Industrial Radiography Devices”

NUREG-1631, “Source Disconnects Resulting From Radiography Drive Cable Failures”

N43.9-1991 - Exposure Devices

- Shielding efficiency test
- Vibration encountered during transport resistance test
- Shock resistance test
- Handle wrench test
- Accidental drop resistance test
- Accidental puncture test
- Accidental fire test

N43.9-1991 - Remote Control Devices

- ❖ Kinking test for flexible sheaths
- ❖ Crushing and bending test for remote control sheaths
- ❖ Tensile test

N43.9-1991 - Projection Sheaths & Exp. Heads

- ❖ Kinking test for flexible projection sheaths
- ❖ Crushing and bending test for projection sheaths
- ❖ Tensile test for Classes P and M devices

N43.9-1991 - Source Holders

- ❖ Tensile test for prototype source holders
- ❖ Tensile test for production source holders

N43.9-1991 - Prototype Devices

- ❖ Projection test under stress
- ❖ Endurance test

Should I Accept the Testing Submitted?

- ❖ Determine the normal conditions of use and likely accident conditions.
- ❖ Review procedures, conditions of the tests, acceptance (pass/fail) criteria, and results to determine whether the testing adequately simulates those conditions.
- ❖ If a design passes a test, it does not imply that the design will maintain its integrity if used continuously under the test conditions.
- ❖ For example, a sealed source tested for one hour at 600°C may, or may not, maintain its integrity if used continuously at 600°C.

Should I Accept the Testing Submitted? (cont.)

- Tests typically considered are:
  - drop
  - temperature
  - external pressure
  - impact
  - cycle/endurance
  - vibration
  - corrosion
- Additional tests or retest may be required depending upon the conditions of use.
- Test the design integrity at the extremes of the typical operating range. Consider the worst case.
- Consider the impact of packaging and transportation
- Not acceptable if only special form tests in 10 CFR 71.75 or IAEA Safety Series 6 (¶ 607 - 611) are performed.

Engineering Analysis

- Detailed, systematic analysis of the design and materials of construction, and the processes used in the manufacturing of the product.

- May consist of calculations, modeling, sample testing, and evaluation.

- If an industrial standard applicable, may demonstrate the product would successfully pass the standard tests.

- Conclusions should be fully justified with supporting documentation describing the analysis and including calculations or other applicable reference material.

Operational History

- Evaluation of performance of identical designs used in equivalent or more severe conditions of normal use.
- Can exclude accessory equipment that has no effect on the safety or integrity of the product.
- Typically includes products used in the US as a custom products or in another country.

Operational History (cont.)

- Should be based on documented, actual use of a specific unit, and not on estimated averages.
- If sufficiently comprehensive, may demonstrate the product integrity for likely accident conditions.
- Would not be sufficient to demonstrate integrity if it has never been subjected to the extremes of expected normal use or likely accident conditions.

Operational History (cont.)

- ❖ Evaluation should consider:
  - environmental and operating conditions
  - numbers of cycles per year
  - results of known accident conditions
  - results and root causes of failure, any design changes if applicable
  - years of use of the product

Comparison to a Similar or Equivalent Registered Model

- ❖ Information concerning a similar or equivalent registered model may be used, if:
  - the design, and the normal and likely accident conditions for the previously registered device are identical or similar
  - can be related through engineering analysis to the requested product.
- ❖ Demonstrate that the new product is:
  - similar to or more robust than the registered product, or
  - differences between the products are such that the integrity and safety would not be affected.

Custom Use Products

- ❖ Full prototype testing may not be required, usually because:
  - only a limited number will be produced
  - use only by one specified user, and/or
  - can require (by the license) that additional administrative controls (e.g., ANSI N43.8-2008) can be implemented by the licensee to reduce the possibility of failure, or to ensure that the licensee is qualified to safely handle a product failure.

Products that do not Require Evaluation and Registration

- Calibration and reference sources if the sources do not exceed the following:
  - For beta and/or gamma emitting material – 3.7 MBq (100 µCi) or ten times the quantity specified in Section 30.71, Schedule B, 10 CFR Part 30, whichever is greater.
  - For alpha emitting material – 0.37 MBq (10 µCi).

Products that do not Require Evaluation and Registration – cont'd

- Sealed sources or devices containing sealed sources that are intended only for use under research and development or broad scope licenses if the following is valid:
  - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

Products that do not Require Evaluation and Registration– **cont'd**

- Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) if:

  – (a) they contain less than 7.4 GBq (200 mCi) of radioactive material or less than 740 GBq (20 Ci) of tritium, and

  – (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

Amendments to Registries

- For older registries with insufficient testing, or no documentation, instead of retesting, may consider:
  - perform a comparative analysis of the source to a source of similar construction, design, etc. and;
  - evaluate the leak test history and field history of the source, including any knowledge the manufacturer may have regarding damaged sources or defects. The reviewer should look for trends in the failures which may indicate a design problem.

Copies of Standards

American National Standards Institute
11 West 42nd Street
New York, New York 10036
(212) 642-4900
www.ansi.org

-or-

Health Physics Society
1313 Dolley Madison Blvd., Suite 402
McLean, Virginia 22101
(703) 790-1745
www.hps.org

Security Considerations

Numerous security measures already in place:

- Additional Security Measures (SGI-M)
- Increased Controls (IC's)
- National Source Tracking System (NSTS)
- Pre-licensing screening
- Pre-licensing inspections
- Shipping escorts

IAEA-Safety Guide RS-G-1.9

Entitled "Categorization of Radioactive Sources"
dated August 2005,
web access:
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf

- graded approach to regulatory control of radioactive material
- 5 categories
- numerical ranking of sources and practices
- formula to calculate aggregation of sources

