

Amer sham Corporation
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Burlington Massachusetts 01803
Telephone (617) 272-2000

June 30, 1989

Mr. John White
US Nuclear Regulatory Commission
Inspection and Enforcement Region 1
475 Allendale Road
King Of Prussia, PA 19406

Dear Mr. White,

This report is furnished to you in accordance with
10 CFR 21.21 (b), and to followup our telephone notification
to you on 19 June 1989.

Amer sham Corporation recently received NRC approval (NRC
registration number NR-628-S-192-S, 31 May 1989) for the
model 899 series source assembly. We had previously
received approval to distribute this source assembly in
Texas. The 899 series was specifically designed to meet
current Texas radiography regulations (TRCR Part 31) and
proposed NRC regulations (10 CFR Part 34). We have been
shipping the model 89911 and 89912 source assemblies to
Texas since May 12, 1989. Since that date we have shipped
34 sources into Texas. No shipments have been made to any
other state.

On 15 June 1989 Amer sham Corp, Burlington MA was informed
that several customers had complained that the 899 source
assembly was hanging up in cameras. This hangup primarily
occurred while the operator tried to crank the source out to
the exposed position.

By the end of 16 June 1989 approximately 12 customers had
experienced a hangup problem although there were no
significant incidents or source retrievals. In each case
the source assembly got stuck in the camera and could not be
cranked out.

Due to the number of complaints Amer sham decided on
16 June 1989 to discontinue distribution of the 899 and
to recall all 899 source assemblies already shipped.
Ms. Ruth McBurney of Texas Bureau of Health was immediately
notified of the problem and our decision to discontinue

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distribution. We were subsequently given verbal approval by John Bass (Texas Department of Health) to continue distributing source assemblies that did not meet current Texas regulations (Models A-2-A, A-1-A, RG-13, RGSA-13). We also called NRC Region 1 and left a message to inform you of the problem.

As of 23 June 1989 we had replaced 21 sources and all sources will be replaced by 30 June 1989.

An engineering evaluation began on 15 June 1989 to determine the cause of the hangups. Preliminary investigations found that the hangups occurred whenever a set of flexible control housings were used. These include the Amersham yellow vinyl housings and the Gamma industries blue vinyl housings. With the flexible control housings an operator can not get enough force on the drive cable to crank the source assembly out of the camera.

When stiff control housings are used such as the Gamma industries black vinyl housings the operator can get enough force to crank the source out.

The majority of the source hangups occurred when the source was being cranked out of the camera and we could duplicate this in the lab. There was one report of the source hanging up while being retracted into the camera, but we could not duplicate this in our lab.

The choice of control housings seems to be the major cause of the source assembly hangup. The use of speedometer cable which is not as flexible as the currently used aircraft cable is also a contributing factor in the hangups.

A prototype model 899 assembly was tested in accordance with ANSI N432 which includes a 20,000 cycle test prior to distribution. We have tested all of our approved source assemblies to the ANSI specification without any problems. We performed the test on the 899 using a Gamma Century Camera and a 89912 source assembly and did not experience any problems. We are currently reevaluating our prototype testing procedures, to determine if other tests are needed.

During our investigation we also discovered that we could get the model 899 source to disconnect under certain conditions. If all four of the following conditions are met it is possible for the source to disconnect.

1. The source capsule gets caught or is pressing against the end of the guide table and does not allow the pigtail to move.
2. The operator pushes on the drive cable.
3. The source tube or S-tube is bent at approximately 90° and has an enlarged or worn S-tube.
4. And the connector is positioned within this bend.

If all three conditions are met the action of pushing the drive cable into the stuck source assembly can create a disconnect if there is enough room in the S-tube or source tube. Though this is a very contrived situation, we feel there is a slight possibility of this occurring in the field. Therefore we have modified the male connector on the drive cable to prevent the disconnect from occurring.

Our investigation is ongoing and we will make whatever design modification needed to prevent any hangups with the 899 source assembly. One solution being investigated is placing the 859 (J) connector on teleflex cable. Initial testing of this assembly showed satisfactory operation but more complete testing needs to be performed.

We will submit further information on this investigation when it is resolved. We hope to have a solution within 2-4 weeks. Please contact me if you require additional information.

sincerely,

Carleton M. Roughan
Radiation Safety Officer

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