Recd 8/26/96

SENTINEL

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Mr. Steven Baggett
Sealed Source Safety Section
Source Containment and Devices Branch
Division of Industrial of Medical Nuclear Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, DC 20555

22 August 1996

Amersham
QSA

Dear Mr. Baggett:

Enclosed, please find the additional information for approval of the Amersham J-tubes and rigid source stops. The information is presented in the same order as in your letter.

Model 660 camera

1. As discussed in our conference call on 4 Jun 96 and followed up on 24 July 1996, we do not need to perform the endurance test for longer length controls and guide tubes while activating the lock slide. The endurance test (without lock slide activation) was performed as described in our letter dated 22 Dec 95, and concludes that with 50 foot controls and 42 feet of guide tube the 660 meets the endurance test requirements of ANSI N432. The lock slide was previously successfully subjected to the required 20,000 cycle test of ANSI N432 and this information is on file with the approved SSDR sheet.

   I have enclosed information that describes how we measured the torque value. The average torque measured 2.1 ft lbs for crankout and 9.7 ft lbs in the retract mode. This was obtained by measuring force using nine different personnel, averaging these values and then determining torque dependent on the length of the crank handle. We feel this is an accurate representation of how the system is used.

2. The materials, construction and labeling for the longer length controls and guide tubes is identical to the controls and guide tubes currently approved. Older versions may not have visible markings, however these would be covered by the checklist that is in the NRC Information Notice 96-20.

3. The 50 foot control length specified is the distance from the crank to the camera.

4. The model 660 that was tested was wipe tested at the conclusion of the test and showed no depleted uranium contamination. We have included an addendum to indicate the results. (The test report reported raw data which led to the statement of progressively higher wipe tests) The tube was also borescoped which indicated that the S-tube did not wear through.

5. See answer to number 1.

Collimators

Information submitted 23 May 1996.

J-tubes/Jet Engine Probes

1. We are not familiar with the details of the medical source scenario that you referenced concerning dissimilar metals. We have not experienced any reported problems relating to the use of these metals together. However the vast majority of J-tubes we have manufactured are constructed completely of steel and do not use aluminum. We have updated the drawing to reflect the use of plated aluminum for the source stop if it is ever used in conjunction with steel.

2. See response to number 1 for Model 660 camera.

3. We have updated the drawings for J-tubes and jet engine probes to help clarify the difference between a J-tube and a jet engine probe. The J-tubes will easily pass the crush test as prescribed by ANSI as long as the minimum specifications as stated in drawing R JTUBE Revision B are met, ie 0.035 inch minimum wall thickness stainless steel tubing, as referenced in Test Plan number 44. In addition we have specified a maximum length of seven feet for the J-Tube.

   As shown in the drawing R 727 Revision A, the jet engine probe can be many different lengths depending on the application, typical lengths are seven to ten feet. The jet engine probes as described in drawing R 727 passed all of the prescribed ANSI N432 tests except for the crush test as described in ANSI N432. These details were provided in Test Plan number 44.The only section of the jet engine probe that did not pass the crush test was the end section due to the thinner wall. Due to their use in a protected environment ie inside a jet engine and the current practice of performing a QC/operational check on the probe prior to use, it is very unlikely that there will be a problem during use. We would recommend that they be considered for an exemption from the requirements.

4. The statement concerning the kinking test not being performed since a rigid guide tube will not encounter the kinking forces described in ANSI N432, is based on the fact that a rigid guide tube will not be subjected to coiling actions as a flexible guide tube would. A kinking resistance test as described by 10 CFR Part 34.20(c)(5) to closely approximate the kinking forces likely to be encountered during use of this equipment was considered to be less mechanically stressful than the tensile test, crush test and the actual endurance test performed. As a result no additional kinking forces from normal operational use were determined and no additional tests were performed, as the components have demonstrated their ability to meet other more stringent mechanical requirements.

Rigid Guide Tubes

A drawing, R RIGIDTUBE revision A has also been included to depict the specifications of a rigid guide tube, ie anything greater than 10 times the length of the source capsule, an ordinary source stop meeting the specifications of drawing R RSTOP Revision A would then be threaded on the rigid guide tube. This category is necessary to cover applications other than J-tubes and jet engine probes such

as pipe centering devices and other specialized applications. As the construction of these meet the requirements of 10 CFR part 34 and ANSI N432 as indicated by Amersham test report 52, we request approval against 10 CFR Part 34.

Please let me know if you require any additional information for registration of these components. Thank you for your assistance with this request.

Sincerely,

Cathleen Roughan

Cathleen Roughan
Regulatory Affairs Manager

MEMO

TO: GREG FIELD

FROM: GEORGE PARSONS GP

DATE: 18 JUN 96

SUBJECT: FORCE ON TELEFLEX CABLE,EXPOSING AND RETRACTING SOURCE

==

A test was set up to measure the typical force applied to the teleflex cable when exposing and retracting the source assembly.

To measure the force in the exposing direction, a gauge was attached to the end of a seven foot guide tube to act as a source stop. A twenty five foot reel type control was attached to the input side of a 660 style "s" tube and the seven foot guide tube was attached to the output side of the "s" tube. The twenty five foot control and the seven foot guide tube were chosen because in previous tests it was found that the longer the control and guide tubes the smaller the force on the teleflex cable. This is because the guide tube and the control housings are flexible and they contract and act as a shock absorber when the source is at the extreme ends of its travel. (See figure 1)

The test was performed by nine different individuals. They were instructed to turn the crank handle as fast as they could until the drive cable came to a stop and then give the handle another hard pull against the stop. They did this five times. The gauge measured the maximum force in pounds of each of the five times. The average of the five trials is listed below for each of the nine individuals.

