NORTH CAROLINA
RADIATION PROTECTION

DOSE TO AN EMBRYO/FETUS OR NURSING CHILD REPORTING FORM

INSTRUCTIONS FOR USE: Read these instructions carefully. Please note that completion and submittal of this form **DOES NOT RELEIVE THE LICENSEE FROM THE NEXT CALENDAR DAY TELEPHONE REPORTING REQUIREMENTS LISTED IN THE REGULATIONS**. The completed form MUST be submitted **within 15 days** of the discovery of the dose. Please mail the completed report to: ***Response Coordinator, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.*** The completed report may also be emailed to travis.cartoski@dhhs.nc.gov

This Guide is not intended to, and does not, create any rights or privileges, substantive or procedural, which are enforceable by person. The publication of this guide, or any version thereof, does not place any limitation of the otherwise lawful prerogatives or discretion of the Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

The Radioactive Materials Branch (Branch) published this guidance to assist medical use licensees comply with the reporting requirements regarding dose to an embryo/fetus or a nursing child (10A NCAC 15 .0365). This regulation deals with doses received by an embryo/fetus or nursing child during the course of medial diagnosis or therapy. This should not be confused with 10A NCAC 15 .1610, which deals with dose to an embryo/fetus (only) that is the result of occupational exposure of the mother. The information contained herein is subject to change and is guidance only. The licensee must evaluate each event carefully and proceed accordingly.

You are strongly encouraged to TYPE the information into the form. This form is posted to the Branch's website (*http://ncradiation.net/rms/rmsforms2.htm(Rev01).htm*). You may download the form(s) and save to your local computer.

Please note that if the information contained in the transmitted report is illegible, the report may be deemed "not timely filed" and the licensee may be subject to compliance and enforcement action(s).

BACKGROUND and DEFINITIIONS

Background:

10A NCAC 15 .0365 "Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child" was recodified on February 1, 2015. N.C. adopted this regulation as part of our Agreement with the U.S. Nuclear Regulatory Commission (NRC). We have included a copy of the regulation within this guidance document for your convenience. However, it is the licensee's responsibility to have the most up-to-date copy of the regulation.

Definitions:

.0104(51) "Embryo/fetus" means the developing human organism from conception until the time of birth.

NOTE: For the purpose of this form, the term "mother" is used to refer to either the pregnant woman or the mother of the nursing child

SECTIONS OF THE FORM

Section I: Use/Procedure/Modality information

This is simply general information gathered about the type of procedure or the modality/equipment being used when the dose was received. The "Other" category should be used for devices such as IVB or Iotrex® systems.

Section II: Information about the dose to the embryo/fetus or child

This portion of the form deals with the language contained within the regulation. The criteria for reporting to the agency is divided into two "types": (1) the embryo/fetus and (2) the nursing child.

A. Check here if the dose is to an embryo/fetus. A licensee must report any dose that exceeds 5 rem dose equivalent UNLESS the physician AU approved the dose to the embryo/fetus IN ADVANCE OF THE ADMINISTRATION of the radioactive material or radiation from radioactive material or an accelerator. Licensees should note that the rule does not differentiate between diagnostic and therapeutic nuclear medicine procedures. Furthermore, the rule does NOT require that a written directive be done – so this rule applies to diagnostic nuclear medicine as well. The only requirement is that the dose is PRE-APPROVED by the authorized user.

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B. Check here if the dose is to a nursing child. Note that only one of the two criteria must be met. A with the dose to an embryo/fetus above, the rule does NOT require that a written directive be in place. So this will apply to diagnostic administration as well. A physician must make the determination that there was unintended permanent functional damage to an organ or physiological system of the child. This determination does not have to be made by the physician authorized user.

Section III: Notifications

Three (3) persons are required to be notified with 24 hours of the DISCOVERY of a medical event:

a. The agency
b. The referring physician,
c. The mother (or mother's responsible relative or guardian)

Agency notifications must be made to (919) 814-2250. If calling during normal business hours (M – F, 8 – 5), ask to speak with a member of the Radioactive Materials Branch. Otherwise, please leave a message for a member of the Radioactive Materials Branch. The message should include the following information:

1. Caller's name
2. Licensee name
3. License Number
4. Date of the event occurred
5. Date of DISCOVERY of event
6. Date and time of phone call to the agency
7. Brief description of the event

Section IV: Reporting Requirements (To The Agency)

The written report is required to be transmitted to the agency within 15 days of discovery of the medical event. The rule (.0364(d)) requires that seven elements must be contained in the report. The licensee name and the name of the prescribing physician are already listed on the reporting form. The remaining five elements that must be addressed are:

1. Brief description of the event;
2. Licensee's evaluation of why the event occurred;
3. The effect, if any, on the embryo/fetus or nursing child who received the dose;
4. What action(s), if any, have been taken or are planned to prevent recurrence;
5. Certification that the licensee has notified the mother (or the mother's responsible relative or guardian) and if not, why not.

ALSO NOTE: The rule requires that the licensee furnish an annotated copy of the report ***to the referring physician*** within 15 days of the discovery of the event. The annotation shall include the name of the individual who is the subject of the event; and the social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event.

Section V: Certification

All medical event reports must be signed by a certifying official before being transmitted to the agency.:

Section VI: Supplemental Information

This section is provided for convenience in reporting information to the agency. Attach additional sheets as necessary.