Appendix E to Part 20--Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

Sources and Devices Designed for Additional Security

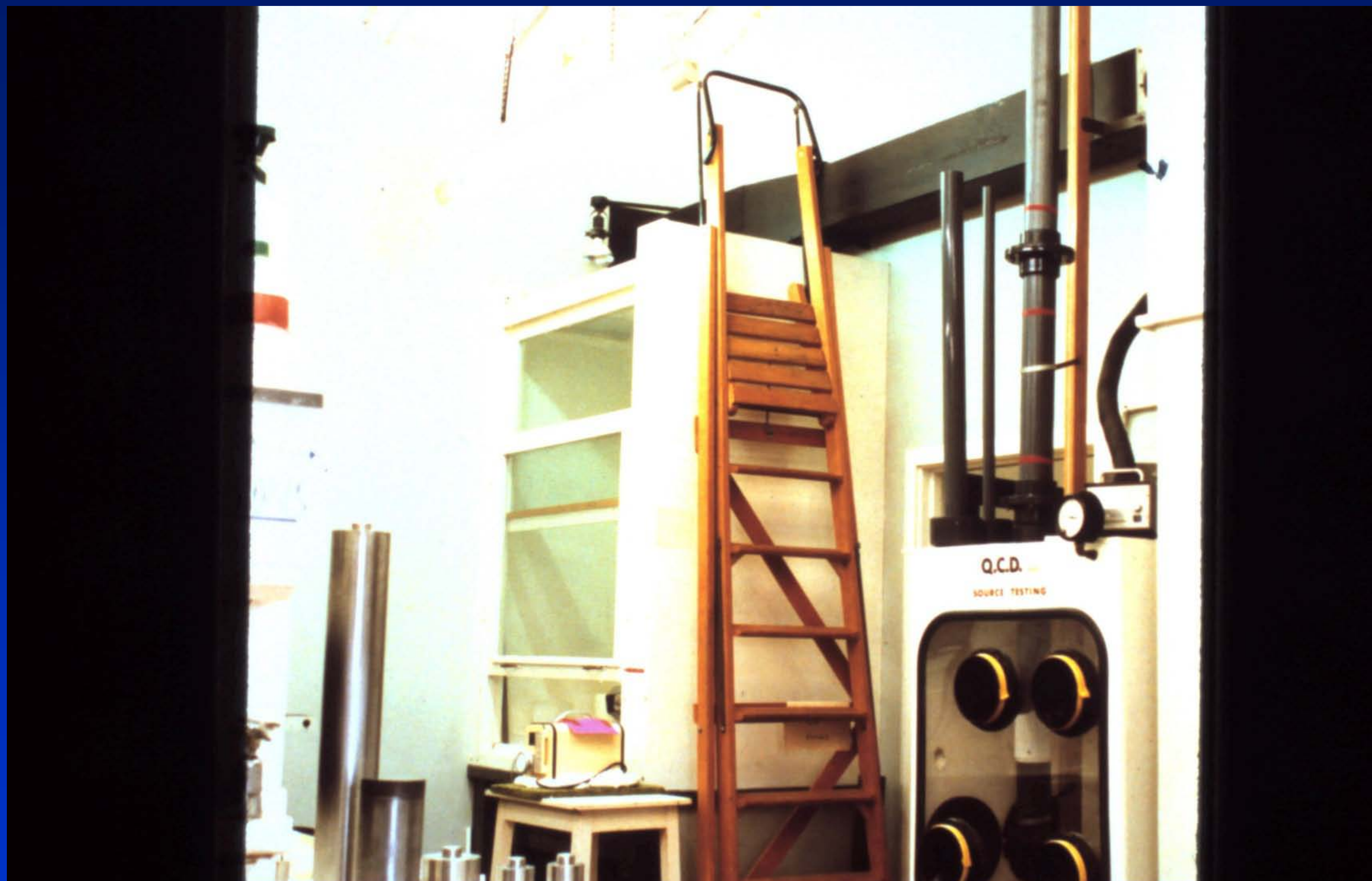
1. GPS/Alarms built into design

2. Immobilization mechanisms

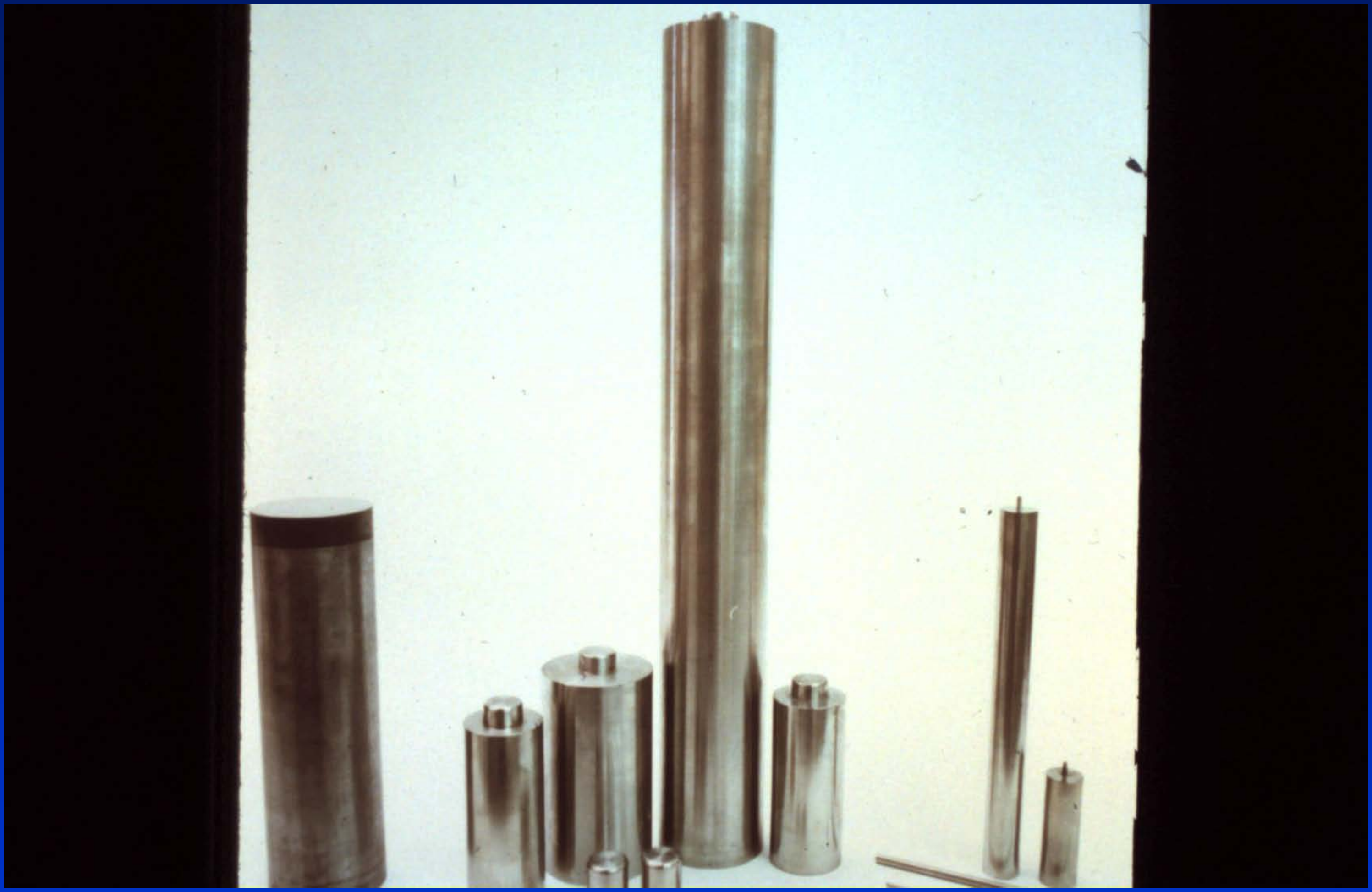
3. GL Devices to be re-evaluated

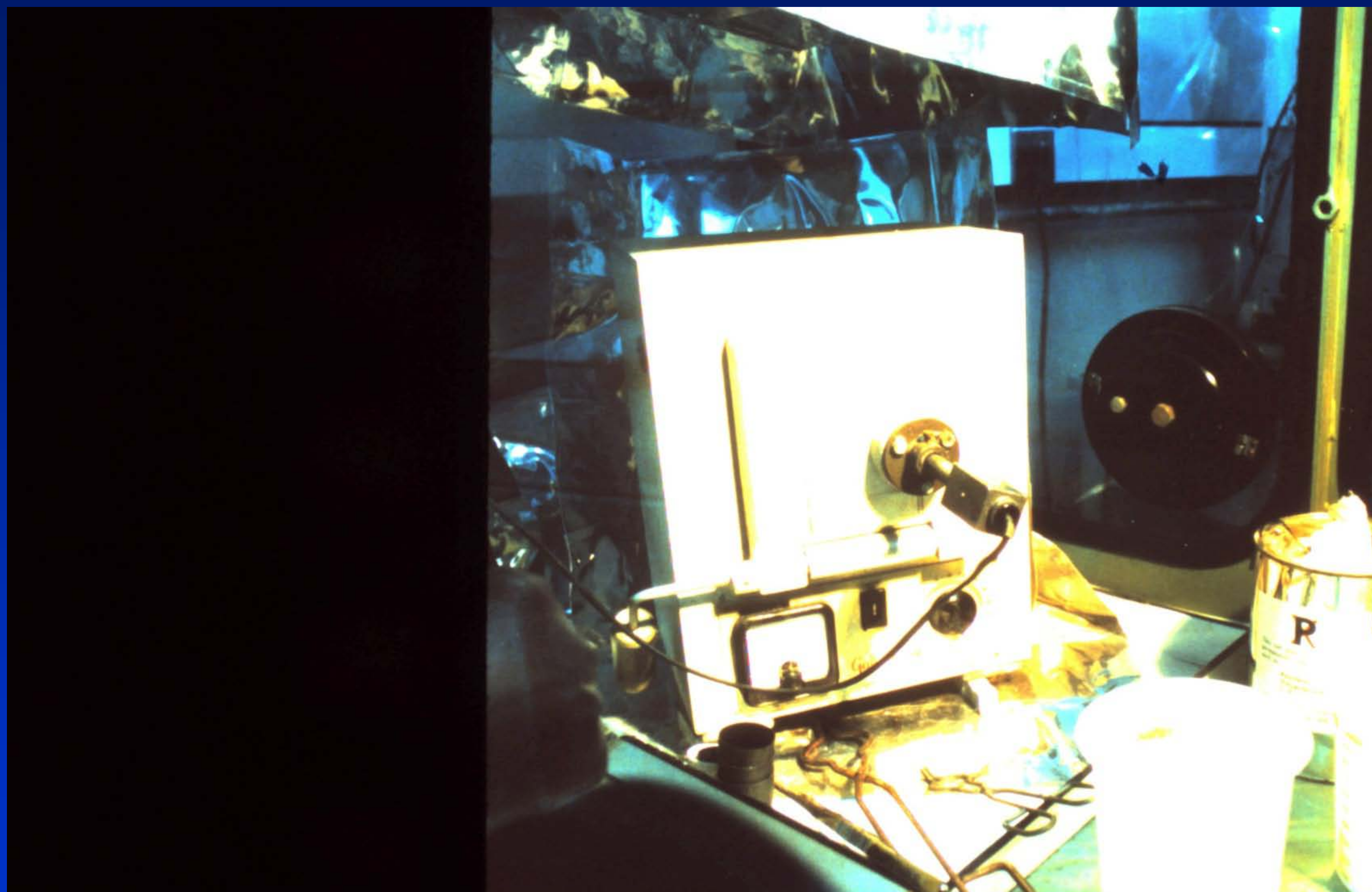
4. Tamperproof housings and mounting points:
   - Spot welds vs. mechanical fasteners
   - One-way screws
   - Hidden fasteners

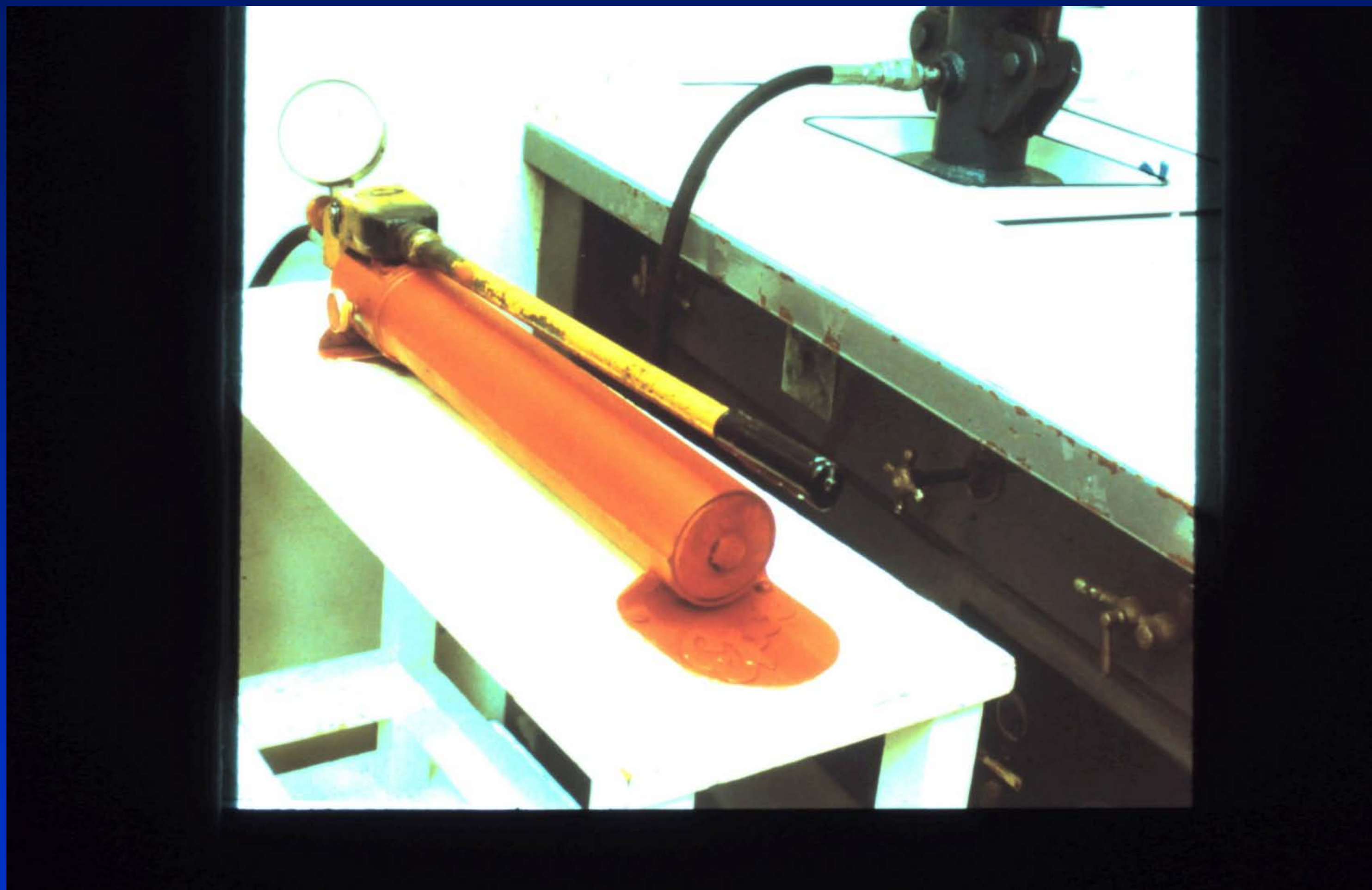
Prototype Testing Facilities and Equipment