D.E. 6.4 LBS
G.P. 7.0 LBS
K.A. 6.4 LBS
R.B. 6.6 LBS
D.W. 6.0 LBS   Average of group 6.4 lbs
F.P. 6.3 LBS
D.A. 6.5 LBS
M.B. 6.5 LBS
C.F. 6.0 LBS

If we multiply this average force by the four inch length of the crank arm of our control we get a maximum of 25.6 in lbs or 2.1 ft lbs of torque in the exposing direction.

To measure the force in the retracting direction a spring scale was attached to the end of the teleflex drive cable after the cable passed thru the "s" tube and the twenty five foot control. (See figure 2)
The same nine individuals were instructed to turn the crank handle as hard as the could and the maximum force was recorded for each of five trials. The average of these five trials is listed below.

D.E. 36.4 LBS	
G.P. 18.4 LBS	
K.A. 49.0 LBS	
R.B. 36.8 LBS	
D.W. 10.6 LBS	Average of group 29.2 lbs
F.P. 21.4 LBS	
D.A. 41.0 LBS	
M.B. 27.2 LBS	
C.F. 22.4 LBS	

Multiplying this average by the four inch crank arm we get a maximum of 116.8 in lbs or 9.7 ft lbs of torque in the retract direction.

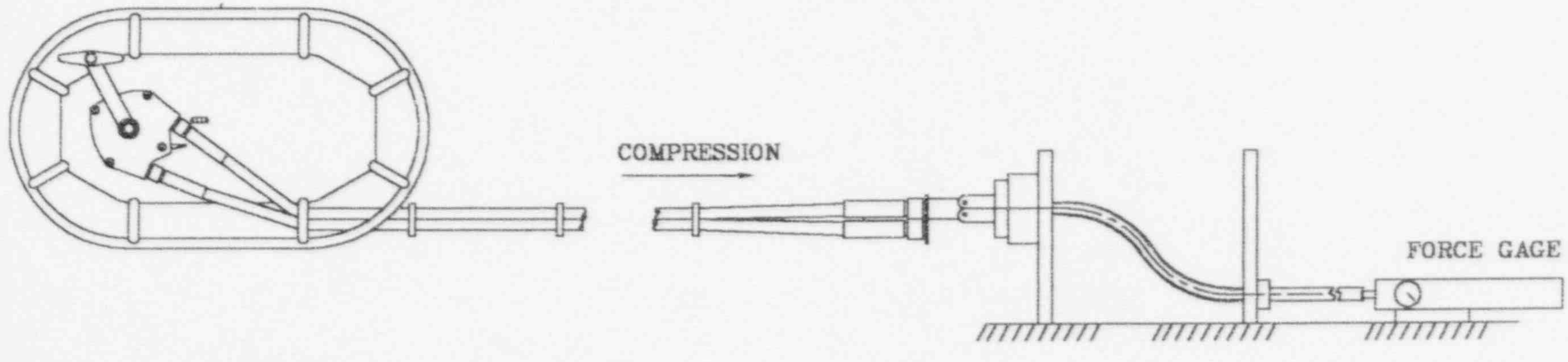


FIG. 1

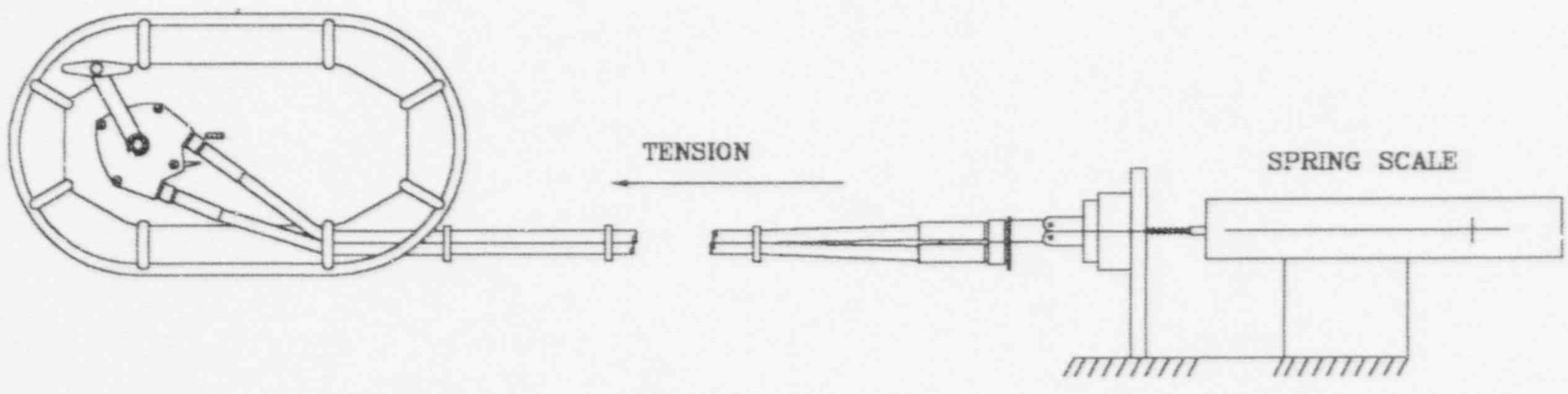
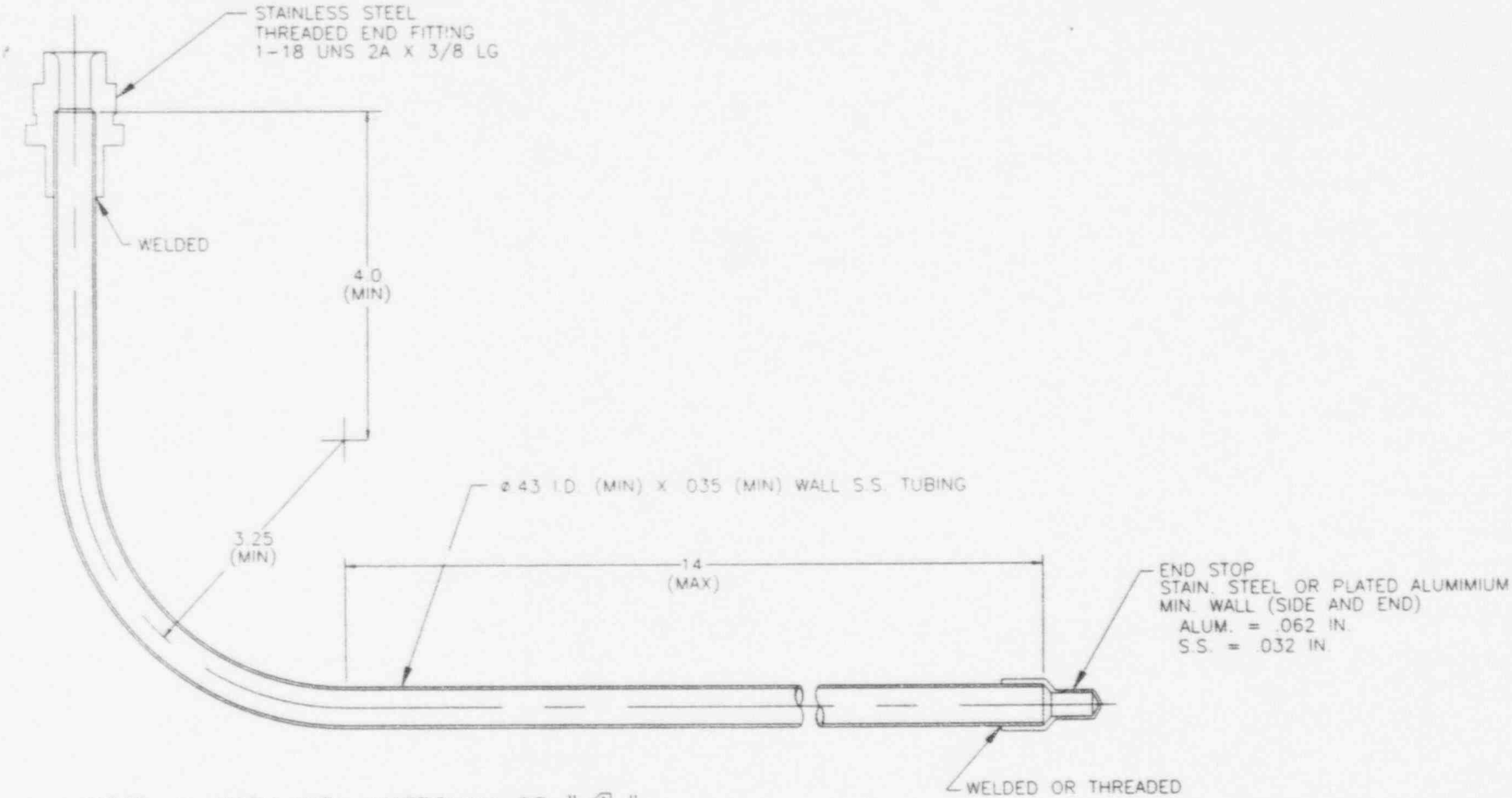


FIG. 2



NOTE: 1. MARK WITH AMERSHAM OR "A"
2. TOTAL NOT TO EXCEED 7 FEET

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ALL DIMENSIONS ARE INCHES AND REFERENCE

