NELCO™

PHYSICIST REPORT (PR1)

ESTIMATED RADIATION EXPOSURE RATES

INTRAVASCULAR BRACHYTHERAPY IRIDIUM-192 PROGRAM

REFERENCE DOCUMENT: SHIELD PLACEMENT DIAGRAM (A2)

UNITED HOSPITAL
90-127-10-042

FINAL REPORT
REV 1.0
12/07/2000

(1) Building and Room Location

Clinical Site: United Hospital
City, State: St. Paul, MN
Cardiac Catheterization Lab #CV1

(2) Identification of Cardiac Cardiology Equipment and Brief Description

C-Arm: Philips Integras
Generator: Philips Integras

(3) Site Plan Information

See reference Drawings A1, A2, S1, S2

(4) Identification of Reference Regulatory Codes for Radiation Protection (NRC or appropriate state codes)

10CFR 20.1301 as it pertains to the general public
10CFR 20.1201 as it pertains to occupational workers

(5) Standards for Protection Against Radiation

Shields – The shields have been designed specifically to meet the needs associated with radiation cases in a Cardiac Catheterization Room. The design criteria for the shields complies with the federal Nuclear Regulatory Commission's, regulations pertaining to allowable exposures in non-occupational (general public) and occupational areas. The criteria is that shields reduce the radiation to a level of 2 mR in one hour and 100 mR in one year in those areas where non-occupational workers or the general public may be present. For those areas that can be controlled and are limited to occupational workers, the exposure level to these workers is 5000 mR in one year. The recommended physics design criteria is to meet the applicable regulatory radiation exposure levels as a minimum standard, however the ALARA (As Low As Reasonably Achievable) principle is customarily utilized.

(6) Protocol: Pre-Market Approval (PMA)

FDA PMA # P990036
NRC Registration # NR187S101S

(7) Statement of Working Assumptions

14 Seeds @ 33 mCi/Seed = 462 mCi
^{192} Ir 0.5 R/hr/Ci @ 1m = 500 mR x 462 mCi hr/1000 mCi = 231 mR/hr @ 1 meter (3.28 ft).
140 Cases per year (Assumed in CV1). Cath Lab CV1 and CV4 will share the caseload for a total of 256 Cases/year.
20 Minute dwell time in patient
There is 1/16" of lead equivalent on all inside walls. This could provide an additional 16% reduction in exposure in outside areas. No credit has been taken in these calculations.
Reference: NCRP Handbook 49

(8) Estimated Radiation Exposure Rates

See Table 1 (PR1)

(9) Source Storage Location

Cabinet in Cath Lab

(10) Shield Placement

The responsible radiation safety individual shall assure that the restenosis shields are placed as shown on the shield placement diagram (A2). The shields shall be utilized with the wings locked in the fully open position during treatment, unless otherwise designated on the shield placement diagram (A2). If there are shields designated as optional, the use and location is at the discretion of the Radiation Safety individual.

(11) Method of Calculation (example point A3 in room CV1)

The measured distance is 16 feet. This gives an unshielded wire exposure (patient attenuation factor, PAF, of 1) equal to:
231 mR/hr x $(3.28/16)^2$ = 9.71 mR/hr Unshielded
Considering Occupancy (T=1) = 9.71/1 = 9.71 mR/hour
Considering Dwell Time = 20 min. = 9.71/3 = 3.24 mR in 1 hour
Considering NELCO Restenosis Shield = 3.24/7.2 = 0.449 mR in 1 hour
For 140 cases/year:
Patient Attenuation Factor (1) = 0.449 x 140 = 62.9 mR/year
Patient Attenuation Factor (2) = 0.225 x 140 = 31.5 mR/year
Patient Attenuation Factor (4) = 0.112 x 140 = 15.7 mR/year

(12) Radiation Measuring Instruments and Survey Points

The radiation area survey should be performed using a calibrated ion chamber and/or GM meter. Those areas noted on the site survey report (S1) shall be surveyed. Other areas within the room may also be surveyed (i.e. areas where oncologist stands). These locations are at the discretion of the radiation safety individual.

(13) Recommendations to Minimize Exposure and Optimize Radiation Safety:

It is recommended that the institution follow all state, federal and national laws regarding radiation exposure. In addition it is recommended that ALARA guidelines be followed.

(14) Site Measurements of Exposure Rates

It is mandatory that actual measured data be taken to confirm these assumptions provided herein. A completed site survey report (S1) shall be forwarded to NELCO.

(15) Radiation Safety Notes and Options

1. Mark shield shadow area on walls in operating room and try to keep staff within this area.
2. The third shield is optional but recommended to reduce exposure to staff in control room within ALARA limits.

NELCO™

Intravascular Brachytherapy Iridium - 192 Program
Site Planning Information for:
Site: United Hospital
City, State: St. Paul, MN
Cardiac Catheterization Lab #CV1
 # Cases per YEAR: 140
PR#1
Job #: 90-127-10-042

(8) TABLE 1 - ESTIMATED RADIATION EXPOSURE RATES

						mR in one hour (mR/yr)					
LOCATION	DISTANCE (FT)	OCCUPANCY	NOTE	T=	SHIELD	NO PAF		PAF = 2		PAF = 4	
A1	14	CORRIDOR		1/4	YES	0.147	(20.5)	0.073	(10.3)	0.037	(5.1)
B1/C1	17	CORRIDOR		1/4	NO	0.717	(100.0)	0.358	(50.0)	0.179	(25.0)
A2	13	OPERATING ROOM	1	1	YES	0.681	(95.3)	0.340	(47.7)	0.170	(23.8)
B2/C2	15	OPERATING ROOM		1	NO	3.682	(515.4)	1.841	(257.7)	0.920	(128.9)
A3	16	CONTROL ROOM	2	1	YES	0.449	(62.9)	0.225	(31.5)	0.112	(15.7)
B3	15.5	CONTROL ROOM		1	NO	3.448	(482.7)	1.724	(241.4)	0.862	(120.7)
C3	20	CONTROL ROOM		1	NO	2.071	(289.9)	1.035	(145.0)	0.518	(72.5)
D	15.5	CV NETWORK		1/16	NO	0.216	(30.2)	0.108	(15.1)	0.054	(7.5)
H	15	OFFICES		1	YES 4.5" CONCRETE	0.584	(81.8)	0.292	(40.9)	0.146	(20.4)
I	15	PATIENT ROOMS		1	YES 4.5" CONCRETE	0.584	(81.8)	0.292	(40.9)	0.146	(20.4)

Note 1: Mark the shield shadow area on walls in operating room and try to keep staff within this area.

Note 2: The third shield is optional and is recommended to reduce exposure to staff in control room within ALARA limits.

PAF = ESTIMATED PATIENT ATTENUATION FACTOR
REFERENCE DOCUMENT: SHIELD PLACEMENT (A2)

NELCO
800 WEST CUMMINGS PARK, SUITE 1200, WOBURN, MA 01801
(781) 933-1940 (781) 933-4763 (FAX)

Intravascular Brachytherapy Iridium-192 Program
Site Planning Information for:
UNITED HOSPITAL
ST. PAUL, MN.
CARDIAC CATHETERIZATION LAB #CV1

DRAWING INDEX		
T1	PROJECT TITLE SHEET	△
A1	ARCHITECTURAL SITE PLAN, ELEVATION & NOTES	△
A2	APPROVED SHIELD PLACEMENT PLAN & NOTES	△A
A3	SHIELD PLACEMENT ELEVATION PLAN	△A
S1	SITE SURVEY REPORT, MEASUREMENT DETAILS & NOTES	△
S2	RESTENOSIS SHIELD DIAGRAM & SAFETY NOTES	△
PR1	PHYSICIST REPORT	△

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PROJECT PHYSICIST CONTACT INFORMATION

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98 Baldwin Avenue
Woburn, MA 01801

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OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
PROJECT TITLE SHEET

SCALE:
NONE

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

DATE: 12-7-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

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(JOB NUMBER)
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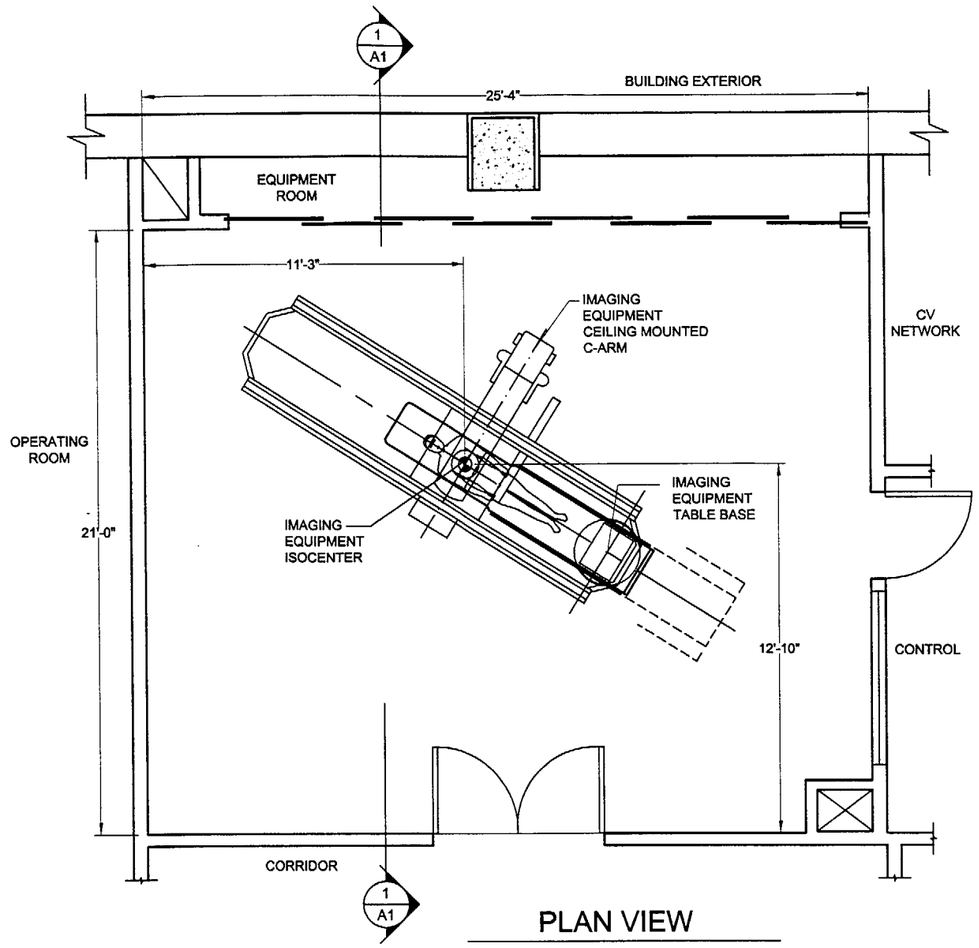
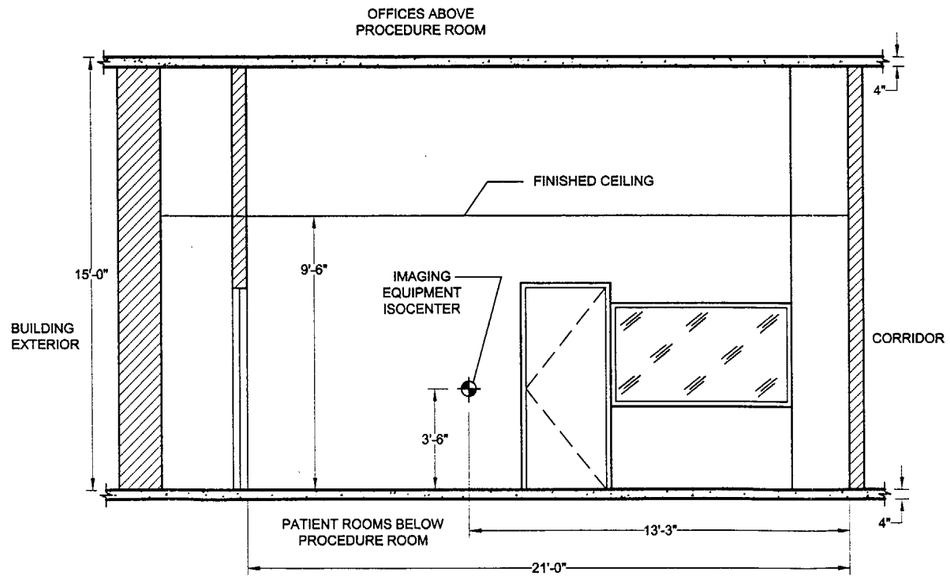
DRAWING NUMBER:
10-042-T1-1



PLAN VIEW



ELEVATION 1/A1

CARDIAC CATHETERIZATION LAB #CV1
3rd FLOOR

REFERENCE NOTES

1. THIS DRAWING IS BASED ON INFORMATION PROVIDED TO NELCO BY THE CUSTOMER OR CUSTOMERS AGENT.
2. THE FACILITY RSO SHOULD VERIFY ALL EXISTING CONDITIONS AND NOTIFY NELCO IF CONDITIONS DIFFER FROM THOSE SHOWN ON THIS DRAWING.

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OWNER:
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345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
ARCHITECTURAL SITE PLAN

SCALE:
3/16" = 1'-0"

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

DATE: 10-4-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

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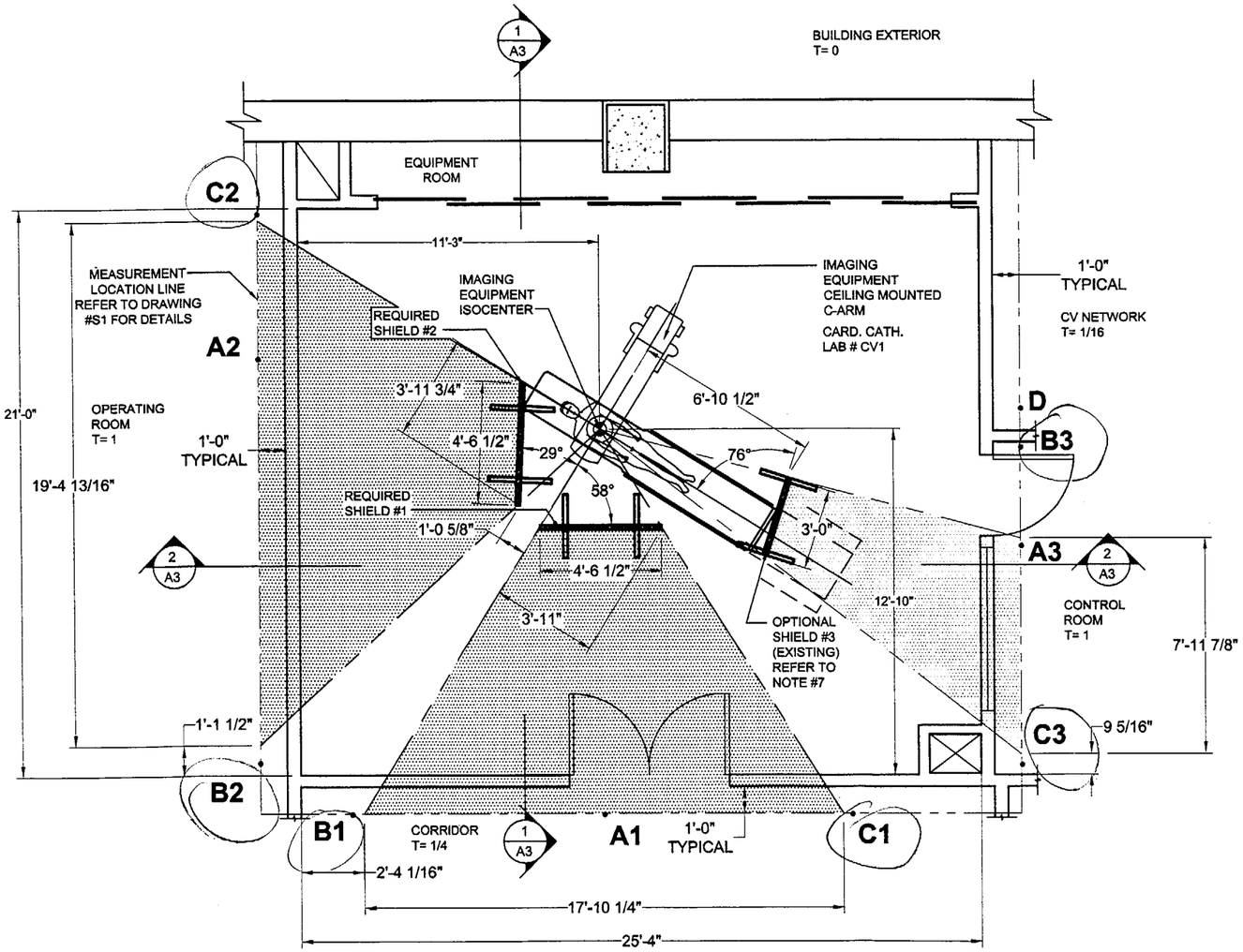
10-042-A1-1



PLAN VIEW
T= OCCUPANCY FACTOR

CARDIAC CATHETERIZATION LAB #CV1
3rd FLOOR

RESTENOSIS SHIELD PLACEMENT NOTES

1. IT IS RECOMMENDED, PRIOR TO THE FIRST CLINICAL USE, THAT THE RESTENOSIS SHIELDS BE POSITIONED IN THEIR SPECIFIED LOCATION AND PERMANENT MARKINGS BE PLACED ON THE FLOOR FOR EASE OF FUTURE SHIELD PLACEMENT.
   REFER TO THE FLOOR PLAN ON THIS DRAWING FOR LOCATIONS.
2. THE LONGITUDINAL PLACEMENT OF THE RESTENOSIS SHIELDS SHALL BE CENTERED ON THE LOCATION OF THE TREATMENT SOURCE.
3. UNLESS OTHERWISE SPECIFIED DUE TO SITE CONDITIONS;
   THE TRANSVERSE PLACEMENT OF THE RESTENOSIS SHIELDS SHALL BE **NO GREATER THAN TWO FEET** FROM THE SIDE EDGE OF THE PROCEDURE TABLE.
   IT IS RECOMMENDED THAT THE SHIELDS BE PLACED CLOSER WHENEVER POSSIBLE.
4. THE HEIGHT OF THE RESTENOSIS SHIELD IS FIXED.
   REFER TO THE ELEVATION PLAN ON THIS DRAWING FOR THE SHIELD HEIGHT DIMENSIONS AND RADIATION PROTECTION RANGE.
5. THE RADIATION PROTECTION SHADOW IN THE VERTICAL DIRECTION MUST REACH A MINIMUM ELEVATION OF 7'–0" OFF OF THE FINISHED FLOOR AT THE SPECIFIED MEASUREMENT POINT AS SHOWN ON THIS DRAWING AND DRAWING #S1. IF DUE TO SITE CONDITIONS, THE RADIATION PROTECTION SHADOW DOES NOT MEET THE MINIMUM HEIGHT SPECIFICATION, THE SHIELD MUST BE MOVED CLOSER TO THE PROCEDURE TABLE. REFER TO THE ELEVATION PLAN ON THIS DRAWING FOR RADIATION PROTECTION SHADOW HEIGHT.
6. THE PLACEMENT OF A RESTENOSIS SHIELD AT THE FOOT END OF THE PROCEDURE TABLE SHALL BE **NO GREATER THAN ONE FOOT** FROM THE REAR EDGE OF THE PROCEDURE TABLE.
   IT IS RECOMMENDED THAT THE SHIELD BE PLACED CLOSER WHENEVER POSSIBLE.
7. THE PLACEMENT OF THE OPTIONAL THIRD RESTENOSIS SHIELD IS AT THE DISCRETION OF THE INSTITUTION RADIATION SAFETY OFFICER. IT IS RECOMMENDED THAT THE INSTITUTION FOLLOW ALL STATE, FEDERAL AND NATIONAL LAWS REGARDING RADIATION EXPOSURE. IN ADDITION IT IS RECOMMENDED THAT "ALARA" GUIDELINES BE FOLLOWED. THE THIRD SHIELD IS EXISTING. THE SHIELD SIZE IS; 36" W x 30" H x 1" T, WITH THE TOP OF SHIELD @ 48" A.F.F.

