

NCS

NC SYSTEMS, INC.
NUCLEAR CARDIOLOGY SYSTEMS
5660 AIRPORT BLVD., SUITE 101
BOULDER, CO 80301

20 May 20, 2002

Certified Mail
7001 2510 0009 4566 7188

Mr. Warren E. Jacobi, Program Manager
Radiation Services
Laboratory and Radiation Services Division
Colorado Department of Public Health
and Environment
8100 Lowry Blvd.
Denver, CO 80230-6928

Re: License #COLO 751

Dear Mr. Jacobi:

Please be so advised that the position taken by your agency, that we must be subject to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and hold a HHS, CMS certification to perform radiological analysis of biosamples, is incorrect. We are not subject to those requirements and, we propose, that no licensee who is not performing 35.100 procedures is subject to those regulations. In addition, please be advised that the CLIA regulations apply to patient procedures and not the analysis of employee biosamples.

Further, be advise that this was the conclusion we had when your agency first addressed the issue. If your agency had been correct, every medical imaging licensee and most non-medical licensees would have been required by HHS to be certified to operate under their NRC/Agreement State license.

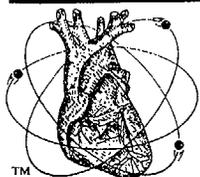
If you have questions, or need additional assistance, please contact me at the office.

Sincerely,

Charles H. Rose
License Administrator & RSO

cc: Donald Cool, Director
Div. of Industrial & Medical Nuclear Safety
US Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike, 3rd Floor
Rockville, MD 20852

NMSS 23



NCS

NUCLEAR CARDIOLOGY SYSTEMS
5660 AIRPORT BLVD., SUITE 101
BOULDER, CO 80301

UNITED STATES POSTAGE
128 4750# 00.340 MAY 20 02
0200 MAILED FROM BOULDER CO 80301

Mr. Donald Cool, Director
Div. of Industrial & Medical Nuclear Safety
US Nuclear Regulatory Commission
One White Flint North
1155 Rockville Pike, 3rd Floor
Rockville, MD 20852

20852-2738 13

