

Date: July 28, 2000

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PN1-00-21

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility:	Licensee Emergency Classification:
Novartis Pharmaceutical	<input type="checkbox"/> Notification of Unusual Event
59 Route 10	<input type="checkbox"/> Alert
East Hanover, New Jersey 07936	<input type="checkbox"/> Site Area Emergency
License No: 29-08978-02	<input type="checkbox"/> General Emergency
Docket No.: 030-05357	<input checked="" type="checkbox"/> Not Applicable

**SUBJECT: POTENTIAL OVEREXPOSURE TO FINGERTIP**

On July 28, 2000, Novartis Pharmaceutical Corporation contacted NRC Region 1 to report an apparent 100 rad dose to the skin of the hand of a worker. On Thursday, June 29, 2000, a worker in the radio-synthesis group at the Novartis facility in East Hanover, NJ was labeling a compound using carbon-14 labeled benzoquinone in dimethoxyethane. During the procedure, he got a drop of the liquid on his left glove a fraction of which went through the glove and contaminated the tip of his left index finger with between two and five microcuries of carbon-14. He reported the contamination to the Novartis radiation safety staff.

Novartis staff attempted to decontaminate the finger using soap and water and other chemical agents, and by putting double latex gloves on the hand to induce sweating. This succeeded in reducing the activity to 120,000 counts per minute, at which point they determined that continuing the effort would not significantly reduce the activity. The individual was sent home with monitoring equipment so that the reduction in activity each day due to skin sloughing could be monitored. The individual was also encouraged to clean the area with mild abrasives periodically. The individual also provided daily urine samples.

Initially, the licensee's radiation safety officer calculated the dose to the skin using a dose factor for skin contamination from the licensee's radiation safety manual and estimated the dose to be 200 mrem. Later, however, he followed up further and became aware that the factor was incorrect and the dose could be much higher. He reevaluated that dose and found that at a depth of 7 mg/cm<sup>2</sup> – the dose at which skin doses must be calculated for regulatory purposes – the dose was 100 rad. Based on this calculation, the licensee determined that the event must be reported to the NRC under the requirements of 10 CFR 20.2202. It should be noted that the International Committee on Radiation Protection would recommend a value of 40 mg/cm<sup>2</sup> for the average thickness of the dead layer of skin at the tip of an index finger, which would lead to a dose to the living skin (derma) of zero. The skin contamination is, therefore, expected to have no health effects. The licensee also evaluated the urine samples and estimates the whole body dose from the event at between 100 and 300 mrem.

The licensee determined that the event occurred because, although the worker employed standard precautions when performing labeling procedures, these precautions were not sufficient for the particular procedure being performed. Although the worker did two dry-runs of the procedure before using the labeled material, he wore only one pair of gloves and wore

gloves that were not sufficiently protective for the compound being used. The licensee also determined that initial decontamination efforts were not sufficiently aggressive due to concern about introducing the material into the blood stream.

To prevent recurrence, the licensee will require two pairs of gloves for similar procedures and will require users to select gloves that provide protection against the material being used if possible. The licensee is also examining whether remote handling tools are appropriate to use for these procedures, and, if so, what type. In addition, it will be providing additional training to all members of the radio-synthesis group.

Region 1 will perform an inspection at Novartis to examine the circumstances surrounding this event.

The State of New Jersey has been notified of this event. The information in this preliminary notification has been reviewed with the licensee. NRC Region I Office of Public Affairs has been briefed and is prepared to respond to inquiries.

This information is current as of 3:30 p.m. on July 28, 2000.

Contact: Keith Brown  
610-337-5048

John McGrath  
610-337-5069

DISTRIBUTION:

OWFN

Chairman Meserve  
Comm. Diaz  
Comm. McGaffigan Jr.  
Comm. Merrifield  
Comm. Dicus

TWFN

IRO  
IRM  
ACRS

LST

PDR

Mail: DOT:Trans only\*\*

OIP

OCA

OGC

OPA

EDO

OE

OSP

NRR

SECY

NMSS

OIG

RES

INPO\*\* \_\_\_\_\_

NSAC\*\* \_\_\_\_\_

Regional Offices \_\_\_\_\_

RI Resident Office

\_\_\_\_\_

Licensee: \_\_\_\_\_  
(Reactor Licensees)

\*\* General list for sending PNs by FAX

Region I Form 83  
(Rev. July 9, 1999)