PLEASE REVIEW THE FORM CAREFULLY BEFORE TRANSMITTING

10A NCAC 15 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by that authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of administration of radioactive material to a breast-feeding individual, that:

(1) Is greater than 5 rem (50 mSv) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) of this Rule.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) in this Rule.

(1) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the embryo/fetus or the nursing child;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under Paragraphs (a) or (b) of this Rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this Paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible guardian, that a written description of the event can be obtained from the licensee upon request, The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the agency with the:

(A) Name of the pregnant individual or the nursing child who is the subject of the event; and

(B) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0365 Eff. February 1, 2015.

NORTH CAROLINA
RADIATION PROTECTION

RADIATION PROTECTION SECTION
RADIOACTIVE MATERIAL BRANCH

DOSE TO AN EMBRYO/FETUS OR NURSING CHILD REPORTING FORM

Revised November 2020

INSTRUCTIONS: Completion and submittal of this form is required by 10A NCAC 15 .0365. This form **MUST** be submitted within **15 days** of the discovery of the administration. Completion of this form does **NOT** relieve the licensee of the telephone reporting requirements in 10A NCAC 15 .0365(c). This report **SHALL NOT** contain the individual's or child's name or any other information that could lead to the identification of the individual or child. Records of a dose to embryo/fetus or nursing child must be maintained until the agency terminates the license. The completed report may also be emailed to travis.cartoski@dhhs.nc.gov. Original forms must be mailed to: ***Radioactive Materials Branch, Radiation Protection Section, 1645 Mail Service Center, Raleigh, N.C., 27699-1645***.

1a. Licensee Name _____ 1b. License No. _____

2. Physical Address _____

3. Mailing Address _____

4. Event Date	5. Discovery Date	6. Telephone Report Date	7. Written Report Date

8. Name of Authorized User or Prescribing Physician _____

9a. Name & Title of Individual to be contacted about this report _____

9b. Telephone No. ( ) - 9c. Facsimile No. ( ) - 9d. E-mail _____

I. USE/PROCEDURE INFORMATION

- ☐ Diagnostic Radiopharmaceutical
- ☐ Iodine-131 greater than 30 microcuries
- ☐ Therapeutic Radiopharmaceutical (other than ^{131}I)
- ☐ Manual Brachytherapy
- ☐ Remote Afterloading Device (HDR, PDR, LDR, etc.)
- ☐ Particle Accelerator
- ☐ Gamma Stereotactic Radiosurgery (gamma knife)
- ☐ Teletherapy
- ☐ Other (explain) _____

II. INFORMATON ABOUT DOSE TO EMBRYO/FETUS OR CHILD

A. ☐ A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual **UNLESS THE DOSE** to the embryo/fetus was ***specifically approved, in advance, by that authorized user***.

B. ☐ A dose to a nursing child that is the result of administration of radioactive material to a nursing individual that:

1. ☐ Is greater than 5 rem (50 mSv) total effective dose equivalent; ***or***
2. ☐ Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician

III. NOTIFICATIONS [1]

Was the agency notified via telephone within 24 hours of discovery?	☐ Yes	☐ No
Was the referring physician notified of the event within 24 hours of discovery	☐ Yes	☐ No
Was the mother (or mother's responsible relative or guardian) notified of the event within 24 hours of discovery?	☐ Yes	☐ No

If "No" to any question, please explain.

[1] *The licensee **MAY NOT DELAY** any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in completing a notification required by this rule.*

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1a. Licensee Name _____ 1b. License No. _____

2. Physical Address _____

3. Mailing Address _____

4. Event Date	5. Discovery Date	6. Telephone Report Date	7. Written Report Date

IV. REPORT REQUIREMENTS (TO THE AGENCY)

DO NOT include patient name or any information IN THIS REPORT that could lead to the identification of the patient.

Provide a written account of the event to include, at a minimum, the following (*Use Supplemental sheet on next page*):

1. Brief description of the event;
2. Licensee's evaluation of why the event occurred;
3. The effect, if any, on the embryo/fetus or nursing child;
4. What actions, if any, have been taken or are planned to prevent recurrence;
5. Certification that the licensee notified the mother (or mother's responsible relative or guardian) and if not, why not

NOTE: *Remember to provide an annotated copy of this report to the referring physician within 15 days of the discovery of the event. .0365(f) outlines required information for annotated copy.* ***DO NOT SUBMIT ANNOTATED COPY TO THE AGENCY***

V. CERTIFICATION

The licensee, or any official executing this certificate on behalf of the licensee identified in Item 1a., certify that all information contained herein, including any supplements attached hereto, has been prepared in conformity with all applicable North Carolina Laws and Regulations and is true and correct to the best of our knowledge and belief.

BY: _____ _____

Signature of Certifying Official* Date Signed

_____

Printed Name and Title of Certifying Official

*** A certifying official is defined as (1) a member of upper management at the licensee's facility or (2) any person to whom the authority to sign for license amendments was granted by management during the application process.***

DO NOT WRITE IN THIS SPACE (FOR OFFICIAL USE ONLY)

Reviewed by: _____ Date reviewed: _____ Medical Event Log No. _____

Incident Log No. _____

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2. Physical Address _____

3. Mailing Address _____

4. Event Date	5. Discovery Date	6. Telephone Report Date	7. Written Report Date

VI. SUPPLEMENTAL / ADDITIONAL INFORMATION