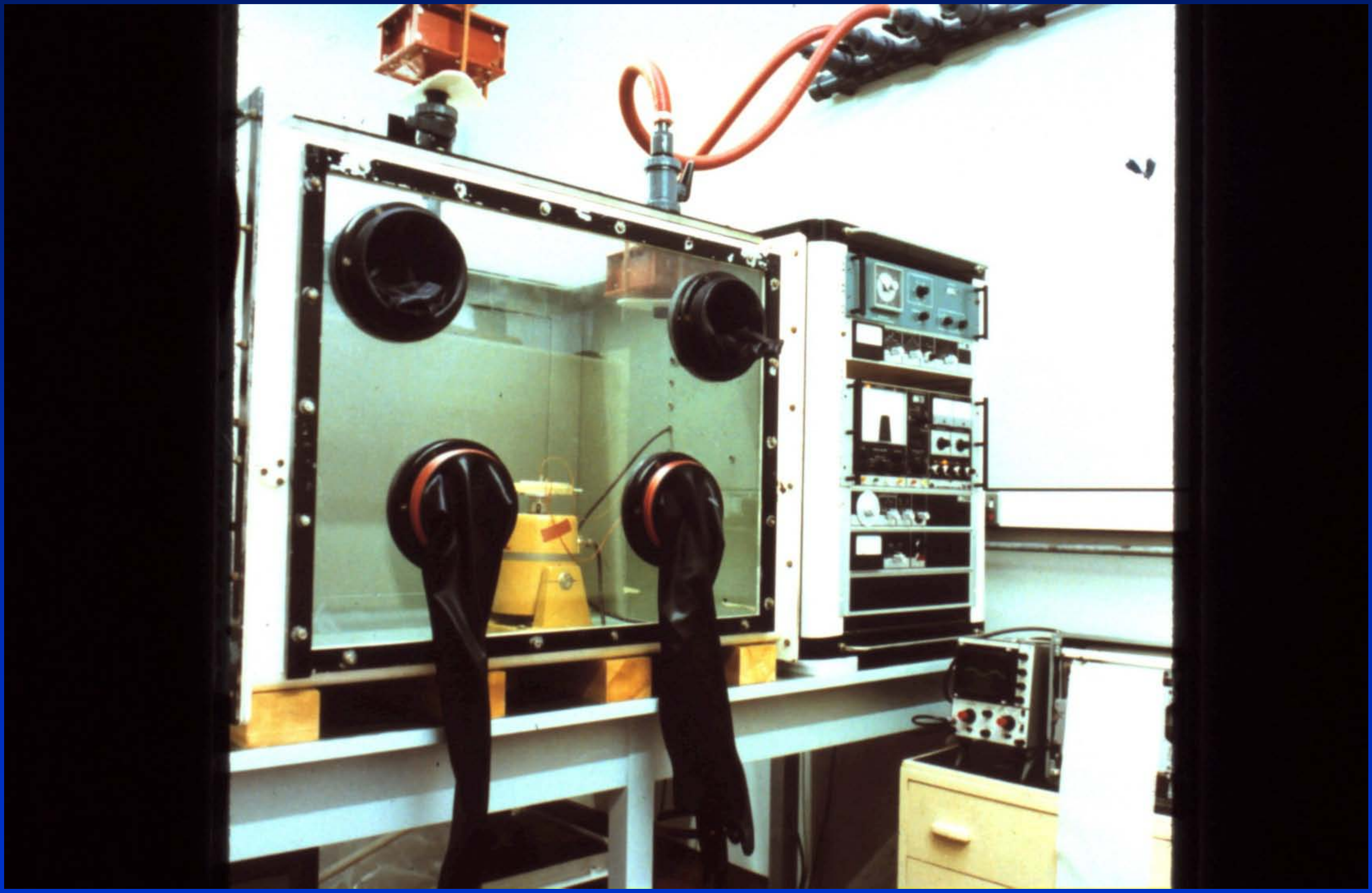

Q.C.D.
SOURCE TESTING

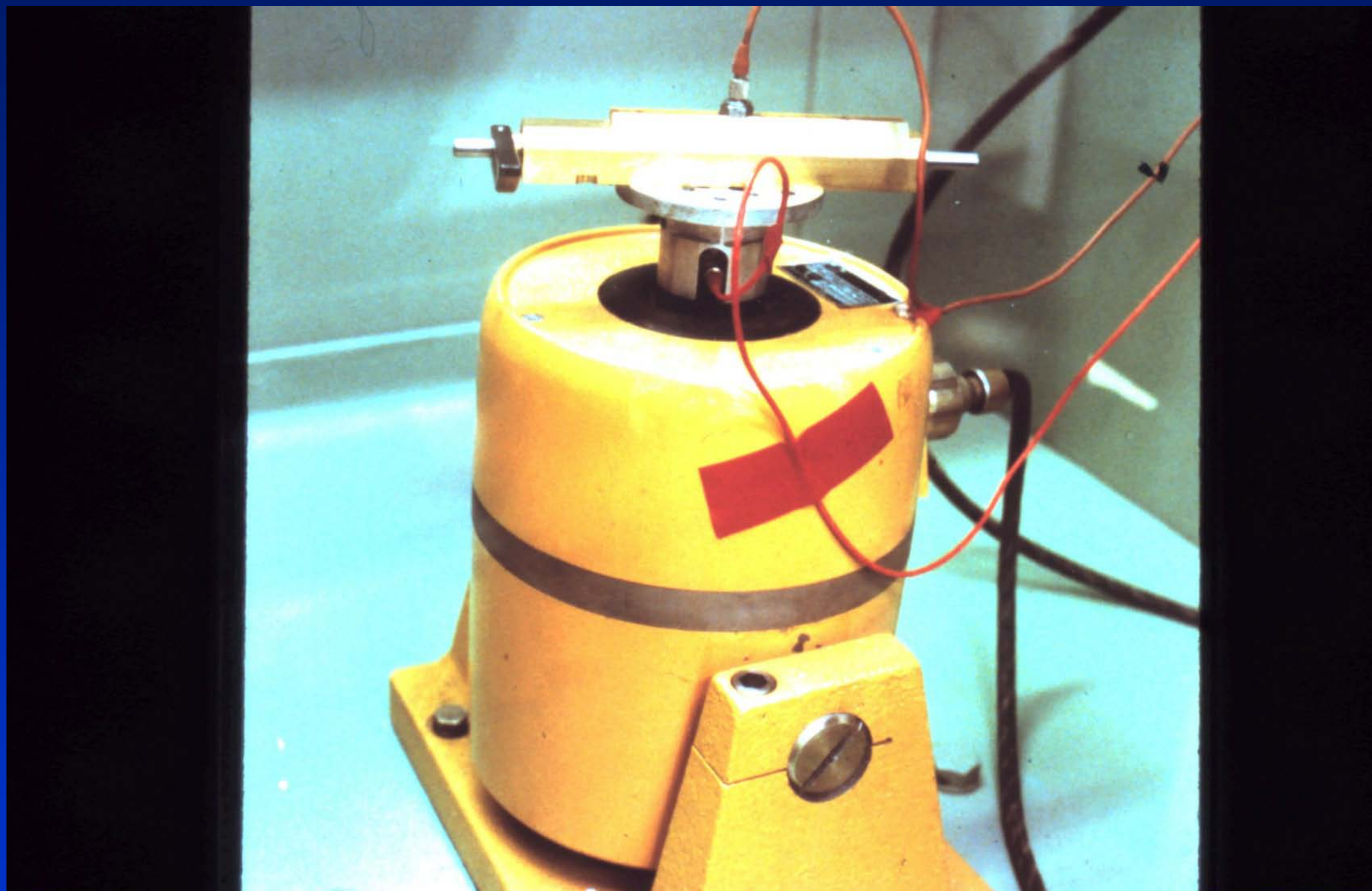

COTTON
WOOL
Balls

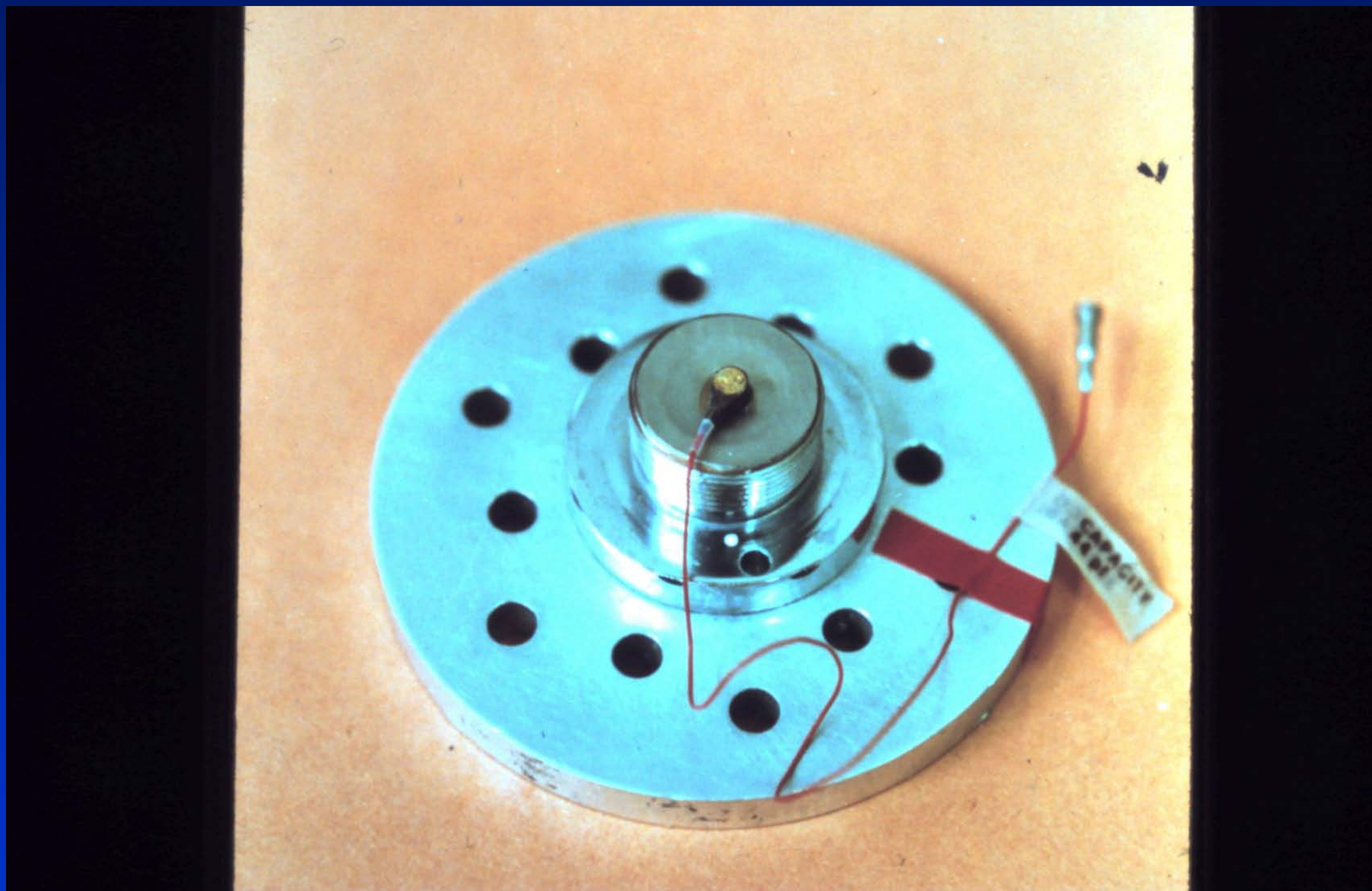


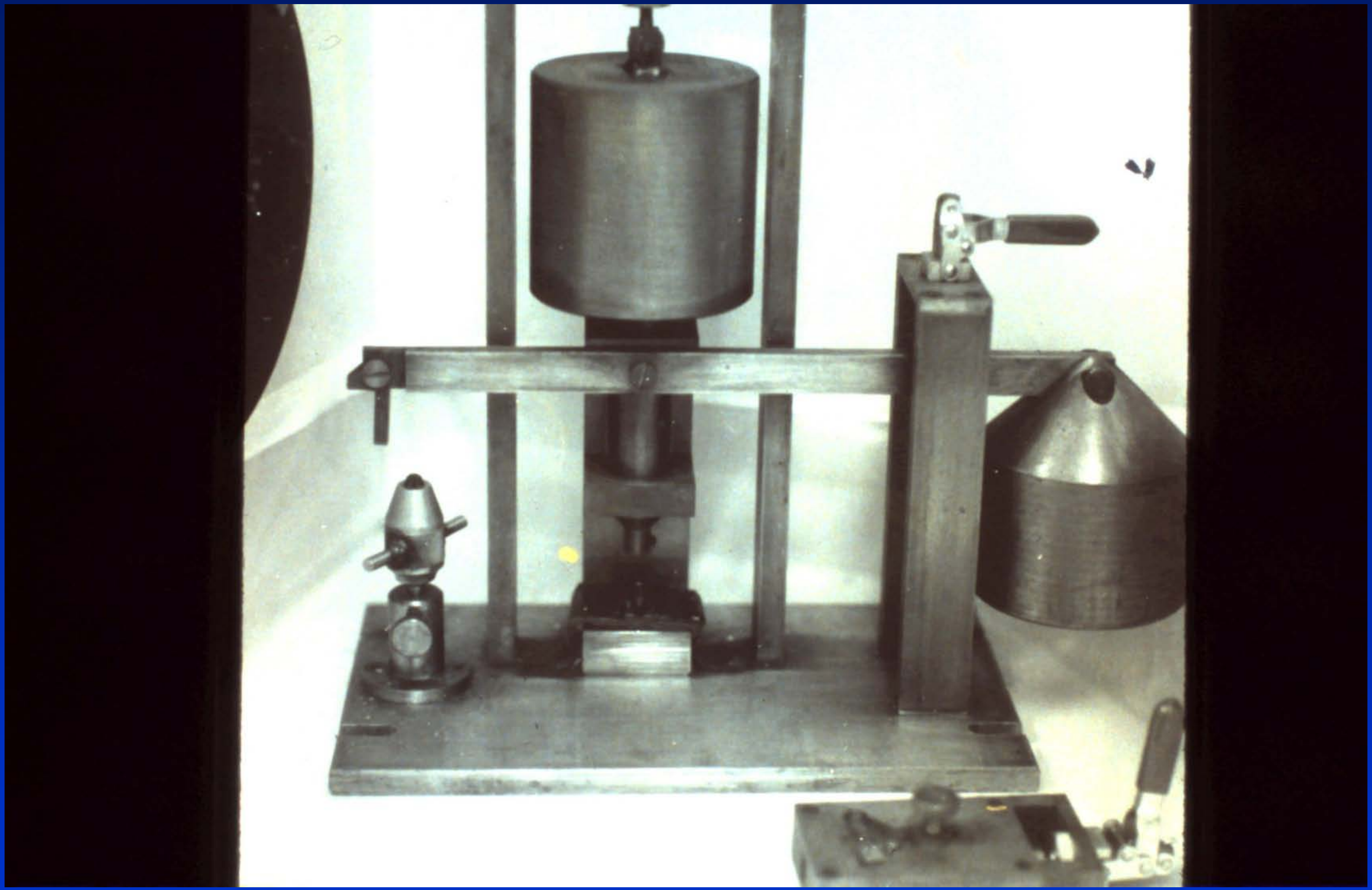


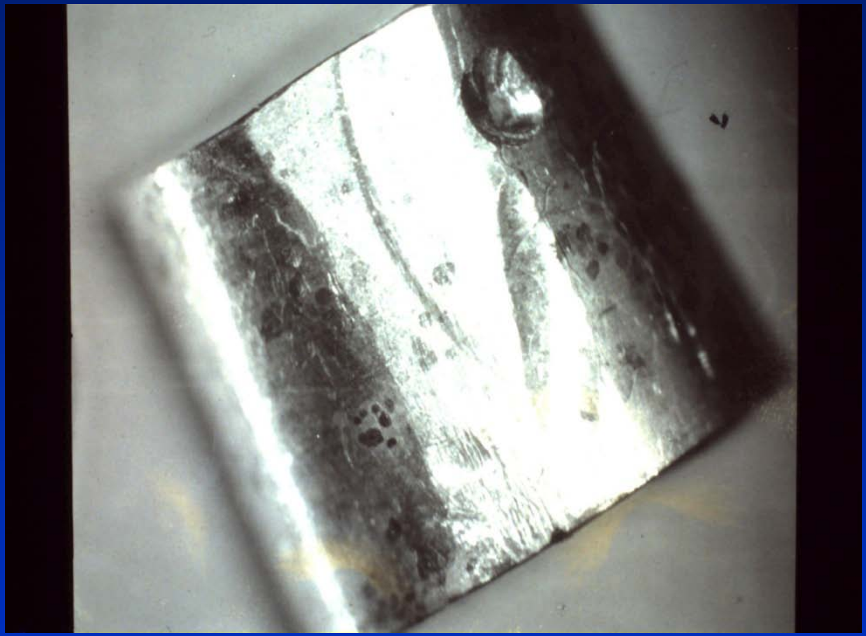