SENTINEL DESCRIPTIVE DRAWING

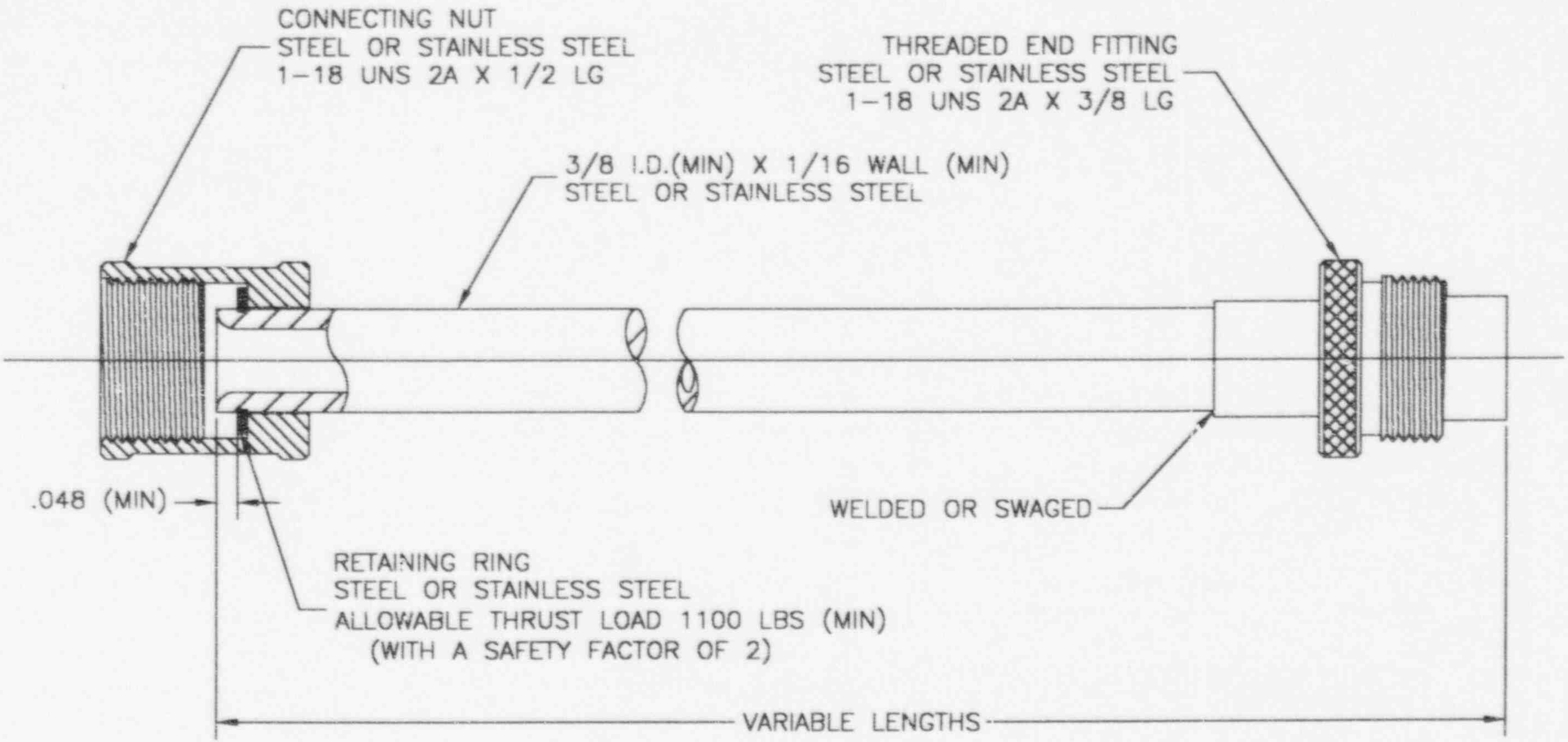
Amersham Corporation
40 NORTH AVE, BURLINGTON, MA 01803

DESCRIPTION	APPROVALS	DATE	LTR
ADDED NOTE 2, PLATED ALUM.	C. Longhan / [illegible]	23 May 96 / 23 MAY 96	B

REVISIONS

TITLE: J TUBE DESCRIPTIVE

SIZE	DWG. NO.		REV
A	R JTUBE		B
	SCALE: NONE	SHEET 1 OF 1	



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DESCRIPTIVE DRAWING

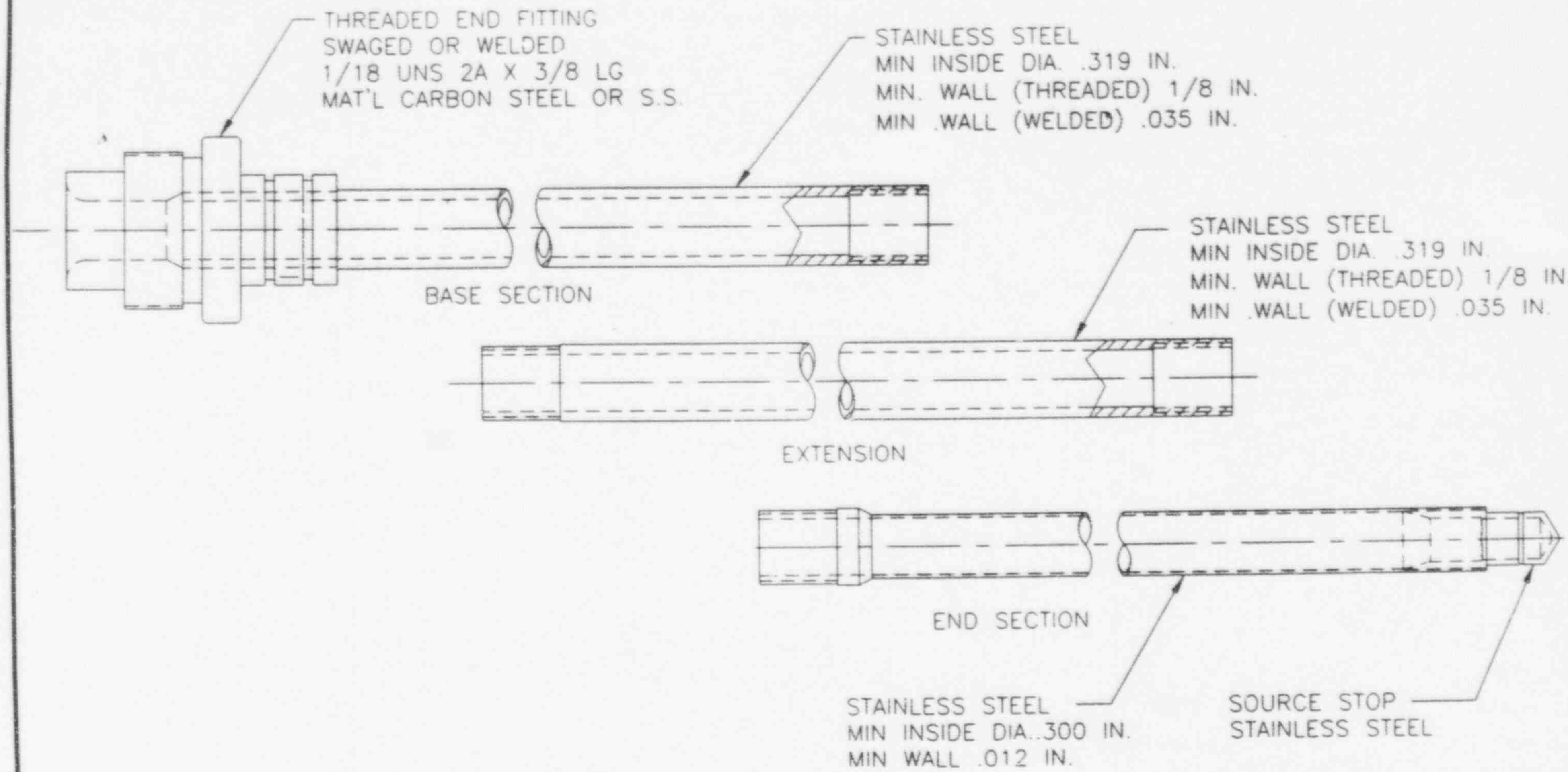
DESCRIPTION	APPROVALS	DATE	LTR
INITIAL RELEASE	[signatures]	20 Aug 96 20 AUG 96	A

