

**From:** Craig Gordon  
**To:** WND1.WNP9(CHM)  
**Date:** 10/10/96 5:08pm  
**Subject:** Maine fax -Reply

Cardelia

The letter looks OK but I really think we should wait to receive the letter from the state rather than responding to a fax.

Craig

**CC:** CWH

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I called the State and they indicated  
that this is their <sup>official</sup> response. If  
this changes, they will call me.

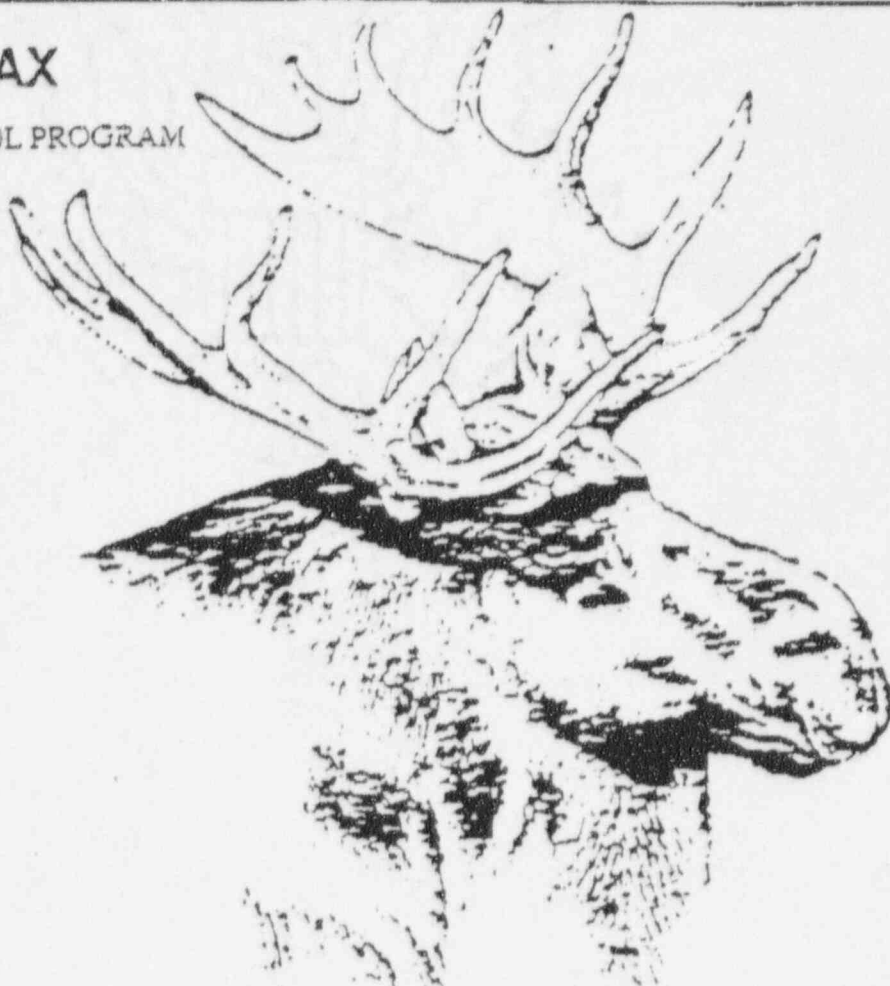
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NO BULL

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## ■ JUST THE FAX

MAINE RADIATION CONTROL PROGRAM  
STATE HOUSE STATION 10  
AUGUSTA, ME 04333



FAX: 207-287-4172  
VOICE: 207-287-5676

TO:

Cardelia Maxie  
OSP

31 - 415 - 3502

FROM:

Shawn Seiler

DATE:

10-9-96

PAGE 1 OF 62 PAGES

Cardelia,

Binar has reduced their possession limit of 125 I  
to 7.5 Curies, bringing them below the limits for  
an e-plan. Any questions call me at 207-287-5676.  
Thank you



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

October 29, 1996

Robert Schell, PE, Manager  
Radiological Health Program  
State House, Station 10  
151 Capitol Street  
Augusta, Maine 04333-0011

Dear Mr. Schell:

This is in response to the fax dated October 9, 1996 from Mr. Shawn Seeley, Radioactive Materials Inspector, Maine Radiological Health Program. Mr. Seeley's fax responded to a concern raised in my October 1, 1996 letter to Dr. DoraAnne Mills regarding the Binax, Inc. license. In the October 1, 1996 letter, a response was requested concerning how the Maine radiation control program would be addressing the application of the emergency planning (EP) rule to the Binax, Inc., license. The fax (enclosed) from Mr. Seeley provided an amendment to the Binax, Inc. license, which indicated that the possession limit for iodine-125 (I-125) had been reduced to 7.5 curies. The NRC regulations provide that an emergency plan is needed if the authorized possession limit on a license exceeds 10 curies of I-125; thus, an emergency plan is no longer applicable to the Binax, Inc license.