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98 Baldwin Avenue
Woburn, MA 01801

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UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
SHIELD PLACEMENT DRAWING

SCALE:
3/16" = 1'-0"

DRAWN: BDR

ENG. MNG.:

PROJ. MNG.:

DATE: 11-1-2000

– REVISIONS –

SYM	DATE	DESCRIPTION
A	12/7/00	REV/PER CONFERENCE CALL

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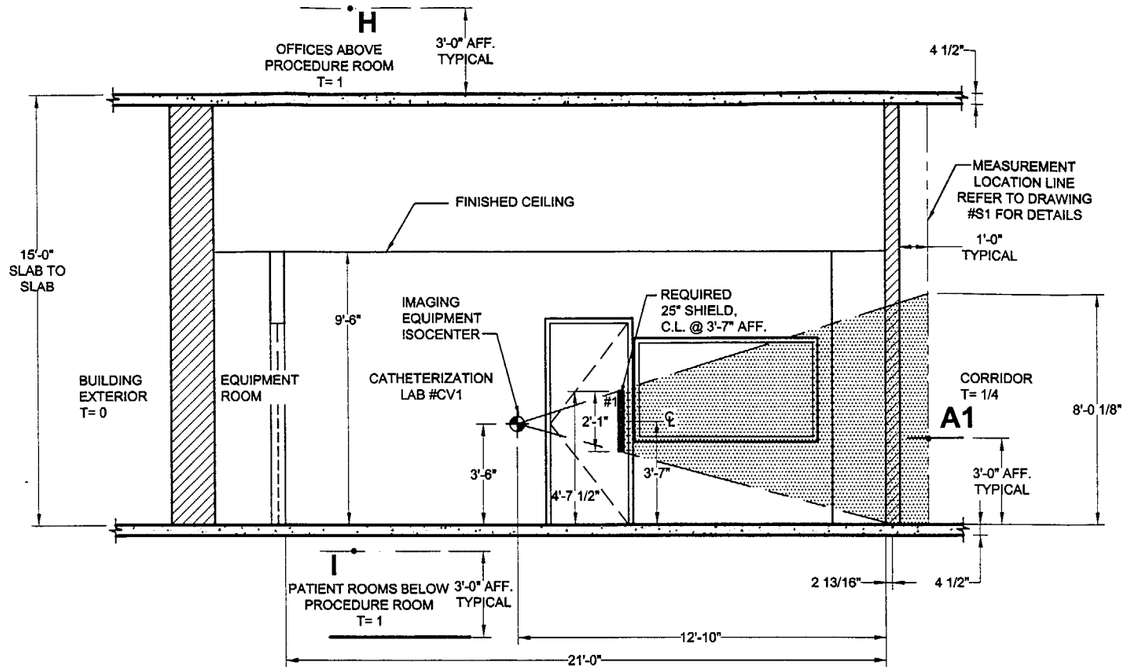
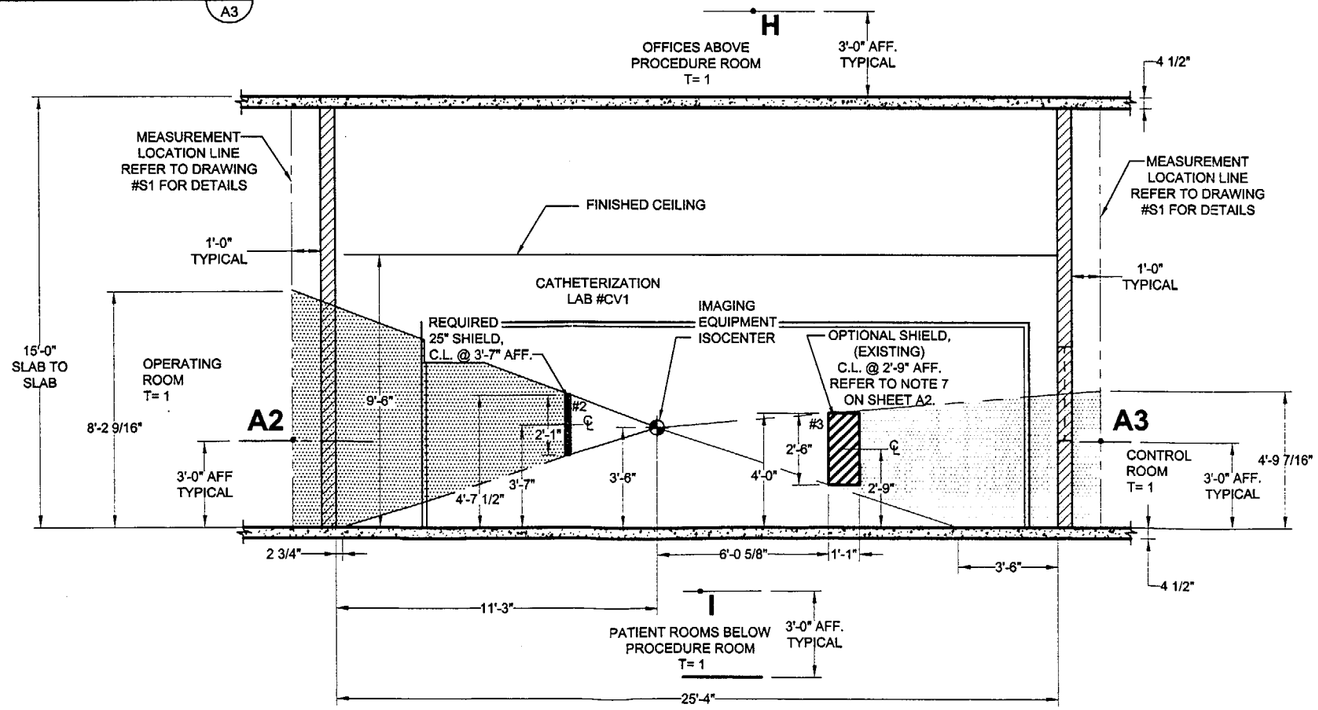
DRAWING NUMBER:
10-042-A2-1

REFER TO DRAWING #A2 FOR SHIELD PLACEMENT NOTES



ELEVATION 1/A3



ELEVATION 2/A3

CARDIAC CATHETERIZATION LAB #CV1
3rd FLOOR

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Woburn, MA 01801

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UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
SHIELD PLACEMENT ELEVATION PLAN

SCALE:
3/16" = 1'-0"

DRAWN: BDR

ENG. MNG.:

PROJ. MNG.:

DATE: 11-1-2000

— REVISIONS —

SYM	DATE	DESCRIPTION
A	12/7/00	REV/PER CONFERENCE CALL

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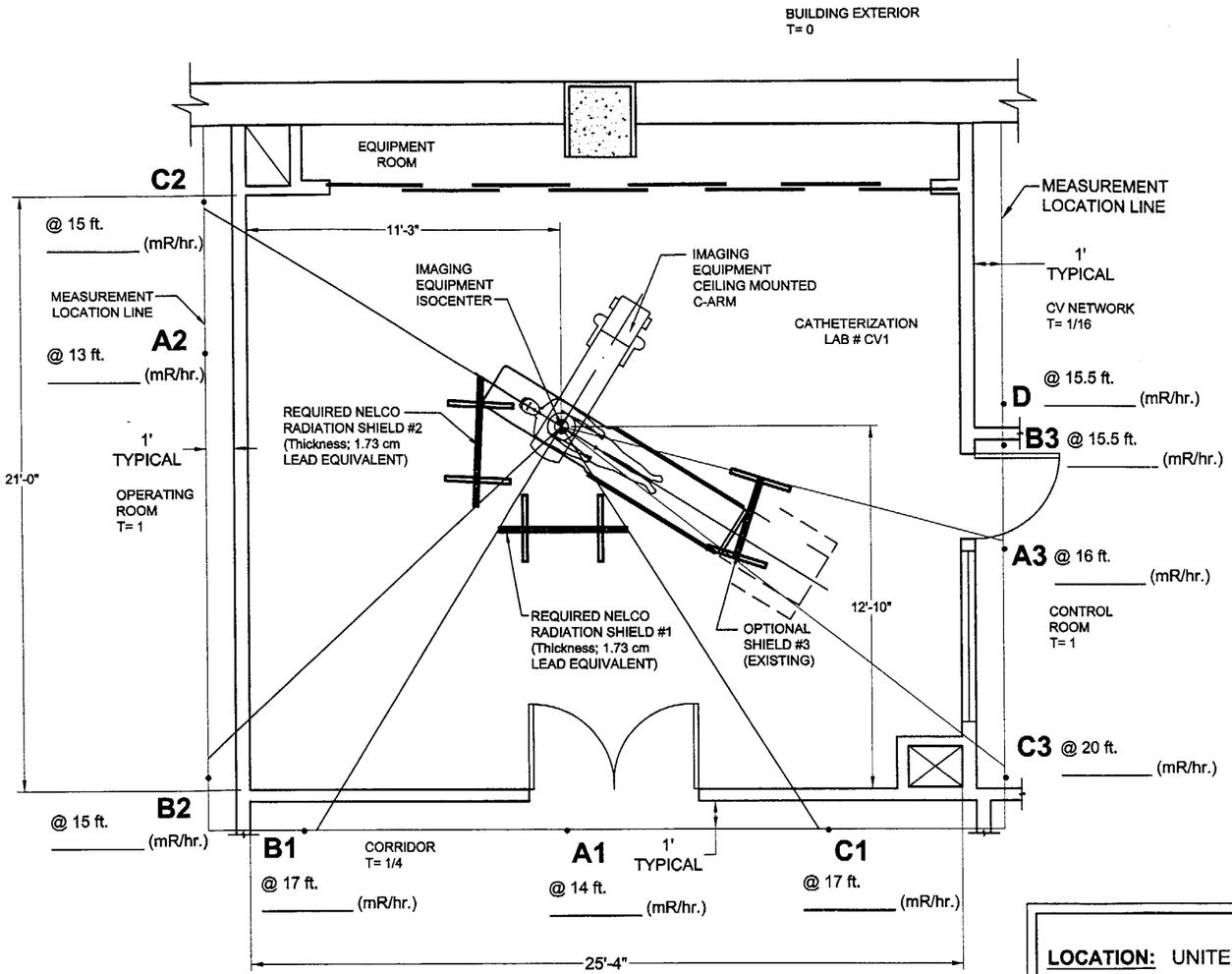

PLAN VIEW

T= OCCUPANCY FACTOR

H @ 15 ft._____ (mR/hr.)

OFFICES ABOVE
PROCEDURE ROOM
T= 1

I @ 15 ft._____ (mR/hr.)

PATIENT ROOMS BELOW
PROCEDURE ROOM
T= 1

CARDIAC CATHETERIZATION LAB #CV1

3 rd FLOOR

RESTENOSIS RADIATION SURVEY RECOMMENDATIONS

1. A 14 SEED SOURCE RIBBON IS TO BE USED FOR THE SURVEY.
2. THE RESTENOSIS SHIELD WINGS ARE TO BE IN THE FULL OPEN POSITION FOR THE SURVEY.
3. MEASUREMENTS SHALL BE TAKEN AT 1 FOOT FROM THE FINISHED SURFACE OF THE WALL OUTSIDE OF THE PROCEDURE ROOM, AT A HEIGHT OF 3 FEET FROM THE FINISHED SURFACE OF THE FLOOR.
4. MEASUREMENTS SHALL BE TAKEN AT A HEIGHT OF 3 FEET FROM THE FINISHED SURFACE OF THE FLOOR IN THE AREA ABOVE THE PROCEDURE ROOM AND THE AREA BELOW THE PROCEDURE ROOM.
5. ALL DISTANCES SHOWN ARE TAKEN FROM THE IMAGING EQUIPMENT ISOCENTER.
6. REFER TO PHYSICIST REPORT (PR1) FOR CALCULATIONS.

LOCATION: UNITED HOSPITAL / CARDIAC CATH. LAB #CV1

SOURCE ACTIVITY (mCi): _____

ON (date): _____

DATE OF SURVEY: _____

SURVEYOR (RSO or MEDICAL PHYSICIST): _____

SIGNATURE: _____

NOTE: THIS SIGNATURE REPRESENTS THAT;
IT IS UNDERSTOOD THAT ANY DEVIATION FROM THESE DRAWINGS, DETAILS, SPECIFICATIONS AND PHYSICIST REPORT MAY ENCROACH UPON RADIATION SAFETY GUIDELINES.

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OWNER:
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345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
SITE SURVEY REPORT

SCALE:
3/16" = 1'-0"

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

DATE: 12-7-2000

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SYM	DATE	DESCRIPTION

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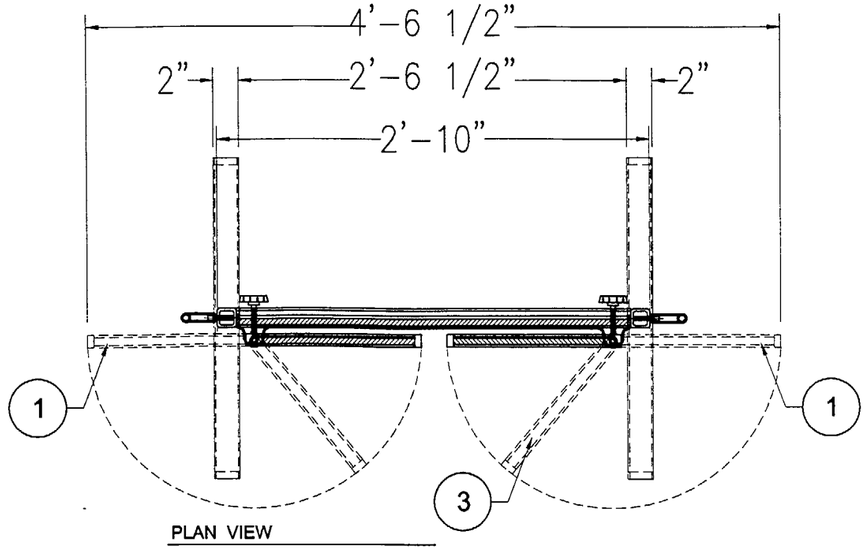
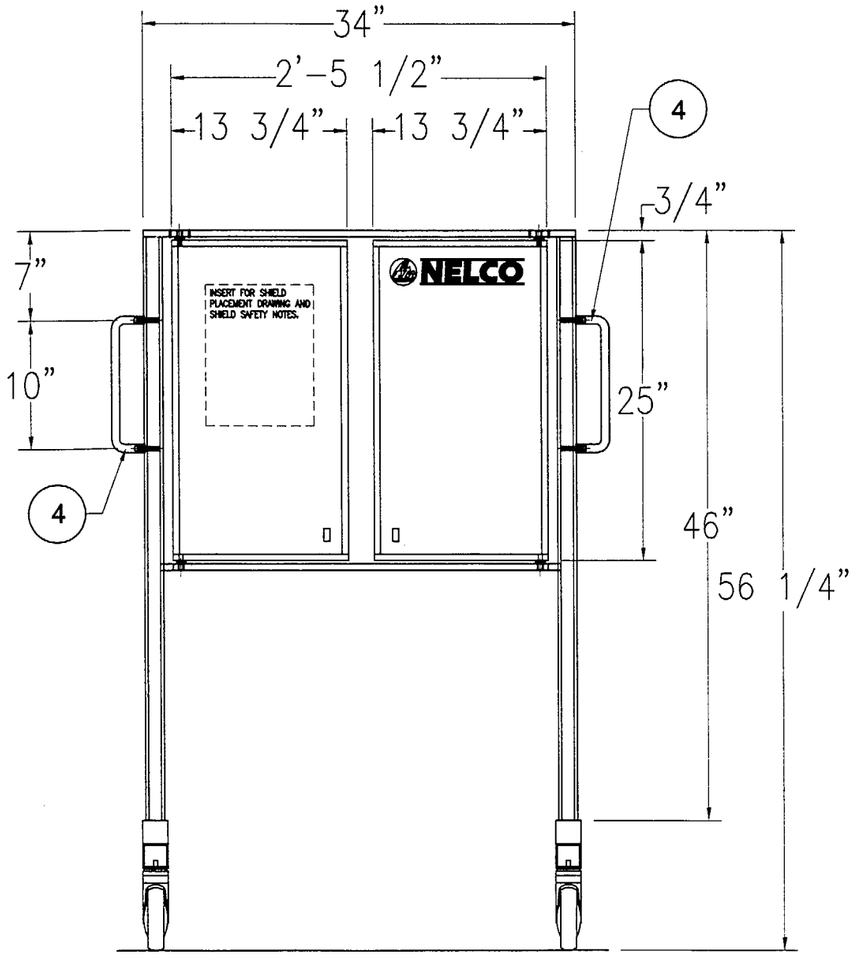
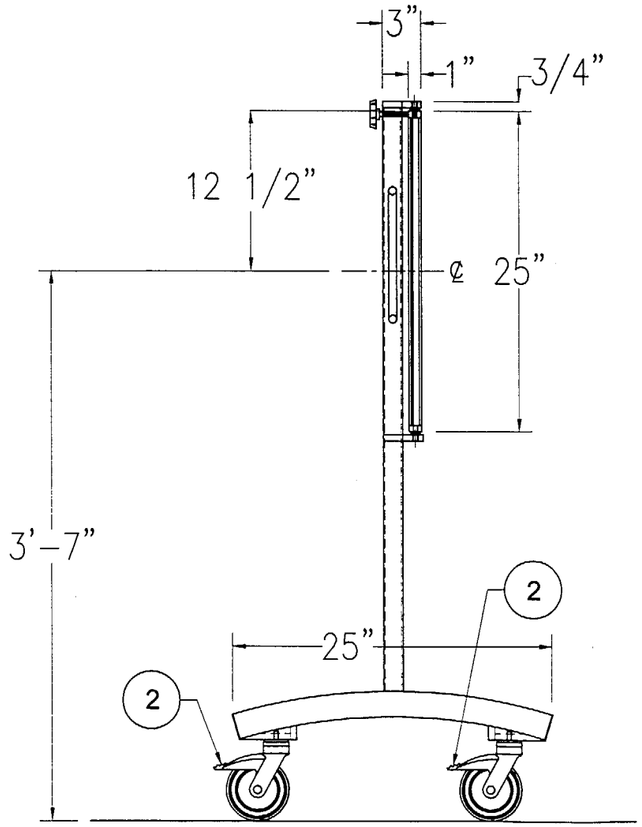


PLAN VIEW



FRONT VIEW
OPERATIONAL WEIGHT - 600 LBS.



SIDE VIEW

RESTENOSIS SHIELD SAFETY NOTES

1. ONCE THE RESTENOSIS SHIELD IS IN PLACE, EACH SHIELD WING SHOULD BE OPENED TO IT'S FULL OPEN POSITION FOR TREATMENT AND LOCKED IN PLACE.
2. ONCE THE RESTENOSIS SHIELD IS IN PLACE, EACH WHEEL LOCK SHOULD BE ENGAGED TO PREVENT INADVERTENT MOVEMENT OF THE SHIELD DURING TREATMENT.
3. THE RESTENOSIS SHIELD SHOULD NEVER BE MOVED WHILE THE SHIELD WINGS ARE IN THE OPEN POSITION OR WHEN THE SHIELD WINGS ARE UNLOCKED.
4. IT IS RECOMMENDED THAT THE RESTENOSIS SHIELD BE TRANSPORTED ONLY BY UTILIZING THE HANDLES ON EACH END OF THE SHIELD.

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OWNER:
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345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
RESTENOSIS SHIELD

SCALE:
1" = 1'-0"

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

DATE: 12-7-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

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DRAWING NUMBER:
10-042-S2-1

NELCO™

PHYSICIST REPORT (PR4)

ESTIMATED RADIATION EXPOSURE RATES

INTRAVASCULAR BRACHYTHERAPY IRIDIUM-192 PROGRAM

REFERENCE DOCUMENT: SHIELD PLACEMENT DIAGRAM (A2)

UNITED HOSPITAL
90-127-10-042

FINAL REPORT
REV 1.1
12/08/2000

(1) Building and Room Location

Clinical Site: United Hospital
City, State: St. Paul, MN
Cardiac Catheterization Lab #CV4

(2) Identification of Cardiac Cardiology Equipment and Brief Description

C-Arm: Philips Integras
Generator: Philips Integras

(3) Site Plan Information

See reference Drawings A1, A2, S1, S2

(4) Identification of Reference Regulatory Codes for Radiation Protection (NRC or appropriate state codes)

10CFR 20.1301 as it pertains to the general public
10CFR 20.1201 as it pertains to occupational workers

(5) Standards for Protection Against Radiation

Shields – The shields have been designed specifically to meet the needs associated with radiation cases in a Cardiac Catheterization Room. The design criteria for the shields complies with the federal Nuclear Regulatory Commission's, regulations pertaining to allowable exposures in non-occupational (general public) and occupational areas. The criteria is that shields reduce the radiation to a level of 2 mR in one hour and 100 mR in one year in those areas where non-occupational workers or the general public may be present. For those areas that can be controlled and are limited to occupational workers, the exposure level to these workers is 5000 mR in one year. The recommended physics design criteria is to meet the applicable regulatory radiation exposure levels as a minimum standard, however the ALARA (As Low As Reasonably Achievable) principle is customarily utilized.

(6) Protocol: Pre-market approval (PMA)

FDA PMA # P990036
NRC Registration # NR-187-S-101-S

(7) Statement of Working Assumptions

14 Seeds @ 33 mCi/Seed = 462 mCi
^{192} Ir 0.5 R/hr/Ci @ 1m = 500 mR x 462 mCi hr/1000 mCi = 231 mR/hr @ 1 meter (3.28 ft).
116 Cases per year (Assumed in CV4). Cath Lab CV1 and CV4 will share the caseload for a total of 256 Cases/year.
20 Minute dwell time in patient
There is 1/16" of lead equivalent on all inside walls. This could provide an additional 16% reduction in exposure in outside areas. No credit has been taken in these calculations.
Reference: NCRP Handbook 49

(8) Estimated Radiation Exposure Rates

See Table 1 (PR4)

(9) Source Storage Location

Cabinet in Cath Lab.

(10) Shield Placement

The responsible radiation safety individual shall assure that the restenosis shields are placed as shown on the shield placement diagram (A2). The shields shall be utilized with the wings locked in the fully open position during treatment, unless otherwise designated on the shield placement diagram (A2). If there are shields designated as optional, the use and location is at the discretion of the Radiation Safety individual.

(11) Method of Calculation (example point A3 in room CV4)

The measured distance is 15.5 feet. This gives an unshielded wire exposure (patient attenuation factor, PAF, of 1) equal to:
231 mR/hr x $(3.28/16)^2$ = 10.3 mR/hr Unshielded
Considering Occupancy (T=1) = 10.3/1 = 10.3 mR/hour
Considering Dwell Time = 20 min. = 10.3/3 = 3.45 mR in 1 hour
Considering NELCO Restenosis Shield = 3.45/7.2 = 0.479 mR in 1 hour
For 116 cases/year:
Patient Attenuation Factor (1) = 0.479 x 116 = 55.6 mR/year
Patient Attenuation Factor (2) = 0.239 x 116 = 27.8 mR/year
Patient Attenuation Factor (4) = 0.120 x 116 = 13.9 mR/year

(12) Radiation Measuring Instruments and Survey Points

The radiation area survey should be performed using a calibrated ion chamber and/or GM meter. Those areas noted on the site survey report (S1) shall be surveyed. Other areas within the room may also be surveyed (i.e. areas where oncologist stands). These locations are at the discretion of the radiation safety individual.

(13) Recommendations to Minimize Exposure and Optimize Radiation Safety:

It is recommended that the institution follow all state, federal and national laws regarding radiation exposure. In addition it is recommended that ALARA guidelines be followed.

(14) Site Measurements of Exposure Rates

It is mandatory that actual measured data be taken to confirm these assumptions provided herein. A completed site survey report (S1) shall be forwarded to NELCO.

(15) Radiation Safety Notes and Options

1. Third shield is optional and is recommended to reduce exposure to staff in control room with ALARA limits.
2. Dictation room shall be controlled during procedure to zero occupancy.
3. Scrub area shows more than 100 mR/yr but for ¼ occupancy lower occupancy will reduce exposure.

NELCO™

Site Planning Information for:
Site: United Hospital
City, State: St. Paul, MN
Cardiac Catheterization Lab #CV$
 # Cases per YEAR: 116
PR#4
Job #: 90-127-10-042

(8) TABLE 1 - ESTIMATED RADIATION EXPOSURE RATES

LOCATION	DISTANCE (FT)	OCCUPANCY	NOTE	T=	SHIELD	mR in one hour (mR/yr)					
						NO PAF		PAF = 2		PAF = 4	
A1	12	CORRIDOR		1/4	YES	0.200	(23.2)	0.100	(11.6)	0.050	(5.8)
B1/C1	15.5	CORRIDOR		1/4	NO	0.862	(100.0)	0.431	(50.0)	0.216	(25.0)
F	13	SCRUB ROOM	3	1/4	NO	1.225	(142.2)	0.613	(71.1)	0.306	(35.5)
A2	13	CORRIDOR		1/4	YES	0.17	(19.7)	0.085	(9.9)	0.043	(4.9)
B2	17	CORRIDOR		1/4	NO	0.717	(83.1)	0.358	(41.6)	0.179	(20.8)
C2	15.5	CORRIDOR		1/4	NO	0.862	(100.0)	0.431	(50.0)	0.216	(25.0)
A3	15.5	CONTROL ROOM	1	1	YES	0.479	(55.6)	0.239	(27.8)	0.120	(13.9)
B3	15	DICTATION ROOM	2	0	NO	—	—	—	—	—	—
C3	20	CONTROL ROOM		1	NO	2.071	(240.2)	1.035	(120.1)	0.518	(60.1)
D	16	EQUIPMENT ROOM		1/16	NO	0.202	(23.5)	0.101	(11.7)	0.051	(5.9)
E	16.5	BUILDING EXTERIOR		0	NO	—	—	—	—	—	—
H	15	BREAK-OUT ROOM W/ KITCHEN		1/4	YES 4.5" Concrete	0.146	(16.9)	0.073	(8.5)	0.037	(4.2)
I	15	PATIENT ROOMS		1	YES 4.5" Concrete	0.584	(67.7)	0.292	(33.9)	0.146	(16.9)

Note 1: The third shield is optional and is recommended to reduce exposure to staff in control room within ALARA limits.