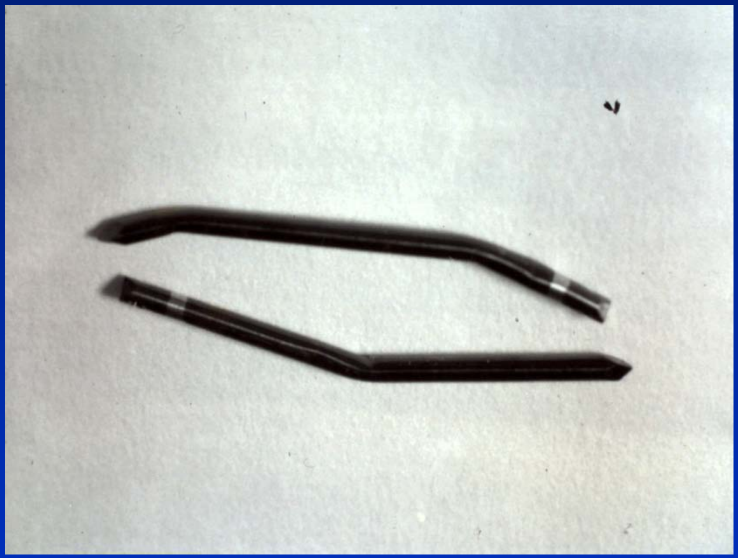


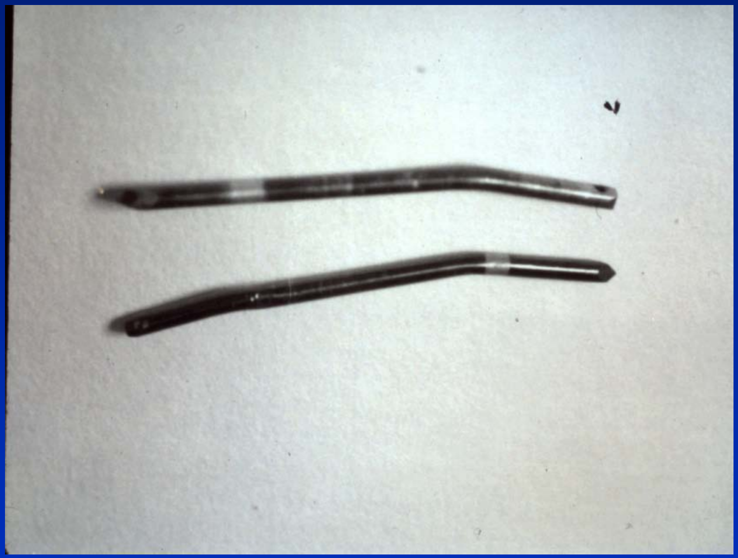


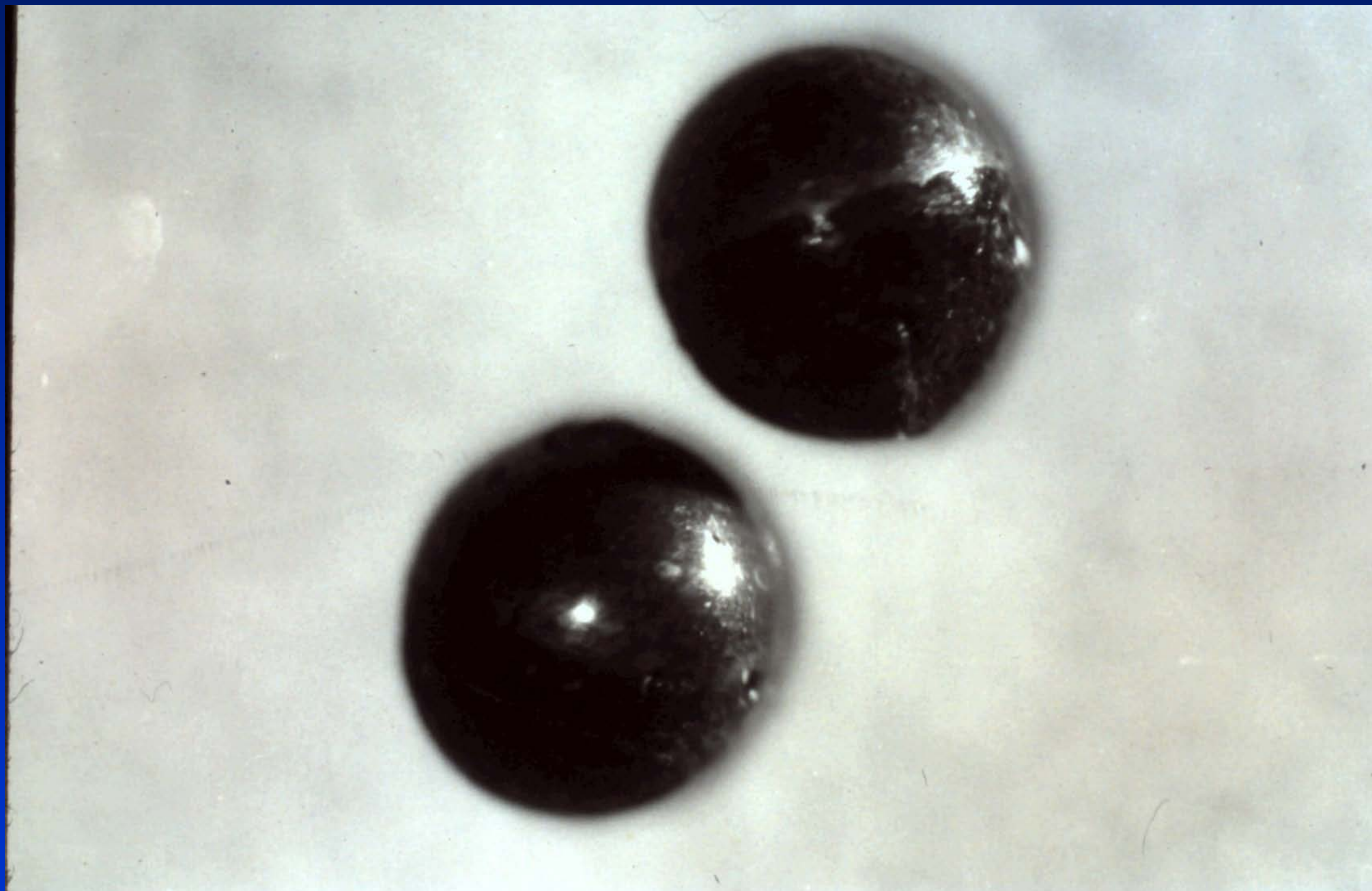


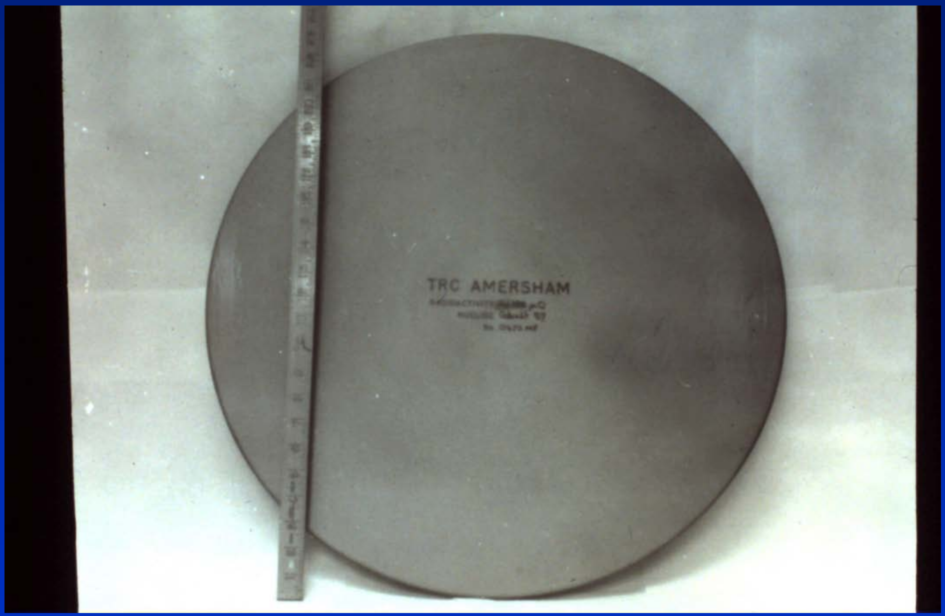








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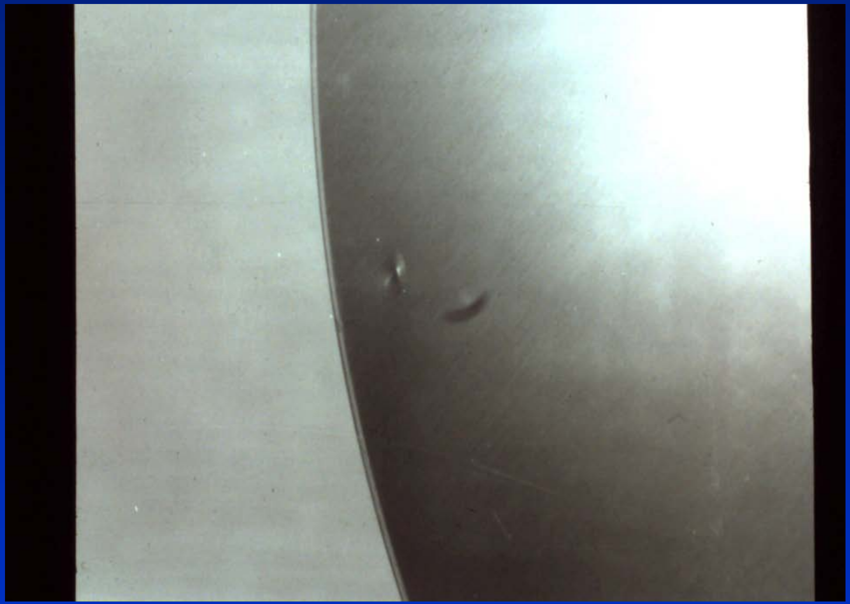