REVISIONS

TITLE: RIGID GUIDE TUBE DESC

SIZE	DWG. NO.	REV
A	R RIGIDTUBE	A

SCALE: NONE SHEET 1 OF 1



NOTE: 1. LENGTH OF SECTION VARIES WITH APPLICATION
2. SECTIONS MAY BE THREADED OR WELDED TOGETHER ALSO CAN BE MADE AS ONE PIECE

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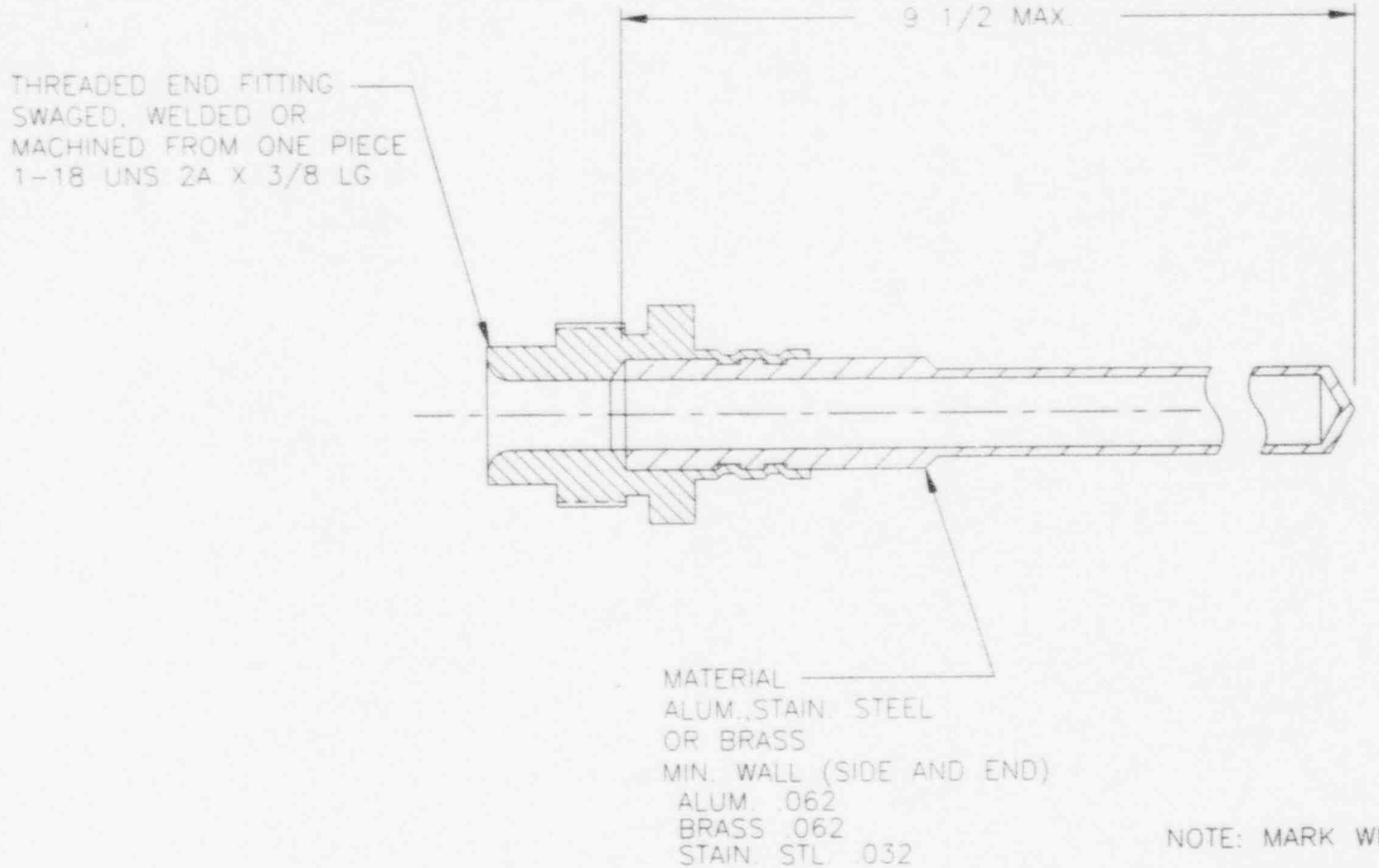
DESCRIPTIVE DRAWING

TITLE: JET ENGINE PROBE

DESCRIPTION	APPROVALS	DATE	LTR
INITIAL RELEASE	[signatures]	20 Aug96 / 23 MAY 96	A

REVISIONS

SIZE	DWG. NO.	SCALE	SHEET	REV
A	R 727	NONE	1 OF 1	A



NOTE: MARK WITH AMERSHAM OR "A"

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DESCRIPTION	APPROVALS	DATE	LTR
INITIAL RELEASE	[signature] [signature]	12 Apr 96 12 APR 96	A