Note 2: Dictation room shall be controlled during procedure to zero occupancy.

Note 3: Scrub area shows more than 100 mR/yr but for 1/4 occupancy, lower occupancy will reduce exposure.

PAF = ESTIMATED PATIENT ATTENUATION FACTOR
REFERENCE DOCUMENT: SHIELD PLACEMENT (A2)

NELCO
800 WEST CUMMINGS PARK, SUITE 1200, WOBURN, MA 01801
(781) 933-1940 (781) 933-4763 (FAX)

Intravascular Brachytherapy Iridium-192 Program
Site Planning Information for:
UNITED HOSPITAL
ST. PAUL, MN.
CARDIAC CATHETERIZATION LAB #CV4

DRAWING INDEX		
T1	PROJECT TITLE SHEET	△
A1	ARCHITECTURAL SITE PLAN, ELEVATION & NOTES	△
A2	APPROVED SHIELD PLACEMENT PLAN & NOTES	△A
A3	SHIELD PLACEMENT ELEVATION PLAN	△A
S1	SITE SURVEY REPORT, MEASUREMENT DETAILS & NOTES	△
S2	RESTENOSIS SHIELD DIAGRAM & SAFETY NOTES	△
PR1	PHYSICIST REPORT	△

NELCO
800 WEST CUMMINGS PARK, SUITE 1200, WOBURN, MA 01801
(781) 933-1940 (781) 933-4763 (FAX)

REGULATORY COPY

PROJECT PHYSICIST CONTACT INFORMATION

JUDY REAVIS, PhD
MAIN TEL: 781-933-1940 FAX: 781-932-8647
DIRECT TEL: 781-537-3011 EMAIL: judy_reavis@nelco-usa.com

NEIL A. GAETA, CHP
MAIN TEL: 781-933-1940 FAX: 781-932-8647
DIRECT TEL: 781-537-3016 EMAIL: neil_gaeta@nelco-usa.com
PAGER: 781-317-0555

NELCO™
1-800-635-2613
98 Baldwin Avenue
Woburn, MA 01801

NELCO

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
PROJECT TITLE SHEET

SCALE:
NONE

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

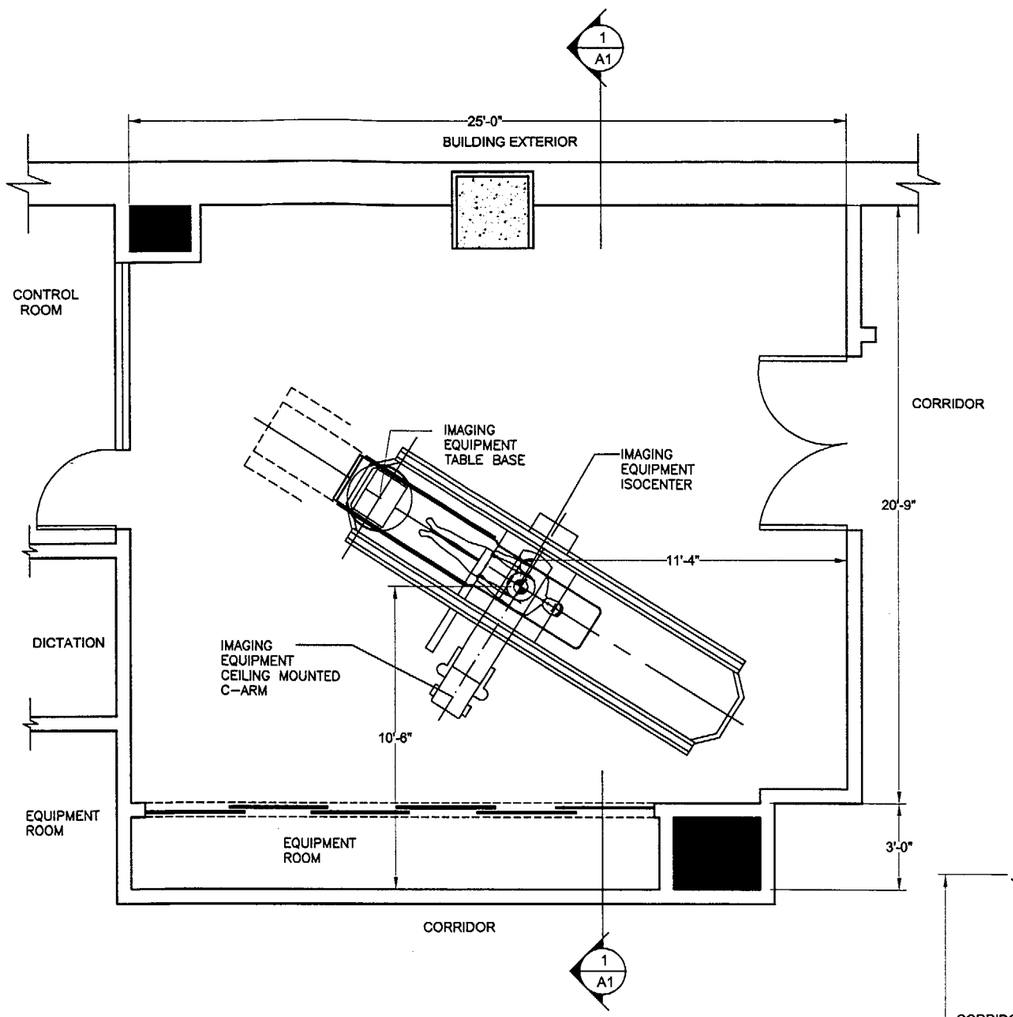
DATE: 12-7-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

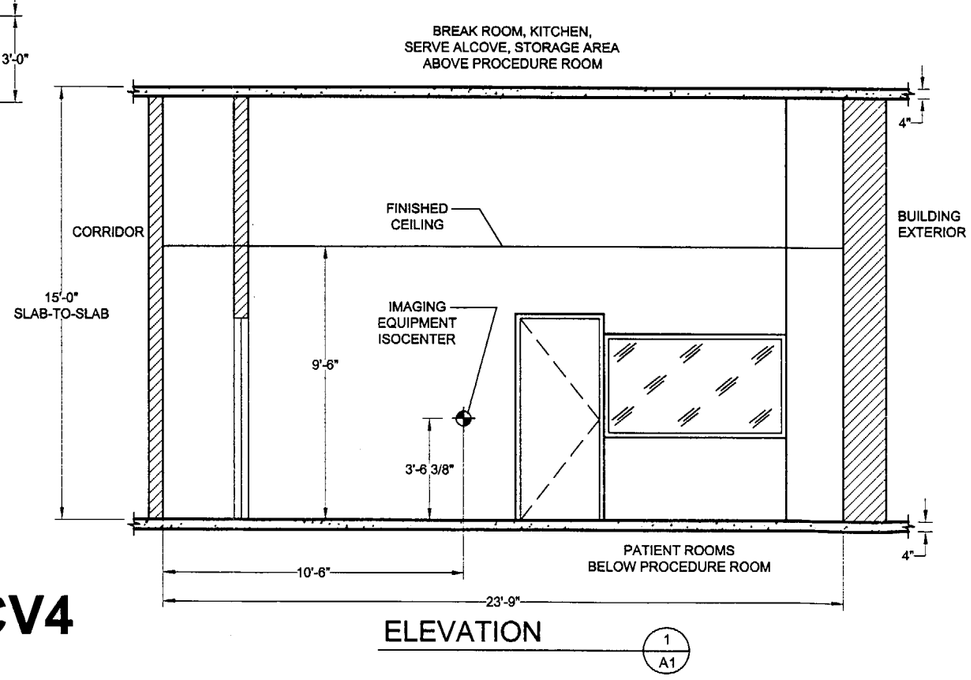
AutoCADR14 FILE:
(JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-000-T1

DRAWING NUMBER:
10-042-T1-4



REFERENCE NOTES

1. THIS DRAWING IS BASED ON INFORMATION PROVIDED TO NELCO BY THE CUSTOMER OR CUSTOMERS AGENT.
2. THE FACILITY RSO SHOULD VERIFY ALL EXISTING CONDITIONS AND NOTIFY NELCO IF CONDITIONS DIFFER FROM THOSE SHOWN ON THIS DRAWING.



ELEVATION 1 / A1

PATIENT ROOMS ABOVE

CARDIAC CATHETERIZATION LAB #CV4
3rd FLOOR

NELCO™
1-800-635-2613
98 Baldwin Avenue
Woburn, MA 01801

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
ARCHITECTURAL SITE PLAN

SCALE:
3/16" = 1'-0"

DRAWN: **MEB**

ENG. MNG.:

PROJ. MNG.:

DATE: 10-4-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

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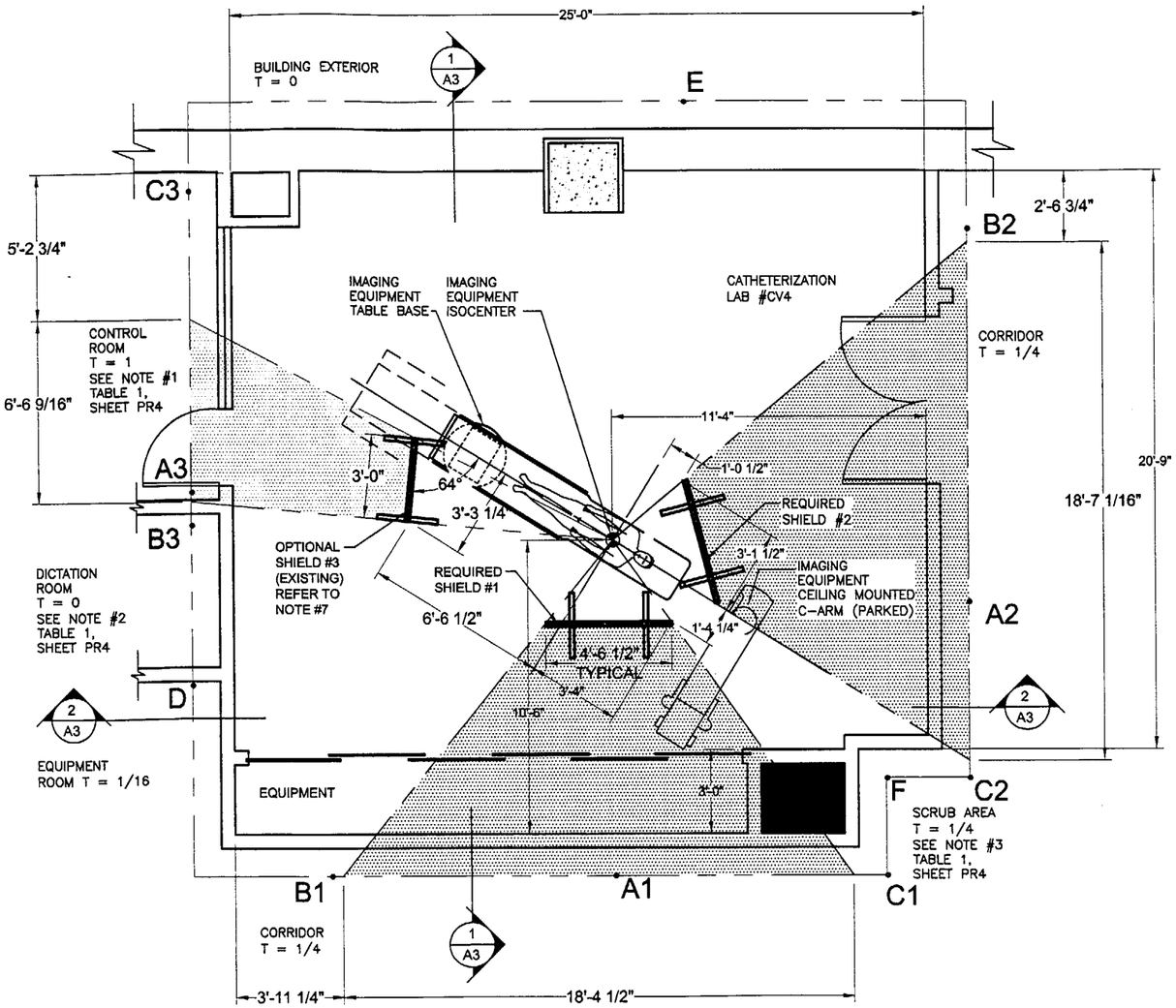
(JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-042-A1-4

DRAWING NUMBER:
10-042-A1-4



PLAN VIEW
T= OCCUPANCY FACTOR

CARDIAC CATHETERIZATION LAB #CV4
3rd FLOOR

RESTENOSIS SHIELD PLACEMENT NOTES

1. IT IS RECOMMENDED, PRIOR TO THE FIRST CLINICAL USE, THAT THE RESTENOSIS SHIELDS BE POSITIONED IN THEIR SPECIFIED LOCATION AND PERMANENT MARKINGS BE PLACED ON THE FLOOR FOR EASE OF FUTURE SHIELD PLACEMENT.
   REFER TO THE FLOOR PLAN ON THIS DRAWING FOR LOCATIONS.
2. THE LONGITUDINAL PLACEMENT OF THE RESTENOSIS SHIELDS SHALL BE CENTERED ON THE LOCATION OF THE TREATMENT SOURCE.
3. UNLESS OTHERWISE SPECIFIED DUE TO SITE CONDITIONS;
   THE TRANSVERSE PLACEMENT OF THE RESTENOSIS SHIELDS SHALL BE **NO GREATER THAN TWO FEET** FROM THE SIDE EDGE OF THE PROCEDURE TABLE.
   IT IS RECOMMENDED THAT THE SHIELDS BE PLACED CLOSER WHENEVER POSSIBLE.
4. THE HEIGHT OF THE RESTENOSIS SHIELD IS FIXED.
   REFER TO THE ELEVATION PLAN ON THIS DRAWING FOR THE SHIELD HEIGHT DIMENSIONS AND RADIATION PROTECTION RANGE.
5. THE RADIATION PROTECTION SHADOW IN THE VERTICAL DIRECTION MUST REACH A MINIMUM ELEVATION OF 7'-0" OFF OF THE FINISHED FLOOR AT THE SPECIFIED MEASUREMENT POINT AS SHOWN ON THIS DRAWING AND DRAWING #S1. IF DUE TO SITE CONDITIONS, THE RADIATION PROTECTION SHADOW DOES NOT MEET THE MINIMUM HEIGHT SPECIFICATION, THE SHIELD MUST BE MOVED CLOSER TO THE PROCEDURE TABLE. REFER TO THE ELEVATION PLAN ON THIS DRAWING FOR RADIATION PROTECTION SHADOW HEIGHT.
6. THE PLACEMENT OF A RESTENOSIS SHIELD AT THE FOOT END OF THE PROCEDURE TABLE SHALL BE **NO GREATER THAN ONE FOOT** FROM THE REAR EDGE OF THE PROCEDURE TABLE.
   IT IS RECOMMENDED THAT THE SHIELD BE PLACED CLOSER WHENEVER POSSIBLE.
7. THE PLACEMENT OF THE OPTIONAL THIRD RESTENOSIS SHIELD IS AT THE DISCRETION OF THE INSTITUTION RADIATION SAFETY OFFICER. IT IS RECOMMENDED THAT THE INSTITUTION FOLLOW ALL STATE, FEDERAL AND NATIONAL LAWS REGARDING RADIATION EXPOSURE. IN ADDITION IT IS RECOMMENDED THAT "ALARA" GUIDELINES BE FOLLOWED. THE THIRD SHIELD IS EXISTING. THE SHIELD SIZE IS; 36" W x 30" H x 1" T, WITH THE TOP OF SHIELD @ 48" A.F.F.

NELCO™
1-800-635-2613
98 Baldwin Avenue
Woburn, MA 01801

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
SHIELD PLACEMENT DRAWING

SCALE:
3/16" = 1'-0"

DRAWN: BDR

ENG. MNG.:

PROJ. MNG.:

DATE: 11-2-2000

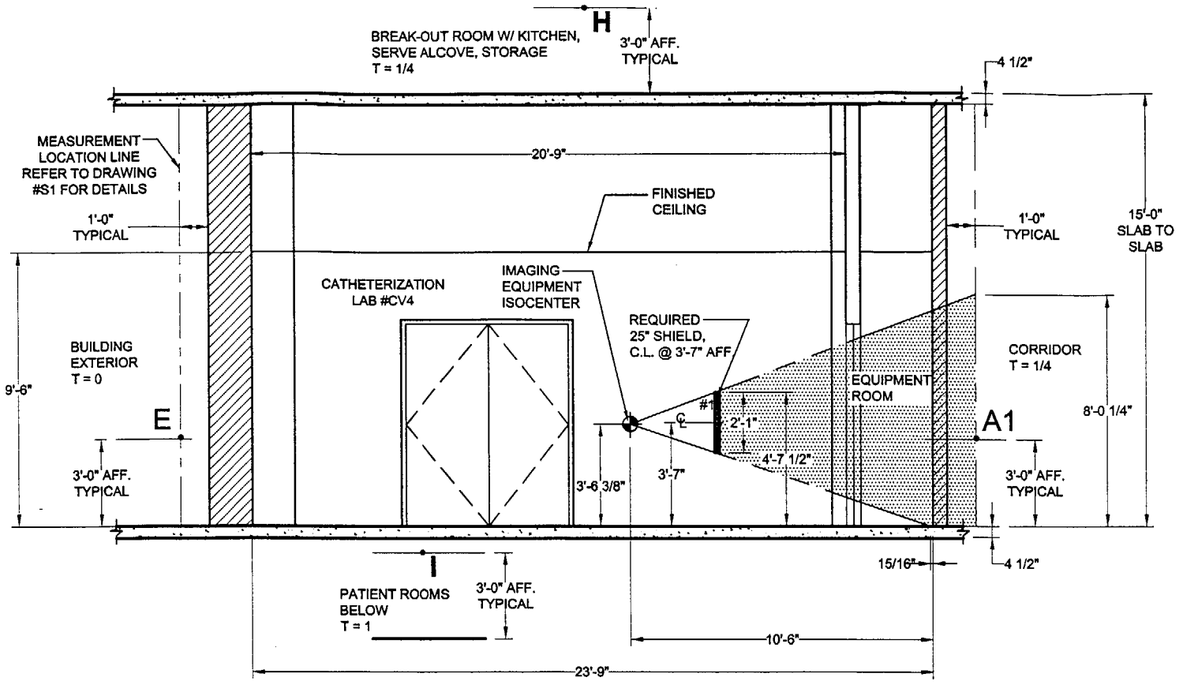
– REVISIONS –

SYM	DATE	DESCRIPTION
A	12-7-00	REV/PER CONFERENCE CALL

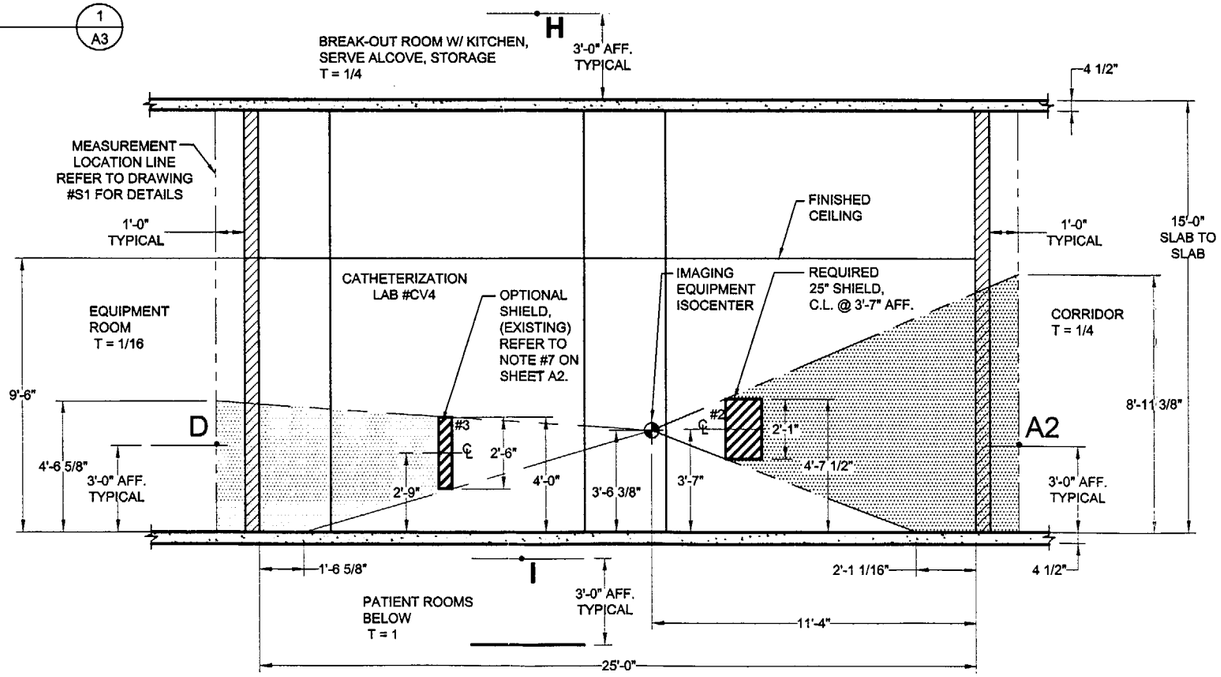
AutoCADR14 FILE:
(JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-042-A2

DRAWING NUMBER:
10-042-A2-4

REFER TO DRAWING #A2 FOR SHIELD PLACEMENT NOTES



ELEVATION 1/A3



ELEVATION 2/A3

CARDIAC CATHETERIZATION LAB #CV4
3rd FLOOR

NELCO™
1-800-635-2613
98 Baldwin Avenue
Woburn, MA 01801

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN 55102

TITLE:
SHIELD PLACEMENT ELEVATION PLAN

SCALE:
3/16" = 1'-0"

DRAWN: BDR

ENG. MNG.:

PROJ. MNG.:

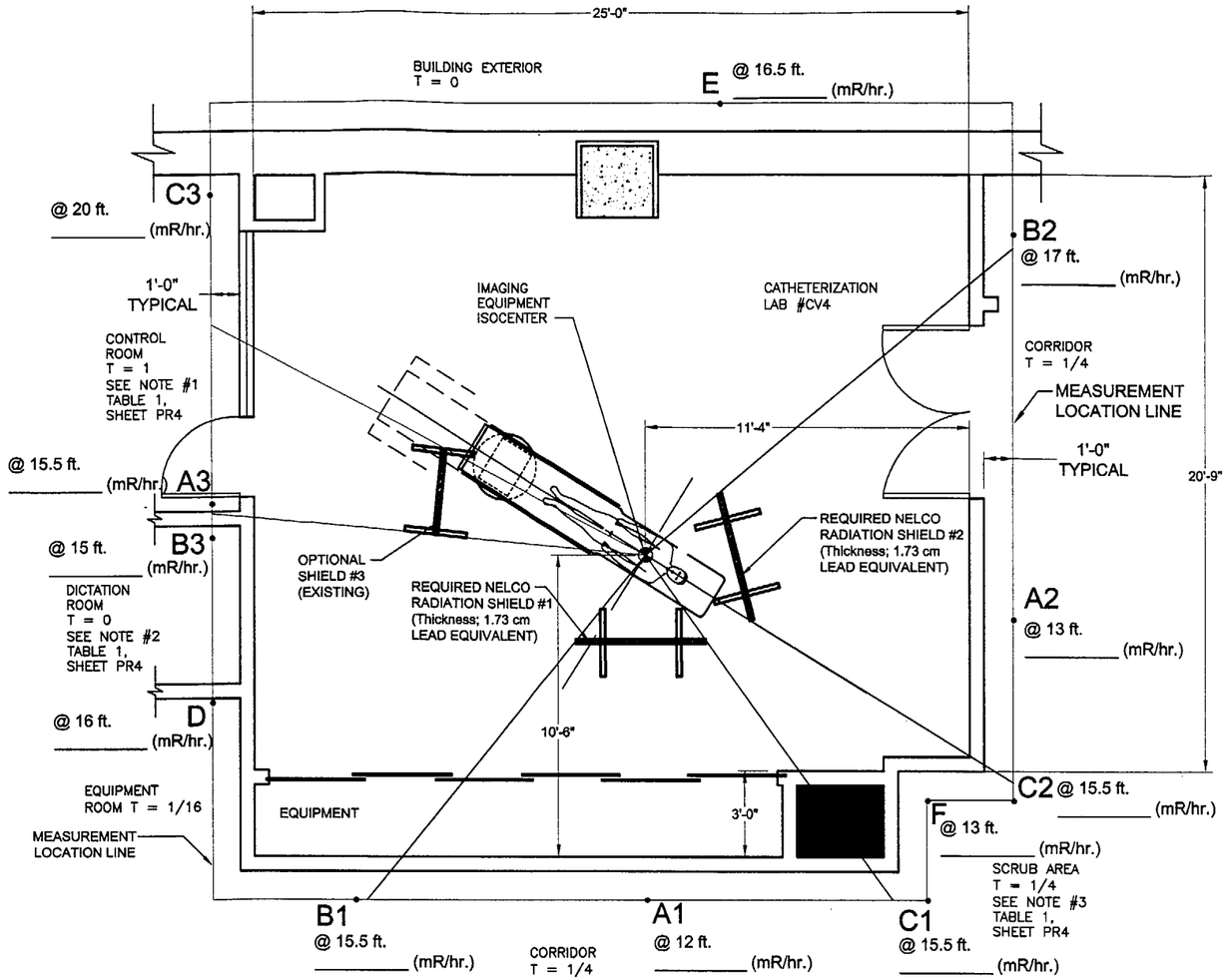
DATE: 11-2-2000

– REVISIONS –

SYM	DATE	DESCRIPTION
A	12/11/00	REV/PER CONFERENCE CALL

AutoCADR14 FILE:
(JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-042-A3

DRAWING NUMBER:
10-042-A3-4



PLAN VIEW

H @ 15 ft._____ (mR/hr.)