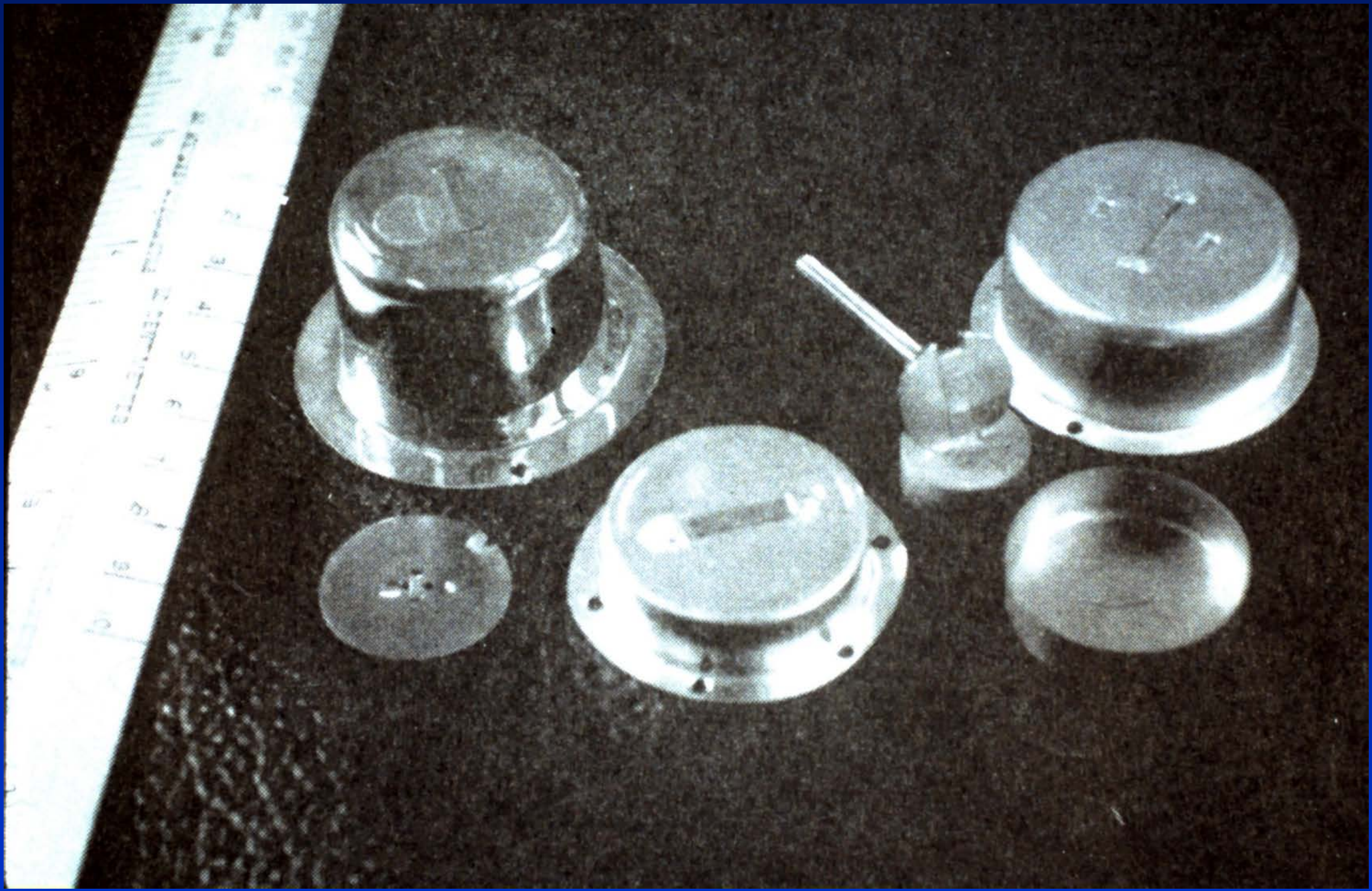

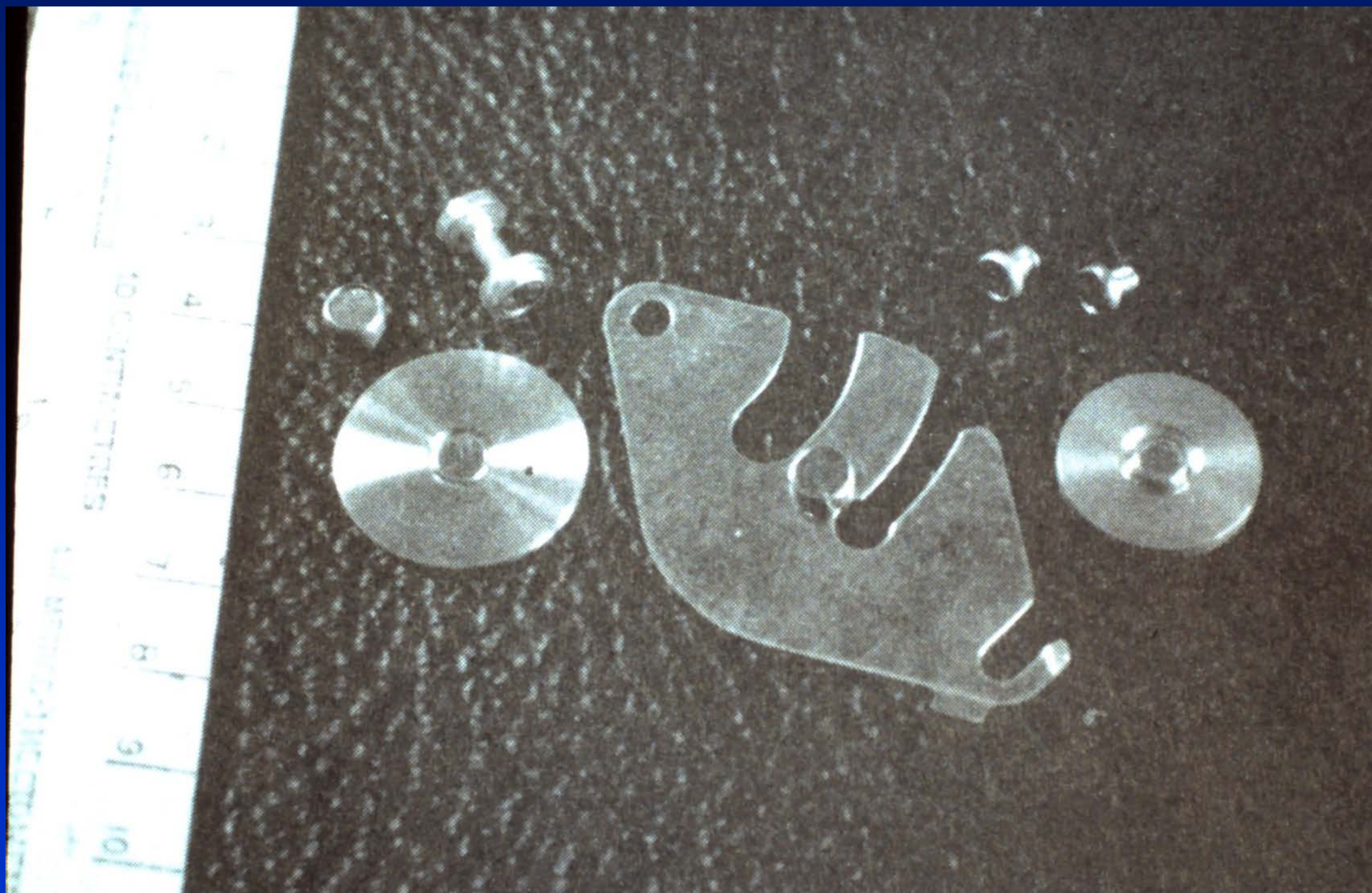

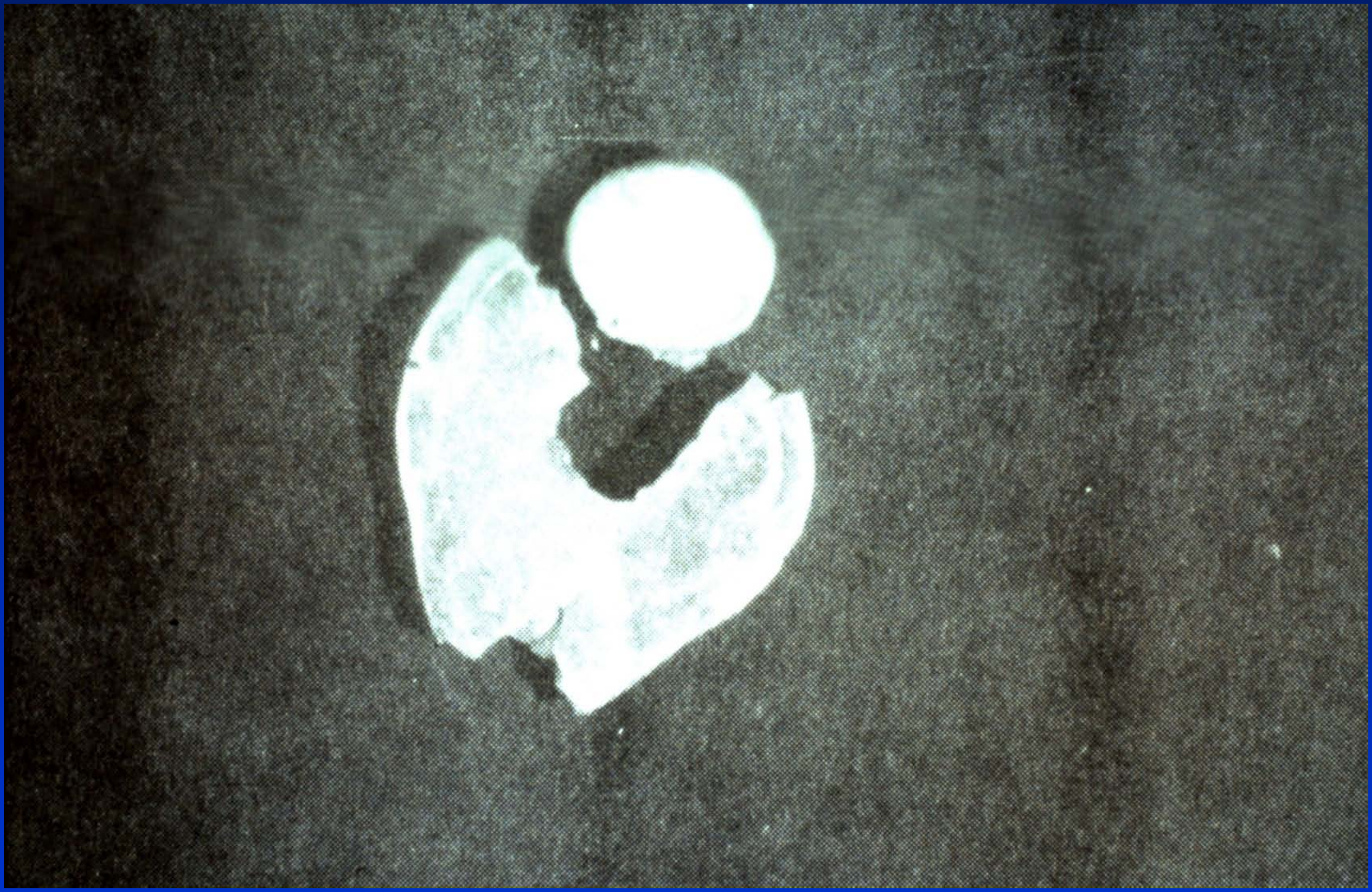

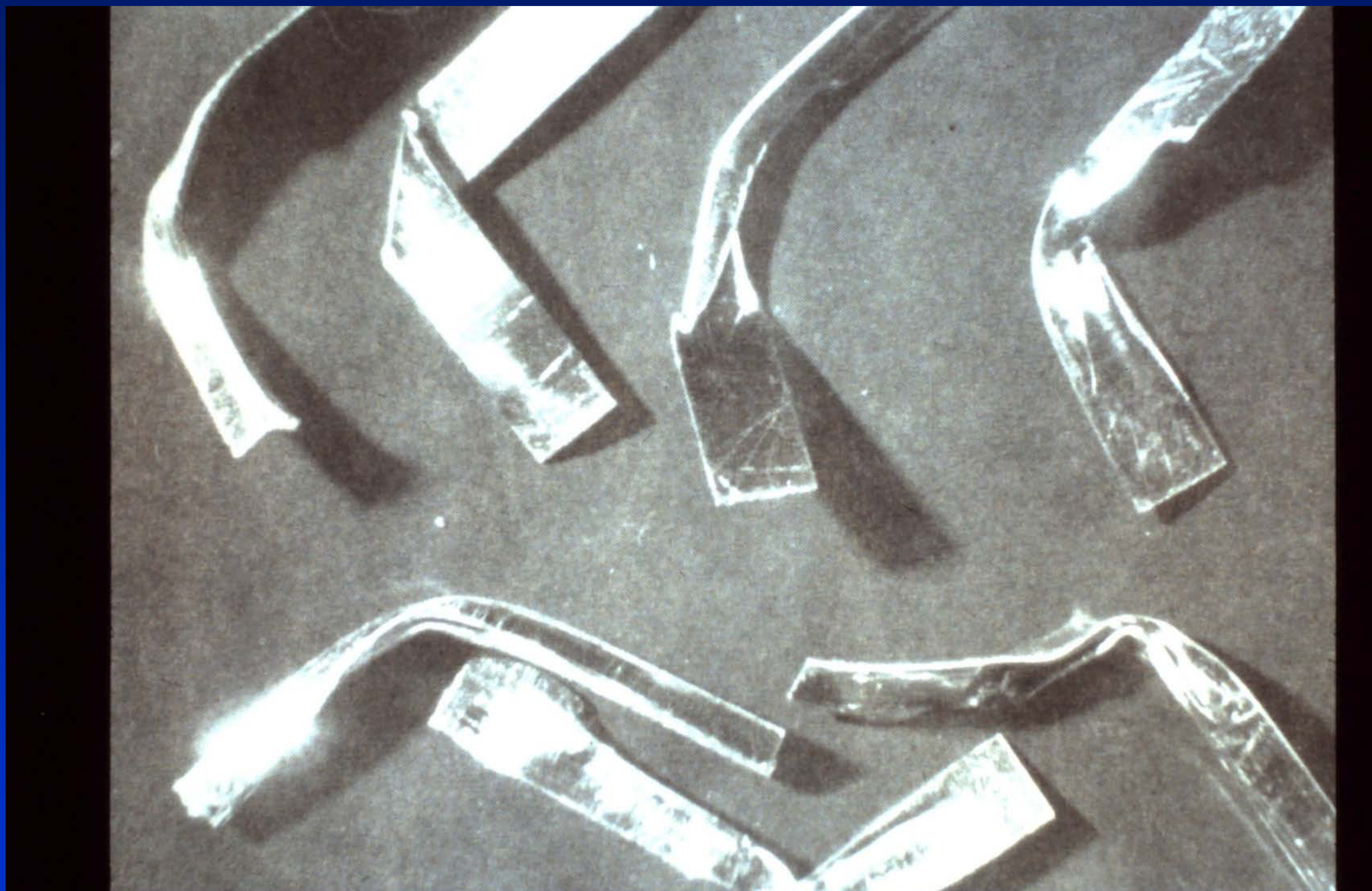

