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M. Thaggard J. Hornor C. Hickey L. McLean R. Woodruff C. Gordon E. Drennon
RLB2 PHL SCD JHM TJO M. Burgess

OSP

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Texas Department of Health

1100 West 49th Street
Austin, Texas 78756-3199
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http://www.tdh.state.tx.us

March 11, 1998

Mr. Richard L. Bangart, Director
Office of State Programs, Mail Stop 3D 23
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Bangart:

We appreciate receiving your letter dated January 26, 1998, concerning the final team report of the Integrated Materials Performance Evaluation Program (IMPEP) evaluation of the radioactive materials regulatory programs of the Texas Department of Health (TDH) and the Texas Natural Resource Conservation Commission. The IMPEP review provides a valuable information exchange for our radiation control staff with the IMPEP team.

Enclosed are our evaluation of and responses to the recommendations and suggestions made in the report. If you have any questions or if we can be of further assistance, please contact Richard Ratliff at TDH's Bureau of Radiation Control, 512/834-6679.

Sincerely,

William R. Archer, III, M.D.
Commissioner of Health

Enclosure

SP-AG-27

Responses to Recommendations and Suggestions in U.S. Nuclear Regulatory Commission IMPEP Report

3.3 Technical Quality of Licensing Actions

Suggestion: The review team suggests that amendments and renewals be prioritized so that amendments which impact health and safety (i.e., new Radiation Safety Officer because the previous one left the company; major proposed procedure changes which could affect radiation safety issues) are completed ahead of the amendments and renewals which are more routine (i.e., adding a source or another user when ten sources or users are already on the license; renewal by letter).

Response: Licensing staff have implemented a prioritization method that will take radiation safety issues into account. New license applications continue to have high priority, as do amendments and renewals that could impact health and safety if not handled as soon as possible after receipt.

3.4 Technical Quality of Inspections

Suggestion: The review team suggests the State consider standardizing their primary and supplementary field note forms. These could be modeled after the NRC forms as discussed with TDH's Bureau of Radiation Control (BRC).

Response: The BRC agrees and is in the process of standardizing inspection forms (primary and secondary forms). These new forms are similar to, but not identical to the NRC forms. Upon completion and issuance to the inspectors, these will be the only forms authorized for inspection notes. To facilitate the use of these forms and to increase productivity, all regional radioactive material inspectors have been issued laptop computers. The forms will be installed on the computers and training provided during the March 1998 Inspector Staff meeting.

Suggestion: The review team suggests documenting in reports summary discussions of inspection findings with management at the conclusion of inspections.

Response: The BRC will include a space on the new field notes for the exit interview with management.

Recommendation: The review team recommends that the State adhere to the policy of annual supervisory accompaniments of all qualified inspectors.

Response: The Deputy Director of Radioactive Material Inspection Program has the task of ensuring that all inspectors are accompanied on an annual schedule.

Recommendation: The review team recommends that all radiation detection instruments used for confirmatory surveys (field measurements) be calibrated for all ranges encountered by inspectors.

Response: Inspectors for the BRC use Ludlum Model 14C ratemeters and Model 44-6 side-window Geiger-Mueller detectors for routine radioactive materials inspections and fixed nuclear facility emergency response excercises as well as other surveys which they may be requested to perform. These instruments are routinely calibrated on the scales which span the range of exposure rates the inspectors are normally expected to encounter.

In addition the BRC possesses two Ludlum Model 77-3 13-foot stretch scopes. The range of this Geiger-Mueller detector and rate meter assembly is 0.1 mR/hr to 100 R/hr. These have in the past only been calibrated on the ranges most likely to be encountered during normal inspections. Based on this recommendation the Bureau of Radiation Control is currently negotiating with the instrument calibration laboratory at the South Texas Project to have the stretch scopes calibrated, if this does not violate any of their license conditions. If this effort does not work out, the Bureau will seek out or contract with a facility which can calibrate the instruments on all scales.

3.5 Response to Incidents and Allegations

Suggestion: The review team suggest that the State initiate actions (through implementation of the procedures provided in the March 1995 Handbook on Nuclear Material Event Reporting in the Agreement States) to directly utilize the Nuclear Materials Events Database (NMED) system.