BREAK-OUT ROOM W / KITCHEN, SERVE ALCOVE, STORAGE ABOVE PROCEDURE ROOM T = 1/4

I @ 15 ft._____ (mR/hr.)

PATIENT ROOMS BELOW PROCEDURE ROOM T = 1

CARDIAC CATHETERIZATION LAB #CV4
3rd FLOOR

RESTENOSIS RADIATION SURVEY RECOMMENDATIONS

1. A 14 SEED SOURCE RIBBON IS TO BE USED FOR THE SURVEY.
2. THE RESTENOSIS SHIELD WINGS ARE TO BE IN THE FULL OPEN POSITION FOR THE SURVEY.
3. MEASUREMENTS SHALL BE TAKEN AT 1 FOOT FROM THE FINISHED SURFACE OF THE WALL OUTSIDE OF THE PROCEDURE ROOM, AT A HEIGHT OF 3 FEET FROM THE FINISHED SURFACE OF THE FLOOR.
4. MEASUREMENTS SHALL BE TAKEN AT A HEIGHT OF 3 FEET FROM THE FINISHED SURFACE OF THE FLOOR IN THE AREA ABOVE THE PROCEDURE ROOM AND THE AREA BELOW THE PROCEDURE ROOM.
5. ALL DISTANCES SHOWN ARE TAKEN FROM THE IMAGING EQUIPMENT ISOCENTER.
6. REFER TO PHYSICIST REPORT (PR4) FOR CALCULATIONS.

LOCATION: UNITED HOSPITAL / CARDIAC CATHETERIZATION LAB #CV4

SOURCE ACTIVITY (mCi): _____

ON (date): _____

DATE OF SURVEY: _____

SURVEYOR (RSO or MEDICAL PHYSICIST): _____

SIGNATURE: _____

NOTE: THIS SIGNATURE REPRESENTS THAT;
IT IS UNDERSTOOD THAT ANY DEVIATION FROM THESE DRAWINGS, DETAILS, SPECIFICATIONS AND PHYSICIST REPORT MAY ENCROACH UPON RADIATION SAFETY GUIDELINES.

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98 Baldwin Avenue
Woburn, MA 01801

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
SITE SURVEY REPORT

SCALE:
3/16" = 1'-0"

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

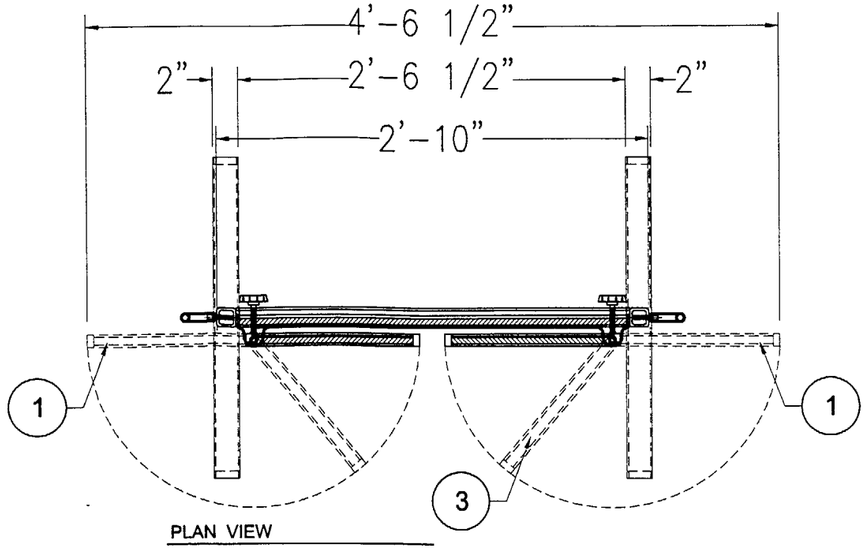
DATE: 12-11-2000

– REVISIONS –

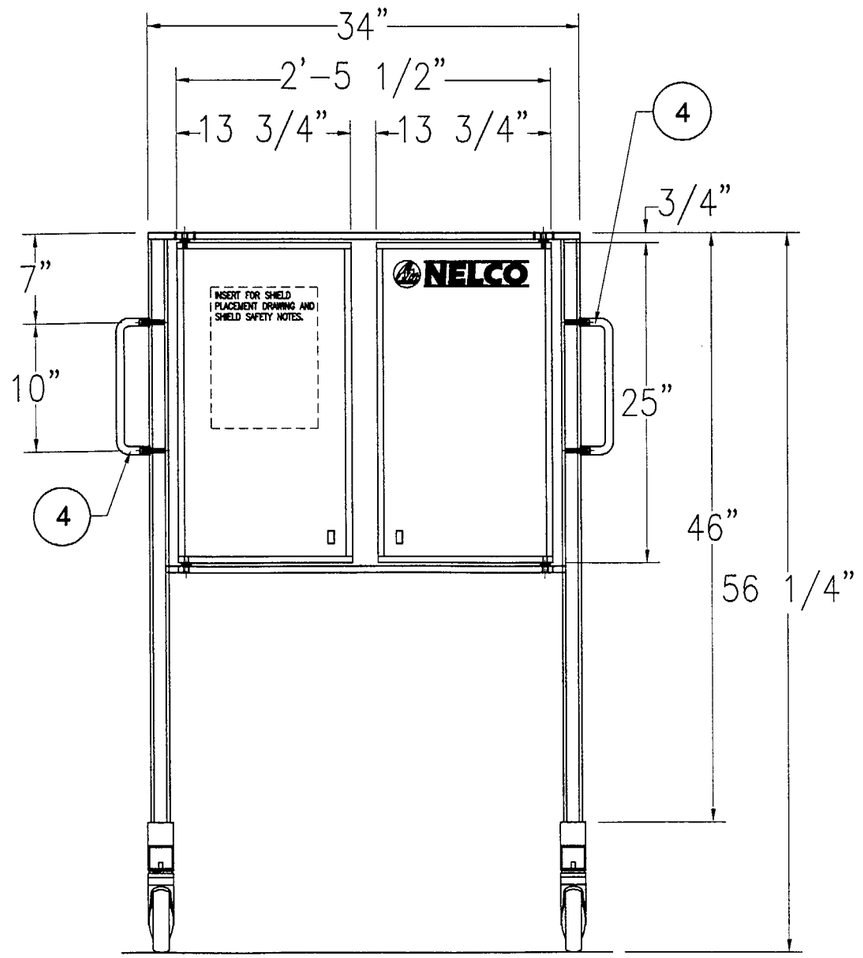
SYM	DATE	DESCRIPTION

AutoCADR14 FILE: (JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-000-S1

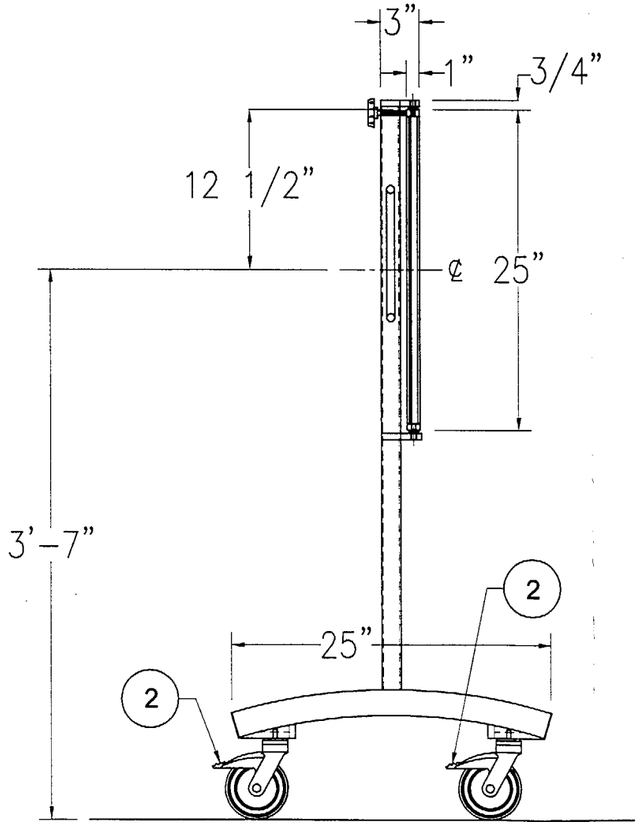
DRAWING NUMBER:
10-042-S1-4



PLAN VIEW



FRONT VIEW
OPERATIONAL WEIGHT - 600 LBS.



SIDE VIEW

RESTENOSIS SHIELD SAFETY NOTES

1. ONCE THE RESTENOSIS SHIELD IS IN PLACE, EACH SHIELD WING SHOULD BE OPENED TO IT'S FULL OPEN POSITION FOR TREATMENT AND LOCKED IN PLACE.
2. ONCE THE RESTENOSIS SHIELD IS IN PLACE, EACH WHEEL LOCK SHOULD BE ENGAGED TO PREVENT INADVERTENT MOVEMENT OF THE SHIELD DURING TREATMENT.
3. THE RESTENOSIS SHIELD SHOULD NEVER BE MOVED WHILE THE SHIELD WINGS ARE IN THE OPEN POSITION OR WHEN THE SHIELD WINGS ARE UNLOCKED.
4. IT IS RECOMMENDED THAT THE RESTENOSIS SHIELD BE TRANSPORTED ONLY BY UTILIZING THE HANDLES ON EACH END OF THE SHIELD.

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98 Baldwin Avenue
Woburn, MA 01801

REGULATORY COPY

OWNER:
UNITED HOSPITAL
345 SHERMAN STREET
ST. PAUL, MN. 55102

TITLE:
RESTENOSIS SHIELD

SCALE:
1" = 1'-0"

DRAWN: CAMP

ENG. MNG.:

PROJ. MNG.:

DATE: 12-7-2000

– REVISIONS –

SYM	DATE	DESCRIPTION

AutoCADR14 FILE:
(JOB NUMBER)
P:\RESTENOSIS\CAD\PROJECTS\10-000-S2

DRAWING NUMBER:
10-042-S2-4

Item 1 Amendment to license. License # 22-01914-02

Item 2 United Hospital
333 Smith Avenue
St. Paul, MN. 55102

Item 3 (1) John Nasseff Heart Hospital – source storage and brachytherapy site.
333 Smith Avenue
St. Paul, MN. 55102
(2) Radiation Oncology/Isotope Storage – source delivery and calibration site.
345 Sherman Street
St. Paul, MN. 55102 – See previous NRC license # 22-01914-02

Item 4 Jane M. Johnson, M.S., RSO

Item 5 35.400
(a) Iridium-192
(b) Iridium seeds in nylon ribbons (6, 10 or 14 seeds) approved under NRC registration number NR187S101S.
(c) Maximum limit 2000 millicuries (74 GBq).

Item 6 Medical Use
To be used for Intravascular brachytherapy (IVB) for treatment of Restenosis coronary vessels, under the Food and Drug administration PMA Number P990036.

Item 7 7.1.1 Authorized User: Seymour Levitt, M.D.
Proposed Uses: 6.d
Qualifications: See previous NRC license # 22-01914-02
7.1.2 Authorized User: Roger Potish, M.D.
Proposed Uses: 6.d
Qualifications: See previous NRC license # 22-01914-02
7.1.3 Authorized User: Kathryn Farniok, M.D.
Proposed Uses: 6.d
Qualifications: See previous NRC license # 22-01914-02
7.2 N/A
7.3 Rad Safety Officer: Jane Johnson, M.S.
Qualifications: See previous license # 22-019114-02

Item 8 All cardiac cath lab personnel will receive training on the irradiation device (including length of sources, dummy ribbon, etc...); identifying radiation-restricted areas; observing posted areas; response during emergencies radiation exposure limits. Annual re-training shall be provided. The RSO/medical physicist shall document this.

Item 9 The Intravascular Brachytherapy shall take place in designated cardiac cath suites. A diagram showing the room and radiation protection calculations is enclosed. The sources shall be kept in a storage area approved by Radiation Safety Officer when not in use. All these items are covered in the enclosed NELCO physics and shielding report.

Item 10 RADIATION SAFETY PROGRAM

(a) All surveys and safety criteria specified in 35.415, including survey of the patient after removal of the sources, will be observed. A GM survey meter shall be used to provide these surveys. This equipment shall be calibrated yearly.

(b) Criteria to meet all 10CFR Part 20 requirements as well as the rules and regulations defined by the NRC as appropriate for IVB procedures shall be maintained.

(c) The only personnel who will remain in the room during the treatment are the (radiation oncologist authorized user) and a qualified Medical Physicist.

(d) The source ribbon will be loaded directly from the source pig into the closed end catheter, which has been placed in position in the coronary artery. This procedure should minimize hand dose but all participants who may assist with source handling will be issued both finger rings and whole body dosimeters.
Since source ribbons will not be altered, to minimize personnel exposure, the source inventory to be conducted before and after each patient use will be conducted by color coded ribbon labels, provided by Best Industries, placed on the leader ends of the nylon ribbons in the shipping pig.

Best Industries supplies these Ir-192 ribbons in a container for which the specifications are attached. The closed end catheter can be attached directly to the port of the shipping container to minimize personnel handling. NELCO Restenosis shields will be available in the area, as well as a brachytherapy emergency transport container (i.e. bailout pig) with a large enough opening to contain the coronary catheter easily and forceps tongs to be used in the event of emergency removal.

When each Ir-192 ribbon is received it will be assayed in the Standard Imaging IVB-1000 dose calibrator and may be autoradiographed to ensure that the correct number and uniformity of seeds are present. For subsequent inventories after each, the inventory will be performed without removing the ribbon from the pig by means of the color-coded leaders. The inventories for each Ir-192 ribbon will be maintained on a separate sheet.

(e) All personnel identified as authorized to handle the Ir-192 sources will receive emergency procedures and will have practice handling, loading dummy ribbons before handling sources during a procedure.

All cath lab personnel will receive training on identifying restricted area, observing postings, and response during emergencies.

The Quality Management Program is enclosed (see attached reference document Cordis Checkmate Instructions for Use, IFU).

(f) Ir-192 seeds encased in a nylon ribbon shall not be used for patient treatment after their manufacturer's expiration date.

(g) An emergency transport container (bailout pig) will be available in the room during procedures for containing broken ribbons or ribbons stuck in catheters.

(h) The following emergency procedures shall be in place (use of an appropriate form shall be used).

MEDICAL EMERGENCY

1) The hospital shall follow the emergency procedures in the Cordis Checkmate Instruction for use (IFU) as well as those that are specific to this hospital.

Item 11 Waste Management – The Ir-192 seeds, in their original container, shall be returned to Best Industries. The same DOT type 7A package that the seeds were shipped in shall be used to return the device to Best Industries. Sources shall not be used beyond the expiration date and will be exchanged within a period in accordance with the Cordis IFU (30 to 35 days). All required tests shall be performed; i.e. wipe test and package surveys.

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES:08/31/2002

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [ ] A. NEW LICENSE
   - [X] B. AMENDMENT TO LICENSE NUMBER 22-01912-02
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL.
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OFJUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

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Region III
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Lisle, Illinois 60532-4351

22-01914-02

To Whom It May Concern:
Attached you will find a license amendment to incorporate *Cortis CHECKMATE, Intravascular Brachytherapy* to our existing license. I heard, from Robert Ayers, that the guidance for this new treatment modality has been completed. We would greatly appreciate if you could expedite the processing of this amendment. We have a large number of patients waiting to be treated.
If you need further information, please feel free to contact me.

Thank-you,

Jane Johnson, M.S., RSO
Medical Physicist
(651) 220-5525

308524
JAN 12 2001

Cordis
a Johnson & Johnson company

Instructions for Use

Cordis CHECKMATE™ Delivery System

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Table of Contents

1. **Device Description**
The Cordis **CHECKMATE** Delivery System is a component of the Cordis **CHECKMATE** System; the other component of the Cordis **CHECKMATE** System is the Cordis **CHECKMATE** Catheter (see also Section 12.1). The Cordis **CHECKMATE** Delivery System (this package) includes:

a. Iridium 192 (Ir-192) Source Ribbon
This ribbon contains a strand of radioactive seeds (6, 10 or 14) with a proximal and distal radiopaque marker.

b. Delivery Device
- Provides the lead shielded housing of the Ir-192 source ribbon during shipment, storage, and transportation to, and from the cath lab. The radioactive section of the source ribbon is completely encased in the shielded delivery device.
- The proximal end of the source ribbon protrudes from the body of the delivery device and is coiled and held next to the delivery device when not in use.
- Both ends of the delivery device are protected by latched end caps.
- A fitting located on the proximal end of the delivery device secures the ribbon in place when not in use.
- A threaded cap is located on the distal end of the delivery device when not in use. When in use, the threaded cap is replaced with a Luer connector.
- The source ribbon is fed by hand from the proximal end of the delivery device into the **CHECKMATE** Catheter, which is attached to the Luer connector.
- Each delivery device is supplied with a Certificate of Activity (Bill of Lading) detailing the radioactive levels and decay profile for the isotope contained within, and the "Use By" date of the radioactive source ribbon.

2. **Indications**
The Cordis **CHECKMATE** Delivery System is intended for the delivery of therapeutic doses of gamma radiation for the purpose of reducing in-stent restenosis. The system is for use in the treatment of native coronary arteries with in-stent restenosis following percutaneous revascularization using current interventional techniques.
- This system is for use in vessels 2.75 – 4.0 mm in diameter and for lesions up to and including 45 mm in length.

3. **Contraindications**
Intracoronary radiation therapy is generally contraindicated in the following patient types:
- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.

4. **Warnings**

Avoid placement of a new stent during the radiation procedure as it has been associated with a higher rate of late thrombosis in comparison to the placebo arm. Every attempt should be made to avoid new stent placement in the irradiated area. However, if placement of a new stent was necessary, it is recommended that the patient be placed on antiplatelet therapy for 12 months. If no new stent was placed it is recommended to prescribe antiplatelet therapy for 6 months. (See also Sections 8 and 8.1).

- This product contains a gamma radiation emitting source and should be handled only by authorized personnel.
- The Cordis **CHECKMATE** System should not be used for indexing procedures as it may result in overexposure of overlapping treatment areas.
- Verify the source location if the delivery device, cart or catheter are moved or if the patient shifts position during the treatment time, to ensure that proper source placement is maintained.

5. **Precautions**
See also Section 12, "Operator Manual."

5.1 Precautions General
- The Cordis **CHECKMATE** Delivery System should only be used in combination with the Cordis **CHECKMATE** Catheter.
- Only physicians who have received adequate training should perform intravascular brachytherapy.
- Intravascular brachytherapy should only be performed at hospitals with the appropriate licensing from the governing nuclear regulatory agency for use of radiation for intravascular therapeutic purposes.
- Intravascular brachytherapy should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Do not expose the source ribbon to solvents (e.g. alcohol, hydrogen peroxide).
- If required, the outside of the delivery device may be wiped with a cloth and alcohol solution. Do not pour liquids directly on the device.
- The **CHECKMATE** Delivery Device weighs approx. 45 lbs. Use caution when removing the delivery device from the transport container, lifting it or positioning it, to prevent injury (two person lift.)
- The delivery device should only be placed on tables or carts (with locking wheels) capable of supporting the device's weight. If accidentally dropped from the table or cart, survey the delivery device to ensure the source is still in the correct position.

5.2 Radiation Precautions
- Follow the "As Low as Reasonably Achievable" (ALARA) policy guidelines.
- Follow the site specific radiation safety procedures.
- When not in use, the Ir-192 source ribbon and delivery device should be stored in a secure, locked area with restricted access separate from other medical devices. Radiation safety regulations for storage of radioactive material should be strictly adhered to.
- Use radiation detection instruments (Geiger counter or appropriate survey meter) while inspecting, unpacking and using Ir-192 source ribbons.
- Use appropriate radiation detection methods (e.g. film badges, ring dosimeters) when handling radioactive source ribbons per the institutional radiation safety protocol and as defined by the governing nuclear regulatory agency.
- Keep the Ir-192 source ribbon in the delivery device at all times except during use.
- Avoid contact with the seeds in the radioactive source ribbon or any unnecessary radiation exposure. Always use long forceps or tongs when handling Ir-192 source ribbons.
- If a seed is cut accidentally during an emergency procedure, be careful in disposing of the damaged seed (use an appropriately shielded container). Check the tools and area for possible contamination and survey the area thoroughly. Do not use tools again until they are completely clean (free of contamination).
- Use appropriate lead shielding when handling Ir-192 source ribbons.
- Survey the area where the Ir-192 source ribbons are used thoroughly after each use and make sure that no seeds or ribbons are lost. Each Ir-192 seed is a radioactive source and, as such, should be accounted for.
- In case of loss of seed(s) or an accident involving the seed(s), it should be reported immediately to the proper Nuclear Regulatory Agency.
- For safe handling of radioactive sources, three factors (time, distance, and shielding) should be observed:
  Time: Less time, less radioactive exposure.
  Distance: More distance from the radioactive source, less radiation exposure.
  Shielding: Better shielding (thicker lead or lead glass shielding), less radiation exposure.