REVISIONS

TITLE REMOVABLE SOURCE STOP

SIZE	DWG. NO.	REV
A	R RSTOP	A

SCALE: NONE SHEET 1 OF 1

SENTINEL™
Amersham Corporation

TEST PLAN NO. 52

ENGINEERING TEST PLAN COVER SHEET

TEST TITLE RIGID SOURCE GUIDE TUBE TESTING

PRODUCT MODEL VARIOUS

ORIGINATED BY: Geo. Parsons DATE: 13 AUG 96

ENG. APPROVAL: [signature] DATE: 14 Aug 96

Q.A. APPROVAL: [signature] DATE: 14 Aug 96

REG. APPROVAL: C. Roughan DATE: 14 Aug 96

COMMENTS:

RESULTS ACKNOWLEDGMENT:

ENG.: [signature] DATE: 20 Aug 96

Q.A.: [signature] DATE: 20 Aug 96

REG.: C. Roughan DATE: 20 Aug 96

KNA 14 Aug 96

Test Plan # 52

Date: 13 Aug 96

Subject: Rigid Source Guide Tube Testing

Purpose: To verify that our rigid source guide tubes meet 10 CFR Part 34 spec.

Scope And Responsibility: Tests will be performed to meet the requirements as outlined In the above specification.
The tests will be performed by the engineering dept. And witnessed by the Q.A. dept.

Reference: 10 CFR Part 34 section 34.20 (c) (5) (8)

Materials: 1/2 O. D. X 1/16 wall stainless steel tube (type 304)
Crush test apparatus to perform required tests

Procedure: The following tests will be performed:

1. Crushing Test (ANSI N432 1980 sect. 8.6)
2. Kinking Test (ANSI N432 1980 sect. 8.5)
   This test will not be performed because a rigid tube can not be formed in a loop and pulled until the loop disappears as required in the test. Also a rigid tube will not encounter a kinking force during use.
3. Tensil Test (ANSI N432 1980 sect. 8.7)

Results Test Plan #52

A length of stainless steel tubing 3/8 ID x 1/16 wall was subjected to the crush test as described in ANSI N432 1980 section 8.6. A mass of 15 kg configured as described in the specification was dropped from a distance 300 mm onto the tubing which was resting on a concrete floor. This was repeated 10 times at various locations along the length of the tubing. A short length of rigid guide tube assembly as shown in drawing R RIGIDTUBE Rev A was manufactured. Each end of this assembly was connected to a piece of guide tube and the 15 kg mass was dropped on each connection. After the crush test, a simulated 424-9 source assembly passed freely through the tubing and the guide tube assembly.

The rigid guide tube assembly used for the crush test was also used for the Tensile Test described in ANSI N432 1980 section 8.7. Each end of the assembly was connected to a mating fitting and a tensile load 525 N (118 lbs) was applied for 30 seconds. This was repeated 10 times.
The guide tube assembly was fully functional after this test.

I conclude that a rigid source guide tube assembly with a minimum of 3/8 ID and a minimum wall thickness of 1/16 in. manufactured per drawing R RIGIDTUBE meets the requirements of 10 CFR Part 34 section 34.20 (c) (5) & (8)

Test performed by:
George Parsons (Eng)
George Parsons

Witnessed by:
Dave Annis (Q A)
Dave Annis

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

55 FR 843

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992 must comply with the requirements of this section.

(e) All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this section.

§ 34.21 Limits on levels of radiation for radiographic exposure devices and storage containers.

(a) Radiographic exposure devices measuring less than four (4) inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at six (6) inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and ten (10) milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

55 FR 843

(b) Paragraph (a) of this section applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers must meet the requirements of § 34.20, and § 34.21 applies only to storage containers (source changers).

§ 34.22 Locking of radiographic exposure devices, storage containers, and source changers.

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in § 34.41. In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

§ 34.23 Storage precautions.

Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

§ 34.24 Radiation survey instruments.

The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and Part 20 of this chapter.

44 FR 50805

Each radiation survey instrument shall be calibrated at intervals not to exceed three months and after each instrument servicing and a record shall be maintained of the results of each instrument calibration and date thereof for three years after the date of calibration.

Instrumentation required by this section shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured.

53 FR 19240

§ 34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Commission to do so.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months prior to the transfer, the sealed source shall not be put into use until tested.

30 FR 8185

sheath(s) so that it does not move in any way during the test. With the sheath make a loop 500 mm in radius on the horizontal surface. Pull the free end of the sheath(s), without allowing it to rotate, along the axis of its original line at a speed of 2.0 m/s until the loop has disappeared and until the sheath(s) has regained its rectilinear position.

Repeat this test 10 times at each of 10 equidistant points over the length of the sheath or sheaths tested, each point being the origin of the loop.

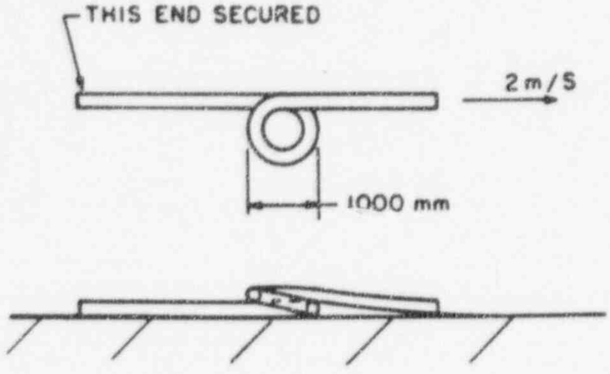


FIGURE 8.4 *Kinking test*

8.6 Crushing Test

8.6.1 **General.** The crushing test requires demonstration that the control unit will remain operational after being impacted by the heel of a walking man.