Response: TDH is currently connected to the NMED system, and the system is fully operational. It is used by three staff persons assigned incident, complaint and assigned technical assistance response.

4.2 Sealed Source and Device (SS&D) Evaluation Program

Recommendation: The review team recommends the State perform an evaluation to determine the safety significance of the issues identified by the review team pertaining to registration certificate number TX-0246-D-103-S and to identify any other issues that may exist, and re-evaluate the application, as necessary, to ensure that all pertinent safety and regulatory issues are adequately addressed.

Response: None of the issues identified by the review team were determined to be of safety significance. Each item identified by the review team was addressed during a subsequent review. The applicant was asked to respond to those items to provide additional data for inclusion in an update of the registration certificate. Attached are a copy of the letter TDH sent to the company concerning the device and a copy of the response we received. Each item in Appendix G of the report is addressed as follows:

1. The exposure device reviewed in TX-0246-D-103-S was determined to be a mobile device. Each item in ANSI N432-1980 which applied to mobile devices was addressed. Under the "Limitations and Considerations of Use" Section, the first statement says, "This device is designed to be used in conjunction with a crawler mechanism for industrial radiography and shall be distributed only to those persons specifically licensed by the NRC or an Agreement State." Although this statement is not as clear as it could be, it does indicate that the device is used only in conjunction with a crawler mechanism.

2. When using the data supplied by the manufacturer (CS Products), a 20 curie Ir-192 source produces an exposure rate of 45 mR/hr at the surface on the side of the source holder. This would indicate that the values supplied by the applicant were faulty and should have been questioned. The applicant was requested to explain the discrepancy and supplied the results of a new survey. This new survey demonstrates that the exposure rate at the surface of the source holder is less than 45 mR/hr.

3. Since this device has to be surveyed when prepared for transport, it was thought that external radiation checks would be accomplished at that time. The applicant has been asked to provide confirmation that surveys are performed on each device to determine that it was constructed in accordance with the drawings submitted.

4. Including "DIAGRAM: See Attachments" twice on the registration certificate was a typographical error. It will be removed when the certificate is amended.

5. The applicant has not yet received information regarding the transit cover and actuator from the manufacturer. The configuration will be discussed in the next amendment of the registration certificate.

6. Source exchange is performed by the source manufacturer and is only performed inside a glove box. The manufacturer's installation procedures will thus eliminate the potential for contamination of the device due to damage to the DU during source installation. It is our determination that no design change is necessary.

7. The applicant has provided new drawings that explain the assembly process of the actuator pencil.

8. The applicant has supplied new drawings that clarify the adequacy of the design.

9. As stated in item 1 above, this device is designed to be used only as a component attached to a crawler. The review was performed on the device as it was intended to be used. The applicant has stated in a subsequent letter that the exposure head is used only when attached to one of their crawlers and will never be used as a separate unit.

Recommendation: The review team recommends that the State evaluate an adequate sample of additional safety evaluations to ensure that the deficiencies identified in TX-0246-D-103-S are adequately addressed in the additional cases, and to demonstrate that this was an isolated occurrence.

Response: Most of the deficiencies identified in TX-0246-D-103-S are unique to industrial radiography equipment. The review performed on that device is the only industrial radiography device review that has been performed by TDH in the past ten to twelve years. However, the other device reviews in the list supplied to the review team were reviewed to determine if surveys met the inverse square law, if all drawings referenced could be accounted for, and if quality assurance/control checks included a radiation survey to assure that radiation levels were within expected values. These reviews indicated that those items identified for TX-0246-D-103-S were unique to that device evaluation.

Recommendation: The review team recommends that the State review the issue of independent technical concurrence reviews for SS&D safety evaluations and implement procedures that require an independent technical review for all future evaluations.

Response: TDH has modified its procedures for performance of SS&D safety evaluations to include a concurrence review. The review sheet for SS&D evaluations now includes a check list for both reviewers. The second reviewer will ascertain that all items have been addressed by the primary reviewer and will also perform a quality assurance audit of the application and the proposed certificate of registration. This is performed to support the findings that a product is acceptable for licensing purposes. If areas of incompleteness are found by the second reviewer, the application will be sent back to the primary reviewer for additional evaluation.