6. **Special Considerations**
Safety and effectiveness has not been demonstrated in the following populations:
- Patients with previous intravascular brachytherapy of the same vessel segment or previous radiation treatment in the immediate vicinity.
- Patients who are pregnant.
- Patients with known genetic radiation sensitivity disorders (e.g. ataxia-telangiectasia, etc.).
- Patients with saphenous vein graft disease.

7. **Adverse Events**
7.1 Observed Adverse Events
A total of 252 patients were enrolled in a single multi-center randomized clinical trial (GAMMA-I trial) to evaluate the use of the Cordis **CHECKMATE** System for treatment of in-stent restenosis. These patients form the basis for the reported observed events (see Clinical Studies).

Additionally, data is provided on the SCRIPPS-I trial (single center, randomized trial, 60 patients) and the WRIST trial (single center, randomized trial, 130 patients). Both studies used the Ir-192 Source Ribbon for treatment of in-stent restenosis.

Table 7-1 Major Adverse Cardiac Events (to 270 days)
All patients in GAMMA-I Trial (N=252)

	Radiation (N=131)	Placebo (N=121)	Relative Risk [95% CI]	Difference [95% CI]
Any MACE (Death, MI, Em. CABG, TLR)	28.2% (37/131)	43.8% (53/121)	0.64 [0.46, 0.90]	-15.6% [-27.3%, -3.8%]
Death	3.1% (4/131)	0.8% (1/121)	3.69 [0.49, 28.03]	2.2% [-1.1%, 5.6%]
Myocardial Infarction (Q or Non-Q)	12.2% (16/131)	6.6% (8/121)	1.85 [0.83, 4.10]	5.6% [-1.5%, 12.7%]
Q Wave MI	5.3% (7/131)	3.3% (4/121)	1.62 [0.49, 5.33]	2.0% [-3.0%, 7.0%]
Non-Q Wave MI	6.9% (9/131)	3.3% (4/121)	2.08 [0.68, 6.40]	3.6% [-1.8%, 8.9%]
Emergent CABG	0.0% (0/131)	0.0% (0/121)	- [-,-]	0.0% [0.0%, 0.0%]
Target Lesion Revascularization	24.4% (32/131)	42.1% (51/121)	0.58 [0.41, 0.83]	-17.7% [-29.2%, -6.3%]
TL-CABG	9.9% (13/131)	20.7% (25/121)	0.48 [0.26, 0.88]	-10.7% [-19.6%, -1.9%]
TL-PTCA	19.8% (26/131)	27.3% (33/121)	0.73 [0.46, 1.14]	-7.4% [-17.9%, 3.0%]
Perforation	0.8% (1/131)	0.0% (0/121)	- [-,-]	0.8% [-0.7%, 2.3%]
Bleeding Complications	2.3% (3/131)	0.8% (1/121)	2.77 [0.32, 23.91]	1.5% [-1.6%, 4.5%]
Vascular Complications	3.1% (4/131)	1.7% (2/121)	1.85 [0.35, 9.66]	1.4% [-2.3%, 5.1%]
Hematological Dyscrasia	0.8% (1/131)	1.7% (2/121)	0.46 [0.04, 4.76]	-0.9% [-3.6%, 1.8%]
CVA	0.8% (1/131)	2.5% (3/121)	0.31 [0.04, 2.58]	-1.7% [-4.9%, 1.4%]
Acute Stent Thrombosis (to 30 days)	0.8% (1/131)	1.7% (2/121)	0.46 [0.04, 4.76]	-0.9% [-3.6%, 1.8%]
Late Thrombosis	5.3% (7/131)	0.8% (1/121)	6.47 [0.81, 51.79]	4.5% [0.3%, 8.7%]
Late Total Occlusion	12.6% (14/111)	5.8% (6/103)	2.17 [0.87, 5.42]	6.8% [-0.8%, 14.4%]

Numbers are % (counts/sample size) or Mean ± SD.
Relative Risk = Radiation/Placebo — SE = sqrt $\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$ — CI = RR*exp(±1.96*SE)
Difference = Radiation – Placebo — SE = sqrt $(p_1*q_1/n_1+p_2*q_2/n_2)$ — CI = Diff±1.96*SE
CI = Confidence Interval

As shown in Table 7-1, 5 patients died during the GAMMA-I trial. The 5 deaths occurred between 0 and 264 days post radiation and were due to: cardiac tamponade (n=1), hemorrhage following bypass surgery (n=1), sudden cardiac death (n=2) and suicide (n=1). There were no device delivery failures and there were 11 cases of stent thrombosis, 3 acute stent thrombosis and 8 late thrombosis.

Table 7-2 Major Adverse Cardiac Events (to 180 days)
All patients in SCRIPPS-I Trial (N=60)

	Radiation (N=29)	Placebo (N=31)	Relative Risk [95% CI]	Difference [95% CI]
Any MACE (Death, MI, Em. CABG, TLR)	20.7% (6/29)	22.6% (7/31)	0.92 [0.35, 2.42]	-1.9% [-22.7%, 18.9%]
Death	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
Myocardial Infarction (Q or Non-Q)	6.9% (2/29)	3.2% (1/31)	2.14 [0.21, 21.40]	3.7% [-7.5%, 14.8%]
Q Wave MI	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
Non-Q Wave MI	6.9% (2/29)	3.2% (1/31)	2.14 [0.21, 21.40]	3.7% [-7.5%, 14.8%]
Emergent CABG	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
Target Lesion Revascularization	17.2% (5/29)	22.6% (7/31)	0.76 [0.27, 2.14]	-5.3% [-25.5%, 14.8%]
TL-CABG	3.4% (1/29)	3.2% (1/31)	1.07 [0.07, 16.68]	0.2% [-8.9%, 9.3%]
TL-PTCA	13.8% (4/29)	19.4% (6/31)	0.71 [0.22, 2.27]	-5.6% [-24.3%, 13.2%]
Perforation	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
Bleeding Complications	0.0% (0/29)	6.5% (2/31)	0.00 [-,-]	-6.5% [-15.1%, 2.2%]
Vascular Complications	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
CVA	0.0% (0/29)	3.2% (1/31)	0.00 [-,-]	-3.2% [-9.4%, 3.0%]
Acute Stent Thrombosis (to 30 days)	3.4% (1/29)	0.0% (0/31)	- [-,-]	3.4% [-3.2%, 10.1%]
Late Thrombosis	0.0% (0/29)	0.0% (0/31)	- [-,-]	0.0% [-,-]
Late Total Occlusion	3.6% (1/28)	0.0% (0/28)	- [-,-]	3.6% [-3.3%, 10.5%]

Numbers are % (counts/sample size) or Mean ± SD.
Relative Risk = Radiation/Placebo — SE = sqrt $\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$ — CI = RR*exp(±1.96*SE)
Difference = Radiation – Placebo — SE = sqrt $(p_1*q_1/n_1+p_2*q_2/n_2)$ — CI = Diff±1.96*SE
CI = Confidence Interval
Late total occlusions were those occlusions in a patient who had angiographic documentation of 100% stenosis at the target site 31 days or more after the index procedure.

As shown in Table 7-2, there were no deaths in the SCRIPPS-I trial. There were no device delivery failures and there was 1 acute stent thrombosis.

Table 7-3 Major Adverse Cardiac Events (to 180 days +/- 30 days)
All patients in WRIST Trial (N=130)

	Radiation (N=65)	Placebo (N=65)	Relative Risk [95% CI]	Difference [95% CI]
Any MACE (Death, MI, Em. CABG, TLR)	29.2% (19/65)	67.7% (44/65)	0.43 [0.29, 0.65]	-38.5% [-54.6%, -22.3%]
Death	4.6% (3/65)	6.2% (4*/65)	0.75 [0.18, 3.22]	-1.5% [-9.4%, 6.4%]
Myocardial Infarction (Q or Non-Q)				
Q Wave MI	0.0% (0/65)	0.0% (0/65)	- [-,-]	0.0% [-,-]
Non-Q Wave MI	16.9% (11/65)	12.3% (8/65)	1.38 [0.59, 3.20]	4.6% [-7.7%, 16.9%]
Target Lesion Revascularization	15.4% (10/65)	63.1% (41/65)	0.24 [0.13, 0.44]	-47.7% [-62.6%, -132.8%]
CABG	7.7% (5/65)	6.2% (4/65)	1.25 [0.35, 4.45]	-1.5% [-7.3%, 10.4%]
PTCA	9.2% (6/65)	61.5% (40/65)	0.15 [0.07, 0.33]	-52.3% [-66.3%, -38.3%]
Vascular Complications	12.3% (8/65)	12.3% (8/65)	1.00 [0.40, 2.50]	0.0% [-11.5%, 11.5%]
TVR (not involving target lesion)	12.3% (8/65)	4.6% (3/65)	2.67 [0.74, 9.61]	7.7% [-1.9%, 17.3%]
CVA	0.0% (0/65)	0.0% (0/65)	- [-,-]	0.0% [-,-]
Subacute Closure (to 30 days)	0.0% (0/65)	0.0% (0/65)	- [-,-]	0.0% [-,-]
Late Thrombosis**	3.1% (2/65)	0.0% (0/65)	- [-,-]	3.1% [-1.1%, 7.3%]
Late Total Occlusion**	13.8% (9/65)	1.5% (1/65)	9.00 [1.17, 69.02]	12.3% [3.4%, 21.2%]

Numbers are % (counts/sample size) or Mean ± SD.
Relative Risk = Radiation/Placebo — SE = sqrt $\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$ — CI = RR*exp(±1.96*SE)
Difference = Radiation – Placebo — SE = sqrt $(p_1*q_1/n_1+p_2*q_2/n_2)$ — CI = Diff±1.96*SE
CI = Confidence Interval
* One patient died on day 212 and one on day 214.
** Additionally, the rates of late thrombosis and late total occlusion for the crossover group are 5.1% (2/39) and 12.8% (5/39), respectively.

As shown in Table 7-3, 7 patients died during the WRIST trial. The 7 deaths occurred between 0 and 214 days post radiation, all were cardiac deaths. There were no device delivery failures and there were 2 cases of late thrombosis.

7.2 **Potential Adverse Events**

Adverse events (in alphabetical order) which may be associated with intracoronary radiation treatment (including those listed in Table 7-1).

- Acute myocardial infarction
- Allergic reaction
- Aneurysm
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Embolization
- Emergent Coronary Artery Bypass Surgery
- Hematological dyscrasia
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and/or pain at the access site
- Ischemia, myocardial
- Malignant or pre-malignant transformation
- Perforation
- Pseudoaneurysm
- Restenosis of the radiated segment
- Spasm, coronary artery
- Stent embolization
- Stent thrombus/occlusion (acute, late)
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery
- Vascular complications (e.g. fibrosis, necrosis, intimal proliferation)

For adverse events associated with antiplatelet and/or anticoagulant therapy, refer to the manufacturer's Instructions for Use.

8. **Clinical Studies**

GAMMA-I Trial (Pivotal Study)

This was a multi-center, prospective, randomized, double-blind trial designed to evaluate the safety and effectiveness of localized radiation therapy following percutaneous revascularization using current interventional techniques in patients with in-stent restenosis. A total of 252 patients were treated at 12 US investigational centers.

Primary Endpoint: The primary endpoint for the GAMMA-I trial was a composite of major adverse cardiac events including death, Q-wave and non-Q-wave myocardial infarction (MI), emergent CABG and target lesion revascularization (TLR) at 9 months post-procedure. TLR was defined as any clinically driven revascularization of the target lesion using either bypass surgery or percutaneous (i.e. angioplasty) techniques. An independent Clinical Events Committee, blinded to treatment assignment, adjudicated all major clinical endpoints for the GAMMA-I trial.

Patients Studied: Patients with in-stent restenosis of native coronary arteries, 2.75 – 4.0 mm in diameter and ≤ 45 mm in length, treated with current interventional techniques were admitted to the GAMMA-I trial.

Methods: Patients with in-stent restenosis underwent redilatation of the restenosis using current interventional techniques including high pressure (> 12 atm [1216 kPa]) balloon inflation with a balloon-to-artery ratio of 1-1.2:1. If by angiography or ultrasound, a <30% residual stenosis was not obtained after this vigorous dilatation, or if a significant dissection was created inside the stent or the stent border, or if the restenotic lesion was at the stent border, another one or two approved non-coil stents were implanted as needed within and/or overlapping the original stent to cover the restenotic segments. New stents were optimally dilated using routine techniques.

Immediately after successful coronary intervention, the Cordis **CHECKMATE** Catheter and dummy ribbon were introduced over the indwelling guidewire, using the catheter's rapid exchange tip. After the **CHECKMATE** Catheter was positioned across the target lesion, the patient was randomized to treatment with either a placebo ribbon or Ir-192 source ribbon. The dwell time for each individual patient was calculated based on the vessel diameter (as determined by intravascular ultrasound measurement), the number of seeds of the treatment ribbon, and the activity of the treatment ribbon on the day of the procedure. This information is used by a radiation oncologist and physicist to determine the time required to deliver 800 cGy to the target farthest from the radiation source, with no more that 3000 cGy delivered to the target closest to the source.

Clinical follow-up was completed at one, six, and nine months; all patients underwent angiographic follow-up at 6 months. Baseline QCA was performed pre- and post-procedure. The baseline characteristics of the two patient populations in the GAMMA-I trial were similar. All treated patients were included in the intent-to-treat analysis. Antiplatelet therapy included aspirin 325 mg/daily (indefinitely) and ticlopidine 250 mg b.i.d. for 8 weeks if a stent was implanted at the target lesion during the study procedure.

Results: In suitable patients with restenotic coronary lesions, an interventional procedure (IP) followed by intravascular brachytherapy (Radiation) resulted in a statistically significant improvement in late angiographic and intravascular ultrasound (IVUS) results, a lower six-month angiographic restenosis rate, and lower major adverse cardiac events (MACE) at 9 months when compared to IP and Placebo intravascular brachytherapy. The rate of late stent thrombosis was higher in the Radiation arm.

Clinical Trials Comparison

	GAMMA-I	SCRIPPS-I	WRIST	SCRIPPS-III	WRIST Plus
Trial	Pivotal Trial Multi center, prospective, randomized	Supportive Trial Single center, prospective, randomized	Supportive Trial Single center, prospective, randomized	Supportive Trial Multi center, registry	Supportive Trial Single center, registry
Total # of Patients Enrolled	252	60	130	500	120
Patients Studied	Native coronary arteries 2.75-4.0 mm diameter ≤ 45 mm length	Native coronary arteries and SVG's 3.0-5.5 mm diameter <30 mm length	Native coronary arteries and SVG's 3.0-5.0 mm diameter <50 mm length	Native coronary arteries and SVG's 2.75-4.0 mm diameter <81 mm length	Native coronary arteries and SVG's 2.5-5.0 mm diameter <80 mm length
Devices Used	6, 10 or 14 seed ribbons 4F Catheter	5 or 9 seed ribbon 4F Catheter	5, 9 or 13 seed ribbon 5F Catheter	6-22 seed ribbons 4F Catheter	6-23 seed ribbons 4F or 5F Catheter
Methods	Outlined above	Similar to GAMMA-I	Similar to GAMMA-I	Similar to GAMMA-I	Similar to GAMMA-I
Dosimetry	IVUS based 800-3000 cGy	IVUS based 800-3000 cGy	No IVUS 1500 cGy at 2 mm from the center of the source	No IVUS 1400 cGy at 2 mm	No IVUS 1400 cGy or 1500 cGy at 2 mm from the center of the source
Antiplatelet Therapy	8-weeks if new stent was placed	2 weeks if new stent was placed	4 weeks (all patients)	6 months if no new stent 12 months if new stent is placed	6 months (all patients)
Follow-up	6 months angiographic 1 & 9 months clinic 2, 24, 36 months telephone F/U	6 & 36 months angiographic 12, 24, 36, 48, 60 months telephone F/U	6 months angiographic 1, 6, 12 & 24 months clinic	1 & 9 months clinic 2 & 12 months telephone F/U	6 & 24 months angiographic 1 & 12 months clinic

Table 8-1 GAMMA-I Principal Effectiveness and Safety Results (to 270 days)
All Patients Treated (N=252)

Effectiveness Measures	Radiation (N=131)	Placebo (N=121)	Relative Risk [95% CI]	Difference [95% CI]
Lesion Success	100.0% (131/131)	98.3% (119/121)	1.02 [0.99, 1.04]	1.7% [-0.6%, 3.9%]
Procedure Success	100.0% (131/131)	98.3% (119/121)	1.02 [0.99, 1.04]	1.7% [-0.6%, 3.9%]
Device Success	100.0% (131/131)	98.3% (119/121)	1.02 [0.99, 1.04]	1.7% [-0.6%, 3.9%]
Post Procedure In-Stent Percent Diameter Stenosis (% DS)				
Mean±SD (N)	8.8% ±17.9% (129)	8.9%±19.0% (117)	N/A	-0.1% [-4.8%, 4.5%]
Range (min, max)	(-49.9%, 48.8%)	(-55.8%, 59.1%)		
Follow-Up In-Stent Percent Diameter Stenosis (% DS)				
Mean±SD(N)	33.6% ±32.3% (111)	50.8% ±22.0% (103)	N/A	-17.2% [-24.7%, -9.7%]
Range (min, max)	(-48.5%, 100.0%)	(-0.8%, 100.0%)		
In-Stent Late Loss (mm)				
Mean±SD (N)	0.73 ±0.79 (111)	1.14 ±0.65 (101)	N/A	-0.40 [-0.60, -0.20]
Range (min, max)	(-0.56, 3.37)	(-0.47, 3.30)		
6 Month In-Lesion (Stent+Probe+Edge) Binary Restenosis Rate	32.4% (36/111)	55.3% (57/103)	0.59 [0.43, 0.80]	-22.9% [-35.9%, -9.9%]
6 Month In-Stent Binary Restenosis Rate	21.6% (24/111)	50.5% (52/103)	0.43 [0.29, 0.62]	-28.9% [-41.2%, -16.5%]
Difference of Index and F/U	-0.75±1.13 (35)	-1.55±1.15 (33)	N/A	0.80 [0.25, 1.35]
Mean Difference of Stent and Lumen	(-3.80, 2.14)	(-4.48, 0.20)		
TLR-Free at 270 days*	74.8% [65.7%, 83.9%]	56.7% [46.1%, 67.3%]	1.32 [1.06, 1.65]	18.1% [4.1%, 32.1%]
TVR-Free at 270 days*	66.2% [56.3%, 76.1%]	52.5% [41.9%, 63.1%]	1.26 [0.98, 1.62]	13.8% [-0.7%, 28.2%]
TVF-Free at 270 days*	62.3% [52.1%, 72.5%]	51.6% [41.0%, 62.3%]	1.21 [0.93, 1.57]	10.7% [-4.1%, 25.4%]
MACE-Free at 270 days*	70.8% [61.2%, 80.4%]	55.0% [44.4%, 65.7%]	1.29 [1.02, 1.63]	15.8% [1.4%, 30.1%]
Safety Measures and Other Clinical Events				
In-Hospital MACE	2.3% (3/131)	3.3% (4/121)	0.69 [0.16, 3.01]	-1.0% [-5.1%, 3.1%]
Out-of-Hospital MACE to 270 days	26.7% (35/131)	42.1% (51/121)	0.63 [0.45, 0.90]	-15.4% [-27.0%, -3.8%]
Bleeding Complications to 270 days	2.3% (3/131)	0.8% (1/121)	2.77 [0.32, 23.91]	1.5% [-1.6%, 4.5%]
Vascular Complications to 270 days	3.1% (4/131)	1.7% (2/121)	1.85 [0.35, 9.66]	1.4% [-2.3%, 5.1%]
Hematologic Dyscrasia to 270 days	0.8% (1/131)	1.7% (2/121)	0.46 [0.04, 4.76]	-0.9% [-3.6%, 1.8%]
CVA to 270 days	0.8% (1/131)	2.5% (3/121)	0.31 [0.04, 2.58]	-1.7% [-4.9%, 1.4%]
Acute Stent Thrombosis	0.8% (1/131)	1.7% (2/121)	0.46 [0.04, 4.76]	-0.9% [-3.6%, 1.8%]
Late Thrombosis	5.3% (7/131)	0.8% (1/121)	6.47 [0.81, 51.79]	4.5% [0.3%, 8.7%]
Late Total Occlusion	12.6% (14/111)	5.8% (6/103)	2.17 [0.87, 5.42]	6.8% [-0.8%, 14.4%]

Numbers are % (counts/sample size) or Mean±SD
Relative Risk = Radiation/Placebo
Difference = Radiation – Placebo
N/A = Not Applicable

$SE = sqrt\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$
$SE = sqrt\ (p_1{}^*q_1/n_1+p_2{}^*q_2/n_2)$

CI =Confidence Interval
CI = RR* exp (± 1.96* SE)
CI = Diff ± 1.96* SE

Lesion Success = Attainment of a <50% residual stenosis using any percutaneous method.
Procedure Success = Attainment of a <50% residual diameter stenosis using any percutaneous method and no in-hospital MACE.
Device Success = Attainment of a <50% residual stenosis and successful delivery of the radiation device.
Restenosis was defined as ≥50% in-stent diameter stenosis at the follow-up angiogram.
*Survival Estimates from Kaplan-Meier estimate. Standard Error estimates by Peto formula.

KM Relative Risk = $S_{Radiation}/S_{Placebo}$
KM Difference = $S_{Radiation} - S_{Placebo}$

$SE_{RR}=sqrt\{(SE_{Radiation}/S_{Radiation})^2+(SE_{Placebo}/S_{Placebo})^2\}$
$SE_{Diff} = sqrt(SE_{Radiation}{}^2+SE_{Placebo}{}^2)$

$CI = RR*exp(\pm 1.96*SE_{RR})$
$CI = Diff\pm 1.96*SE_{Diff}$

TLR-Free = No target lesion revascularization.
TVR-Free = No target vessel revascularization.
TVF-Free = No death, MI, or target lesion revascularization.
MACE-Free = No death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
In-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization after hospital discharge.
Bleeding Complications = Transfusions of blood products due to blood loss resulting from the percutaneous revascularization procedure.
Vascular Complications = Hematoma > 4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, and vascular surgical repair.
CVA = Acute neurological deficits recorded by the clinical sites that persisted > 24 hours.
Acute Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain or ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days was considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency.
Late Thrombosis = Myocardial infarction attributable to the target vessel with angiographic documentation (site-reported or by QCA) of thrombus or total occlusion at the target site and in a newly implanted bypass graft at the target site > 30 days after the index procedure in the absence of an intervening revascularization of the target vessel.
Late Total Occlusion = Consists of Late Thrombosis and Total Occlusion.

