



NORTH DAKOTA DEPARTMENT OF HEALTH  
Environmental Health Section

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FILE

MEMO TO : All Medical Use Licensees  
FROM : Terry L. O'Clair, P.E.  
Director  
Division of Air Quality  
RE : Information Notice 08-14-03: Implementation of  
Chapter 7.1, "Medical Use of Radioactive Material"  
DATE : August 14, 2003

Enclosed is a copy of North Dakota Department of Health Radiation Control Program Information Notice 08-14-03: Implementation of Chapter 7.1, "Medical Use of Radioactive Material". This information notice was issued to remind licensees of the upcoming implementation dates for North Dakota Radiological Health Rules Chapter 33-10-07.1, "Medical Use of Radioactive Material."

A copy of Chapter 33-10-07 is attached. This chapter, as well as all other chapters of the North Dakota Radiological Health Rules are available in Adobe Acrobat (pdf) format on the internet at: <http://www.health.state.nd.us/ndhd/envIRON/ee/rad/>.

It is expected that you will review this information for applicability to your licensed activities and consider actions, as appropriate, to ensure the safe and legal use of radioactive materials in the State of North Dakota.

This notice is for your information only. No written response is required. If you have any questions concerning this issue, please contact the Radiation Control Program at 701.328.5188.

TLO/JMG:csc  
Enc:

Environmental Health  
Section Chief's Office  
701-328-5150

Air  
Quality  
701-328-5188

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Quality  
701-328-5210



# NORTH DAKOTA DEPARTMENT OF HEALTH Radiation Control Program

## Information Notice 08-14-03 Implementation of Chapter 7.1, "Medical Use of Radioactive Material"

### **Purpose:**

The North Dakota Department of Health's Radiation Control Program (RCP) is issuing this information notice to remind licensees of the upcoming implementation dates for North Dakota Radiological Health Rules Chapter 33-10-07.1, "Medical Use of Radioactive Material" (see attached copy). It is expected that you will review the revised regulations for applicability to your licensed activities and implement the new regulations, as appropriate, to ensure the safe and legal use of radioactive materials in the State of North Dakota. No written response to this information notice is required.

### **Discussion:**

On March 1, 2003, a revised version of the North Dakota Administrative Code in Article 33-10, "Radiological Health Regulations" became effective. In this revision, the old Chapter 33-10-07, "Use of Radionuclides in the Healing Arts" was repealed and replaced with the new Chapter 33-10-07.1, "Medical Use of Radioactive Material" in order to maintain compatibility with the corresponding U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 35.

The implementation deadline for most requirements of Chapter 33-10-07.1 was set at six months from the effective date of Article 33-10. Therefore licensees must implement the provisions of this chapter on or before September 1, 2003, with the exception of certain training requirements which must be implemented on or before October 25, 2004 as described in the regulations.

### **Related Information and Guidance:**

Chapter 33-10-07.1 (as well as all other chapters of the revised regulations) is also available in Adobe Acrobat (pdf) format on the internet at <http://www.health.state.nd.us/ndhd/enviro/ee/rad/>. If you have any questions about the Radiological Health Rules or would like a free copy of the applicable chapters emailed directly to you, please contact the RCP at 701.328.5188; or send an email message to Ken Wangler, P.E. ([kwangler@state.nd.us](mailto:kwangler@state.nd.us)).

Online resources published by the NRC for medical use of radioactive material are available for viewing or download from:

<http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html>

The above NRC link includes the availability of NUREG-1556, Vol. 9, "Program-Specific Guidance about Medical Use Licensees" published in October 2002, a "Guide for Diagnostic Nuclear Medicine" prepared by the American College of Nuclear Physicians and the Society of Nuclear Medicine and other helpful and informative links. If you are unable to view these documents online, we could send you copies upon request.

Please note that NRC's NUREG-1556, Vol. 9 will refer to the federal requirements described in 10 CFR Part 35. Keep in mind that although N.D.'s regulations are compatible with 10 CFR Part 35, the regulations regarding the medical use of radioactive material in N.D. are provided in Chapter 33-10-07.1 of our "new" rules.

Subsection 6 of Chapter 33-10-07.1 states the required implementation dates. This subsection is copied below for your convenience.

**33-10-07.1-06, "Implementation."**

1. A licensee shall implement the provisions in this chapter on or before **September 1, 2003**, with the exception of the requirements listed in subsection 2.
2. A licensee shall implement the following training requirements on or before **October 25, 2004**:
  - subsection 1 of section 33-10-07.1-20 (training for radiation safety officer),
  - subsection 1 of section 33-10-07.1-21 (training for an authorized medical physicist),
  - subsection 1 of section 33-10-07.1-22 (training for an authorized nuclear pharmacist),
  - section 33-10-07.1-24 (recentness of training),
  - subsection 1 of section 33-10-07.1-36 (training for uptake, dilution, and excretion studies),
  - subsection 1 of section 33-10-07.1-40 (training for imaging and localization studies),
  - subsection 1 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required),
  - subsection 1 of section 33-10-07.1-45 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries]),
  - subsection 1 of section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]),
  - subsection 1 of section 33-10-07.1-55 (training for use of manual brachytherapy sources),
  - subsection 1 of section 33-10-07.1-58 (training for use of sealed sources for diagnosis), and
  - subsection 1 of section 33-10-07.1-75 (training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units)
3. Prior to October 25, 2004, a licensee shall satisfy the training requirements of this chapter for a radiation safety officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:
  - a. The appropriate training requirements in sections 33-10-07.1-76 through 33-10-07.1-88; or
  - b. The appropriate training requirements in sections 33-10-07.1-14 through 33-10-07.1-24 or sections 33-10-07.1-35 through 33-10-07.1-75.
4. If a license condition exempted a licensee from a provision of this chapter on September 1, 2003, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of this chapter.
5. When a requirement in this chapter differs from the requirement in an existing license condition, the requirement in this chapter shall govern.
6. A licensee shall continue to comply with any license condition that requires it to implement procedures required by sections 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma Stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), and 33-10-07.1-70 (periodic spot checks for gamma Stereotactic radiosurgery units) until there is a license amendment or renewal that modifies the license condition.

**For More Information:**

If you have questions or concerns about implementation of Chapter 33-10-07.1, please contact Jim Killingbeck (jkilling@state.nd.us) at 701.328.5188.