Suggestion: The review team suggest that the State consider the comments in Appendix G, and take action as the State deems appropriate.

Response: Staff have reviewed the individual suggestions in Appendix G of the draft report regarding sealed source and device reviews. Suggested changes on individual device registration certificates will be made the next time those certificates are amended. We will also implement the suggestion that when a registration certificate is made inactive, that the reviewer determine the total number of units distributed, the number of units still in the field, and ensure that all letters listed in the REFERENCE section of the registration certificate are in the file. Concerning the comment on File No. 6, Registry No. TX-0634-D-138-B: "The reviewers completed but the file did not document that the reviewer evaluated the impact the reduced wall thickness resulting from enlarging the inside of the source holder would have on the integrity of the holder. The review team suggests that this be documented," the following responses are provided:

1. The difference in the diameter of the two sealed source proposed for the source holder was only a few thousandths of an inch. Since the precision of the attenuation coefficient is only two decimal places to the left of the decimal point, there will be no calculated difference between the shielding for the two sources.

2. The larger source was the sealed source that was originally evaluated for this device. Hence, placing a smaller diameter source in the cavity with appropriate shims will not reduce shielding.

Suggestion: The review team suggests that the State consider assigning safety evaluations to those staff members currently being trained to perform SS&D safety evaluations to enable them to gain enough experience and obtain registration certificate signature approval before the staff member currently performing the initial review retires.

Response: We are currently assigning the initial review on all medical devices to a staff member in the Medical Licensing program. As workload permits, we are also assigning some industrial sources and devices to a staff member in the Industrial Licensing program. For other devices, these staff may also be used for second quality assurance reviews.

Suggestion: The review team suggests that the State take a more aggressive approach to forwarding information to the agency responsible for the product evaluation and registration certificate where there is a possibility that the failure or problem may be a generic issue.

Response: One person has been assigned to review all incidents and notify the appropriate state, NRC, and the manufacturer as necessary when evidence of equipment failure is involved.

4.4 Uranium Recovery Regulatory Program

Recommendation: The review team noted that the 2 year inspection interval (for uranium facilities) is not consistent with IMC2800, and recommends that the criteria for assignment of inspection intervals greater than called for in IMC2800 be evaluated, justified and fully documented. The review team recommends that an action plan be developed and implemented by TDH to overcome the inspection backlog in the uranium recovery program.

Response:

The regulation of uranium recovery and byproduct material disposal has now been transferred from the Texas Natural Resource Conservation Commission to the TDH. TDH will maintain all uranium inspections on a one year interval, as a minimum. No problems are anticipated with such a schedule. Two inspectors have been hired and all overdue inspections should be completed within six (6) months. Existing experienced staff will also participate in eliminating the inspection backlog.

TDH
TEXAS DEPARTMENT OF HEALTH

Texas Department of Health

Patti J. Patterson, M.D.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Carol S. Daniels
Deputy Commissioner for Programs

Randy P. Washington
Deputy Commissioner for Health Care Financing

Radiation Control
(512) 834-6688

Roy L. Hogan
Deputy Commissioner for Administration

August 5, 1997

George Spencer
Oceaneering International, Inc.
Solus Schall Division
11921 FM 529
Houston, Texas 77041

RE: License No. L04463 and
SSD TX0246D103S

Dear Mr. Spencer:

During a recent review of our program by the U.S. Nuclear Regulatory Commission (NRC), several questions concerning the safety review of the C.S. Products Model CS 0316 gamma head. In order to determine if any health and safety issues exist concerning the use and operation of this device, we must ask several questions concerning this device. Those questions are:

1. On page 2 of the addendum with your letter dated September 12, 1995, you provide the exposure rates of @5cm - 36mr, @30cm - 10mr, @100cm - 1.6mr. During the NRC's review, it was determined that these values do not obey the inverse square rule. Please explain.

2. No specific procedure or commitment was found that you will perform a radiation survey on each new device to ensure that external radiation levels fall within acceptable parameters and that a program has been developed to ensure that all devices are manufactured according to the drawings submitted in support of your application for this device.