8.6.2 **Equipment.** The plane horizontal test surface shall be of mass 150 kg and sufficiently hard not to be deformed by the steel punch applied without the presence of the object to be tested.

The steel punch, called a heel, shall be of mass 15 kg divided equally between the heel and the arm, with the arm having a uniform cross section as shown in figure 8.5 adequately rigid for the test, with the crank axle horizontal.

8.6.3 **Procedure.** Place the heel at a point on the sheath. By lifting the punch, raise the bottom of the heel 300 mm. Drop the punch in a free-swinging movement. Repeat this test 10 times on randomly selected points of the sheath, one of which shall be made at a joint if there is one.

Dimensions in millimetres

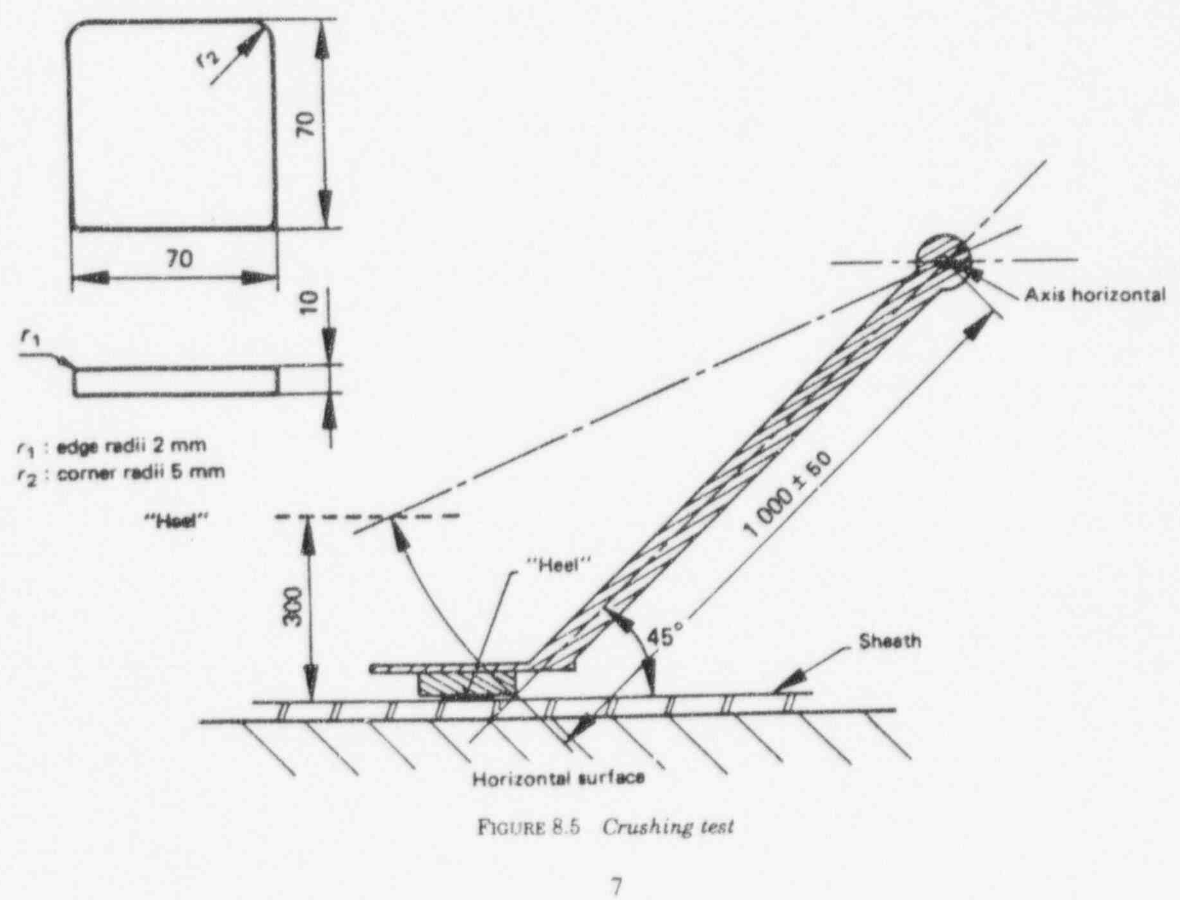


FIGURE 8.5 *Crushing test*

ANSI N432 1980

8.7 Tensile Test for Controls

8.7.1 General. The tensile test requires demonstration that the control will remain operational after experiencing tensile loads likely to be applied during use.

8.7.2 Procedure. Attach the remote control to the exposure device and secure the exposure device so that it does not move during the test. To the final position of the remote control apply a tensile load of 500 N for 30 s. Repeat this test 10 times.

Secure the remote control so that it does not move during the test. Lock the control lever, for example the crank, in relation to the mechanism. Apply a force of 1000 N for 10 s to the end portion of the remote control cable which links with the source assembly. Repeat this test 10 times.

8.8 Tensile Test for Source Assemblies

8.8.1 General. The tensile test requires demonstration that the source assembly will maintain its integrity after experiencing tensile loads likely to be applied during use.

8.8.2 Procedure. Apply a tensile load of 890 N for 30 s to each of the following attachments (if applicable).

Sealed Source to Source Assembly
Stop Ball to Source Assembly
Source Assembly Connector to Source Assembly

Connect the drive cable to the source assembly. Secure the source capsule and apply a tensile load of 890 N to the drive cable for 30 s.

8.9 Endurance Test

8.9.1 General. The endurance test requires demonstration that the gamma radiography system will remain operational after 20,000 cycles.

