ACNP-SNM PETITION FOR RULEMAKING

The petition was docketed June 8, 1989, and published for public comment September 15, 1989.

The primary issues are:

- Use of byproduct material in research using human subjects
- Use of biologics containing byproduct material
- Departures by medical use licensees from the manufacturer's instructions for eluting generators and preparing reagent kits

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The primary issues (cont'd)

- Departures from the package insert for unlisted indications and routes of administration
- Departures by nuclear pharmacies from the manufacturer's instructions for eluting generators and preparing reagent kits, and
- Compounding radiopharmaceuticals from reagent chemicals by either medical use or radiopharmacy licensees

PUBLIC COMMENTS

- ✓ The public comment period ended December 14, 1989
- ✓ 466 comment letters were received
- ✓ Almost all letters supported the petition
- ✓ The majority of the letters did not provide specific supporting rationale
- ✓ Some letters provided examples of clinical cases to demonstrate the need for departure from the package insert
- ✓ Some letters stated that requesting each specific exemption from the regulations is time consuming and cumbersome

COORDINATION WITH FDA

- ✓ The issues in the petition require coordination with FDA because of our overlapping regulatory responsibilities
- ✓ Several discussions with FDA were held in 1989 and early 1990
- ✓ A draft of the staff's proposed rule was first provided to FDA in March 1990 with a revision provided in April 1990
- ✓ We received FDA's final comments on May 18, 1990

STAFF PROPOSAL

The Commission is currently considering staff's proposed rule to address:

a. Departures from the manufacturer's instructions for eluting generators and preparing reagent kits, and

b. Departures from the package insert for indications or routes of administration.