3. There was confusion concerning the configuration of the gamma head when you receive it. The C.S. Products Manual shows a transit plate over the end of the source holder and your drawings show the actuator mechanism attached. How do you receive the device? How is the device shipped? The concern here is the exposure of the unprotected DU (depleted uranium) shield to an uncontrolled environment and the spread of DU contamination.

4. The stainless steel tube inside the DU shield does not extend to the end of the hole in the shield. Can damage to the shield occur during source replacement or exchange?

5. Two questions arose concerning drawings referenced in your application and the letter dated September 12, 1995. Drawing CS0316004A references a part no. CS031600401 and a part no. CS031600403. We only received a copy of CS031600401 and did not receive a copy of CS031600403. The drawing of CS031600401 does not resemble that part referenced in CS0316004A. Please explain.

6. Finally, it is our understanding that you will only use or lease this device when it is attached to a crawler. Is this understanding correct? Will there ever be a case where the gamma head will be distributed to another licensee without being attached to a crawler? Will another licensee be allowed to remove the gamma head from your crawler?

Please respond as soon as possible so that we may expedite our response to the NRC. Please reference the above mentioned license in your reply.

Sincerely,

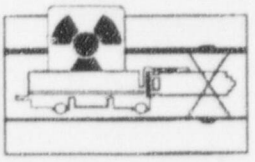
Floyd R. Hamiter

Floyd R. Hamiter, Chief
Industrial Programs
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

bcc: file, insp. file

OCEANEERING
SOLUS SCHALL

11921 FM 529
HOUSTON, TEXAS 77041
Tel: (713) 329-4759
Fax: (713) 329-4701



TELEFAX

TO:	Texas Department of Health.	DATE:	August 20, 1997
ATTN:	Mr. Floyd R. Hamiter	FROM:	George Spencer
C.C.:	S. Pierce	REF.:	GS97209
SUBJ:	Copy of Reply to SSD TX0246D103S		
FAX#:	(512)834-6690	PAGES:	#7

Message: URGENT ROUTINE CONFIDENTIAL

Dear Mr. Hamiter

Here are copies of the letter, chart and drawings, as requested. This information is , not as yet complete, but we will continue to collect the information required to formulate our answers.

Should you have any questions, please give me a call at the number above

Regards

George Spencer
R.S.O.
Oceaneering International, Inc. - Solus Schall Division

OCEANEERING

Solus Schall Division

11921 FM 529
Houston, Texas 77041
Telephone: (713) 329-4700
Fax: (713) 329-4701

August 20, 1997
GS97208

Texas Department of Health
Attn: Mr. Floyd R. Hamiter, Chief
Industrial Programs
Division of Licensing, Registration and Standards
Bureau of Radiation Control
1100 West 49th Street
Austin Texas 78756-3189

Subject: **License No. L04463 and SSD TX0246D103S**

Dear Mr. Hamiter

With reference to our telephone conversation and our request for more time to answer the questions in your letter of August 5,1997, we are still awaiting information from the manufacturer and the companies that perform the loading of sources into these cameras.

We will deal with each of your questions in order and attempt to show where we are in the process of producing a satisfactory answer:

1. We agree that these values do not obey the inverse square law rule, we are now in possession of the corrected data:

@5cm - 42mr, 30cm - 3.5mr, @100cm - 0.36mr

Please also see the enclosed chart

2. As yet incomplete, as we await information from the companies that load these cameras, to formulate our answer. C.S.Products, (Testing and Equipment), Ltd. Are approved by the U.K. Department of Environment, Transport and the Regions for the Design and Manufacture of Type B(U) Packages. Approval requires audit and acceptance of a Quality and Assurance and Control System to a recognized Standard ie. ISO 9000. C.S.Products apply these Standards to the design and production of Type "A" Packages.

These Standards were applied to the design and manufacture of C.S.Products Crawler Control and Tattle Tale isotope containers, (Type "A" Packages), which were submitted for, and received, approval in 1984:

CSP Crawler Control	Certificate # NR 242-D-101-5
CSP Tattle Tale	Certificate # NR 242-D-102-5

3. As yet incomplete.

4. As yet incomplete

OCEANEERING

5. We are enclosing a copy of CS031600403, this should explain the assembly of the actuator pencil in it's entirety. To further assist we are also including a copy of drawing 06CR/618/F/A3.