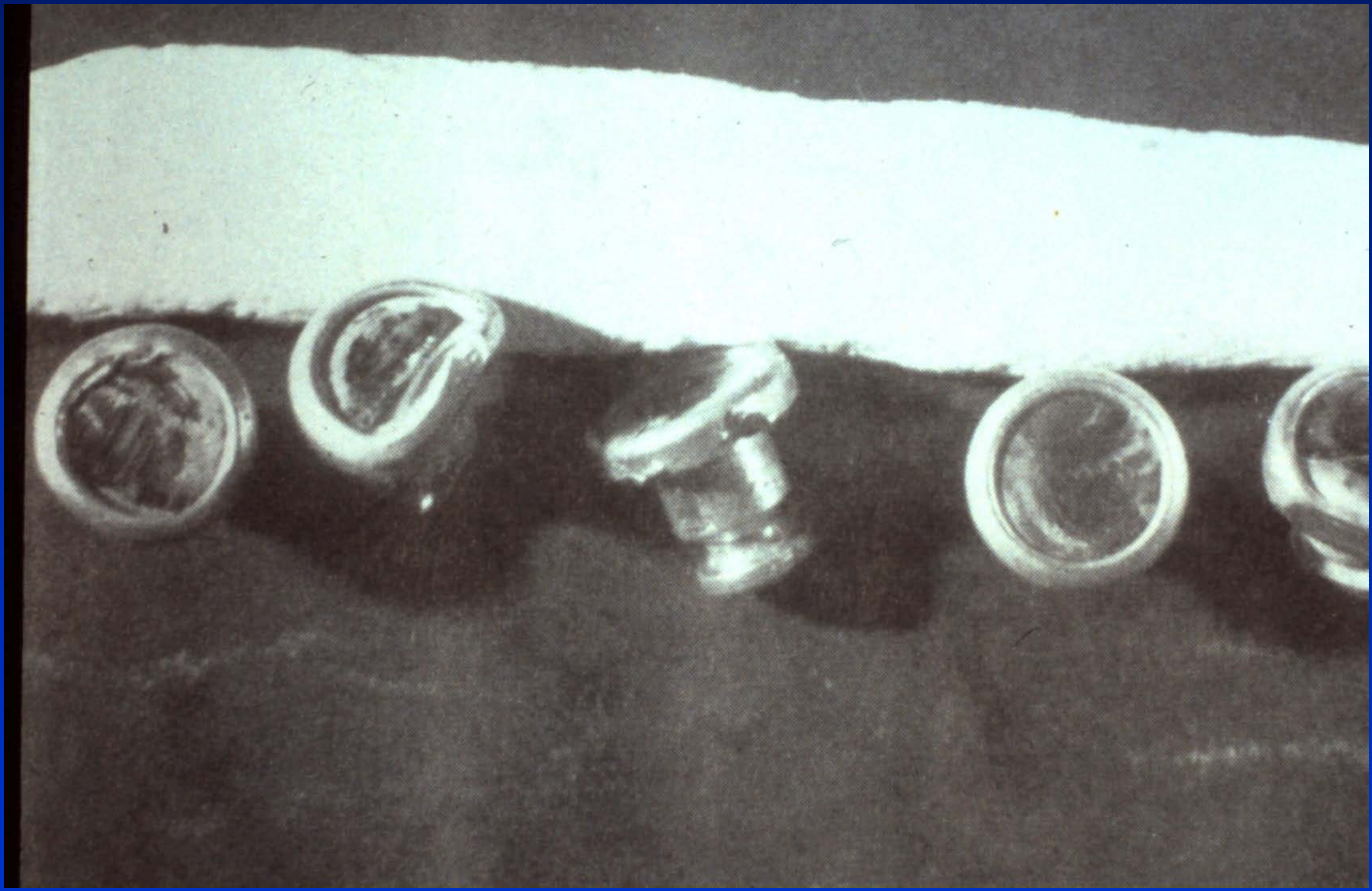

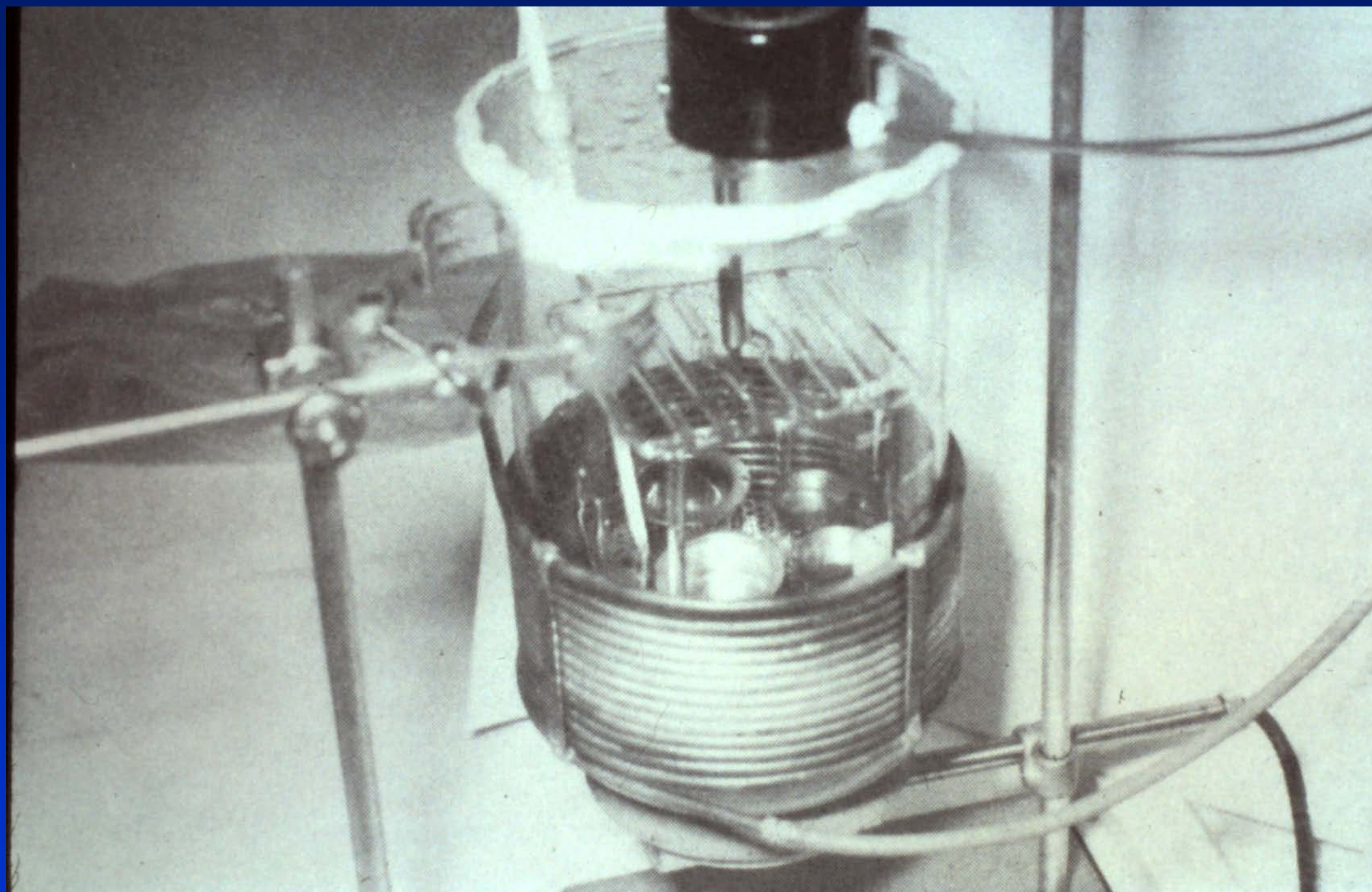

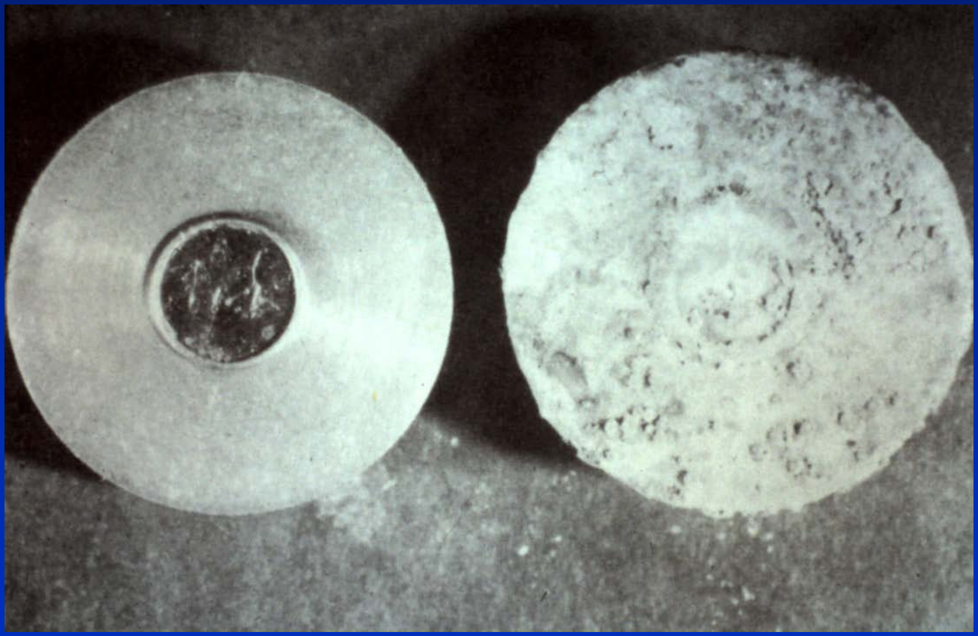