The actions taken by the Maine radiation control program have adequately addressed our earlier comment and recommendation regarding the adoption of the EP rule. In view of these actions and the information provided in letter dated July 23, 1996 from Dr. Philip Haines, NRC agrees with the Maine radiation control program deferral of the adoption of the EP rule since there are no licensees in the State subject to this rule. If a license application subject to the provisions of this rule is received subsequent to this letter, applicable provisions of the EP rule should be incorporated through license condition or through other legally binding means.

We appreciate the prompt action taken by the Maine radiation control program.

Sincerely,

*Richard L. Bangart*  
Richard L. Bangart, Director  
Office of State Programs

Enclosures:  
As stated

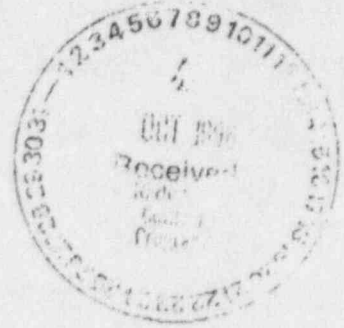
cc w/encl: Dr. DoraAnne Mills, M.D., Director of Bureau of Health  
W. Clough Toppan, State Liaison Officer  
Shawn Seeley, Radioactive Materials Inspector

9701300050 1p.



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

October 1, 1996



DoraAnne Mills, M.D.  
Director, Bureau of Health  
Maine Department of Human Services  
11 State House Station  
161 Capitol Street  
Augusta, Maine 04333-0011

Dear Dr. Mills:

This is in response to the letter dated July 23, 1996 from Philip Haines, Acting Director, Bureau of Health which responded to the comments and recommendations from our March 21, 1996 review of the Maine radiation control program. The responses provided detailed information on how the Maine radiation control program has addressed, or is addressing, our recommendations. We appreciate the positive actions that the Maine radiation control program has taken with regard to our comments and recommendations.

However, we believe additional action is needed by the Maine radiation control program to resolve one comment and recommendation. This comment concerns the application of the emergency planning rule requirements to a Maine licensee, Binax. In your response, you indicated that this licensee currently physically possesses material below that requiring submittal of an emergency plan; however, the Binax license authorizes the company to possess amounts of material which require an emergency plan. The amount of radioactive material authorized by the license, not the amount in actual possession by the licensee, should determine whether an emergency plan is required. In light of this, the Maine radiation control program should either request the submittal of an emergency plan by Binax, condition the Binax license to reduce its authorized possession limit, or if justified, formally exempt the licensee from this requirement.

We request a response addressing this issue regarding the emergency planning rule. In addition, we will review the status of other comments and recommendations as a part of our next program review.

Thank you for your support of the Maine program.

Sincerely,

*Richard L. Bangart*  
Richard L. Bangart, Director  
Office of State Programs

cc: R. Schell, RCP  
W. Clough Toppan, State Liaison Officer

9616100203 lp.



STATE OF MAINE  
DEPARTMENT OF HUMAN SERVICES  
11 STATE HOUSE STATION  
AUGUSTA, MAINE  
04333-0011

ANGUS S. KING, JR.  
GOVERNOR

KEVIN W. CONCANNON  
COMMISSIONER

October 9, 1996

Roger Piasio, President  
Binax, Inc.  
217 Read Street  
Portland, Maine 04103

Dear Mr. Piasio:

Please find enclosed the amendment to your State of Maine Materials License number 05243-01. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact the Division of Health Engineering at 287-8401, so that we can provide answers.

Please be advised that you must conduct your program in accordance with the conditions of your State of Maine license application, and State of Maine regulations. Failure to do so could result in enforcement action against you as specified in Part B of the Maine Rules Relating to Radiation Protection. The Department expects licensees to pay meticulous attention to detail and to achieve a high standard of compliance with Maine regulations.