6. We will only lease or use this device when attached to a crawler. We will not ever use, or allow to be used, this device without a crawler. All the equipment owned by Oceaneering International, Inc., Solus Schall Division is used and maintained solely by ourselves and no other license is allowed to access our equipment.

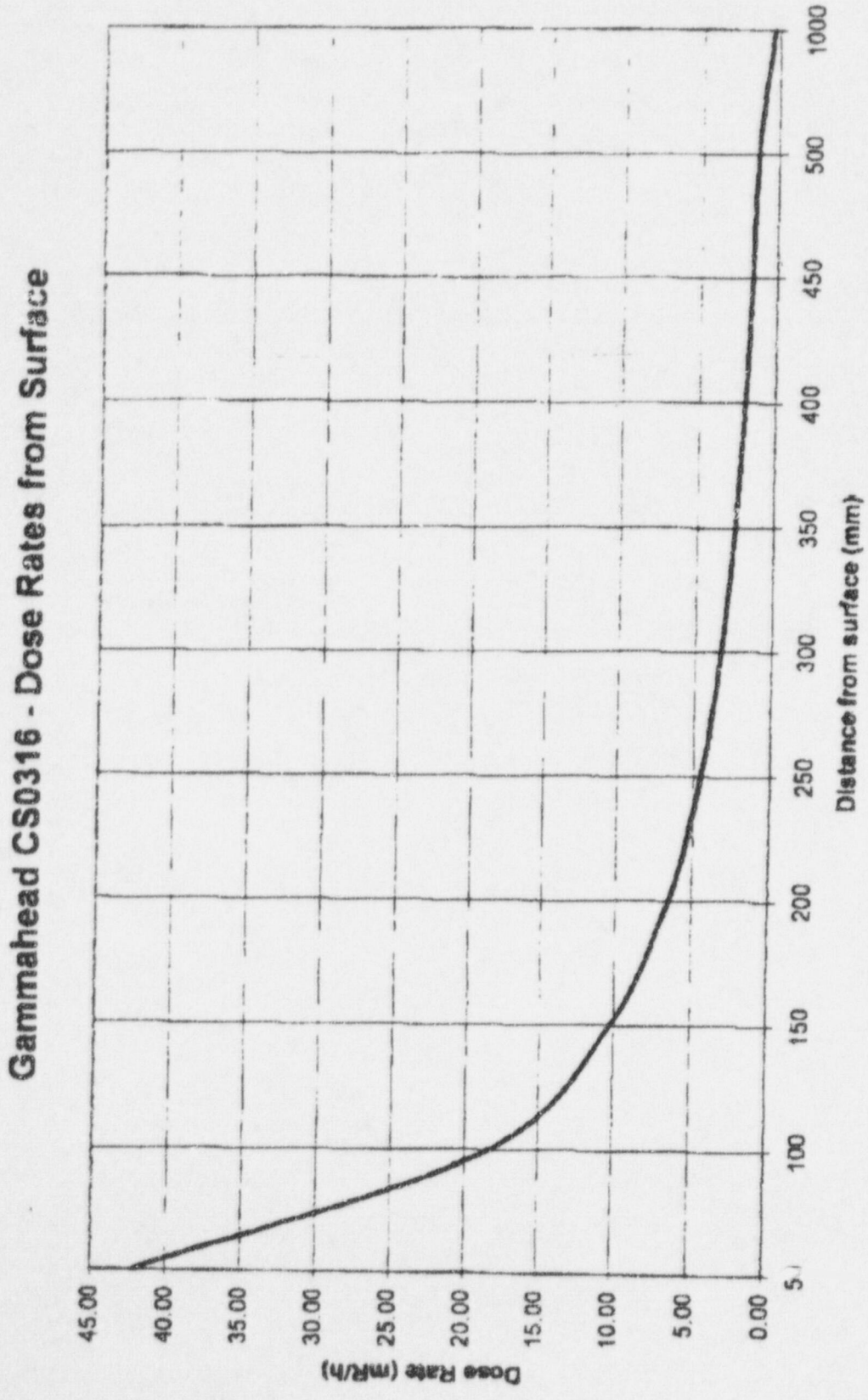
Thank-you for your forbearance in this matter, we are striving to supply the answers to your questions in the most timely manner, should there be any further questions please contact me, at the number above.

