NRCREP - NUREG-1556 Volume 13 Comments - Michigan

7/13/07
72FR36526
(2)

From: "Robert Skowronek" <skowronb@michigan.gov>
To: <nrcrep@nrc.gov>
Date: 07/20/2007 3:41:00 PM
Subject: NUREG-1556 Volume 13 Comments - Michigan

Our comments are attached. If we can be of additional assistance, please contact me.

Robert D. Skowronek, Chief
Radioactive Materials Unit
Radiological Protection Section
Waste and Hazardous Materials Division
Michigan Department of Environmental Quality
Telephone: 517-241-1253

SUNSI Review Complete
Template = ADM-013

E-RIDS = ADM-03
Add = T. Taylor
(TMT)

Mail Envelope Properties (46A10FBC.8DF : 11 : 43231)

Subject:	NUREG-1556 Volume 13 Comments - Michigan
Creation Date	Fri, Jul 20, 2007 3:39 PM
From:	"Robert Skowronek" <skowronb@michigan.gov>
Created By:	skowronb@michigan.gov

Recipients
nrc.gov
TWGWPO01.HQGWDO01
NRCREP

Post Office	**Route**
TWGWPO01.HQGWDO01	nrc.gov

Files	**Size**	**Date & Time**	
MESSAGE	283	Friday, July 20, 2007	3:39 PM
TEXT.htm	606		
NUREG-1556 Volume 13 Comments - Michigan.pdf			348398
Mime.822	479309		

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

Junk Mail Handling Evaluation Results
Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

Junk Mail settings when this message was delivered
Junk Mail handling disabled by User
Junk Mail handling disabled by Administrator
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled

STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

STEVEN E. CHESTER
DIRECTOR

July 20, 2007

Mr. Michael T. Lesar, Chief
Rulemakings, Directives, and Editing Branch
Division of Administrative Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lesar:

We appreciate the opportunity to review and comment on the draft NUREG-1556 Volume 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

General Comments

1. Radiochemical synthesis units using positron emission tomography (PET) radiopharmaceuticals release radioactive material to the air during their normal processes. The integrity of the transfer line or other hardware can catastrophically fail, releasing a bolus to the atmosphere. We strongly urge the Nuclear Regulatory Commission (NRC) to require PET radiopharmacies to submit an assessment of the potential doses to members of the public during routine use and during a catastrophic failure.

   We do not believe that the average NRC or state agreement inspector can adequately evaluate the ventilation system design and the computer modeling of public doses during a routine inspection. The complexity of the ventilation systems, the inherent limitations of the different computer codes, and the breadth of input data for the computer codes would be difficult for an inspector to evaluate during an on-site inspection. With the dose assessment submitted during licensing of the facility, NRC staff can adequately evaluate the premises and conclusions of the dose assessment. Then the inspector knows before the inspection that an annual release to the atmosphere of "x" curies of a radionuclide means a dose of "y" millirems to a member of the public. The inspector would need to verify during the inspection that the other input parameters in the dose assessment had not changed.

2. The ANSI standards referenced in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" and Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," have been revised. These Regulatory Guides should be reviewed and revised.
   - ANSI N42.18 "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004.
   - ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."

Specific Comments

- Add to Abbreviations

DU	Depleted Uranium
LSC	Liquid Scintillation Counter
NaI	Sodium Iodide
NaI(Tl)	Sodium Iodide (thallium activated)
rad	unit of absorbed dose
gy	gray - SI unit of absorbed dose
rem	roentgen equivalent man

- Delete from Abbreviations

cm	centimeter
mGy	milliGray
mR	milliroentgen
mrem	millirem
mrem/hr	millirem per hour
mSv	millisievert
mSv/hr	millisievert per hour

- Add table under SI

SI Prefixes

Prefix	Symbol	Factor	Examples
micro	μ	10^{-6}	μCi
milli	m	10^{-3}	mCi, mR
centi	c	10^{-2}	Cm
kilo	k	10^{+3}	kg, kBq
Mega	M	10^{+6}	MBq
Giga	G	10^{+9}	GBq
Tera	T	10^{+12}	TBq

Page 1-2. Change "Roentgen ®" to "Roentgen (R)."

Page 8-30, "8.9.2 Facilities and Equipment for PET Radiopharmacies." We applaud the NRC for having a separate section describing the unique requirements for a radiopharmacy handling PET radionuclides.

Page 8-31, "Response from Applicant" regarding "Facilities and Equipment" and page C-9, "Facilities and Equipment." These sections state "Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d)." What would be considered sufficient verification? Does a facility need to submit a computer model calculating the projected doses to members of the public at various nearby locations or will an unsupported statement that public doses are ALARA be considered sufficient?

APPENDIX J, "Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program" should include a discussion on the calibration of radiation detection equipment installed to monitor and quantify the activity released to the atmosphere. For PET

radiopharmacies, stack exhaust monitors may be sodium iodide detectors mounted adjacent to the exhaust system. They are calibrated by releasing a known millicurie quantity of radioactive material. The number of counts above background can then be correlated with a known activity. This guidance document should state if the NRC will require subsequent periodic releases to annually (quarterly, monthly) "calibrate" these monitors or will the NRC accept a procedure using check sources to confirm that the response to the check sources has not changed since the initial calibration.

Appendix K, "Public Dose" should mention that air intakes for the radiopharmacy building and for adjacent buildings need to be considered in the evaluation of doses to members of the public due to atmospheric releases.

Page R-4, "Air Stack Release Monitoring." ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."

Page R-6, "References."

- ANSI N13.1, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."
- ANSI N42.18, "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004.

Spelling Errata

Page	Misspelling	Correction
8-27, 8-29	ventillation	ventilation
8-28, 8-30	contraints	constraints
8-32	syntehsis	synthesis
8-51	radiopharmceutical	radiopharmaceutical
8-56	ampule	ampoule
C-6 (twice)	broadscope	broad-scope
K-2	radiopharmcies	radiopharmacies
U-7	distributer	distributor

If we can be of additional assistance, please contact me.

Sincerely,

Robert D. Skowronek, Chief
Radioactive Materials Unit
Radiological Protection Section
Waste and Hazardous Materials Division
517-241-1253

RDS:JK