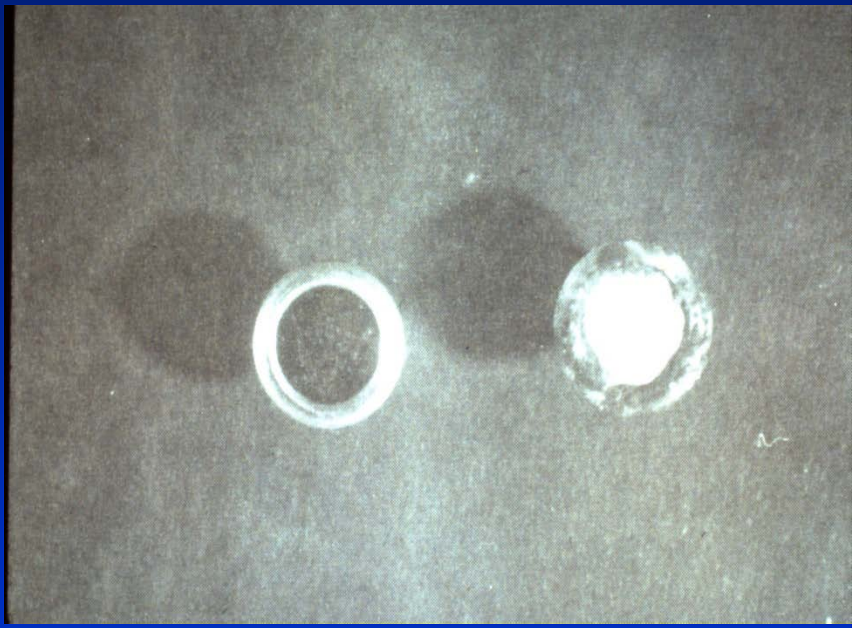

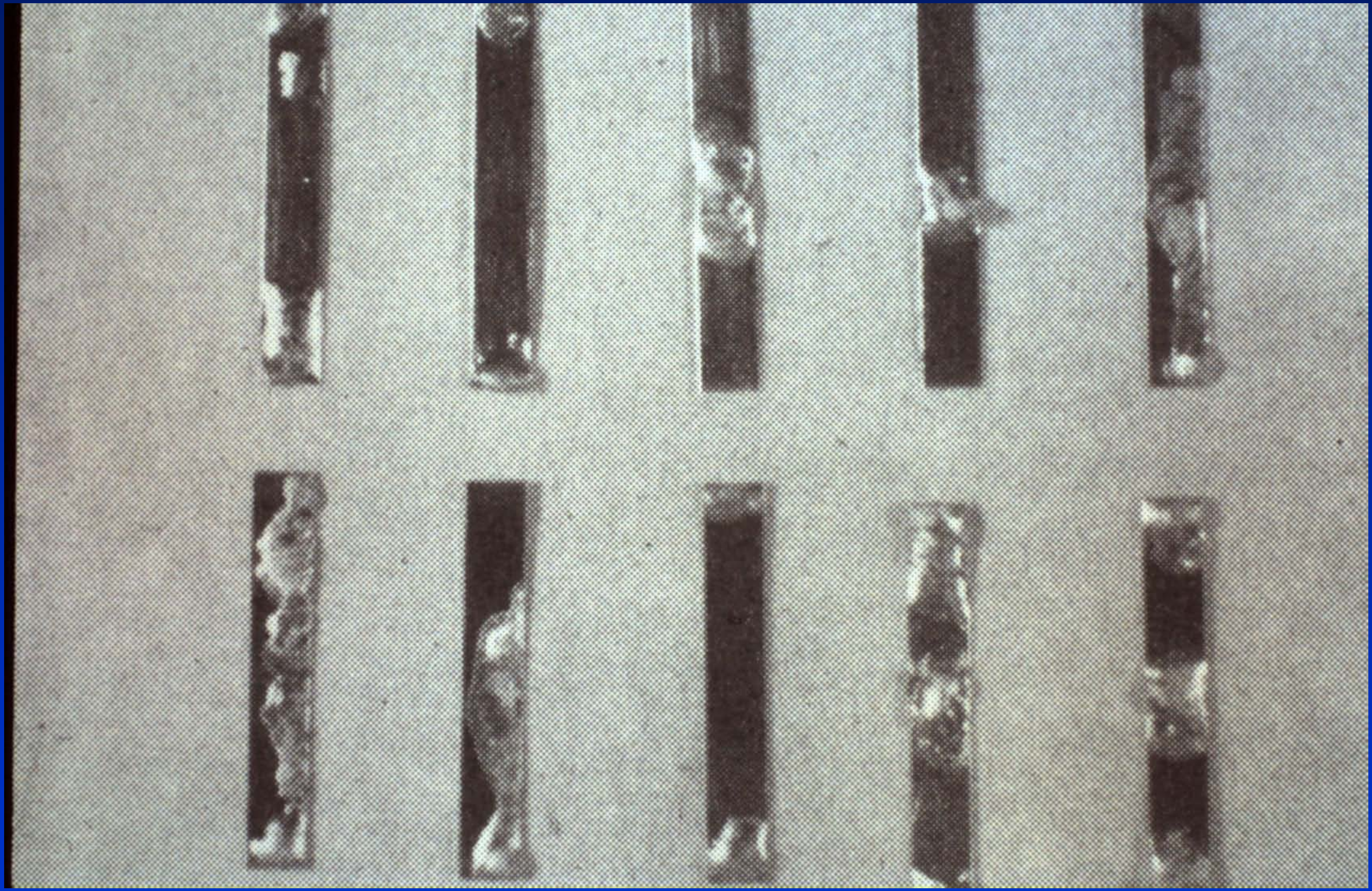

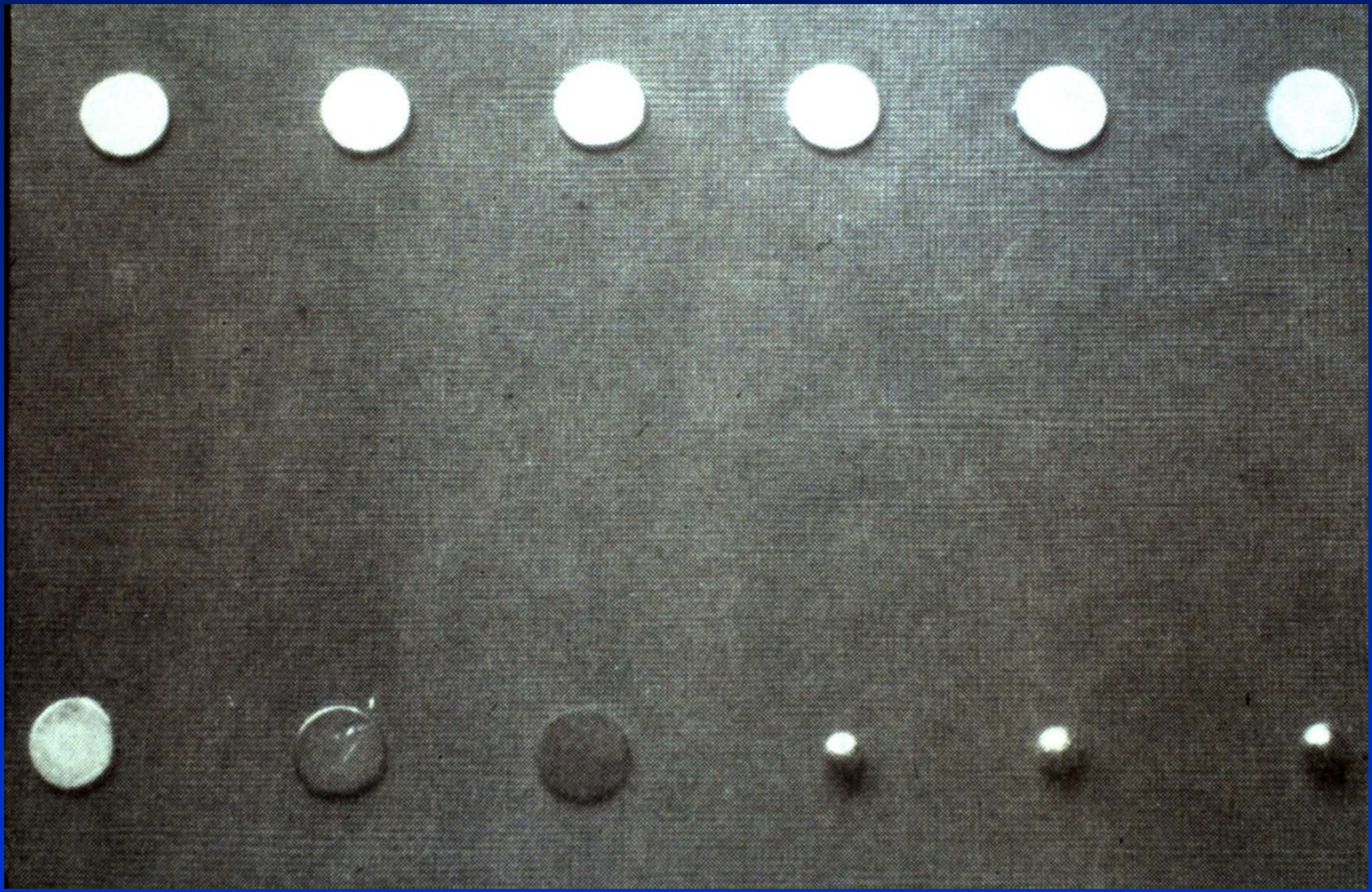

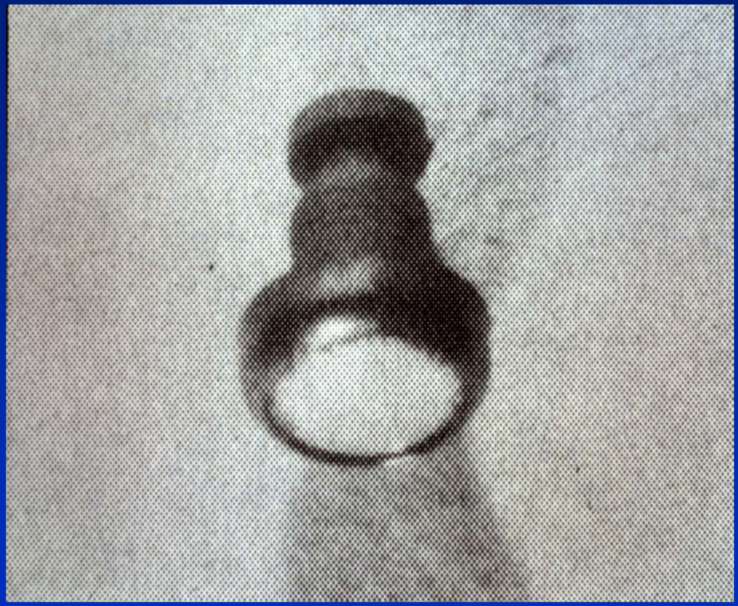