Table 8-2 SCRIPPS-I Principal Effectiveness and Safety Results (to 180 days)
All Patients Treated (N=60)

Effectiveness Measures	**Radiation (N=29)**	**Placebo (N=31)**	**Relative Risk [95% CI]**	**Difference [95% CI]**
Lesion Success	100.0% (29/29)	93.5% (29/31)	1.07 [0.97, 1.18]	6.5% [-2.2%, 15.1%]
Procedure Success	100.0% (29/29)	93.5% (29/31)	1.07 [0.97, 1.18]	6.5% [-2.2%, 15.1%]
Device Success	100.0% (29/29)	90.3% (28/31)	1.11 [0.98, 1.24]	9.7% [-0.7%, 20.1%]
Post Procedure In-Stent Percent Diameter Stenosis (% DS)				
Mean±SD (N)	9.4% ±22.8% (29)	7.0%±23.9% (31)	N/A	2.5% [-9.6%, 14.5%]
Range (min, max)	(-64.1%, 38.0%)	(-36.0%, 46.4%)		
Post Procedure In-Stent+Border (% DS)				
Mean±SD(N)	24.4% ±9.5% (29)	18.9% ±18.1% (31)	N/A	5.6% [-2.0%, 13.1%]
Range (min, max)	(-0.8%, 39.8%)	(-24.3%, 53.2%)		
6 Month F/U In-Stent+Border (% DS)				
Mean±SD (N)	43.2% ±23.5% (28)	41.8% ±24.2% (28)	N/A	1.4% [-11.4%, 14.2%]
Range (min, max)	(16.5%, 100%)	(-23.8%, 78.6%)		
6 Month F/U In-Stent+Border Late Loss				
Mean±SD (N)	0.66 ±0.91 (28)	0.78 ±0.94 (28)	N/A	-0.13 [-0.62, 0.37]
Range (min, max)	(-0.62, 2.73)	(-0.46, 3.49)		
6 Month In-Stent+Border Restenosis Rate	21.4% (6/28)	46.4% (13/28)	0.46 [0.21, 1.00]	-25.0% [-48.9%, -1.1%]
Difference between Post-Procedure and 6-Month F/U Mean Intimal Hyperplasia CSA (mm^2)				
Mean±SD (N)	-0.68 ±0.97 (18)	-2.14 ±1.66 (18)	N/A	1.47 [0.55, 2.39]
Range (min, max)	(-2.90, 0.70)	(-5.60, -0.40)		
TLR-Free at 180 days*	82.6% [68.5%, 96.7%]	77.4% [62.4%, 92.5%]	1.07 [0.82, 1.38]	5.2% [-15.4%, 25.8%]
TVR-Free at 180 days*	82.8% [68.7%, 96.8%]	71.0% [54.6%, 87.3%]	1.17 [0.88, 1.55]	11.8% [-9.8%, 33.3%]
TVF-Free at 180 days*	79.3% [64.2%, 94.4%]	71.0% [54.6%, 87.3%]	1.12 [0.83, 1.51]	8.3% [-13.9%, 30.6%]
MACE-Free at 180 days*	79.2% [64.1%, 94.3%]	77.4% [62.4%, 92.5%]	1.02 [0.78, 1.34]	1.7% [-19.6%, 23.1%]
Safety Measures and Other Clinical Events				
In-Hospital MACE	0.0% (0/29)	0.0% (0/31)	- [-, -]	0.0% [-, -]
Out-of-Hospital MACE to 180 days	20.7% (6/29)	22.6% (7/31)	0.92 [0.35, 2.42]	-1.9% [-22.7%, 18.9%]
Bleeding Complications to 180 days	0.0% (0/29)	6.5% (2/31)	0.00 [-, -]	-6.5% [-15.1%, 2.2%]
Vascular Complications to 180 days	0.0% (0/29)	0.0% (0/31)	- [-, -]	0.0% [-, -]
CVA to 180 days	0.0% (0/29)	3.2% (1/31)	1.00 [-,-]	-3.2% [-9.4%, 3.0%]
Acute Stent Thrombosis (to 30 days)	3.4% (1/29)	0.0% (0/31)	- [-, -]	3.4% [-3.2%, 10.1%]
Late Thrombosis	0.0% (0/29)	0.0% (0/31)	- [-, -]	0.0% [-, -]
Late Total Occlusion	3.6% (1/28)	0.0% (0/28)	- [-, -]	3.6% [-3.3%, 10.5%]

Numbers are % (counts/sample size) or Mean ± SD
Relative Risk = Radiation/Placebo
Difference = Radiation – Placebo
N/A = Not applicable.

$SE = \text{sqrt}\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$
$SE = \text{sqrt}\ (p_1{}^*q_1/n_1+p_2{}^*q_2/n_2)$

CI = Confidence Interval
CI = RR* exp (± 1.96* SE)
CI = Diff ± 1.96* SE

Device Success = The attainment of a <50% residual stenosis and successful delivery of the radiation device.
Lesion Success = The attainment of a <50% residual stenosis using any percutaneous method.
Procedure Success = The attainment of a <50% residual stenosis using any percutaneous method and no in-hospital MACE.
In-Hospital MACE = Death, Q wave or non-Q wave MI, target lesion revascularization, and emergent CABG prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, target lesion revascularization, and emergent CABG after hospital discharge.
*Survival Estimates from Kaplan-Meier estimates. Standard Error estimates from Peto formula.

KM Relative Risk = $S_{Radiation}/S_{Placebo}$
KM Difference = $S_{Radiation} - S_{Placebo}$

$SE_{RR}=\text{sqrt}\{(SE_{Radiation}/S_{Radiation})^2+(SE_{Placebo}/S_{Placebo})^2\}$
$SE_{Diff} = \text{sqrt}\{SE_{Radiation}{}^2+SE_{Placebo}{}^2\}$

$CI = RR^*\exp(\pm 1.96^*SE_{RR})$
$CI = Diff \pm 1.96^*SE_{Diff}$

TLR-Free = No target lesion revascularization.
TVR-Free = No target vessel revascularization.
TVF-Free = No death, Q wave or non-Q wave MI, or target vessel revascularization.
MACE-Free = No death, Q wave or non-Q wave MI, target lesion revascularization, or emergent CABG.
Bleeding Complications = Bleeding complications were defined as transfusions of blood products due to blood loss resulting from the percutaneous revascularization procedure.
Vascular Complications = Hematoma > 4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, and Vascular surgical repair.
CVA = Cerebrovascular accident was defined as acute neurological deficits recorded by the clinical sites that persisted > 24 hours.
Acute Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain or ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days was considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency.
Late Thrombosis = Myocardial infarction attributable to the target vessel with angiographic documentation (site-reported or by QCA) of thrombus or total occlusion at the target site and in a newly implanted bypass graft at the target site > 30 days after the index procedure in the absence of an intervening revascularization of the target vessel.
Late Total Occlusion = Consists of Late Thrombosis and Total Occlusion.

Table 8-3 WRIST Principal Effectiveness and Safety Results (to 180 days +/- 30 days)
All Patients Treated (N=130)

Effectiveness Measures	Radiation (65=Patients, 65=Lesions)	Placebo (65=Patients, 65=Lesions)	Relative Risk (95% CI)	Difference (95% CI)
Lesion Success	100.0% (64/64)	98.4% (63/64)	1.02 (0.99, 1.05)	1.6 (-1.5, 4.7)
Device Success	100.0% (64/64)	96.9% (62/64)	1.03 (0.99, 1.08)	3.1 (-1.2, 7.5)
Procedure Success	100.0% (64/64)	98.4% (63/64)	1.02 (0.99, 1.05)	1.6 (-1.5, 4.7)
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS)				
Mean±SD (N)	28.32 ±11.93 (64)	27.30 ±11.99 (64)	N/A	1.02 (-3.16, 5.20)
Range (min, max)	(-10.07, 63.21)	(2.29, 55.88)		
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)				
Mean±SD (N)	19.77 ±15.16 (64)	20.45 ±14.75 (64)	N/A	-0.68 (-5.91, 4.56)
Range (min, max)	(-18.80, 43.01)	(-20.23, 50.46)		
Late Loss In-Stent (QCA)				
Mean±SD (N)	0.24 ±0.84 (59)	0.96 ±0.68 (55)	N/A	-0.72 (-1.01, -0.44)
Range (min, max)	(-1.20, 2.95)	(-0.82, 2.62)		
Restenosis Rate In-Lesion Binary Restenosis	23.7% (14/59)	60.7% (34/56)	0.39 (0.24, 0.65)	-37.0 (-54.1, -19.9)
Mean Lumen Area at 6 month follow-up (IVUS)				
Mean±SD (N)	7.04 ±2.38 (47)	4.85 ±2.88 (50)	N/A	(1.12, 3.26)
TLR-free at 6 months	84.6% (55/65)	36.9% (24/65)	2.29 (1.64, 3.20)	47.7 (32.8, 62.6)
TVR-free at 6 months	72.3% (47/65)	32.3% (21/65)	2.24 (1.53, 3.28)	40.0 (24.0, 56.0)
MACE-free at 6 months	70.8% (46/65)	32.3% (21/65)	2.19 (1.49, 3.22)	38.5 (22.3, 54.6)
Safety Measures				
In-Hospital MACE	1.5% (1/65)	0.0% (0/65)	3.00 (0.12, 72.31)	1.5 (-1.5, 4.6)
Out-of-Hospital MACE to 6 months	29.2% (19/65)	67.7% (44/65)	0.43 (0.29, 0.65)	-38.5 (-54.6, -22.3)
MACE to 30 days (cumulative)	3.1% (2/65)	1.5% (1/65)	2.00 (0.19, 21.52)	1.5 (-3.7, 6.8)
MACE to 6 months (cumulative)	29.2% (19/65)	67.7% (44/65)	0.43 (0.29, 0.65)	-38.5 (-54.6, -22.3)
Abrupt Closure to 30 days	0.0% (0/65)	0.0% (0/65)		
Subacute Closure to 30 days	0.0% (0/65)	0.0% (0/65)		
Stent Thrombosis to 30 days	0.0% (0/65)	0.0% (0/65)		
CVA to 30 days	0.0% (0/65)	0.0% (0/65)		
In-Hospital Vascular Complications	10.8% (7/65)	10.8% (7/65)	1.00 (0.37, 2.69)	0.0 (-10.8, 10.8)
Vascular Complications to 6 months (cumulative)	12.3% (8/65)	12.3% (8/65)	(0.40, 2.50)	0.0 (-11.5, 11.5)
Late Thrombosis	3.1% (2/65)	0.0% (0/65)		3.1 (-1.1, 7.3)
Late Total Occlusion	13.8% (9/59)	1.5% (1/56)*	9.00 (1.17, 69.02)	12.3 (3.4, 21.2)

Numbers are % (counts/sample size) or Mean ± SD
Relative Risk = p_1/p_2, $p_i = n_{i1}/n_i$
Difference = p_1-p_2
N/A = Not applicable

SE = sqrt $[(1-p_1/n_{11}+(1-p_2)/n_{21})]$
SE = sqrt $[(p_1*q_1/n_1+p_2*q_2/n_2)]$

CI = Confidence Interval
CI = RR* exp (± 1.96* SE)
CI = Diff ± 1.96* SE

Lesion success = Lesion success was defined as the attainment of <50% residual stenosis (by QCA) using percutaneous method.
Device Success = Device success was defined as the attainment of a <50% residual stenosis using assigned treatment and delivery of the ribbon for the desired dwell time.
Procedure Success = Procedure success was defined as the attainment of a <50% residual stenosis by QCA and freedom from death, Q wave MI or emergent CABG.
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS) = The % diameter stenosis post procedure was defined as (1-MLD/RVD) *100 as is identified within the stenotic segment ("in lesion"). Whenever possible, normal and minimal lesion diameters are calculated from two orthogonal projections. Range (min, max) measurement of smallest stenosis and largest stenosis, respectively.
Post Procedure In-Stent Percent Diameter Stenosis (% DS) = The stent % diameter stenosis post procedure was defined as (1-MLD-RVD) * 100 as is identified within the stent ("in stent"). Whenever possible, normal and minimal lesion diameters are calculated from two orthogonal projections. Range (min, max) measurement of smallest stenosis and largest stenosis, respectively.
Late Loss = Late loss is defined as the late change in dimensional minimal lumen diameter that occurred during the follow-up period measured by quantitative coronary angiography based on the average from two orthogonal views after the final post-dilatation to follow-up. Final MLD – F/U MLD. Reported for in-stent.
Binary Restenosis = Angiographic restenosis ≥ 50% minimum lumen diameter stenosis at the follow-up angiogram. Restenosis is recorded for in lesion.
Mean Lumen Area = Average lumen area over the length of treated segment as measured by intravascular ultrasound at 6 months follow-up in mm^2.
TLR-free at 6 months = Target lesion revascularization was defined as a clinically driven repeat revascularization of a target lesion that was angiographically narrowed. The definition of "clinically driven" included a positive functional ischemia study, resting ischemic ECG changes in a distribution consistent with the target vessel, ischemic symptoms, and angiographic minimal lumen diameter stenosis ≥ 50% by QCA; revascularization of a target lesion with diameter stenosis ≥ 70% by QCA without either angina or a positive functional study was also considered clinically driven.
TVR-free at 6 months = Target vessel revascularization was defined as a target lesion revascularization (defined above) or revascularization due to narrowing of any segment of the target vessel proximal or distal to the target lesion. This definition assumed that the entire vessel was vulnerable to late failure because of guide catheter or guidewire trauma or progression of disease remote from the treatment site. The target vessel revascularization definition required that: target vessel revascularization was clinically driven (as defined for the target lesion revascularization, see above). The angiographic core laboratory determined that the target lesion had a diameter stenosis of ≥ 50% by QCA or the clinical site reported a narrowing of another site in the target vessel with diameter stenosis ≥ 50%.
MACE-free at 6 months = MACE was defined as target vessel revascularization, Q wave myocardial infarction or cardiac death that could not be clearly attributed to a non-target vessel. Therefore, target vessel failure included any revascularization or adverse endpoints due to renarrowing of any segment of the target vessel. Target vessel failure was reported when: target vessel revascularization occurred (defined below); myocardial infarction occurred and the territory was not clearly other than that of the target vessel; or cardiac death occurred and could not be clearly attributed to a non-target vessel.
In-Hospital MACE = In-hospital MACE (Major Adverse Cardiac Events) were defined as cardiac death, target Q wave MI, and target *vessel* revascularization (CABG or PTCA of the target vessel) as determined by the independent Clinical Events Committee from index procedure through the hospital discharge.
Out-of-Hospital MACE = Out-of-hospital MACE (Major Adverse Cardiac Events) were defined as death, Q wave MI, and target vessel revascularization (CABG or PTCA of the target vessel) as determined by the independent Clinical Events Committee from discharge through the 6 month contact.
MACE to 30 days (cumulative) = The occurrence of any major adverse cardiac event including cardiac death, QWMI, CABG, or repeat PTCA within 30 days of the index procedure. One event should be reported per patient.
MACE to 6 months (cumulative) = The occurrence of any major adverse cardiac event including cardiac death, QWMI and target vessel revascularization that occurred from the index procedure to the 6 month follow-up. One event should be reported per patient.
Abrupt Closure = Abrupt closure is defined as the occurrence of new reduced flow (TIMI 0 or 1) of the target vessel and required rescue by another device or emergency surgery or resulted in myocardial infarction or death. Abrupt closure is related to the mechanical dissection (of the treatment site or other instrumental site), coronary thrombus, or severe spasm. Abrupt closure does not connote no re-flow in which the artery was patent but reduced flow persisted. Abrupt closure also does not connote transient closure unless a Class 2 or 3 MI or death occurred. Threatened abrupt closure was defined as a NHLBI dissection Grade B with a 50% diameter stenosis or any Grade C dissection or higher. Threatened closure was not used as a primary endpoint but was used to adjudicate the use of other devices.
Subacute Closure to 30 days = Subacute closure was defined as abrupt closure that had occurred after the index procedure was completed and the patient had left the catherization laboratory and was within 30 days of the index procedure.
Stent Thrombosis = Cardiac death, Q wave MI, angiographic total occlusion at follow-up or evidence of angiographic thrombus (core laboratory and investigator), reported at 30 days. In the absence of the QCA, total occlusion was adjudicated by the Clinical Events Committee.
CVA to 30 days = The occurrence of a new permanent stroke following the procedure within 30 days of the index procedure.
In-Hospital Vascular Complications = In-hospital vascular complications were defined as the occurrence of any of the following: hematoma at the access site of > 4 cm in maximum diameter, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure-related blood transfusion, or vascular surgical repair between index procedure to discharge date of hospital stay.
Vascular Complications to 6 months (cumulative) = Vascular complications were defined as the occurrence of any of the following: hematoma at the access site of > 4 cm in maximum diameter, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related blood transfusion, or vascular surgical repair both in hospital from index procedure to discharge and out of hospital.
Late Thrombosis = Myocardial infarction attributable to the target vessel with angiographic documentation (site-reported or by QCA) of thrombus or total occlusion at the target site and in a newly implanted bypass graft at the target site > 30 days after the index procedure in the absence of an intervening revascularization of the target vessel.
Late Total Occlusion = Consists of Late Thrombosis and Total Occlusion.

*Additionally, the rates of late thrombosis and late total occlusion for the crossover group are 5.1% (2/39) and 12.8% (5/39), respectively.

Table 8-4: Major Adverse Cardiac Events, In-Hospital vs. Out-of-Hospital
All Patients Treated

	GAMMA-I			SCRIPPS-I			WRIST		
	Radiation (N=131)	Placebo (N=121)	All (N=252)	Radiation (N=29)	Placebo (N=31)	All (N=60)	Radiation (N=65)	Placebo (N=65)	All (N=130)
In-Hospital Complications									
MACE (Death, MI, Emergent CABG, TLR)*	2.3% (3)	3.3% (4)	2.8% (7)	0.0% (0)	0.0% (0)	0.0% (0)	1.5% (1)	0.0% (0)	0.8% (1)
Death (for WRIST: non-cardiac death only)	0.8% (1)	0.0% (0)	0.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Myocardial Infarction (Q or Non-Q)	2.3% (3)	2.5% (3)	2.4% (6)	0.0% (0)	0.0% (0)	0.0% (0)	10.8% (7)	7.7% (5)	9.2% (12)
Q Wave MI	0.8% (1)	0.8% (1)	0.8% (2)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Non-Q Wave MI	1.5% (2)	1.7% (2)	1.6% (4)	0.0% (0)	0.0% (0)	0.0% (0)	10.8% (7)	7.7% (5)	9.2% (12)
Emergent CABG	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Target Lesion Revascularization	0.0% (0)	1.7% (2)	0.8% (2)	0.0% (0)	0.0% (0)	0.0% (0)	1.5% (1)	0.0% (0)	0.8% (1)
TL-CABG	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
TL-PTCA	0.0% (0)	1.7% (2)	0.8% (2)	0.0% (0)	0.0% (0)	0.0% (0)	1.5% (1)	0.0% (0)	0.8% (1)
Perforation	0.8% (1)	0.0% (0)	0.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Bleeding Complications	0.8% (1)	0.0% (0)	0.4% (1)	0.0% (0)	6.5% (2)	3.3% (2)	6.2% (4)	1.5% (1)	3.8% (5)
Vascular Complications	2.3% (3)	0.8% (1)	1.6% (4)	0.0% (0)	0.0% (0)	0.0% (0)	10.8% (7)	10.8% (7)	10.8% (14)
Hematologic Dyscrasia	0.0% (0)	0.0% (0)	0.0% (0)	N/A	N/A	N/A	N/A	N/A	N/A
CVA	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Acute Stent Thrombosis (to 30 days)	0.0% (0)	0.8% (1)	0.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Late Thrombosis	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	N/A	N/A	N/A
Late Total Occlusion	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	N/A	N/A	N/A
Out-of-Hospital Complications**									
MACE (Death, MI, Emergent CABG, TLR)	26.7% (35)	42.1% (51)	34.1% (86)	20.7% (6)	22.6% (7)	21.7% (13)	29.2% (19)	67.7% (44)	48.5% (63)
Death	2.3% (3)	0.8% (1)	1.6% (4)	0.0% (0)	0.0% (0)	0.0% (0)	4.6% (3)	6.2% (4)	5.4% (7)
Myocardial Infarction (Q or Non-Q)	9.9% (13)	4.1% (5)	7.1% (18)	6.9% (2)	3.2% (1)	5.0% (3)	9.2% (6)	7.7% (5)	8.5% (11)
Q Wave MI	4.6% (6)	2.5% (3)	3.6% (9)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Non-Q Wave MI	5.3% (7)	1.7% (2)	3.6% (9)	6.9% (2)	3.2% (1)	5.0% (3)	9.2% (6)	7.7% (5)	8.5% (11)
Emergent CABG	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	N/A	N/A	N/A
Target Lesion Revascularization	24.4% (32)	40.5% (49)	32.1% (81)	17.2% (5)	22.6% (7)	20.0% (12)	15.4% (10)	63.1% (41)	39.2% (51)
TL-CABG	9.9% (13)	20.7% (25)	15.1% (38)	3.4% (1)	3.2% (1)	3.3% (2)	7.7% (5)	6.2% (4)	6.9% (9)
TL-PTCA	19.8% (26)	25.6% (31)	22.6% (57)	13.8% (4)	19.4% (6)	16.7% (10)	9.2% (6)	61.5% (40)	35.4% (46)
Perforation	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Bleeding Complications	1.5% (2)	0.8% (1)	1.2% (3)	0.0% (0)	0.0% (0)	0.0% (0)	N/A	N/A	N/A
Vascular Complications	0.8% (1)	0.8% (1)	0.8% (2)	0.0% (0)	0.0% (0)	0.0% (0)	3.1% (2)	3.1% (2)	3.1% (4)
Hematologic Dyscrasia	0.8% (1)	1.7% (2)	1.2% (3)	N/A	N/A	N/A	N/A	N/A	N/A
CVA	0.8% (1)	2.5% (3)	1.6% (4)	0.0% (0)	3.2% (1)	1.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Acute Stent Thrombosis (to 30 days)	0.8% (1)	0.8% (1)	0.8% (2)	3.4% (1)	0.0% (0)	1.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Late Thrombosis	5.3% (7)	0.8% (1)	3.2% (8)	0.0% (0)	0.0% (0)	0.0% (0)	3.1% (2)	0.0% (0)	1.5% (2)
Late Total Occlusion***	12.6% (14)	5.8% (6)	9.3% (20)	3.6% (1)	0.0% (0)	1.7% (1)	13.8% (9)	1.5% (1)	7.7% (10)

* MACE for GAMMA-I and SCRIPPS-I = Death, MI (Q Wave and non-Q Wave), Emergency CABG and TLR
MACE for WRIST = Cardiac death, Q Wave MI, Emergency CABG and TVR.

** Out of Hospital Complications: GAMMA-I: to 270 days
SCRIPPS-I: to 180 days
WRIST: 180 days +/- 30 days

*** Based on follow-up angiogram.

8.1 **Additional Late Thrombosis Information**

Summarized in Table 8-5 is the late thrombosis information based on data collected from the GAMMA-I, SCRIPPS-I and WRIST trials up to June 2000, which is beyond the primary study endpoints. (See Table 8-5 for further details.)