The ACMUI has reviewed staff's proposed rule and recommended publication

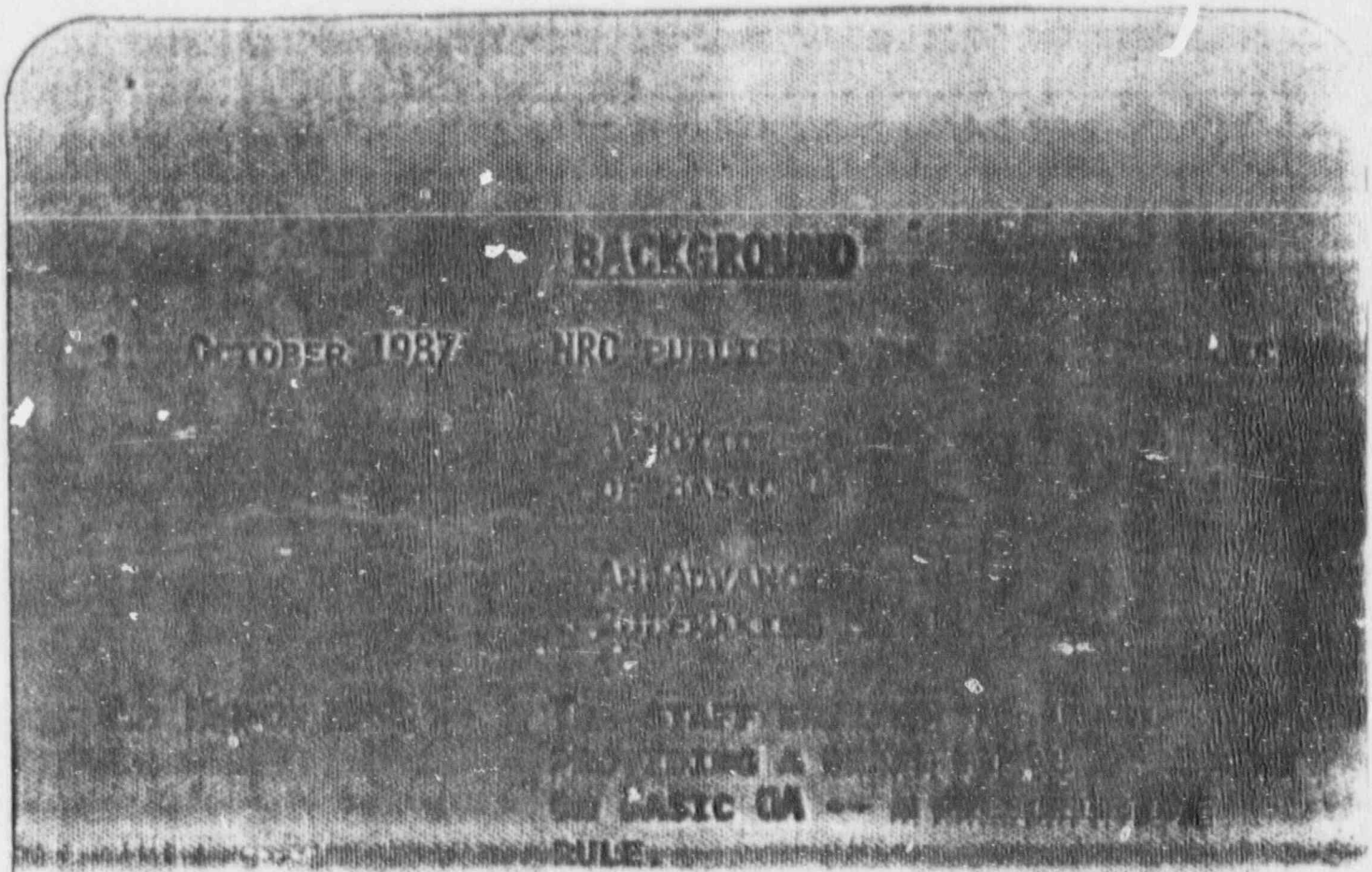
FUTURE ACTIVITIES

The remaining issues will be resolved in one or more rulemakings

The remaining primary issues are:

- Use of byproduct material in research using human subjects
- Use of biologics containing byproduct material
- Compounding radiopharmaceuticals by either medical use or radiopharmacy licensees

The schedule will be about two years



BACKGROUND

2. OCTOBER 1987 -- HRO PUBLIC

BASIC QA -- [illegible]

RULE.