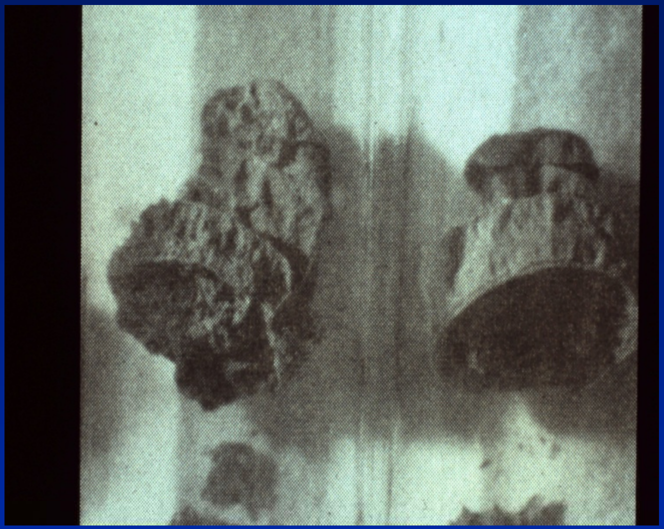

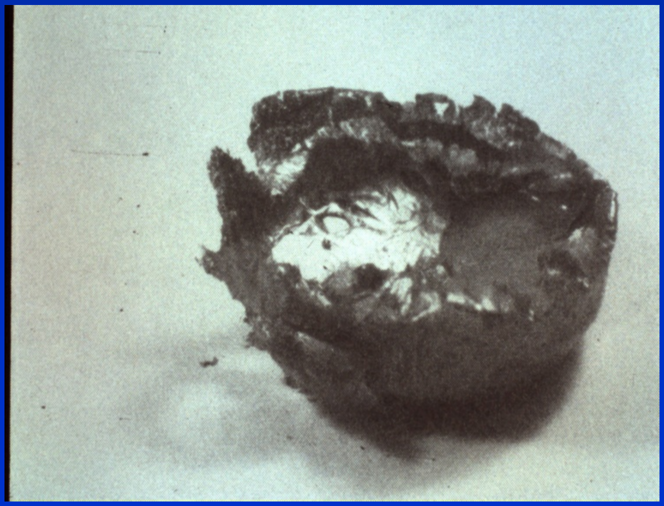

Thank You!

GIBB VINSON

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