Table 8-5: Late Thrombosis GAMMA-I, SCRIPPS-I, WRIST*

	Radiation	Placebo
GAMMA-I	5.3% (7/131)	0.8% (1/121)
SCRIPPS-I	0.0% (0/29)	0.0% (0/31)
WRIST	6.2% (4/65)	1.5% (1/65)
WRIST (Crossover)	5.1% (2/39)	--
TOTAL	**4.9% (13/264)**	**0.9% (2/217)**

GAMMA-I: Results in this table represent data at 1.5 years. Patients with new stents received 8 weeks of antiplatelet therapy.
SCRIPPS-I: Results in this table represent data at 3 years. Patients with new stents received 2 weeks of antiplatelet therapy.
WRIST: Results in this table represent data at 2 years. All patients received 4 weeks of antiplatelet therapy.
Late Thrombosis = Myocardial Infarction attributable to the target vessel with angiographic documentation (site-reported or by QCA) of thrombus or total occlusion at the target site and in a newly implanted bypass graft at the target site > 30 days after the index procedure in the absence of an intervening revascularization of the target vessel.

Additionally, the use of prolonged antiplatelet therapy was evaluated during the SCRIPPS-III and WRIST Plus registry trials. During the SCRIPPS-III trial, patients who received a new stent are placed on 12 months of antiplatelet medication, and 6 months if no new stent is placed. During the WRIST Plus trial all patients received 6 months of antiplatelet medication. A summary of late thrombosis events up to August 18, 2000 can be found in Table 8-6. **Note:** The follow-up in these two trials is not yet complete, since the studies are still on-going.

Table 8-6
Survival Free From Late Thrombosis: SCRIPPS-III, WRIST Plus Trials Event-Free Survival; All Patients Treated (n=534)

Time After Initial Procedure (days)	0	30	60	90	120	150	180	210
Effective Sample Size	508.5	481.5	447.5	413.5	379.0	333.5	269.5	206.0
Number Censored	19	35	31	35	34	57	71	54
Number of Events	0	1	1	0	0	0	1	0
% Survival	100%	100%	99.79%	99.56%	99.56%	99.56%	99.56%	99.17%
% Failure	0.00%	0.00%	0.21%	0.44%	0.44%	0.44%	0.44%	0.83%
% Peto Survival SE	0.00%	0.00%	0.21%	0.32%	0.33%	0.35%	0.38%	0.57%
% Failure 95% Lower Conf. Limit	0.00%	0.00%	0.03%	0.10%	0.10%	0.09%	0.08%	0.22%
% Failure 95% Upper Conf. Limit	0.00%	0.00%	1.53%	1.81%	1.92%	2.05%	2.36%	3.18%

9. **Patient Selection and Treatment**

9.1 **Individualization of Treatment**

The risks and benefits described above should be considered carefully for each patient before use of intravascular brachytherapy. Patient selection factors to be assessed should include a judgement regarding risk of prolonged anticoagulation. Intravascular brachytherapy with stenting is generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease, see Contraindications.)

Premorbid conditions that increase the risk of a poor initial result and the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed. The relation of baseline and procedural variables to Major Adverse Cardiac Events (MACE) was examined. The only significant univariate predictors of MACE in the GAMMA-I trial were lesion length and post-procedural mean in-stent minimum lumen diameter (MLD). MACE was more likely with longer lesions and smaller MLD.

9.2 Use in Special Populations

The safety and effectiveness of the Cordis **CHECKMATE** System has not been established because it has not been adequately studied in:

- Patients with coronary artery **reference vessel diameter < 2.75 mm and > 4.0 mm.**
- Patients with target **lesions longer than 45 mm.**
- Patients with **vascular disease other than in-stent** coronary artery stenosis.
- Patients with recent **acute myocardial infarction** and there is evidence of thrombus.
- Patients with **lesions located** in the left main coronary artery, saphenous vein grafts, or internal mammary arteries.

10. Patient Counseling Information

Physicians should consider the following in counseling the patient about this device:

- Discuss the risks associated with exposure to radiation.
- Discuss the risk/benefit issues for this particular patient.
- Discuss alterations to current lifestyle immediately following the procedure and over the long term.

11. How Supplied

STERILITY. The Ir-192 source ribbon and delivery device **ARE NOT STERILE**. Do not autoclave the Ir-192 source ribbon and delivery device. Exposure to temperatures above 54°C (130°F) and pressures in excess of 15 psi (103 kPa) may damage the components.

CONTENTS. One (1) Ir-192 source ribbon and one (1) **CHECKMATE** Delivery Device.

STORAGE. When not in use, the Ir-192 source ribbon and delivery device should be stored in a secure, locked area with restricted access separate from other medical devices. Radiation safety regulations for storage of radioactive material should be strictly adhered to. Store in a cool, dark, dry place.

Table 11-1
Device Specifications

	Ir-192 Source Ribbon	Delivery Device
Device Specifications	Overall Length: 230 cm Ribbon O.D.: 0.030" Treatment Length: 6-seed: 23 mm 10-seed: 39 mm 14-seed: 55 mm Ribbon Color: clear Filament Color: 6-seed: blue 10-seed: green 14-seed: purple	
Compatible With	Cordis **CHECKMATE** Catheter	Cordis **CHECKMATE** Catheter

12. Operator Manual

12.1 Materials Required

The following materials are required to perform a **CHECKMATE** intravascular brachytherapy procedure after a successful revascularization procedure has been performed:

Quantity	Material
	Appropriate guiding catheter(s) (See Table 11-1, Device Specification)
1	Guidewire (See Table 11-1, Device Specification)
1	Cordis **CHECKMATE** Catheter (with dummy ribbon)
1	Rotating Luer connector
As required	Portable lead shield(s)
As required	Radiation detection equipment

12.2 Preparation and Inspection

Warnings

- Avoid performing the intervention and/or injuring a vessel segment outside of the radiation treatment area.

Precautions

- **For multiple uses.** Do not sterilize.
- DO NOT use after the "Use By" date as the function may be compromised.
- Carefully inspect the package before opening. If the package is damaged, the contents may be damaged as well.
- If radioactivity readings register above the acceptable range, notify the institutional radiation safety officer immediately and follow the established institutional radiation safety protocol.
- Until ready for use, the transport cart carrying the shielded delivery device with the radioactive source ribbon should remain in a secure, locked location with restricted access separate from other medical devices.

12.2.1 CHECKMATE Delivery Device

Step	Action
1.	Upon receipt at the institution, inspect the shipping/storage container of the shielded delivery device. Using a calibrated survey meter, survey the exterior of shipping/storage container to verify that the radioactivity level is within the acceptable range as defined by the standards established by the governing nuclear regulatory agency.
2.	Open the shipping container, carefully remove the shielded delivery device (two person lift) and place on a sturdy transport cart. **Note:** The shielded delivery device is heavy. Retain the shipping container for return shipping. See "Return Shipping Guidelines."
3.	Survey the outside surface of the shielded delivery device with a calibrated survey meter. **Note:** It is recommended that survey readings are made throughout the procedure to ensure that radioactivity remains within an acceptable level.
4.	Verify the "Use By" date of the radioactive source ribbon from the labeling. Do not use a source ribbon after the "Use By" date.

12.2.2 Source Calibration

Precautions

- If radioactivity readings register above the acceptable range, notify the institutional radiation safety officer immediately and follow the established institutional radiation safety protocol.
- DO NOT use the source ribbon if the specific activity is above the site license limit for the procedure room.
- DO NOT use the source ribbon if kinks are detected. Return the source ribbon per the "Return Shipping Guidelines."

Step	Action
1.	Remove the metal caps from both ends of the shielded delivery device. Uncoil the ribbon from the spool (proximal end of the shielded delivery device).
2.	Remove the threaded cap at the distal end of the shielded delivery device. Open the fitting at the proximal end of the delivery device and advance the source ribbon by pushing it from the proximal end. Verify the activity of the Ir-192 source ribbon per the site (incoming) calibration procedure. - it is recommended to standardize the calibrator using an ADCL or NIST traceable Ir-192 seed. - it is recommended to verify the linearity and geometry variation of the calibrator that is used. **Note:** The air kerma strength conversion factor is 4.030 U mCi^{-1}(AAPM TG-43).
3.	Verify by using calibrated instruments, that the activity of the Ir-192 source ribbon matches that listed on the Calibration Certificate (or Bill of Lading) and verify that the number of seeds matches the product labeling. The activity information will be used to calculate dosimetry.
4.	Notify the manufacturer if there are any discrepancies between the measured and labeled activity and the number of seeds of the Ir-192 source ribbon.
5.	Withdraw the source ribbon into the shielded delivery device. Use the visual markers on the source ribbon and a survey meter to ensure that the source ribbon is correctly positioned within the delivery device. Secure the source ribbon by tightening the fitting on the proximal end of the delivery device. Place the threaded cap over the exit port on the distal end of the delivery device.
6.	Inspect the proximal length of the source ribbons protruding from the delivery device. Verify that there are no kinks in the ribbon that may impede advancement through the catheter. Recoil the ribbon as needed.

12.2.3 CHECKMATE Catheter, Dummy Ribbon and Source Lumen Plug

Step	Action
1.	Follow the instructions provided with the Cordis **CHECKMATE** Catheter for procedures associated with preparing the **CHECKMATE** Catheter, dummy ribbon and source lumen plug.

12.3 **Recommended Procedure** (See also the Instructions for Use of the **CHECKMATE** Catheter)

12.3.1 Treatment Prerequisite

Step	Action
1.	Perform revascularization of the previously stented target lesion using current interventional techniques. **Note:** Refer to "System Compatibility" section for catheter size and compatibility information.
2.	Verify satisfactory result with angiography and/or IVUS. **Note:** It is important that an optimal redilatation of the restenotic lesion is achieved prior to intravascular brachytherapy.
3.	Maintain the position of the procedure guidewire across the target lesion.

12.3.2 Dosimetry

Warnings

- The biological risks of doses above 3000 cGy to the near wall have not been established.

Step	Action
1.	Using intravascular ultrasound (IVUS), measure the distance from the center of the IVUS catheter to the leading edge of the tunica media. Measure a minimum of three (3) sites along the stent vessel segment.
2.	Determine the maximum and minimum source to target distances along the stented vessel.
3.	Calculate the dwell time to deliver the desired dose by using the maximum and minimum source to target distances and the specific activity level of the Ir-192 source from the Certificate of Activity (Bill of Lading) supplied with the **CHECKMATE** Delivery System. See also Attachment 1, the Radiation Therapy Worksheet. • The dwell time should be calculated such that a dose of 800 cGy is delivered to the target farthest from the radiation source provided that no more than 3000 cGy is delivered to the target closest to the radiation source. • If the dose to the near wall is calculated to be more than 3000 cGy, the dwell time should be based on delivering 3000 cGy to the near wall. In this case, calculate and use the dose to be delivered to the far wall.
4.	Document the dose calculations.

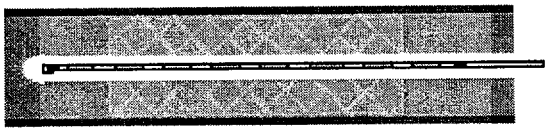
12.3.3 CHECKMATE Catheter Introduction and Positioning

Precautions

- Care should be taken when inserting the **CHECKMATE** Catheter into the hemostasis valve and during tightening of the hemostasis valve in order to avoid crimping or kinking of the catheter.
- DO NOT advance the **CHECKMATE** Catheter within the vasculature unless it is preceded by a guidewire. The catheter can disengage from the guidewire if it is pushed past the guidewire tip. If this occurs, remove the catheter while leaving the guidewire in place and repeat steps 2-4 for catheter introduction.
- DO NOT advance the catheter over the floppy portion of the guidewire as the guidewire may prolapse when the catheter is withdrawn. If this occurs, attempt to resolve the prolapse by gently pulling back on the guidewire while simultaneously advancing the catheter. If the prolapse persists, disengage the catheter from the guidewire by continuing to advance the catheter while gently pulling back on the guidewire. Remove the catheter (or the catheter and guidewire as a unit).
- DO NOT flush the source lumen with saline or other liquids. If the source lumen gets wet, remove the **CHECKMATE** Catheter and discard.

Step	Action
1.	Attach a hemostasis valve to the Luer port of the guiding catheter positioned in the vasculature.
2.	Under fluoroscopy, verify that the procedure guidewire is correctly positioned across the target lesion.
3.	Protect the proximal end of the **CHECKMATE** Catheter from blood or fluid contact.
4.	Insert the proximal end of the indwelling guidewire into the distal end of the **CHECKMATE** Catheter. The guidewire will exit through the port on the catheter tip. **Note:** Before inserting the **CHECKMATE** Catheter, wipe the proximal end of the guidewire with a saline soaked gauze to remove any excess contrast medium.
5.	Under fluoroscopy, advance the **CHECKMATE** Catheter over the guidewire. Position the catheter across the target lesion using the radiopaque markers on the catheter and dummy ribbon to define the target lesion. **Note:** It is recommended that the treatment zone includes a margin of approximately 3-5 mm (1-1.33 seeds) on either side of the target lesion (see Illustration). **Note:** Care should be taken to avoid rotating the **CHECKMATE** Catheter as it is advanced over the guidewire. Such action may cause the guidewire to wrap around the catheter making further advancement difficult.
6.	Make any adjustments to the catheter position when the dummy ribbon is in place. When satisfied that the catheter is correctly positioned across the intended treatment site, tighten the hemostasis valve to maintain the catheter position.
7.	Remove the source lumen plug. Withdraw the dummy ribbon proximal to the hemostasis valve and re-insert to verify the ability to access the treatment site.
8.	Remove the dummy ribbon from the **CHECKMATE** Catheter and discard .
9.	Visually check that there are no kinks in the proximal section of the **CHECKMATE** Catheter.
10.	Ensure that an ACT taken just prior to the radiation dwell time is greater than 300 sec. (> 350 sec. if a Hematec analyzer is used).

Illustration



12.3.4 Intravascular Radiation Therapy Procedure

Warnings

- Do not completely withdraw the source ribbon from the shielded delivery device. If this occurs, reinsert the source ribbon into the delivery device. Notify the institutional radiation safety officer immediately and follow the established radiation safety protocol.

Precautions

- The **CHECKMATE** Delivery System and the transport cart are **NON-STERILE** and should remain outside of the sterile field.
- It is recommended that survey meter readings are recorded several times during the procedure to ensure that the radioactivity remains within an acceptable level.
- Maintain visual and audio contact with the patient during the intravascular brachytherapy procedure.
- Maintain hemodynamic monitoring of the patient during the intravascular brachytherapy procedure.
- If excessive resistance is encountered during the insertion, retract the source ribbon back into the **CHECKMATE** Delivery Device. Do not re-advance the radioactive source ribbon until the cause of resistance has been remedied, or a new **CHECKMATE** Catheter has been introduced.
- If significant symptoms of ischemia occur, the treatment may be fractionated. Rapidly retract the source ribbon into the **CHECKMATE** Delivery Device. Record the exposure time. Resolve the ischemic symptoms before re-introducing the source ribbon for the remaining treatment time. Fractionation of treatment time increases the radiation exposure to the radiation oncologist and to the patient. Use fractionation only if significant ischemia occurs.
- The proximal end and the source lumen of the catheter are no longer sterile after connection to the **CHECKMATE** Delivery Device. Handle per site procedures.

Step	Action
1.	Transport the **CHECKMATE** Delivery System to a location within range of the patient but outside of the sterile field.
2.	Remove the metal end caps from both ends of the shielded delivery device. Uncoil the ribbon from the spool (proximal end of the shielded delivery device).
3.	Remove the threaded cap from the distal end of the shielded delivery device; replace it with a rotating Luer connector. Connect the catheter hub to the rotating Luer connector of the delivery device. **Note:** DO NOT rotate the catheter.
4.	Transport the portable lead shield(s) to the side(s) of the patient to minimize radiation exposure to attending personnel. Position the shields as defined by institutional radiation safety procedures.
5.	When ready to initiate the intravascular brachytherapy, all personnel should be positioned behind appropriate shielding as defined by institutional radiation safety procedures.
6.	Open the fitting at the proximal end of the delivery device. The radiation oncologist rapidly advances the radioactive source ribbon through the **CHECKMATE** Catheter to the end of the source lumen. Verify the position of the source ribbon with the fluoroscope, utilizing the radiopaque markers and contrast injection. Secure the source ribbon in place.
7.	Begin timing of the dwell time as soon as the radioactive source ribbon is positioned.
8.	Monitor the patient closely during the treatment time with the Ir-192 source ribbon. **Note:** Verify the source location if the delivery device, cart or catheter are moved, or if the patient shifts position during the treatment time.
9.	At the conclusion of the elapsed dwell time, the radiation oncologist releases the source ribbon and rapidly withdraws the source ribbon into the **CHECKMATE** Delivery Device. Use the visual markers on the source ribbon and a survey meter to ensure that the source ribbon is correctly positioned within the delivery device.
10.	Secure the fully retracted source ribbon by tightening the fitting on the proximal end of the delivery device. Remove the Luer connector and replace the threaded cap over the exit port on the distal end of the delivery device. Appropriately licensed personnel performs a radiation survey to ensure that the source ribbon is properly contained within the **CHECKMATE** Delivery Device. Record the measurements.
11.	Personnel may move from behind the radiation shielding. **Note:** Standard shielding practices for fluoroscopy must still be followed.

12. Disconnect the catheter from the **CHECKMATE** Delivery Device.
Note: Placement of a new stent during the radiation procedure has been associated with a higher rate of late thrombosis in comparison to the placebo arm. Every attempt should be made to avoid new stent placement in the irradiated area. However, if placement of a new stent was necessary, it is recommended that the patient be placed on antiplatelet therapy.
13. Transport the **CHECKMATE** Delivery Device to a secure, restricted access area that has been designated for and meets the requirements for radioactive storage.

12.4 Withdrawal Procedure

Precautions

- DO NOT advance the catheter over the floppy portion of the guidewire as the guidewire may prolapse on withdrawal of the catheter. If this occurs, attempt to resolve the prolapse by gently pulling back on the guidewire while simultaneously advancing the catheter. If the prolapse persists, disengage the catheter from the guidewire by continuing to advance the catheter while gently pulling back on the guidewire. Remove the catheter (or remove the guidewire and catheter as a unit).
- If the radioactivity readings register above the acceptable limits, notify the institutional safety officer immediately and follow the established institutional radiation safety protocol.

Step	Action
1.	Remove and discard the **CHECKMATE** Catheter.
2.	Use a survey meter to survey the patient and the catheter for any radiation. Record the measurements.
3.	Perform a post procedure angiogram if required.
4.	Remove the guidewire, guiding catheter and the sheath introducer from the vasculature per standard techniques.
5.	Close the arterial opening per desired technique.

12.5 Emergency Ir-192 Source Ribbon Removal

Precautions

- This procedure should only be performed by, or under the direction of, appropriately trained personnel.

Step	Action
1.	Disconnect the **CHECKMATE** Catheter from the delivery device.
2.	Withdraw the Ir-192 source ribbon manually from the patient and immediately deposit the radioactive portion of the Ir-192 source ribbon in a shielded emergency container. **Note:** Ensure that the emergency container provides appropriate shielding.
3.	Appropriately licensed personnel perform a radiation survey of the patient and general vicinity to ensure that the radioactive portion of the Ir-192 source ribbon is completely deposited in the shielded emergency container.
4.	Cut off the ribbon proximal of the shielded emergency container. Follow site specific requirements for handling of the shielded emergency container.
5.	The **CHECKMATE** Delivery System and all parts of the Ir-192 source ribbon need to be returned to Best Industries (Springfield, VA, USA). Refer to the Return Shipping Guidelines.
6.	Contact Cordis at (800) 327-7714 or (732) 562-3097.
7.	Follow site specific requirements for documentation of this emergency procedure.

12.6 Emergency CHECKMATE Catheter/Ir-192 Source Ribbon Removal

In the event of a (suspected) ribbon fracture, determined visually or by high radiation survey readings following the withdrawal of the Ir-192 source ribbon, the **CHECKMATE** Catheter and Ir-192 source ribbon should be removed as one unit.

For detailed instructions on removal of the **CHECKMATE** Catheter, see the **CHECKMATE** Catheter Instructions for Use.

Precautions

- This procedure should only be performed by, or under the direction of, appropriately trained personnel.

After removal of the **CHECKMATE** Catheter and the Ir-192 source ribbon, follow this procedure:

Step	Action
1.	Using wire cutters, cut off the distal section of the catheter which contains the radioactive seed train and deposit this in an emergency container. **Note:** Ensure that the emergency container provides appropriate shielding.
2.	Appropriately licensed personnel perform a radiation survey of the patient and general vicinity to ensure that the radioactive portion of the Ir-192 source ribbon is completely deposited in the shielded emergency container.
3.	Follow site specific requirements for handling of the shielded emergency container.
4.	The **CHECKMATE** Delivery System and all parts of the Ir-192 source ribbon need to be returned to Best Industries (Springfield, VA, USA). Refer to the Return Shipping Guidelines.
5.	Contact Cordis at (800) 327-7714 or (732) 562-3097.
6.	Follow site specific requirements for documentation of this emergency procedure.

12.7 Return Shipping Guidelines

Step	Action
1.	Refer to the return shipping guidelines supplied with the **CHECKMATE** Delivery System (in the Return Shipping Package) for the return procedure. The **CHECKMATE** Delivery Device and Ir-192 source ribbon need to be returned to Best Industries (Springfield, VA, USA), phone (703) 451-2378, fax (703) 451-4977.

13. References

P. Teirstein, V. Massullo, S. Jani, et al., "Catheter-Based Radiation Therapy to Inhibit Restenosis after Coronary Stenting", NEJM, v. 336, n. 24, pp. 1697-1703.

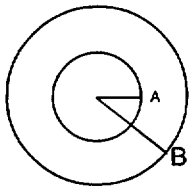
Date of Labeling Modification: November 2000.

Attachment 1: RADIATION THERAPY WORKSHEET

Dosimetry calculation

Target Vessel: Take measurements using IVUS at a minimum of three (3) sites along the stented vessel segment to determine the shortest and longest distance between the midpoint of the catheter and the leading edge of the media.