3. APRIL 1988 -- THE MEDICAL COMMUNITY BRIEFED THE COMMISSION TO ADVISE AGAINST THE PRESCRIPTIVE FINAL AMENDMENT.

4. JUNE 1988 -- THE STAFF PROVIDED RULEMAKING OPTIONS TO THE COMMISSION.

5. JULY 1988 -- THE COMMISSION REQUESTS A PERFORMANCE-BASED QA RULE.

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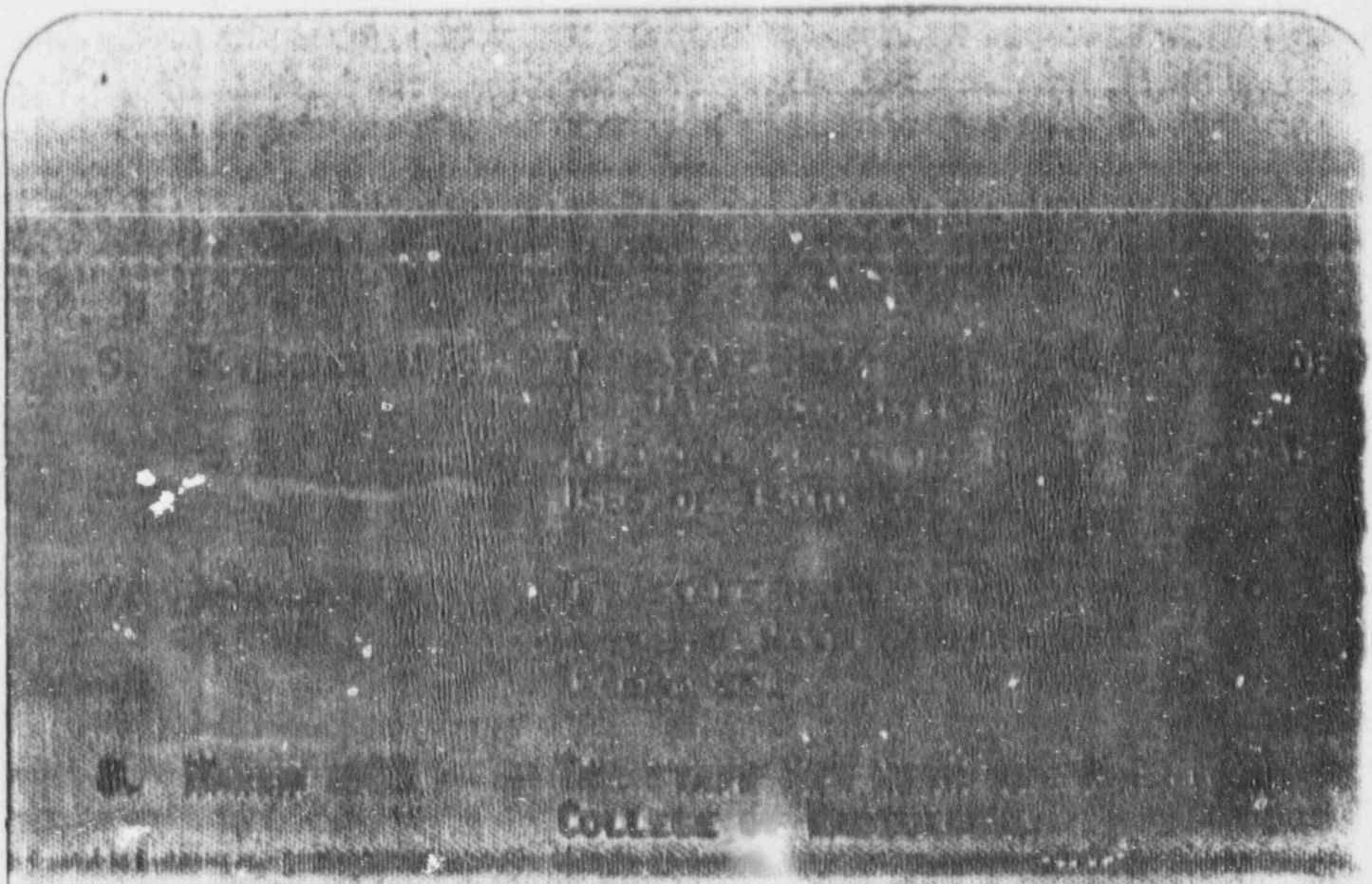
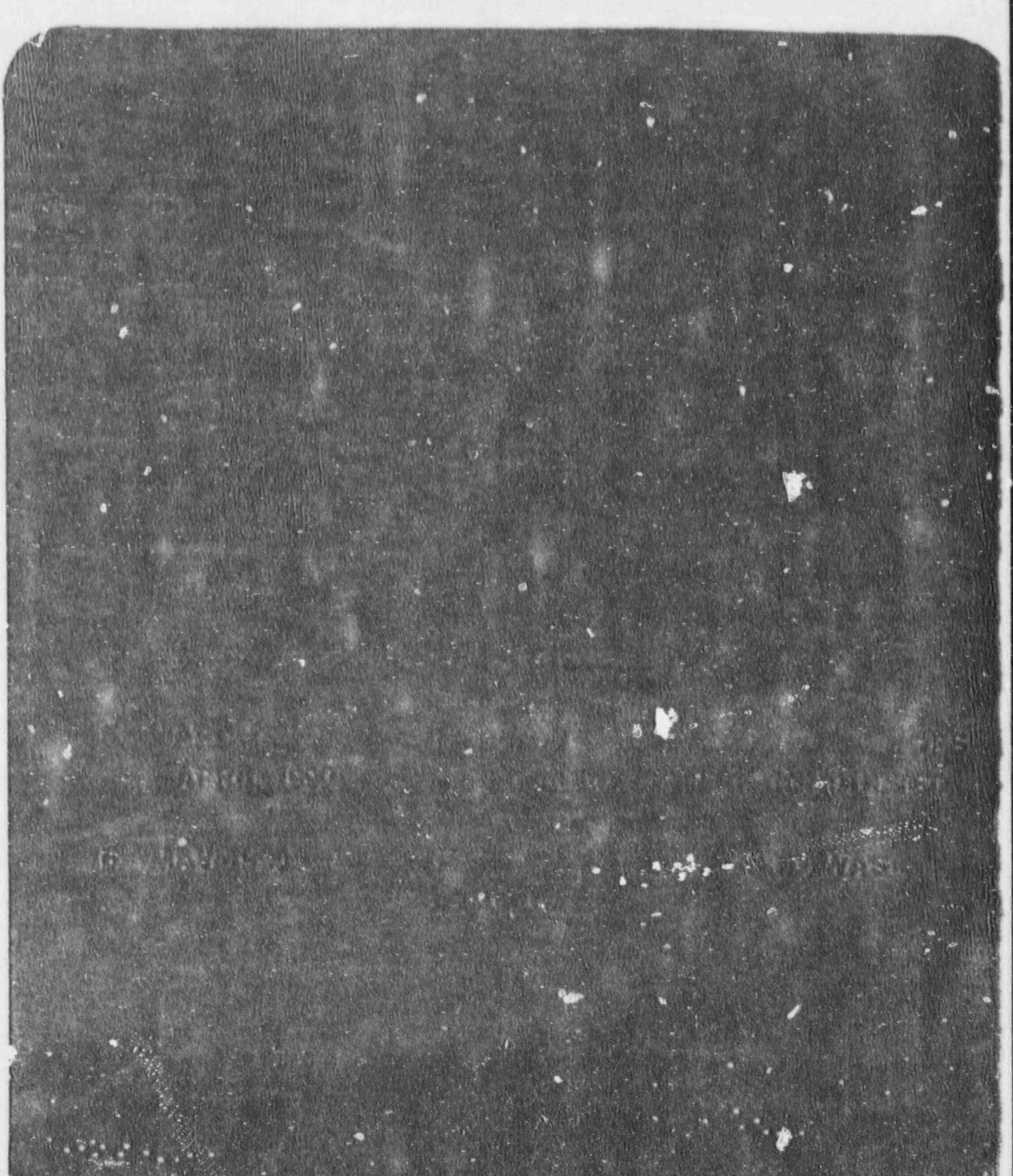
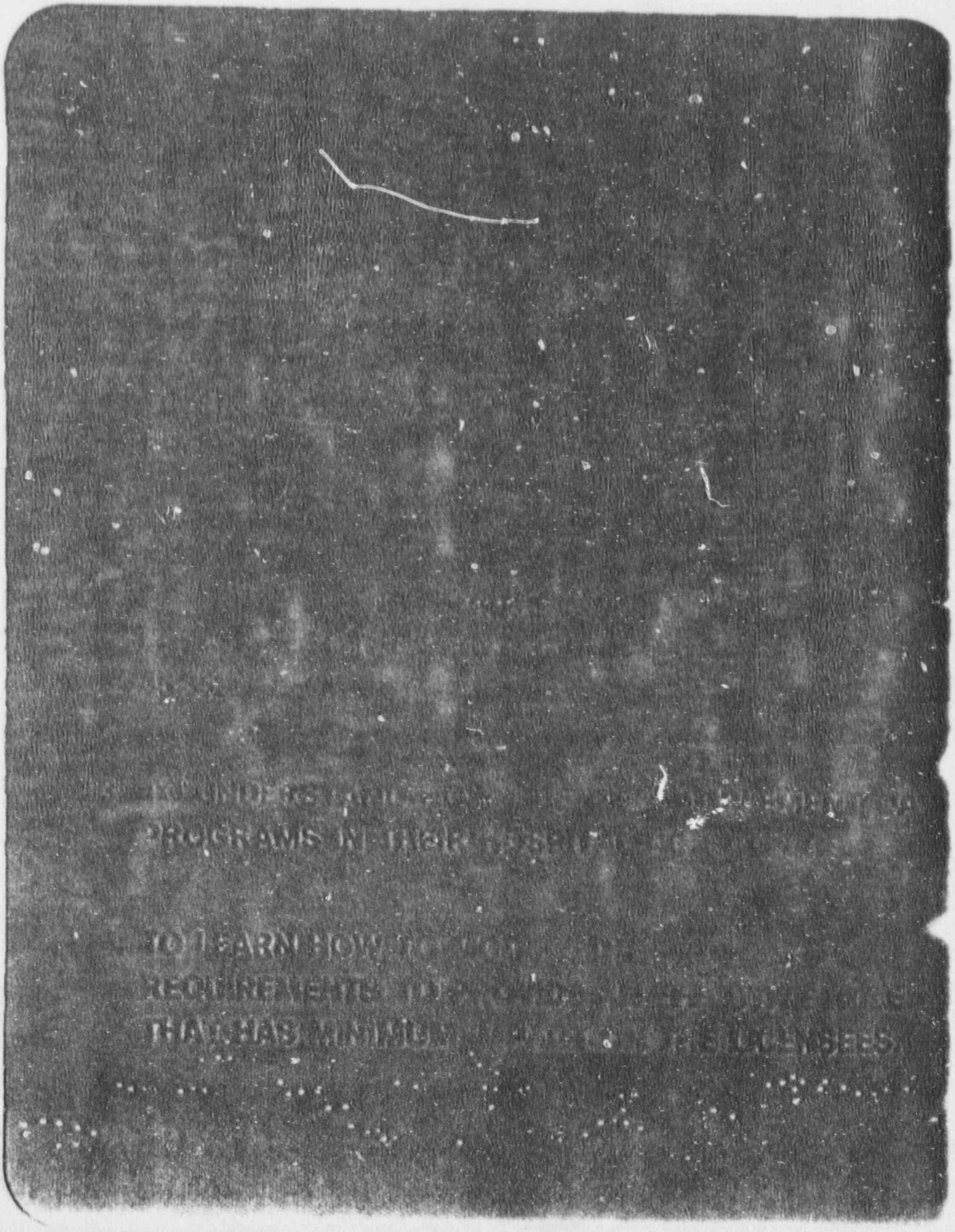