*Hand to  
Craig  
10/9/96  
1233m*

You will be periodically inspected by the State of Maine Radiation Control Program as delineated in Section A.5 and Appendix A to Part C. Failure to conduct your program as specified above could result in enforcement action against you as specified in Part B of the Maine Rules Relating to Radiation Protection.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Robert J. Schell, P.E., Manager  
Radiation Control Program  
Division of Health Engineering





# STATE OF MAINE MATERIALS LICENSE

Page 1 of 2  
License No. 05243-01  
Amendment No. 6

Pursuant to the Maine Radiation Statutes (22 MRSA 677) and Maine Department of Human Services regulations on radiation (10-144A CMR 220), and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive material as designated below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maine Department of Human Services now or hereafter in effect and to any conditions specified below.

|  |   |                       |
|--|---|-----------------------|
| 1. Name<br>Binax, Inc.                                 | This license is issued in accordance with<br>correspondence dated:<br>October 3, 1996 |                       |
| 2. Address<br>217 Read Street<br>Portland, Maine 04103 | 3. License Number<br>05243-01   | Amendment Number<br>6 |
| 4. Expiration Date<br>September 30, 1998               |   |                       |

- |                 |                     |                     |
|-----------------|---------------------|---------------------|
| 5. Radionuclide | 6. Form of Material | 7. Maximum Activity |
| A. Iodine 125   | A. Any              | A. 7.5 Curies       |
| B. Iodine 129   | B. Sealed Source    | B. 2 microcuries    |

## 8. AUTHORIZED USE

- A. For the receipt, possession, storage, research, development and manufacture of radioimmunoassay kits for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.
- B. For calibration of instruments.

## CONDITIONS

9. Licensed material may be used only at the licensee's facilities at 217 Read Street, Portland, Maine.
10. A. Licensed material shall be used by, or under the supervision of Timothy Marsh, David G. Cabral, Pamela Angell, or Myron Whipkey.  
B. The Radiation Safety Officer for this license is Myron Whipkey.
11. Licensed material shall not be used in or on human beings.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:  
A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.

STATE OF MAINE  
MATERIALS LICENSE

Supplementary Sheet


Page 2 of 2  
License No. 05243-01  
Amendment No. 6

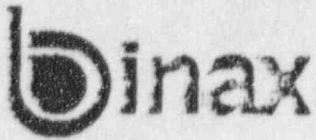
B. Prior to disposal as normal waste, radioactive waste shall be surveyed in accordance with procedures described in the licensee's application to determine that its radioactivity cannot be distinguished from background. The survey conducted prior to disposal must confirm that the radioactivity of the waste cannot be distinguished from background. All radiation labels shall be removed or obliterated.

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Agency's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated July 19, 1993
- B. Amendment dated August 12, 1993
- C. Letter dated August 26, 1993
- D. Letter dated October 1, 1993
- E. Letter dated October 14, 1993
- F. Letter dated October 16, 1993
- G. Letter dated January 3, 1994
- H. Letter dated March 30, 1994
- I. Letter dated October 3, 1996

Date: October 9, 1996

  
Robert J. Schell, P.E., Manager  
Radiation Control Program  
Division of Health Engineering



277 READ STREET  
PORTLAND, MAINE 04103 USA  
ADMINISTRATIVE OFFICES  
207-772-3988  
FAX 207-871-5751  
CUSTOMER SERVICE  
207-772-2199  
FAX 207-761-2074

October 3, 1996

Mr. Jay Hyland  
Radiological Health Program  
Dept. of Human Services  
Div. of Health Engineering  
State House Station #10  
Augusta, Maine 04333

Dear Mr. Hyland,

This letter concerns an amendment to Binax's State of Maine Materials License # 05243-01. As we discussed over the phone the 10 Curie possession limit for Iodine-125 is in excess of what we actually have here at the facility. Therefore, we request to lower our Iodine-125 possession limit to 7.5 Curies. Also we request to remove from section 10.A. the following personnel: Benjamin T. Priest and Elaine J. Lachance.

If you have any questions concerning this request, please contact me at 207-772-3988 Ext-169.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Myron D. Whipkey'.

Myron D. Whipkey  
Radiation Safety Officer

A handwritten signature in dark ink, appearing to read 'Roger N. Piasio'.

Roger N. Piasio  
President & CEO