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Bradley M. Campbell
Commissioner

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Subject: 21 CFR Part 1021, Docket no. 01N-0275, published December 10, 2002

Dear Mr. Shope:

The New Jersey Department of Environmental Protection (NJDEP), Radiation Protection Programs, offers the following comments in support of the proposed amendments to the performance standards for diagnostic x-ray systems and their major components:

1. The NJDEP congratulates the FDA for its efforts in developing and proposing these amendments. We are particularly pleased with the anticipated reductions in patient exposure to radiation that the FDA estimates will occur. However, based on the experience we have had in New Jersey, we believe that the exposure reductions, in particular those associated with the display of cumulative dose, will be greater than the 16 percent estimated by the FDA. Several years ago, New Jersey established a non-regulatory program in which our state inspectors measure entrance skin exposure. After the inspection, a report is sent to the physician identifying the exposure measured and comparing it to exposures measured at similar facilities throughout the state. There are no reference values or maximum limits on exposure; we are just providing information with the recommendation to reduce the exposure if it is found to be high or extremely high. This effort has resulted in reducing the average radiographic entrance skin exposure in New Jersey by 30 to 35 percent from where it was when the program started. We believe that most physicians will respond responsibly to the information that will be provided through the display of cumulative fluoroscopic doses. This should result in the average dose for these procedures to be reduced by greater than 16 percent.

2. In section II. A. (Page 76057) of the proposal, the FDA describes its decision to move to the metric system. In proposing this conversion, the FDA made sure that the radiation

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protection standards would not be relaxed. We applaud the FDA for its decision to do the right thing notwithstanding the fact that when the NCRP adopted the use of the metric system, it resulted in increasing its recommended limits by approximately 15 percent. As a result of this decision, the numeric values of the standards may not be integer numbers or multiples of five or ten, but the level of protection established by the FDA rules will remain constant.

3. In section II. K. 1. (Page 76066) of the proposal, the FDA asked for comment on whether the display of the cumulative irradiation time should be visible to the fluoroscopist at his or her working position or whether it is sufficient to display the cumulative time at the control console. In light of the discussion in 1. above, it is New Jersey's position that the information is most useful to the fluoroscopist at their working position. It is he or she who will be making decisions as whether, and for how long, to activate the x-ray tube; to be effective, they are the ones who need the information. In this section the FDA also asked for comments on the proposed provisions establishing standards for the audible signal. New Jersey agrees with and supports the FDA proposal on this issue.

4. In section II. K.2. (Page 76066) of the proposal, the FDA asked for comment on the proposed standardized display formats in section 1020.32(k)(1) through (k)(7). New Jersey agrees with and the supports FDA's proposal to establish a standardized display formats for the cumulative irradiation time. This will help to maximize the effectiveness of the display in particular when a physician performs fluoroscopic procedures either at different facilities or using different units.

5. In section II. L. (Page 76067) of the proposal, the FDA asked for comment on the proposed "last-indeed hold" provisions proposed for section 1020.32(j). New Jersey finds that these provisions are both appropriate and needed. Allowing the physician to study a particular fluoroscopic scene more carefully without the need for continuous irradiation of the patient will clearly reduce the amount of radiation needed to successfully complete the procedure.

6. In section II. S. (Page 76068) of the proposal, the FDA explains how re-publication of entire sections subject to amendment results in a more reader-friendly version of the proposal. Although New Jersey agrees that simply publishing the provisions being amended makes reviewing a proposal more difficult, publishing entire sections without identifying which provisions are new and which provisions are being deleted also makes reviewing the proposal difficult. To be truly user-friendly, New Jersey would like to see the FDA publish the entire section(s) and highlight (underline) the proposed new provisions and to identify, using either brackets or cross out, the sections or terms that are proposed for deletion.

7. New Jersey notes one area of disappointment. Several years ago the FDA established a policy regarding disabling PBL systems. This policy provided several important safeguards and provisions to help ensure that operators and new owners are aware when

the PBL has been disabled. These amendments would have been an appropriate place to codify the PBL policy.

8. New Jersey has reviewed the FDA's **Analysis of Impacts** and finds the analysis is both comprehensive and compelling. Clearly the benefits to public health of the proposed amendments far out weigh the anticipated costs. New Jersey encourages the FDA to adopt the amendments as soon as possible.

We hope these comments are helpful, if there are any questions please do not hesitate to contact me or Anthony McMahon, Chief, Bureau of Radiological Health at 609-984-5634.

Sincerely,

Jill Lipoti, Ph.D.
Assistant Director