9. JUNE 1989 -- THE STAFF BRIEFED THE COMMISSION PROVIDING A DRAFT PROPOSED AMENDMENT FOR A PERFORMANCE-BASED RULE.

10. JUNE 1989 -- THE COMMISSION REQUESTS CHANGES.

11. AUGUST 1989 -- THE PROPOSED AMENDMENT SUBMITTED FOR COMMISSION APPROVAL.





PILOT PROGRAM

1. WE WOULD LOOK TO ENSURE THAT [illegible]
   VOLUNTEER

2. COMPLETE IN 5 MONTHS
   -- 1 MONTH TO DEVELOP QA PROGRAM
   -- 1 MONTH TO IMPLEMENT
   -- 2 MONTHS FOR ACTUAL TESTING
   -- 1 MONTH TO COLLECT RESULTS

3. PUBLIC WORKSHOPS
   -- BEFORE - TO DISCUSS GROUND RULES
   AFTER - TO DISCUSS RESULTS

4. WILL TEST INSPECTION AND LICENSING FOR A SUBSET OF THE VOLUNTEERS

PILOT PROGRAM OUTLINE

2. VOLUNTEERS
QA PROGRAM MEETS PROPOSED
MEET PROPOSED § 35.35

3. PRE-TEST WORKSHOPS ON MARCH 2ND, APRIL
VOLUNTEERS BRING COPIES OF THEIR QA PROGRAMS

4. VOLUNTEERS DEVELOP WRITTEN INSTRUCTIONS OR TRAIN PERSONNEL, IF REQUIRED, DURING APRIL TO PREPARE FOR QA PROGRAM 60-DAY TRIAL.

5. VOLUNTEERS CONDUCT 60-DAY TRIAL, DURING THE PERIOD MAY 14 TO JULY 13, 1990, OF THEIR "35.35 QA PROGRAM" AND RETAIN SPECIFIC RECORDS; THE NRC QA TEAM WILL VISIT 18 VOLUNTEERS FOR ONE DAY AT EACH SITE.

6. POST-TEST WORKSHOPS WILL BE DURING AUGUST 1990. VOLUNTEERS BRING COPIES OF THEIR EVAULATIONS. VOLUNTEERS WILL DISCUSS THEIR "35.35" EXPERIENCE, EVAULUATIONS, AND SUGGESTIONS FOR IMPROVEMENTS TO PROPOSED § 35.35, THE REGULATORY GUIDE, AND THE RECORDKEEPING AND REPORTING REQUIREMENTS. THE NRC QA TEAM WILL DISCUSS: (A) THE CRITERIA USED TO EVALUATE THE 18 QA PROGRAMS, (B) THE RESULTS FROM THE EVAULUATION OF 18 QA PROGRAMS, (C) THE CRITERIA USED FOR 18 SITE VISIT EVAULUATIONS, AND (D) THE FINDINGS FROM THE 18 SITE VISITS.