Best regards,

George Spencer
R.S.O.
Oceaneering International, Inc. - Solus Schall Division

cc S. Pierce

enc


Gammahead CS0316 - Dose Rates from Surface
Dose Rate (mR/h)
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40.00
35.00
30.00
25.00
20.00
15.00
10.00
5.00
0.00
Distance from surface (mm)
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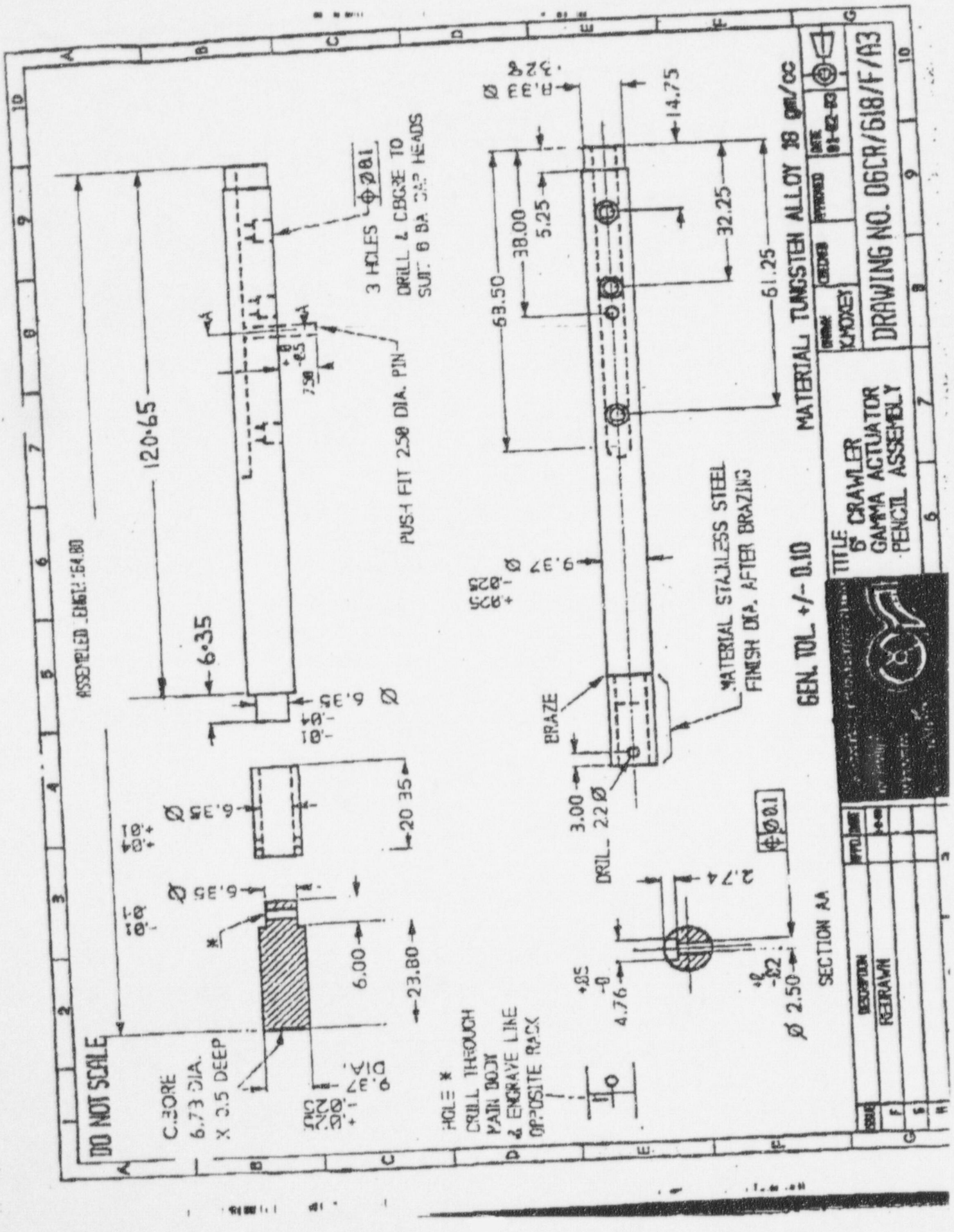
100
150
200
250
300
350
400
450
500
1000