8.9.2 Equipment. A device shall be used for automatically actuating the apparatus, according to the manufacturer's instructions:

(a) by moving any manually operated lever on the apparatus from one extreme position to the other in 1 s.

(b) by rotating any manually operated crankshaft at a speed of 1 r/s minimum.

(c) when no overload clutch is built into the apparatus, by exerting a torque of 500L N·m instantaneously to the lever or crankshaft at both extremities of its normal movement, where L is the length, in meters, of the lever or crankshaft; or when an overload clutch is built into the apparatus, by exerting a torque, equivalent to the highest transmissible to the apparatus by the built-in clutch, instantaneously to the lever or crankshaft at both extremities of its normal movement. During this test, the overload clutch is suitably locked in the engaged position.

8.9.3 Procedure. Connect the automatic testing device to the fully equipped system.

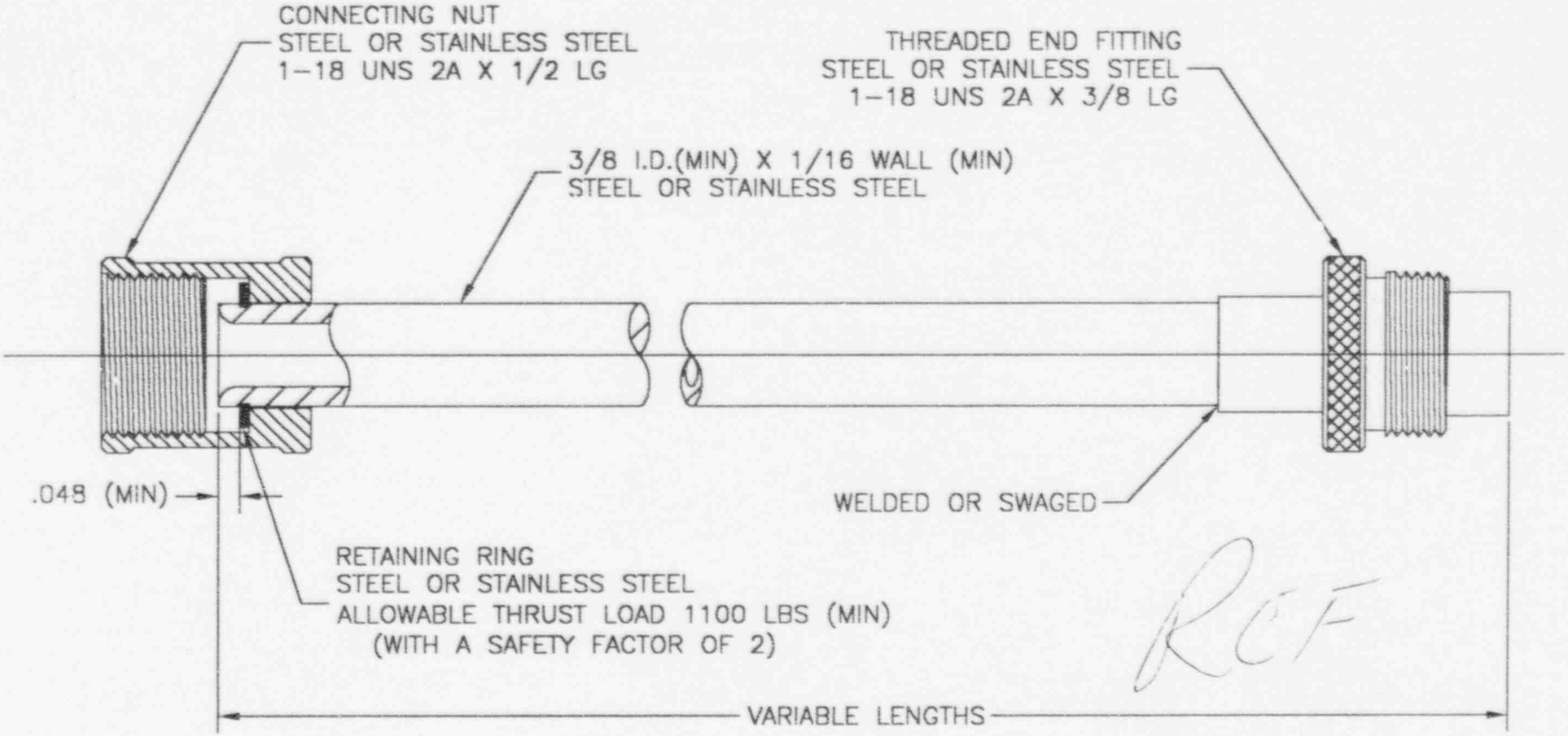
Check that the movement speeds and instantaneous extremity torques are adjusted.

Place the exposure container in such a way that any remote control cable fitted with its source holder is approximately in a straight line.

Fit the source guide tube of the largest diameter and maximum length specified by the manufacturer of the apparatus and attach the exposure head. Place this casing in a horizontal line.

Perform 20,000 operation cycles of the gamma radiography system.

At the conclusion of this test, perform the tensile test of section 8.8 on the source assembly and drive cable used for the endurance test.



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SENTINEL
Amersham Corporation
40 NORTH AVE, BURLINGTON, MA 01803

DESCRIPTIVE DRAWING

TITLE: RIGID GUIDE TUBE DESC

SIZE: A | DWG. NO.: R RIGIDTUBE | REV: A
SCALE: NONE | SHEET 1 OF 1

DESCRIPTION	APPROVALS	DATE	LTR
INITIAL RELEASE			A

REVISIONS

SENTINEL

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Source Containment and Devices Branch
Division of Industrial of Medical Nuclear Safety, NMSS
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Amersham QSA