A = _____ mm (shortest distance)
B = _____ mm (longest distance)



Dose Prescription:
Ribbon: ____ Seeds
Dose: _____cGy at ____ mm distance

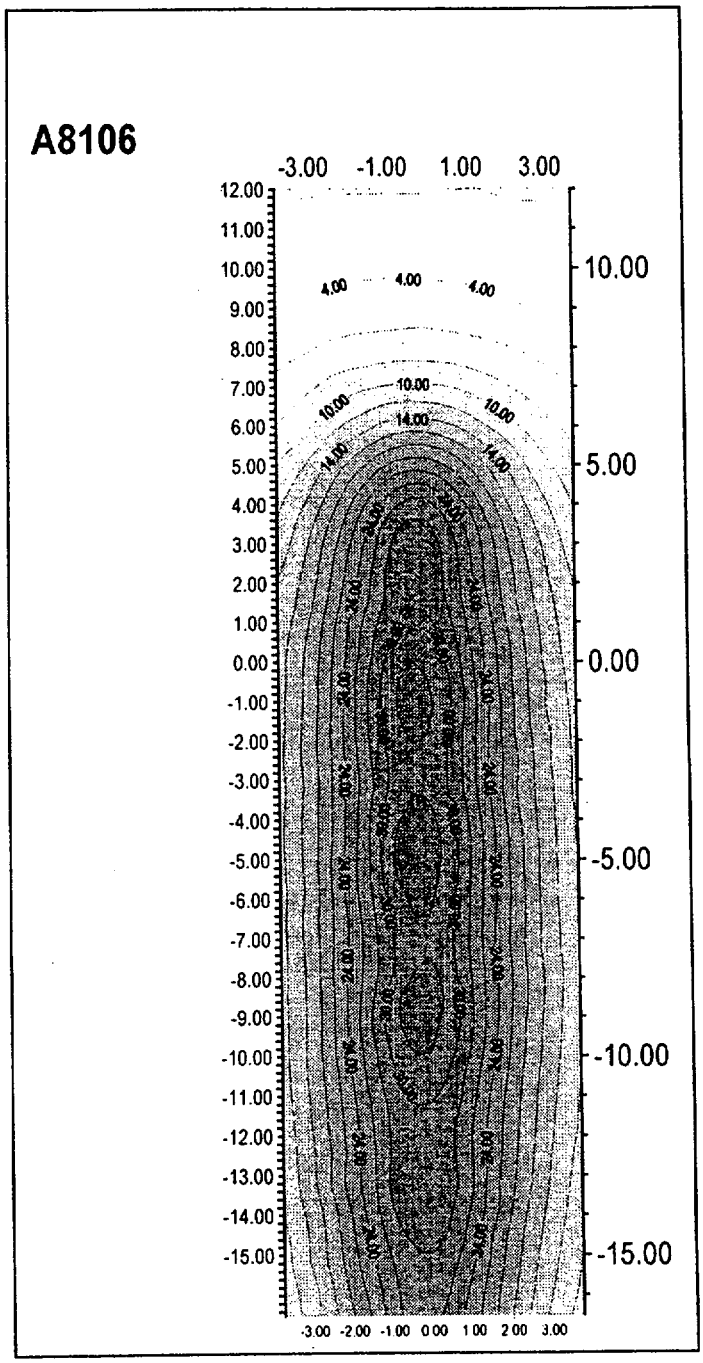
Dose Calculation:
D_A = _____cGy
D_B = _____cGy
Total Activity = _____mCi on __/__/__ (date)
Activity per seed= _____mCi

Distance	Dose Rate (cGy/min) for 1 mCi per seed			TX Time (min) = Prescribed Dose (cGy) / (Activity per seed (mCi) x Dose Rate (cGy/min) at the prescribed distance. (See adjacent Table))
	6 Seeds*	10 Seeds*	14 Seeds*	
0.9	7.04	7.13	7.16	
1.0	6.22	6.31	6.34	
1.1	5.55	5.64	5.67	
1.2	5.01	5.09	5.12	
1.3	4.55	4.64	4.66	
1.4	4.16	4.25	4.26	
1.5	3.83	3.92	3.93	
1.6	3.55	3.64	3.65	
1.7	3.30	3.39	3.40	
1.8	3.08	3.17	3.18	
1.9	2.89	2.98	2.99	
2.0	2.72	2.81	2.82	
2.1	2.57	2.65	2.66	
2.2	2.43	2.51	2.54	
2.3	2.30	2.39	2.41	
2.4	2.19	2.28	2.30	
2.5	2.08	2.17	2.20	
2.6	1.99	2.08	2.11	
2.7	1.91	1.99	2.02	
2.8	1.82	1.92	1.94	
2.9	1.74	1.84	1.87	
3.0	1.68	1.77	1.80	
3.1	1.61	1.71	1.74	
3.2	1.55	1.65	1.68	
3.3	1.49	1.59	1.63	
3.4	1.44	1.54	1.57	
3.5	1.39	1.49	1.53	
3.6	1.34	1.44	1.47	
3.8	1.25	1.35	1.39	
4.0	1.18	1.27	1.31	
4.2	1.12	1.21	1.26	
4.4	1.06	1.15	1.19	

* At distances less than 2.1 mm from the source ribbon the maximum dose rate at the perpendicular bisector of a central seed is listed. At distances greater than 2.1 mm from the source ribbon the average dose rate over two central seeds and the space between them is listed.

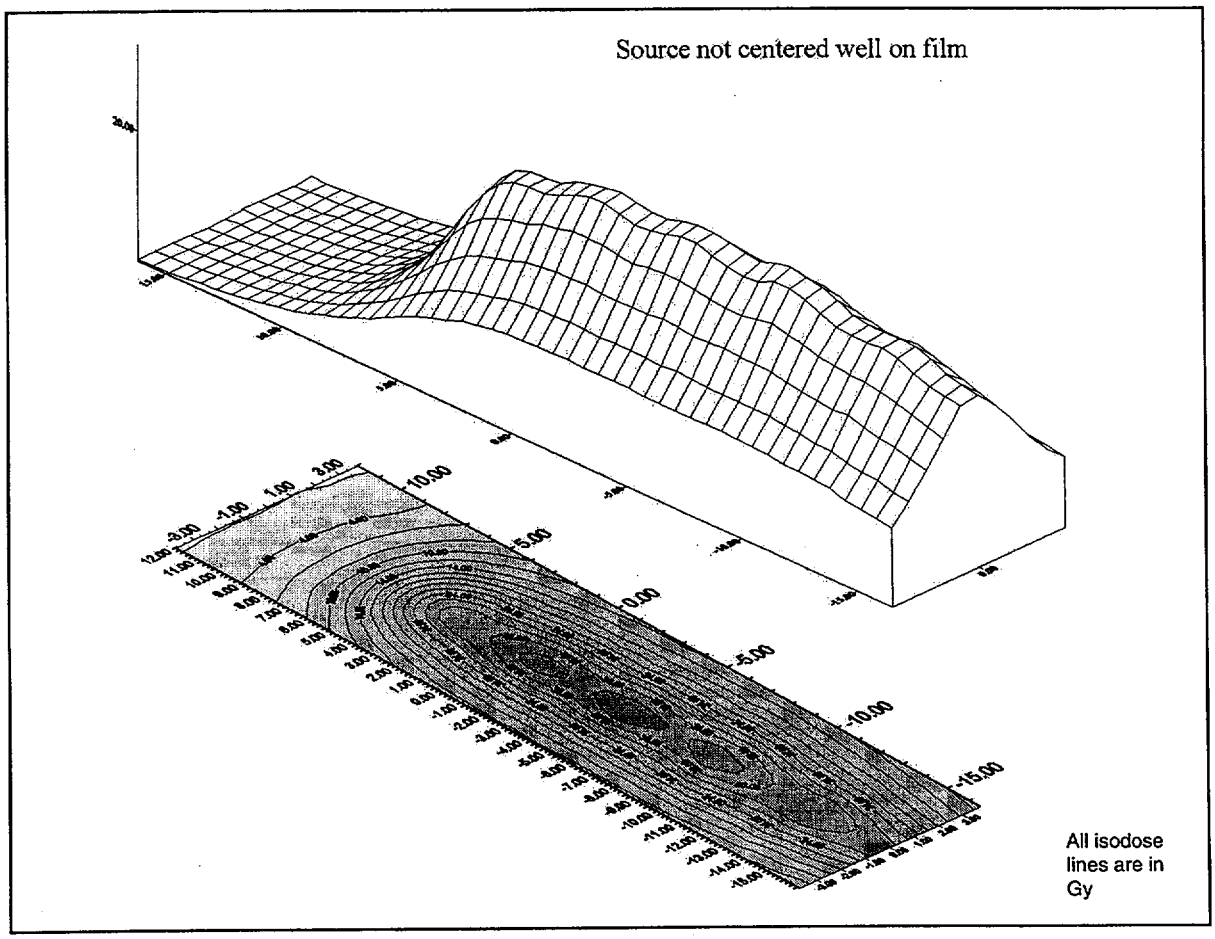
Treatment Time: _____ minutes _____ seconds.

Attachment 2: Isodose Distribution for 6-Seed Ir-192 Source Ribbon at Depth of 2.06 mm from Source Center



Attachment 2: Isodose Distribution for 6-Seed Ir-192 Source Ribbon at Depth of 2.06 mm from Source Center *(continued)*

A8106 (depth of 2.06 mm)
Ir-192 ribbon
Surface view of isodose lines



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100% Recycled Fibers
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November 2000

1083-0215R1 154-2797-1

CHECKMATE™

Customer Training Program

A product specific training program for interventional cardiologists, radiation oncologists, physicists and radiation safety officers

Cordis

a Johnson & Johnson company

Overall Program Description

The CHECKMATE Customer Training Program is designed to teach Interventional Cardiologists, Radiation Oncologists, Medical Physicists, and Cardiac Cath Lab Staff Personnel on the proper use of the CHECKMATE Ir-192 Intravascular Brachytherapy System from Cordis Corporation. The program includes both an off-site Didactic Workshop Component and In Hospitals In-Service & Procedural Support Component. It is based on the methodology used for training of investigational sites prior to the Gamma 1 Trial.

The multidisciplinary team will be required to attend both the didactic workshop and the in hospital in-service. Cordis Customer Service will maintain accurate training records documenting program completion by each institution prior to product shipment. In addition, hospitals will be regulated by the NRC/NRC agreement states and will not be able to initiate procedures until their radiation license is properly amended.

Didactic Workshop

Interventional Cardiologists, Radiation Oncologists, and Medical Physicists from interested institutions will be offered a one-day didactic workshop on essential aspects of this new procedure. The didactic workshops will be held at Regional Training Centers (RTC) throughout the country. RTC have been selected from high volume investigational sites. A list of the initial RTC can be found in ***Appendix A***.

The agenda for the didactic workshop can be found below. Faculty from all three critical disciplines will be involved in the workshop. Workshops will be offered live or via broadcast numerous times throughout each month.

CHECKMATE System Didactic Workshop Agenda

Topic	Discussion Leader
Introduction to Intravascular Brachytherapy	Radiation Oncology Faculty
Clinical Experience with the CHECKMATE System • Indications & Contraindications • Review of Clinical Results • Critical Success Factors • Complication Management	Interv. Cardiology Faculty
Review of CHECKMATE System Procedure (Video Presentation)	All Faculty
IVUS Based Guidelines for Dosimetry	Radiation Oncology Faculty
Staff and Patient Safety Guidelines	Medical Physicist Faculty
Live Case with the CHECKMATE System (Emphasis on Procedural Step by Step Guidelines)	All Faculty
Key Aspects for Introducing IVBT into Your Cardiac Cath Lab	Interv. Cardiology Faculty

Each didactic workshop attendee will receive a workshop manual. The Table of Contents for the workshop manual can be found in ***Appendix B.***

Hospital In-Service

Multiple hospital in-services will be conducted at each institution prior to performing the first procedures. In-services will conducted by the highly trained, dedicated Radiation Technical Specialist Field Group. A list of items covered during the In-service is found below.

Hospital In-Service
Program Description

- **PowerPoint Presentation on Product Description, Clinical Results Highlights, and Practical Considerations**
- **Hands-on Demonstration with CHECKMATE System**
- **Review of Procedure Video**
- **Review of Patient Education Video**
- **Dry Run of Procedure**

Procedural Support

Initial procedural support will be conducted by the highly trained, dedicated Technical Specialist Field Group. The Technical Specialist will be present during the first set of procedures by each new set of operators.

Procedural support education will emphasize the team approach and procedural step by step guidelines. Practical considerations related to the CHECKMATE System will also be stressed.

Appendix A
Regional Training Centers

1. Washington Hospital Center
   Washington, DC

2. Lenox Hill Hospital
   New York, NY

3. Grant Riverside Hospital
   Columbus, OH

4. St. Lukes Episcopal Hospital
   Houston, TX

5. Scripps Green Hospital
   San Diego, CA

Appendix B
Didactic Workshop Manual
Table of Contents

UNITED HOSPITAL **St. Paul, MN.**

Patient Name:	Date:

Treatment Plan

Isotope: Ir^{192} CV Lab:

Date of Implant: Time of Implant:

Pre-plan

Source Length: # of Seeds:	Time:	Dose:

Physician Signature/Date: _____

Post Plan

Source Length: # of Seeds:	Time:	Dose:

Physician Signature/Date: _____

Notes:

Temporary Coronary Implant
Ir^{192} Written Directive

United Hospital **St. Paul, MN.**

Patient Name:	Hosp. #:
Date of Implant:	

I. BEFORE INSERTION OF RADIOACTIVE SOURCES INTO THE PATIENT.

1. Preliminary written directive signed and on file according to *RT Worksheet* (source usage, time and dose).

_____
attending physician

2. Patient positively identified by two independent methods.

_____
attending physician

3. Verification that source length and time agrees with signed pre-plan written directive.

_____
physicist

4. Lead shields are in place per *NELCO* specifications

_____
physicist

II. AFTER INSERTION OF RADIOACTIVE SOURCES INTO THE PATIENT.

5. Position of sources within the patient verified under fluoroscopy/digital acquisition.

_____
attending physician

III. AFTER SOURCE REMOVAL.

6. Inventory the Ir^{192} Ribbon.

_____
physicist

7. Survey the CV Lab and patient.

_____
mR/hr. – physicist

8. Check that administered dose agrees with final written directive to within $\pm$10%*.

_____
attending physician

9. Final written directive signed and on file according to the competed implant (source length, time and dose).

_____
attending physician

* If implant dose differs from final written directive dose by more than 10% but less than 20%, this is a recordable event. Notify the attending physicians and the physics staff immediately.

* If implanted dose differs from final written directive dose by more than 20%, this is a misadministration. Notify the attending physician and physics staff immediately.

Attending physician administering Therapy (signature):	Date:

Temporary Coronary Implant
Ir^{192} QMP Checklist

QUALITY MANAGEMENT PROGRAM (QMP)

POLICY and PROCEDURES

This document is a quality management program (QMP) required to implement the Coronary Restenosis Intravascular Radiation (IVB) program at United Hospital in St. Paul, MN. The policies and procedures as outlined in this QMP document are authorized only for the Cordis Ir-192 System currently under the PMA (P990036) approved for clinical use. These policies and procedures comply with all rules and regulations defined by the NRC as appropriate for Intravascular Brachytherapy (IVB) procedures.

PURPOSE:

1. To promote confidence that Restenosis (IVB) radiation treatments with the Ir-192 will be administered as directed by the authorized user using the Cordis Ir-192 Instructions for Use (IFU).
2. To insure that in doing so, patient, staff, and public are not exposed to unnecessary radiation.

To achieve these goals, the following policies are to be followed.

1. Prior to administration of the radioactive material, a written directive, that is, an order in writing for a specific patient will contain the following information: the patient's name, date, the treatment site, radioisotope (Ir-192), length of source ribbon and the number of Ir-192 seeds, the time for treatment, the dose to be delivered and where the dose is specified to. This directive will be dated and signed by the authorized physician user in the patient chart

(See attached Checkmate Instructions for Use (IFU) Section 12.3.2 page 11 and Radiation Therapy Worksheet – Attachment 1, page 13, to Instructions for Use.).

An authorized user must supervise a non-authorized user of radioactive material and the authorized user on all RESTENOSIS IVB written directive records must countersign his/her signature.

If a written directive is unclear or there is a discrepancy in the written directive, the treatment will not proceed until it is clarified.

If, because of the patient's medical condition, i.e. an emergency situation that would jeopardize the patient's health, an oral revision to an existing written directive will be documented immediately in the patient's record. This will be dated and signed by the authorized physician user within 24 hours of the change in the original written directive order.

2. The following procedures will be used to verify the identity of the patient as the individual named in the written directive:
   a) Prior to initiation of treatment, the patient's name and hospital number or ID number will be confirmed and documented using two different sources of information or two independent checks by staff.
   b) This procedure will be recorded and initialed on the QMP Checklist at the time of verification of patient identification.
3. Before each treatment, the medical physicist or designee of the authorized physician user will perform a QA and Radiation Safety check. The checks will include but not be limited to the following:

a. Radiation signs will be posted in the appropriate locations around the designated Cardiac Cath Suite (as described in the license amendment) and surrounding hallways, if needed.

b. Radiation shields will be placed per the Shield Diagram for the Cardiac Cath Suite (see attached NELCO Shield Placement Plan document). The location and use of each shield will be documented on the QMP Checklist.

c. Source calibration and assay in the source storage location and calibration location (as stated in the license amendment).

d. Source check for integrity of the source ribbons (See attached Registry of Radiation Sealed Sources and Devices Safety Evaluation of Sealed Source document and Section 12.2 of the Checkmate IFU).

e. Today's source strength, date, and serial number of the ribbons will be recorded on a radiation summary sheet or source record log.

f. Survey equipment is in place on the source cart.

g. A reliable method of monitoring time is checked (i.e. stop watch).

h. Emergency equipment (i.e. Restenosis Emergency Transport Container, forceps) is on the source cart or in the Cardiac Cath Suite.

i. All personnel involved in the procedure are wearing film badges including ring badges, as appropriate. It is required that the radiation oncologist and the medical physicist or designee or the authorized physician user, have external and under apron dosimetry as well as ring badges.

j. Sources are logged out for use in the source record log.

4. The authorized physician user will confirm the specific details of the brachytherapy administration with the medical physicist or designee of the authorized physician user prior to administration of the treatment.
5. All personnel involved in the delivery of treatments and the Cardiac Catheterization procedure for Restenosis with the Cordis Ir-192 Restenosis System will be properly trained (See attached Checkmate Customer Training Program document) and are documented in the personnel file. Also, this will be documented in the Radiation Safety Committee's records.

   The Radiation Safety Officer will conduct annual training for radiation safety and emergency procedures. Workers will be encouraged to ask questions about what to do or how it should be done before the procedure, rather than continuing the procedure when there is doubt. Emphasis will be placed on administration of the dose prescribed, radiation safety, and patient quality care.
6. Verification of the position of the non-radioactive "dummy" source ribbon will be done prior to the placement of the radioactive sources. Visualization will be by fluoroscopy per the Cordis Ir-192 System Instructions for Use (Section 12.3.3, steps 5 & 6). The procedure for placement of the radioactive source is covered in Section 12.3.4, Step 6.
7. The Radiation Therapy Worksheet will be completed by the physicist or designee of the authorized physician user, under the supervision of the radiation oncologist (authorized physician user). The following must be checked by the radiation oncologist and his or her designee (i.e. if not the medical physicist):
   a. Correct number of seeds in the ribbon (i.e. ribbon corresponds with the color coding on the source survey sheet).

b. Correct treatment date vs. calibration date.

c. Correct calculated treatment time.

8. The radiation oncologist and the medical physicist or designee of the authorized user, will independently check the dose calculations prior to the treatment.

9. The radiation oncologist shall initiate the treatment. (See Section 12.3.4, Step 6).

10. During the treatment the radiation oncologist and the medical physicist or the RSO will monitor and record the treatment time independently (i.e. redundant check by 2 stopwatches, or 1 stopwatch and a clock.).

11. The medical physicist, RSO, or the designee of the authorized user will monitor the radiation to the areas as noted on the radiation patient survey including those around the shields, doorways, and control areas.

12. After the completion of the treatment, the authorized physician user place a copy of the completed Written Directive in the patient' chart.

13. After completion of the treatment, the patient and the area will be surveyed to verify the complete removal of the sources. Sources are then returned to the storage and documented in the source record log.

14. Upon receipt of the sources the following will be done (Checkmate IFU Section 12.2, 12.2.1 and 12.2.2, page 10):

a. Visual inspection of the source ribbons to ensure the color-coding is correct (i.e. 6 seed – blue, 10 seed – green, 14 seed – purple).

b. A calibration of the each ribbon source must be completed.

c. Optional film dosimetry of each ribbon may be provided.

15. All equipment used for source calibration, the well chamber and electrometer, and dose monitoring will be calibrated every two years. The calibration certificate will be kept in the Medical Physics Office.

16. All radiation survey meters will be calibrated on a yearly basis. The calibration certificates will be kept in the Medical Physics office. Wipe tests will be completed on the source containers upon arrival of the sources to the Hospital.

17. All emergency procedures are as documented in the license amendment and comply with the Cordis Ir-192 Restenosis procedures (See Section 12.5 and 12.6, page 12 of the Checkmate IFU). Additional site specific emergency procedures include but are not limited to the following:

    a. The shielded emergency container, holding the removed CHECKMATE catheter and/or Ir192 ribbon, will be transported to the Isotope Storage room in Radiation Oncology.

    b. The physicist, or designee, will remove the sources from the shielded emergency container and prepare them for shipment to Best Industries in their original shipment container.

18. A quarterly review of the IVB cases will be performed. All of the patients will be reviewed and be evaluated for:

    a. A representative sample of patient administration.

    b. All recordable events.

    c. All misadministrations.

    For each patient's care, a comparison will be made between what was administered versus what was prescribed in the written directives. If feasible, the physician conducting the

review should not review his/her own work. If this is not possible then a review by the Quality Management Committee within the Hospital will review the findings of the periodic review to incur that the QMP program is effective.

The evaluation will determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives set in these policies. A record of each review, including the evaluations and findings of the review, will be maintained in a separate binder. Any deviations from the written directives will be identified and the action required to prevent recurrence will be noted. The actions may include new or revised policies, new or revised procedures, additional training or increased supervisory review of work.

It is the duty of the RSO to insure the QA program will be reviewed quarterly to determine effectiveness of the program and to identify actions required making the program more effective. Records of the review will be maintained in the QA minutes to the Radiation Safety Committee for the month when the report is rendered.

19. An authorized physician user must be present in the cardiac Cath suite area when treatment is being delivered to the patient. There will always be a medical physicist and/or RSO or designee of the authorized user, present to monitor radiation safety and assist the authorized user during the treatment administration.
20. Records of the evaluation and audits will be maintained for a minimum of 3 years. The records will be located in the Medical Physics Section.
21. Any changes or modifications to the QMP will be submitted to the NRC Region III, within 30 days of the implementation.

22. Recordable events will be discussed at the Radiation Safety Committee Meetings and will include all of the facts, causes and any corrective action taken. Records will be kept for 3 years.

23. Misadministration rules will be strictly followed. Within 24 hours of occurrence, the NRC Region III, will be notified as well as the authorized physician user. The patient will be notified upon the physician's approval and given a copy of a written report. If the referring physician or patient cannot be reached within 24 hours of discovery of the occurrence of the misadministration, the licensee, United Hospital will notify the patient as soon as possible. Records will be maintained for 5 years.

Each written directive and a record of each administered radiation dose will be maintained in legible form for three years.

GLOSSARY:

Misadministration: means the administration of a Restenosis IVB Ir-192 radiation dose:

a. Involving the wrong patient or wrong treatment site

b. Involving a sealed source that is leaking

c. When the calculated administered dose differ from the prescribed dose by more than 20 percent of the prescribed dose.

Prescribed Dose: means for Ir-192 IVB, as documented in the written directive per the Cordis Checkmate IFU.

Recordable Event: means the administration of a brachytherapy dose when the calculated administered dose differs from the prescribed dose by more than 10 percent and less than 20% of the prescribed dose.

Written Directive: means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation.

Attachment Document to be used with the QMP: Cordis Checkmate IVB Instructions for Use, #1083-0215R1 154-2797-1.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 2
Fee Category: 7C 2B
Exp. Date: 20001130
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: UNITED HOSPITAL
   Received Date: 20010112
   Docket No: 3002207
   Control No.: 308524
   License No.: 22-01914-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: _____

3. COMMENTS

Signed D. A. Hersey
Date 1-11-2001

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____