DO NOT SCALE
ASSEMBLED LENGTH 64.80
120.65
6.35
3 HOLES Ø.81
DRILL & CBORE TO SUIT O RING HEADS
PUSH FIT 2.50 DIA. PIN
63.50
38.00
5.25
14.75
32.25
61.25
BRAZE
3.00
DRIL 2.20Ø
MATERIAL STAINLESS STEEL
FINISH DIA. AFTER BRAZING
GEN. TOL +/- 0.10
MATERIAL TUNGSTEN ALLOY 18 gm/cc
TITLE
6" CRAWLER
GAMMA ACTUATOR
PENCIL ASSEMBLY
DRAWING NO. 06CR/618/F/A3
C.BORE
6.73 DIA.
X 3.5 DEEP
6.00
23.80
20.35
HOLE *
DRILL THROUGH
MAIN BODY
& ENGRAVE LINE
OPPOSITE RACK
4.76
Ø 2.50
SECTION AA
DESCRIPTION
REDRAWN

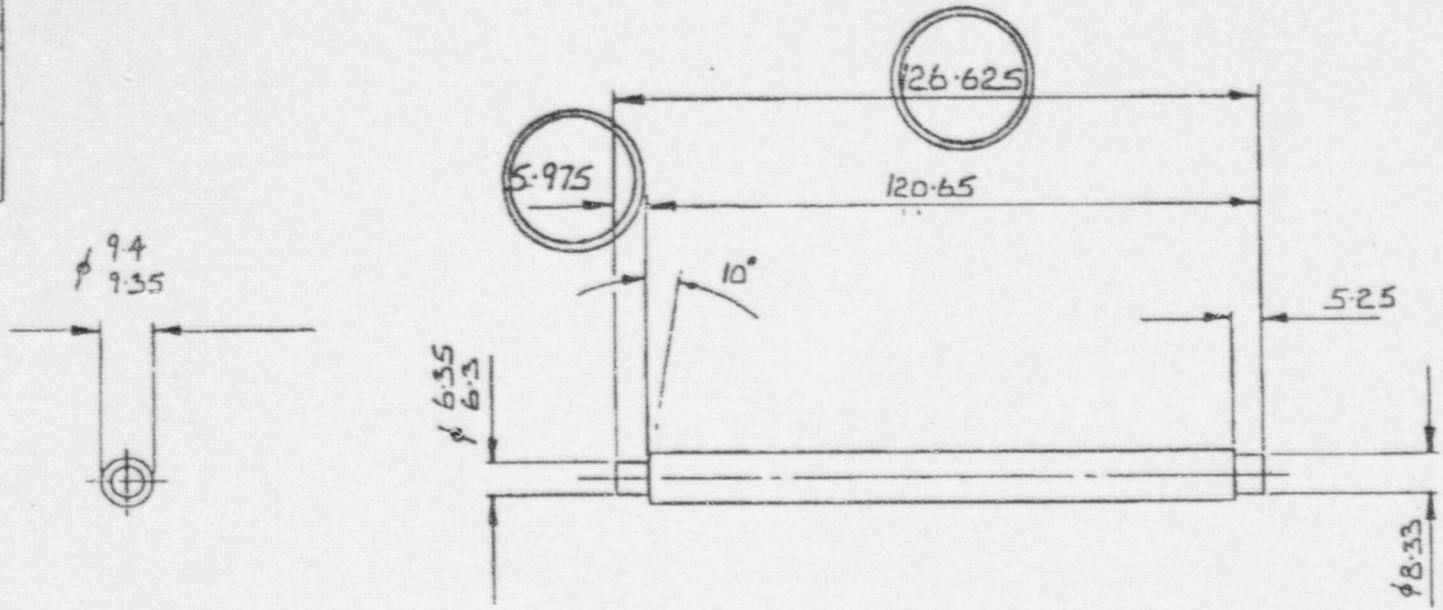
DRAWING No. CS031600401 | 3rd ANGLE PROJECTION | DO NOT SCALE | DIMENSIONS : MM

MOD. NOTE REF.
M0108I JULY 95 ISSUE 2
M01099 AUG 95 ISSUE 3

PART No. CS031600401

ALSO USED ON

GAMMA HEAD CS04



REMOVE ALL SHARP EDGES

C.S. Products (Testing Equipment) Ltd.

'THE HOLLIES', WRANGATON, DEVON. TQ10 9HB
TELEPHONE. SOUTHBRENT (03847) 3279.

NTS.

TITLE CS0316 GAMMAHEAD ACTUATOR PENCIL BACK SHIELD

TOLERANCES:- UNLESS OTHERWISE STATED	CUSTOMER	ISSUE 3	DRAWN SEDES	SCALE F.S.	JOB No.	FINISH
DEC. MK ±0·125 ANGULAR ±½°	MATERIAL TUNGSTEN ALLOY	DATE 18-8-95	DATE 10·06·91	No. OFF	CHK'D BY	USED ON

DRAWING No. / PART No. CS031600401

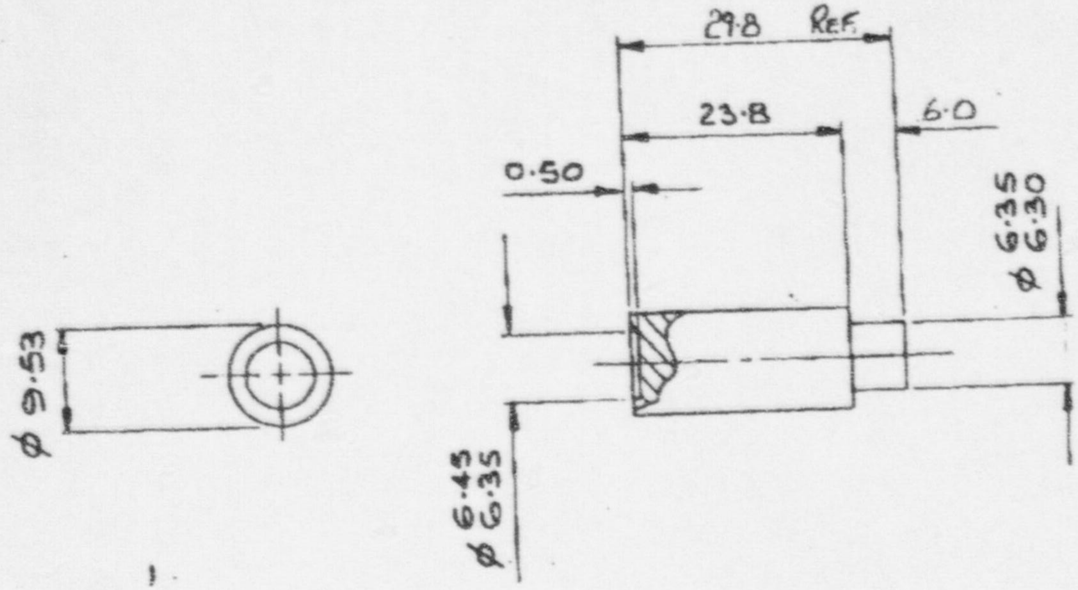
DRAWING No. CS031600403	3RD. ANGLE PROJECTION

DO NOT SCALE

DIMENSIONS IN MM. (BS 308)

PART No.
CS031600403
ALSO USED ON
GAMMA HEAD CS0416

MOD NOTE REF
M01081 JULY 93 ISSUE 2



C.S. Products (Testing Equipment) Ltd.

THE HOLLIES, WRANGATON, DEVON. TQ10 9HB
TELEPHONE. SOUTHBRENT (0364) 3279.

TITLE CS0316 GAMMAHEAD ACTUATOR PENCIL FRONT SHIELD

DRAWING No. / PART No. CS031600403

ISSUE 02	DRAWN [signature]	SCALE 2 : 1	JOB No.	FINISH	
DATE 12-7-93	DATE 18 AUG. '92	No. OFF	CHK'D BY	APP'D BY	

TOLERANCES - UNLESS OTHERWISE STATED
GEN. MR ± ·125mm ANGULAR ± ½°

CUSTOMER

MATERIAL TUNGSTEN ALLOY 18 gm/cm³

3-0037